

# Mental health care

## A handbook for pharmacists

2022



**Mental health**  
FIP Practice  
Transformation  
Programme on NCDs



International  
Pharmaceutical  
Federation

# Colophon

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## Executive summary

Mental illness is a significant global health concern that affects more than one billion people around the world.<sup>1</sup> Despite the substantial impact mental health conditions have on morbidity and mortality, many individuals do not receive adequate mental health care services. In fact, in low and middle income countries, more than 75% of people with mental, neurological or substance use disorders receive no treatment for their conditions.<sup>1</sup> These issues have been furthered exacerbated by the COVID-19 pandemic, which contributed to both increased rates of mental illness as well as reduced availability of mental health care services.<sup>2,3</sup> Many of these issues can be traced back to the global shortage of mental healthcare professionals and expertise.<sup>4</sup> To address this shortage and contribute to improving global health, pharmacists have an opportunity to increase their engagement in mental health care service delivery. With their knowledge and training, pharmacists are well-suited to provide a range of mental health care services.

Pharmacists can promote mental health and well-being among their patients to prevent individuals from developing mental illnesses. They can also leverage their accessibility to identify patients who may be experiencing a mental illness by recognising symptoms of mental illnesses or administering screenings to determine if a patient needs to be referred for further assessment or follow-up care.

Beyond this, pharmacists can take on a variety of roles to support those with diagnosed mental illnesses. Given their frequent interactions with patients, pharmacists can play a role in responding to mental health crises and ensuring patients receive appropriate emergency care should these situations arise. Pharmacists can also contribute to preventing suicide through efforts such as means restriction.

Further, there are many opportunities for pharmacists to optimise a patient's therapeutic regimen. As experts in medicines, pharmacists are well-placed to play essential roles in identifying and resolving medication-related problems, supporting the development of treatment and monitoring plans, engaging in deprescribing efforts, providing comprehensive education to patients, promoting adherence, and more. As pharmacists engage in these roles, they should also take steps to develop a positive therapeutic relationship with their patients that is built on trust, open communication, cooperation, mutual respect and shared decision making.<sup>5</sup> Ethical considerations will also be an important factor to consider when working with those with mental illnesses.

When engaging in roles related to the management of mental illnesses, pharmacists are encouraged to work collaboratively with other healthcare professionals to ensure optimal outcomes for their patients. To support this, pharmacists should also endeavour to create referral pathways for their patients who may be identified in the community setting as needing additional care. They should also consider how they can contribute to transitions of care efforts to ensure continuity of care. Ultimately, mental health care should not be provided in a silo, and interprofessional communication is key to ensure optimal outcomes.

In addition to providing direct patient care services, pharmacists also have an opportunity to be involved in practice-based research to evaluate the impact of new mental health care services in their practice setting.

There are numerous opportunities for pharmacists to engage in mental health care and provide services to their patients, ranging from prevention to screening to management and more. With the proper knowledge and skills, experience and expertise, pharmacists will be well-positioned to address the global burden of mental illness and promote mental health and well-being in their communities.

## Acknowledgements

FIP thanks the European Society of Clinical Pharmacy for their expert contributions to this publication.



## Foreword

Mental health is defined by the World Health Organization (WHO) as “a state of wellbeing in which every individual realises his or her own potential, can cope with the normal stresses of life, can work productively and fruitfully and is able to make a contribution to their community”.<sup>6</sup> Many people struggle with their mental health from time to time, whether it’s brought on by stress from work, financial issues or relationship strain.

The importance of good mental health and well-being has gained attention over the past decade due to an increased burden of disability and loss of quality of life associated with mental health conditions. According to the recently launched WHO World Mental Health Report, in 2019, an estimated 970 million people in the world were living with a mental disorder, 82% of whom were in low- or middle-income countries. Of this global figure, 31% of people lived with anxiety disorders, and 28.9% lived with depressive disorders, the two most prevalent illnesses.<sup>7</sup>

Also, it is estimated that 7% of all global burden of disease as measured in Disability-Adjusted Life Years (DALYs) and 19% of all years lived with disability are attributed to mental and addictive disorders.<sup>8</sup> These have a direct effect on well-being affecting daily activities, work performance and personal life. Gaps in the care and management of mental health conditions are worsened by factors like social stigma, fragmented care delivery models, insufficient health workforce capacity and lack of research intelligence that supports policy change and implementation of new care models.<sup>9</sup>

Young people are one of the main groups affected by these conditions, with suicide as one of the main causes of death among people aged 15–29.<sup>10</sup> Depression and anxiety are the most common mental health conditions, affecting more than 300 million people worldwide. Both conditions are linked to socioeconomical determinants such as poverty, unemployment, physical illness or emotional distress.<sup>11</sup>

The WHO Special Initiative for Mental Health (2019–2023): Universal Health Coverage for Mental Health focuses on scaling up mental health care as part of universal health coverage, leaving no one behind. The WHO’s strategic actions are to advance mental health policies, advocacy and human rights and scale up interventions and services across community-based, general health and specialist settings.<sup>12</sup>

The COVID-19 pandemic has had many emerging detrimental effects on healthcare professionals and societies at large — not only physically, socially and financially but also mentally. Additional signs of mental distress highlighted during the pandemic include fear, anger, denial, insomnia and stress, and all those directly impact patients’ quality of life.<sup>13</sup> People affected by COVID-19, as well as their families and friends, were likely to suffer a heavier burden on their mental health, due to the associated isolation and emotional state.<sup>14</sup>

In addition, the COVID-19 pandemic may have increased the prevalence of mental illnesses and reduced access to care in many parts of the world, especially for those in limited resource settings.<sup>15, 16</sup> In this case, it is important to expand the health workforce that can flag mental health issues, provide Mental Health First Aid, refer people with lived-experience of mental illness to specialists and provide subsequent support.

Pharmacists can and need to be engaged in mental health.

Pharmacists themselves were also affected by the pandemic and were subject to increased pressure and stress, as they were among the first line of care, and were exposed to a higher risk of contagion. They were part of the pandemic response and had to adopt new roles and professional services, fight misinformation through evidence-based advice, navigate new evidence and mobilise their expertise about treatment options, and manage medicines shortages and workplace pressure.<sup>17</sup>

FIP has done some work in the area of mental health, including the FIP publication [“Focus on Mental Health: The contribution of the pharmacist”](#) from 2015 and two digital events in 2021 on [“Suicide prevention, burnout and pandemics: Supporting pharmacists' mental health and wellbeing”](#) (10 September 2021) and [“Pharmacist-led mental health care during the COVID-19 pandemic and beyond”](#) (5 October 2021).

That said, considering the global prevalence and burden of mental health conditions, it is important that the role of pharmacists in this area is expanded and consolidated, and that professional organisations, including FIP, support practitioners to adopt and provide services in this area.

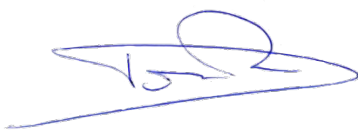
In the framework of FIP’s work on non-communicable diseases, and particularly as part of FIP’s Practice Transformation Programme on NCDs initiated in 2021, FIP has collaborated with an international group of experts to develop this practice-support handbook and its [companion guide on the knowledge and skills](#) required to deliver a range of proposed interventions in the area of mental health. This work highlights the important role that pharmacists can play in identifying individuals experiencing mental health conditions, promoting mental well-being, identifying mental health symptoms, recognising relapse, signposting possible cases that require referral for further support, and providing support to ensure the safe and effective use of medicines by people experiencing or living with mental health conditions, especially in managing medication that may require closer monitoring by a healthcare professional.<sup>18</sup>

Furthermore, mental health is a component that may be present to some extent in all other NCDs. Chronic physical diseases often produce anxiety or depression in patients that needs to be addressed as part of a holistic approach to NCD management.

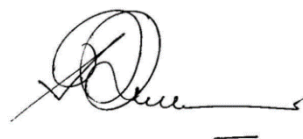
In summary, pharmacists can contribute to the prevention, care and management of mental health conditions and the stigma associated with them, by supporting people with lived-experience of mental illness through different roles, including:<sup>19</sup>

- Health promotion and education
- Addictions, substance use disorder, overdose prevention
- Early detection
- Triage and referral
- Mental health first aid
- Treatment optimisation
- Helping to shape public policies
- Interprofessional collaborative practice
- Research

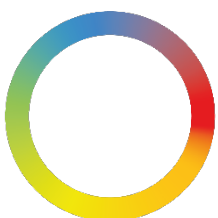
The 2022 WHO World Global Health Report is aptly subtitled “Transforming mental health for all”. This is also the aspiration of FIP’s Practice Transformation Programme on NCDs, under which this handbook is being published. Pharmacists have shown that they are valuable assets in providing evidence-based advice to patients,<sup>20</sup> and can be valuable members of the healthcare team in the prevention, care and management of mental health illnesses. FIP looks forward to working together with its member organisations and individual pharmacists around the world in transforming pharmacy practice to better serve patients and health systems, and improve the mental health and well-being of our communities.



Dominique Jordan  
FIP President



Paul Sinclair, Chair  
FIP Board of Pharmaceutical Practice



**Mental health**  
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# 1 Introduction

## 1.1 Definition of mental illness

As defined by the World Health Organization (WHO), mental health is a “state of well-being in which an individual realises his or her own abilities, can cope with the normal stresses of life, can work productively and is able to make a contribution to his or her community”.<sup>6</sup>

Mental health disorders, on the other hand, are defined by the Diagnostic and Statistical Manual of Mental Disorders – 5<sup>th</sup> Edition (DSM-5) as “a syndrome characterised by clinically significant disturbance in an individual’s cognition, emotion regulation, or behaviour that reflects a dysfunction in the psychological, biological, or developmental processes underlying mental functioning. Mental disorders are usually associated with significant distress or disability in social, occupational, or other important activities. An expectable or culturally approved response to a common stressor or loss, such as the death of a loved one, is not a mental disorder. Socially deviant behaviour (e.g., political, religious, or sexual) and conflicts that are primarily between the individual and society are not mental disorders unless the deviance or conflict results from a dysfunction in the individual, as described above.”<sup>21</sup>

Within the DSM-5, diagnostic criteria are provided for a range of mental illnesses, including neurodevelopmental disorders, schizophrenia, bipolar disorder, depressive disorders, anxiety disorders, obsessive-compulsive disorder, trauma and stressor-related disorders, dissociative disorders, feeding and eating disorders, and many others. In addition to the DSM-5, the ICD-11 (International Classifications of Diseases, 11<sup>th</sup> Revision) is another common resource, developed by the WHO, that is used to define and categorise mental health diagnoses. Similar to the DSM-5, the ICD-11 has diagnostic criteria for a wide range of mental health disorders.<sup>22</sup>

This handbook will not delve into the details of each of these individual mental illnesses but will instead provide an overview of the many roles that pharmacists can play in promoting mental health and well-being, as well as supporting people living with mental illnesses.

## 1.2 Mental health as a public health issue

Mental illnesses are an extremely important public health issue as they cause considerable morbidity and mortality and affect more than one billion people worldwide.<sup>1</sup> It is estimated that around 14.3% of all deaths globally (around eight million) can be attributed to mental disorders each year.<sup>23</sup> Despite this, most people do not have access to adequate mental health care services, which increases the negative impacts of these conditions. In low and middle income countries, more than 75% of individuals with mental, neurological or substance use disorders receive no treatment for their conditions.<sup>1</sup>

Lack of treatment for mental illness is largely due to a lack of mental healthcare workers around the globe. According to the 2020 WHO Mental Health Atlas, there is a concerning shortage of mental health workers globally.

This shortage is most noticeable in the African and South-East Asian regions, where there are 1.6 and 2.8 mental health care workers per 100,000 population, respectively. This is in contrast to the 44.8 mental health workers per 100,000 population present in the European region, which is 40 and 20 times higher than the African and South-East Asia regions, respectively. In the Eastern Mediterranean region, there are 8.8 mental health workers per 100,000 population, while in the Americas region and the Western Pacific region there are 14.9 and 15.4 mental health workers per 100,000 population, respectively.<sup>4</sup>

The disparity in mental health care workers can be seen even more clearly when comparing the mental health workforce among the different World Bank income groups.

In low-income countries, there are only 1.4 mental health workers per 100,000 population compared with 62.2 in high income countries. Lower-middle countries have 3.8 and upper-middle countries have 14.7 mental health

workers per 100,000 population. Thus, there is a clear discrepancy in the availability of mental health care workers in different regions of the world, and those who live in lower income countries are much less likely to have access to mental health services.<sup>4</sup>

Given the significant impact that mental illnesses have on individuals' physical health and quality of life around the world, this issue has been highlighted by several international organisations as a pressing public health issue that must be addressed.

The 17 Sustainable Development Goals (SDGs) adopted by all United Nations member states to promote international development highlight the importance of addressing mental illnesses. First, SDG 3.4 states that, by 2030, the world should aim to “reduce by one third premature mortality from non-communicable diseases through prevention and treatment and promote mental health and well-being”. Secondly, SDG 3.5 states that the world should aim to “strengthen the prevention and treatment of substance abuse, including narcotic drug abuse and harmful use of alcohol”.<sup>24</sup>

The WHO has developed several different resources and initiatives aimed at addressing the public health issue of mental health. First, it has created a Special Initiative for Mental Health (2019–2023), which aims to achieve universal health coverage for mental health and ensure that “all people achieve the highest standard of mental health and well-being”. This initiative will focus on 12 priority countries and aim to increase access to quality and affordable mental health care for 100 million more people.<sup>12</sup> The WHO has also called attention to the public health issue of mental health through its 13<sup>th</sup> General Programme of Work, which covers the years 2019–2023.

As part of this programme of work, the WHO aims to increase service coverage for treatment interventions (pharmacological, psychosocial and rehabilitation and aftercare services) for severe mental health conditions to 50%, and reduce the suicide mortality rate by 15%.<sup>25</sup> Finally, the WHO Comprehensive Mental Health Action Plan (2013–2030) includes quantitative goals for promoting mental health and well-being in four broad areas: (i) more effective leadership and governance for mental health; (ii) provision of comprehensive, integrated mental health and social care services in community-based settings; (iii) implementation of strategies for promotion and prevention, and (iv) strengthened information systems, evidence and research.<sup>26</sup>

### 1.2.1 Mental health during the COVID-19 pandemic

Mental health has been increasingly at the forefront of people's minds due to the impacts of the COVID-19 pandemic. According to a March 2022 report by the WHO, the global prevalence of anxiety and depression increased by more than 25% during the first year of the COVID-19 pandemic.<sup>2</sup> It is estimated that there was an additional 53.2 million cases of major depressive disorder and 76.2 million cases of anxiety disorders globally due to the COVID-19 pandemic.<sup>3</sup>

Rates of mental illness vary by country, with some countries experiencing greater increases in mental illnesses than others. Specifically, lower-middle income countries experienced a higher prevalence of mental illnesses during the COVID-19 pandemic than upper-middle- or high-income countries. Furthermore, there were variations in the prevalence of different mental illnesses across countries. For example, the prevalence of depression ranged from 14.5% in South Africa to 63.3% in Brazil, the prevalence of anxiety ranged from 7.7% in Vietnam to 49.9% in Mexico, and the prevalence of post-traumatic stress symptoms ranged from 10.5% in the United Kingdom to 52% in Egypt.<sup>27</sup> Additionally, certain populations within each country may have been more at risk for developing a mental illness during the pandemic, including those who were younger, female or had pre-existing health conditions.<sup>2</sup>

It has also been suggested that those who have contracted COVID-19 may be at a greater risk for developing a range of mental health conditions, including anxiety, depression, stress and adjustment disorders, opioid use disorders, substance use disorders, and neurocognitive decision and sleep disorders. This risk is believed to hold true even for those who were not admitted to the hospital as a result of their COVID-19 infection.<sup>28</sup> Similarly, those who had mental disorders prior to contracting COVID-19 were at greater risk of severe illness and death from the virus.<sup>2</sup>

COVID-19 not only led to increased rates of mental illnesses, but it also contributed to reductions in availability of mental health care services. According to the WHO, around a third of WHO member states reported

disruptions to mental, neurological or substance use services between November and December 2021. The services that were most impacted were school mental health programmes and alcohol prevention and management programmes. As a result of disruptions to mental health care services, many countries began to broaden their offerings of electronic mental health care services. While these electronic, or telehealth, services helped to mitigate some of the impacts of COVID-19 on access to care, there were several barriers encountered during their implementation, including “inadequate infrastructure, pre-existing inequalities, and low levels of technological literacy” as well as concerns related to cost, privacy and inexperienced providers.<sup>2</sup>

## 1.3 Health and economic burden of mental illnesses

The health and economic implications of mental illnesses are staggering and far-reaching. Mental illnesses cause one in five years lived with disability globally.<sup>2</sup> And those with mental illnesses also have higher mortality rates and are more likely to die prematurely than those without mental illnesses. Individuals with severe mental illnesses, specifically, have a 10–25-year life expectancy reduction compared with those without a mental illness.<sup>29</sup> For those with major depressive disorder and schizophrenia, there is a 40–60% higher chance of premature death than for those without these conditions.<sup>26</sup> Individuals with bipolar mood disorders experience mortality rates that range from 35% to twice as high as the general population.<sup>29</sup> This increased mortality is often due to either suicide or physical conditions that are overlooked and untreated, such as cancers, cardiovascular diseases, diabetes and HIV infections.<sup>26</sup> This is worsened by the fact that those with severe mental illnesses often receive lower quality health care and also face discrimination and stigma as a result of their condition.<sup>29</sup>

Mental illnesses can put individuals at greater risk for physical health conditions and make them more likely to participate in health behaviours that are detrimental to their overall health. Having a physical health condition can also make someone more likely to develop a mental illness. For example, those with schizophrenia are two to three times more likely to have diabetes than the general population.<sup>29</sup> Further, diabetes and obesity were both found to increase the risk of depression, and depression was found to increase the risk of developing diabetes or becoming obese.<sup>30–32</sup> One meta-analysis showed that individuals with type 2 diabetes have a 24% increased risk of developing depression compared with those without diabetes.<sup>33</sup>

Mental illnesses also lead to worsened outcomes for those with chronic conditions. For example, one study showed that those with type 2 diabetes who also had a mental illness had a greater risk of mortality and hospitalisation than those without a mental illness.<sup>34</sup> Another study showed that depression is associated with around a 1.5-fold increased risk of mortality in people with diabetes.<sup>35</sup> These worsened outcomes may be due to a variety of factors. Studies have shown that having depression almost doubles the likelihood of physical inactivity among those with type 2 diabetes and increases the likelihood of poor diets and decreased adherence to medication.<sup>36,37</sup> Thus, there is a bidirectional relationship between mental illnesses and diabetes, and this relationship holds true for other chronic diseases as well. Thus, it is imperative to be aware of the implications of chronic diseases on mental illnesses, and vice versa.

Individuals with mental illnesses are also more likely to experience higher rates of infectious diseases such as HIV and hepatitis.<sup>29</sup> Mental health conditions can increase the risk of contracting HIV by about four- to 10-fold. Mental illnesses can also weaken HIV prevention efforts, including HIV testing and adherence to pre-exposure prophylaxis.<sup>38</sup> Mental illnesses have also been associated with tuberculosis.<sup>29</sup> Those with mental illnesses, including depression and schizophrenia, are more likely to have tuberculosis than the general population.<sup>39</sup> And those with mental illnesses are more likely to experience worsened treatment outcomes and are more likely to die from tuberculosis than those without mental illnesses.<sup>40</sup> The increased risk of infectious disease may be due to the fact that those with mental illnesses are often of lower socioeconomic status and are more likely to participate in risky behaviours, such as intravenous drug use or unprotected sex.<sup>29</sup>

Finally, the high rates of mental illnesses globally and the considerable impacts of these conditions lead to high rates of suicide. In 2019, there were around 700,000 deaths attributed to suicide — one in every 100 deaths. This means that more people die as a result of suicide than HIV, malaria, breast cancer or homicide.<sup>41</sup> The risk of dying by suicide is highest among those who are aged 15–29 years old and suicide is the fourth leading cause of death for people in this age group, behind road injury, tuberculosis and interpersonal violence. Males are more than twice as likely to die by suicide than females. For males, rates of suicide are highest in higher-income countries and, conversely, for females, rates of suicide are highest in lower-middle-income countries.

The lowest suicide rates are seen in the Eastern Mediterranean region (6.4 deaths per 100,000) and the highest are seen in the African region (11.2 per 100,000), the European region (10.5 per 100,000), and the South-East Asian region (10.2 per 100,000). Despite these high values, generally, the suicide rate is decreasing everywhere except in the Americas. From 2000 to 2019, the global suicide rate decreased by 36% but, in the Americas region, it increased by 17%.<sup>41</sup>

Despite the significant health burden that mental illnesses place on countries worldwide, countries only spend around 2% of their health budgets on mental health. Similarly, international development assistance for mental health has never been greater than 1% of all developmental assistance.<sup>1</sup> In 2020, the global median government expenditure on mental health per capita increased to USD 7.49 from USD 2.50 in 2017. However, this benefit is primarily felt by those in high-income countries with a per capita spending of USD 52.73 compared to USD 0.08 in low-income countries, USD 0.37 in lower-middle income countries, and USD 3.29 in upper-middle income countries. Further, of this spending, over 80% of countries reported that they allocate less than 20% of their total government mental health expenditure to primary health care and mental health prevention and promotion programmes. Most funding is instead allocated towards mental hospitals.<sup>4</sup> This lack of investment in comprehensive, holistic mental health care services is concerning given the cost of mental illnesses on global economies and health systems. Currently, depression and anxiety cost the global economy USD 1 trillion per year. Overall, poor mental health is estimated to cost the global economy around USD 2.5 trillion per year as a result of poor health and reduced productivity. It is estimated that this cost may increase to around USD 6 trillion by 2030. It is therefore imperative that governments increase their investments in mental health care services. It is also a cost-effective investment, as for every USD 1 invested in scaling up treatment for depression and anxiety, there is a USD 4 return in improved health and productivity.<sup>42</sup>

## 1.4 Integration of pharmacists in mental health care: current and future

Involvement of pharmacists in mental health care service delivery is imperative in efforts to close the gap in access to care, considering mental health workforce shortages globally, i.e., according to the WHO Mental Health Atlas 2022, the median number of mental health workers was 13 per 100,000 population.<sup>4</sup> This is on the backdrop of a growing global burden attributable to mental illnesses and the associated requirement for mental health care services to support those affected.

Pharmacists are the most accessible healthcare professionals<sup>43</sup> and often the first point of contact with the healthcare system in most countries, i.e., through community pharmacies. Additionally, pharmacists in hospitals and other clinical settings serve as the last point of contact with most health systems at the point of dispensing medicines to patients. These strategic positions that pharmacists occupy present opportunities for them to deliver much needed primary health care services including mental health services, especially with a growing need and attention to task sharing and task shifting arrangements in the healthcare system.<sup>44</sup>

Through task sharing and shifting (reallocation), healthcare providers, or others, who are not normally involved in providing certain services are tasked with providing these services in order to increase access to care. This is particularly important in the context of mental health care given the shortage of mental health workers. Thus, as task sharing and shifting continue to become more commonplace, there will be more opportunities for pharmacists to leverage their accessibility to provide mental health care services to their patients.<sup>45</sup>

Since the second half of the 20<sup>th</sup> century, there has been a growing shift in the treatment of individuals living with mental illnesses from institutionalised care to outpatient services with a need for multidisciplinary practice.<sup>46</sup>

This places pharmacists at the centre of mental health care through their roles as medicines experts and public health specialists. It is noted that lack of funding for pharmacist-delivered mental health care is a barrier to not only their roles in this area, but also to researchers being able to evaluate and publish about these roles in the literature. However, with growing need and attention, professional associations such as FIP, the Royal

Pharmaceutical Society (UK) and the Pharmaceutical Society of Australia <sup>47</sup> have published frameworks and reports outlining the role of pharmacists in mental health service delivery. These have set the stage for the integration of pharmacists in mental health care but more needs to be done to streamline, evaluate and optimise the outcomes of pharmacist-delivered mental health care. These advances can be brought about by:

- **Establishing the importance and scope of mental health care services needed by patients in different geographic locations** — This will enable pharmacists to design interventions suited to these needs. Different patient populations experience different mental health problems with varied social contexts thus there may be a need to consider individualising care.
- **Understanding of the mental health care landscape** — This is crucial for pharmacists' integration in mental health care teams and for pharmacist-delivered mental health services. Cognisant of the different stakeholders and their potential versus current roles in healthcare service delivery, it is important for pharmacists to understand the environment, so that they can better comprehend and prepare for the role they can play in mental health practice, as well as to establish clear frameworks for collaboration in service delivery. By doing so, potential conflicts and competition in service delivery across different cadres of practice can be better prepared for and mitigated. An understanding of the health care landscape also serves to put into context the spectrum of services needed, ranging from health promotion to curative, rehabilitative and palliative services and the health system drivers critical for optimal care delivery. The integration of pharmacists in mental health care calls for a working healthcare system with robust health information systems for data flow, use and sharing in patient management, as well as for financing mechanisms, governance frameworks and efficient supply chain systems.
- **Modelling the integration of pharmacists in mental health care service delivery through competency based training and best practice sharing** — Pharmacists are technically equipped to address the medication needs of patients through their training. With a growing need for pharmacists' involvement in mental health care, there is a need to model this level of practice for current and future pharmacists through examples. Through this handbook, FIP is setting the stage by sharing best practices and insights on pharmacists' roles in mental health service delivery. National associations will then be needed to contextualise these experiences and advances, as well as engage with respective faculties to integrate these principles into pharmacy curricula as well as continuous professional development programmes in their countries. Such contributions drawing from the FIP Global Competency Framework will help shape the future of practice in the various regions while advancing pharmacy globally and improving mental health care.<sup>48</sup>
- **Recognition of pharmacist-led mental health services through policy and advocacy** — With continued delivery of mental health services by pharmacists, without adequate remuneration, recognition or support, there is a need to ensure these services are documented, recognised and evaluated so that advances in this area are not lost. This, to a greater extent, is dependent on policy advocacy, as well as integration of pharmacists and recognition of their roles in mental healthcare within policy documents so that provisions have a legal standing, especially in dynamic environments where priorities shift from government to government and within and across countries.

Currently, pharmacists practise in the following areas of mental health care:<sup>46, 49</sup>

- Dispensing medicines;
- Medication reconciliation;
- Medication therapy management;
- Medication review;
- Medication counselling and education;
- Adherence promotion and education;
- Monitoring safety and efficacy of psychotropic medicines;
- Alcohol and substance use counselling and management ;
- Referrals;
- Primary healthcare services;
- Team-based care in mental health departments (e.g., hospitals); and
- Administering long-acting injectables.

The new frontiers of practice for pharmacists in mental health may include:

- Early intervention for mental illnesses, including expanded roles in screening for mental illnesses;
- Policy development;
- Projects and programme management;
- Medication prescribing and monitoring within the context of a collaborative agreement with a primary care provider;
- Involvement in specialty clinics (e.g., clozapine clinics, lithium clinics);
- Expanded roles as part of team-based care in hospitals, psychiatric hospitals or outpatient clinics; and
- Provision of mental health care services in the community.

## 1.5 Advocating policy changes to improve patient access to mental health services and treatments

Health policy refers to a set of overarching principles and goals that dictate how care is delivered and accessed by patients. These policies can be local, national, international or even institutional with an aspirational outlook focusing on showing health stakeholders the kind of outcomes they are aiming for through their work. The WHO defines health policies as a vision for the future which, in turn, helps to establish targets and points of reference for the short and medium terms.<sup>50</sup> Health policies can help to clarify priorities, establish clarity in roles and expectations for different stakeholders, and support consensus building towards the realisation of set goals.

Considering the advances in pharmacy practice that involve pharmaceutical service delivery beyond medicines dispensing and supply, there is need for a structured framework that provides for these additional services. The inclusion of pharmacists in health policies at global, national and even local institutional levels may serve to remove barriers that pharmacists face when participating in mental health care service provision, including collaboration apathy from other professional groups in the healthcare practice. Additionally, these policies may help to ensure that the ongoing efforts to have pharmacists involved in mental health care are sustained long-term.

Drawing from the Healthy Policy and Service Delivery Programme by the WHO African regional office,<sup>51</sup> focused on offering technical support to countries for the development of evidence-based health policies and plans and the implementation of these through primary healthcare values and principles, there are different roles that pharmacists must play to drive policy change to improve patient access to mental health services and treatment.

Some of the strategies that pharmacists may adopt in advocating for policy change include:

- **Community Involvement** — pharmacists, through their involvement in healthcare service delivery including in provision of mental health services, will need to engage with their communities to establish an irrefutable value proposition in care delivery. This will be in the spirit of patient-centred care, with patients as allies helping pharmacists to build a case for consideration as mental health service providers across the different facets of their practice.
- **Coordination and harmonisation of partnerships and their support** — leveraging on their contextual knowledge of the mental health landscape, pharmacists need to form strategic partnerships with key stakeholders, including physicians, mental health specialists, psychiatric nurses, patient support groups, biopharmaceutical companies and health insurance companies, among others with a role in the delivery of mental health services. Through such engagements, the key driver for pharmacists is to establish a structured proposition on their offering in addressing shortfalls in the current matrix of practice. This can include community assessment and referral of mental health patients, medication review and adherence counselling, among others with an aim of established an integrated mental health services ecosystem for improved access to quality services.

- **Best practice modelling and development** — with focus on evidence-informed policies, there is need for pharmacists to model best practices across the continuum of care for patients living with mental illnesses. Such models would then serve as source of evidence of this contribution to mental health care with a focus on highlighting these in different forums in advocating policy changes. Model examples of such are the Bloom programme funded by the Nova Scotia Department of Health and Wellness, Government of Nova Scotia, Canada, and the PharMIbridge programme in Australia.<sup>46</sup>
- **Health policy development** — to change policies and introduce new provisions towards improving access to mental health services, pharmacists have to contribute to policies through consultative processes and stakeholder engagement frameworks, and support these with evidence collated from practice as modelled to shape these advances. In policy making, the different incentive models for practitioners, including financing and remuneration for services, have to be factored in to ensure these provisions are feasible and sustainable.

Advocacy of policy change will not be a one-off activity considering the dynamic environment in which pharmacists practise. It will therefore be critical for practitioners to pivot their practice models from time to time, generating new evidence and championing the integration of these new service streams and care delivery models in subsequent policy framework cycles. Professional associations will have to be at the forefront in championing these continuous improvements in policies, cognisant of their key role in representation of members and their mandate to advance practice.

### 1.5.1 Pharmaceutical policy

Pharmaceutical costs and access can be major challenges to mental health care providers, with many therapies considered in different ways.

Food and drug authorities should attempt efforts to implement appropriate utilisation management strategies that enhance the quality of care for those with mental health and substance use conditions while balancing pharmaceutical costs and promoting medication access. This can be achieved through actively involving healthcare professionals, including pharmacists, in drug approval and medication safety boards concerned with antipsychotic and psychotropic medicines.<sup>52, 53</sup>

Pharmacists can have an enormous contribution in developing medicine selection and distribution process, ensuring efficacy and safety of antipsychotic medicines, dictating pricing of medicines and performing or evaluating cost-effectiveness studies. Moreover, pharmacists who are researchers in the mental health domain are ideally positioned to evaluate evidence-based guidelines of mental health illness management using medicines, and monitor their utilisation.<sup>54</sup> Working within a multidisciplinary healthcare team will support and reinforce the role of pharmacists as pharmaceutical policy changers.

## 2 Promoting mental well-being and preventing illness

When working within the realm of mental health, pharmacists should not only consider how to address mental health conditions, but also consider how to promote mental well-being among their patients to potentially prevent mental illnesses from developing in the future. The WHO defines mental well-being as a state in which an individual realises their own ability to cope with the normal stressors of life and can proceed to contribute productively towards their community.<sup>6</sup> The WHO differentiates between mental well-being and mental illness (see Figure 1).

Figure 1: WHO continuum of mental health and mental health conditions<sup>55</sup>



Promoting mental well-being, therefore, is important to help prevent progression towards mental illness. While it is not always possible to prevent mental illness, it is still imperative to implement strategies to promote mental well-being. This is especially important among those at highest risk of developing a mental illness in the future. There is no singular factor that contributes to an individual developing a mental illness, but it is instead the interaction between a variety of factors. In a study conducted by the Sax Institute for the Victorian Health Promotion Foundation, a comprehensive evaluation of the literature was conducted to identify risk factors and protective factors for mental illnesses:<sup>56</sup>

- **Risk factors** — Social isolation and loneliness, insecure employment and unemployment, unsupportive work conditions, economic inequality, migration, homelessness, caregiving, physical health conditions, stressful events (including intimate partner violence and drought), and being part of a sexual minority.
- **Protective factors** — Employment, physical activity, strong social relationships and networks, diet and alcohol reduction, and green space.

With these factors in mind, it is important to consider how pharmacists can contribute to helping their patients achieve and maintain mental well-being.

### 2.1 Pharmacists' role in promoting mental well-being

There are many potential methods by which pharmacists can promote mental well-being; however, these roles will vary depending on the practice setting of the pharmacist, the regulations governing pharmacy practice in a country, reimbursement associated with potential services, and the time a pharmacist has to commit to providing certain services.

In order to determine the services that would be most impactful for a particular community or patient population, the WHO's Mental Health Gap Action Programme (mhGAP) outlines a framework, which includes questions that can help guide pharmacists in developing programmes to promote mental well-being (see Table 1).



Table 1: WHO Mental Health Gap Action Programme framework<sup>55</sup>

Four questions to develop a programme plan	Related questions
What is the need?	Where are the service gaps? Which populations are not being served? What are the mental health needs of the community?
What is the aim of the activity or intervention?	What do you hope to achieve? What are the short- and long-term goals?
What activities or interventions are required?	Which activities or interventions can fill the service gaps? What does the evidence tell us about what works?
What resources are available?	Where can these activities or interventions take place? Who can carry out the activities or interventions? Who can you partner with?

For pharmacists, the most feasible methods for promoting mental well-being are likely informal and formal awareness-raising, as outlined in the mhGAP community toolkit. Informal methods include having conversations with patients about mental well-being, intervening when individuals speak about mental illnesses in an unkind or stigmatising way, and improving awareness of mental health and mental illness among patients and community members. Formal methods that pharmacists could pursue include workshops, community forums, flyers or factsheets, radio advertisements or campaigns, newspaper or magazine advertisements, and more. Ultimately, pharmacists should ask themselves the following questions to determine the approach they wish to pursue:<sup>55</sup>

- How do you want to reach members of your community?
- What topic would you like to teach to them?
- Whom might you want to partner with?

There is a range of topics pharmacists can select that will promote mental well-being among their patients. They can focus on the benefits of connecting with others, being physically active, learning new skills, giving to others, participating in mindfulness activities, reducing stress, or getting sufficient sleep.<sup>57</sup> Pharmacists can also focus on reducing the stigma associated with mental illness and psychiatric treatments (including medicines and psychotherapy). One example of current efforts to promote mental health and well-being in pharmacies is in England, where almost all pharmacies are classified as Healthy Living Pharmacies. Through this classification, pharmacy teams are encouraged to promote issues related to these topics, particularly if there is an awareness day about a certain issue (e.g., World Mental Health Day, World Suicide Prevention Day, etc.).<sup>58</sup>

Beyond involvement in awareness and sensitisation programmes to promote mental well-being, pharmacists can use their position as healthcare service providers to inform policies and national guidance documents on mental health to ensure that governments play their role in promoting mental wellness. This can include championing policies that address risk factors such as unemployment, social safety nets for the needy, substance misuse and access policies, among others.

There are many ways through which pharmacists can promote mental well-being among their patients and they should evaluate the most effective and appropriate methods by which this can be accomplished in their specific practice setting, informed by patient needs and their own capability to design and deliver these interventions.

## 2.2 Prevention of addictions, substance use disorder and overdoses

Substance use disorder is a concerning public health issue worldwide, with approximately 500,000 deaths each year attributed to illicit drug use. Further, 35 million people globally are estimated to be experiencing drug use disorders.<sup>59, 60</sup> The use of psychoactive substances without medical supervision has social, economic and health consequences, including but not limited to increased mortality and morbidity, increased healthcare expenditures, lost productivity and other costs related to social welfare.<sup>61</sup> Given the significant impact of substance use disorder globally, it is imperative that all members of the healthcare team contribute to addressing this issue in their communities.

Pharmacists show great promise in delivering services that aim to address substance use disorder and prevent overdoses. As medicines experts, pharmacists have an opportunity to leverage their knowledge to support patients who may be struggling with addiction or who are at risk of overdose. A systematic review of primary care-based interventions that address opioid use disorder found that the most successful programmes included interprofessional teams with advanced practice clinicians, such as pharmacists. Pharmacists were primarily involved in ensuring doses were appropriate (e.g., for buprenorphine and methadone).<sup>62</sup> Another recent systematic review highlighted the important role pharmacists can play in identifying patients at risk of overdose as well as in dispensing naloxone and counselling patients on its appropriate use.<sup>63</sup> Given the trust patients have in their local pharmacists, there is a clear opportunity to get involved in addressing issues related to substance use disorder.

### 2.2.1 Naloxone

Studies have found the benefits of implementing pharmacy-based take home naloxone programmes across rural areas in the United States, making naloxone more accessible to the community, limiting stigma associated with opioid use, and facilitating the process of patient identification and counselling.<sup>64</sup>

Naloxone is an opioid antagonist indicated for emergency treatment of opioid overdose. It is suggested that patients should have naloxone if they are on 50 morphine milligram equivalents (MMEs) or more of opioids. Naloxone intranasal spray is administered as a single spray into one nostril, and administration can be repeated every two to three minutes until emergency medical staff arrive, as long as the patient does not respond by relapsing into respiratory depression. Some of the adverse effects of naloxone are, but are not limited to, increased blood pressure, musculoskeletal pain, headache, nasal dryness, oedema, congestion and inflammation.

Naloxone has been made more readily available in recent years with the implementation of take-home naloxone programmes in the United States and several countries in Europe.<sup>65</sup> These programmes have made naloxone available for people who would otherwise go without a method to reverse an opioid overdose. An example of a country that provides naloxone without a prescription requirement is the United States, where it can be purchased over the pharmacy counter. However, many individual states have their own programmes where individuals can obtain naloxone at no cost. More information on naloxone can be found [here](#). On the front lines, pharmacists have the opportunity to promote awareness for naloxone, since it is not more readily available without a prescription around the world. Many individual countries have their own naloxone take-home programmes where patients can obtain naloxone at a discounted price or free of charge.

### 2.2.2 Prescription monitoring

Prescription drug monitoring programmes aim to track controlled substances that are dispensed to patients and prevent overprescribing, “doctor shopping,” fraudulent prescribing and prescription misuse. These programmes have primarily been implemented in countries with electronic health records, including North American countries, Australia and European countries.<sup>66</sup> However, these programmes are more difficult to implement in low- and middle-income countries that do not currently utilise electronic health records and rely on paper prescriptions. Pharmacists working in countries with existing prescription monitoring programmes should utilise the programme to its fullest potential and ensure they are validating prescriptions for controlled substances prior to dispensing them to patients. For those practising in countries without

prescription monitoring programmes, it is still important to review repeat prescription records to determine whether a patient might be receiving controlled substances at a more frequent rate than prescribed.

## 2.3 Social prescribing

Social prescribing occurs when healthcare providers refer patients to support services in their community. This approach recognises the impact that social determinants of health have on an individual's health and well-being and highlights that a patient may need assistance beyond what can be provided in traditional healthcare settings. Ultimately, social prescribing aims to promote holistic care and address environmental or social factors that may be contributing to a person's health issues.<sup>67</sup> Social prescribing has been suggested to work particularly well for those who have mental health needs, are lonely or isolated, have one or more long-term conditions, or have complex social needs.<sup>68</sup> Social prescribing has primarily been implemented in the UK by the National Health Service (NHS) and is considered a key component of the NHS long term plan due to its ability to contribute to expanded personalised care. In its long term plan, the NHS emphasises the importance of hiring additional link workers to specifically focus on social prescribing and connecting patients with appropriate services.<sup>69</sup> And even although the UK delegates social prescribing to link workers, the role of a social prescriber can be held by any healthcare provider, including pharmacists. Pharmacists have a great opportunity to engage in social prescribing due to their presence in their community and their frequent interactions with patients.

Social prescribing can include a wide range of services and activities. For example, employment services, financial advice, mobility support, carer support, volunteering, arts activities, learning activities, gardening, group support, healthy eating advice, sports, etc.<sup>67, 70</sup> Ultimately, anything that contributes to improving a patient's well-being can be considered social prescribing. Thus, to effectively participate in social prescribing, pharmacists should be knowledgeable about their community and the services that exist through community or volunteer organisations.

Current evidence suggests that there may be many benefits of social prescribing, particularly in terms of health and well-being outcomes, such as quality of life, emotional well-being, levels of depression and anxiety, social connectedness, and mental and general well-being. Social prescribing may also help to encourage the adoption of positive health-related behaviours. However, despite these positive results, the literature is still mixed on the impact of social prescribing, due to limitations in previously conducted studies and difficulties in comparing the various methodologies used by researchers.<sup>67, 71</sup> Future high-quality studies are needed to fully understand the benefits of this service. Evidence is similarly limited with regard to pharmacists' role in social prescribing. A recent scoping review found that pharmacists are engaged in social prescribing initiatives and are primarily assessing patients and referring them to others for additional care or services. This review also found that the methods used to evaluate the impact of these services varied widely between studies, but suggest potential benefits on blood pressure, blood glucose, quality of life, reductions in accessing other health services, among others. However, given the small body of evidence evaluating pharmacists' impact as social prescribers, the impact of these services cannot yet be fully understood.<sup>72</sup> This presents an opportunity for pharmacists to continue to implement social prescribing services and evaluate their impact in order to add to the evidence base.

For pharmacists who are interested in social prescribing, there is a free online course created by the Social Prescribing Pharmacy Association [here](#). This course aims to educate community pharmacists on the principles of social prescribing and help them prepare a plan to integrate social prescribing into their practice setting.<sup>73</sup>

### 3 Identifying signs and symptoms of mental illnesses

Signs and symptoms of mental illnesses vary depending on the specific mental illness an individual is experiencing. While pharmacists will not be diagnosing patients with mental illnesses, they have an opportunity to identify potential signs and symptoms that might indicate their patients require an intervention or referral to a mental health care provider. By being aware of symptoms their patients are experiencing, pharmacists may also be able to identify whether their mental illness is being adequately treated or if they need to make adjustments in their treatment regimen. Thus, pharmacists should be aware of the major signs and symptoms of mental illnesses so they can identify patients who may be in need of referrals or medication adjustments. Broadly, according to National Alliance on Mental Illness in the US, there are several common symptoms of mental illnesses that pharmacists should be aware of, including:<sup>74</sup>

- Excessive worrying or fear
- Feeling excessively sad or low
- Confused thinking or problems concentrating and learning
- Extreme mood changes, including uncontrollable “highs” or feelings of euphoria
- Prolonged or strong feelings of irritability or anger
- Avoiding friends and social activities
- Difficulties understanding or relating to other people
- Changes in sleeping habits or feeling tired and low energy
- Changes in eating habits, such as increased hunger or lack of appetite
- Changes in sex drive
- Difficulty perceiving reality (delusions or hallucinations, in which a person experiences and senses things that do not exist in objective reality)
- Inability to perceive changes in one’s own feelings, behaviour or personality (“lack of insight” or anosognosia)
- Overuse of substances like alcohol or drugs
- Multiple physical ailments without obvious causes (such as headaches, stomach aches, vague and ongoing aches and pains)
- Thinking about suicide
- Inability to carry out daily activities or handle daily problems and stress
- An intense fear of weight gain or concern with appearance

Pharmacists should ensure that they are aware of these symptoms and know what to do should these symptoms be identified in their patients. They should also take steps to make their patients aware of these symptoms and know what to do should they notice these symptoms in themselves or others. As pharmacists become more engaged in the provision of mental health care services, it is imperative for pharmacy educators to incorporate these topics into their curricula in order to prepare pharmacists to assume these roles. Pharmacists who are already practising may wish to pursue continuing professional development opportunities to educate themselves on these topics or pursue additional training in mental health (e.g., Mental Health First Aid, suicide prevention training, etc).

Beyond these general symptoms, it is also beneficial for pharmacists to be aware of the common categories of mental illness they may encounter in their patient population as well as some potential symptoms that are associated with those conditions. Table 2 lists categories and descriptions of mental illnesses as outlined in the DSM-5 as well as some potential symptoms associated with those categories:

**Table 2: Overview of common mental illnesses and their symptoms**

Category of mental illness <sup>21</sup>	Example diagnoses <sup>21</sup>	DSM-5 description <sup>21</sup>	Potential symptoms
Anxiety disorders	Panic disorder, phobias, generalised	Presence of excessive fear and anxiety and related behavioural disturbances. Panic attacks feature prominently within these disorders.	<b>Emotional:</b> Feeling dread, apprehension, tense, jumpy, restless, irritable <b>Physical:</b> Pounding or racing heart, shortness of breath, sweating, tremors, fatigue

Category of mental illness <sup>21</sup>	Example diagnoses <sup>21</sup>	DSM-5 description <sup>21</sup>	Potential symptoms
	anxiety disorder		headaches, insomnia, upset stomach, diarrhoea <sup>75</sup>
Bipolar and related disorders	Bipolar I disorder, bipolar II disorder	Presence of unusual shifts in mood from mania to depression, energy, activity levels, concentration, and the ability to carry out day-to-day tasks <sup>76</sup>	Experiencing episodes of mania and depression that can last for weeks or months. <b>Mania:</b> Feeling very happy or elated, self-important, full of energy, full of great new ideas. Talking quickly, being easily distracted or agitated, not sleeping or eating, making decisions out of character <b>Depression:</b> Symptoms as outlined in the row below <sup>77</sup>
Depressive disorders	Major depressive disorder, persistent depressive disorder, premenstrual dysphoric disorder	Presence of sad, empty or irritable mood, accompanied by somatic and cognitive changes that significantly affect the individual's capacity to function	Changes in sleep or appetite, lack of concentration, loss of energy, lack of interest in activities, hopelessness or guilty thoughts, physical aches and pains, suicidal thoughts, changes in movement (less activity or agitation) <sup>78</sup>
Feeding and eating disorders	Anorexia, bulimia, binge eating disorder (BED)	Persistent disturbance of eating or eating-related behaviour that results in the altered consumption or absorption of food and that significantly impairs physical health or psychosocial functioning	<b>Anorexia:</b> Denying food to point of starvation, obsession with weight loss. Feelings of irritability, lack of mood or emotion, fear of eating in public. Inadequate nutrition leading to constipation, irregular heart rhythms, low blood pressure, dehydration, etc. <b>Bulimia:</b> Forced vomiting, abusing laxatives or excessive exercise to rid themselves of food/calories. Feelings of low self-esteem, being out of control, guilty, shameful, withdrawal from friends and family. Potential dehydration leading to cardiac arrhythmias or heart failure. <b>BED:</b> Loss of control when eating, leading to very large amounts of food consumed in a short period. Feelings of embarrassment, disgust, depression, guilt about behaviour. <sup>79</sup>
Obsessive compulsive and related disorders	Obsessive-compulsive disorder, body dysmorphic disorder, hoarding disorder	Presence of obsessions, compulsions, preoccupations, or repetitive behaviours or mental acts in response to preoccupations. Some disorders are characterised primarily by recurrent body-focused repetitive behaviours and repeated attempts to decrease or stop the behaviours.	<b>Obsessions:</b> Intrusive, irrational thoughts or impulses that repeatedly occur (e.g. thoughts of harming or having harmed someone, doubts about not having done something right) <b>Compulsions:</b> Repetitive acts that temporarily relieve stress caused by obsessions (e.g. hand washing, recounting money, checking if a door is locked) <sup>80</sup>
Psychotic disorders	Schizophrenia	Abnormalities in one or more of the following domains: delusions, hallucinations, disorganised thinking (speech), grossly disorganised or abnormal motor behaviour (including catatonia), and other negative symptoms	Hallucinations (hearing voices, seeing things, or smelling things others cannot), delusions (false beliefs), negative symptoms (being emotionally flat, speaking in a dull, disconnected way), poor memory, trouble organising thoughts or completing tasks <sup>81</sup>

Category of mental illness <sup>21</sup>	Example diagnoses <sup>21</sup>	DSM-5 description <sup>21</sup>	Potential symptoms
Substance use disorders	Alcohol use disorder, opioid use disorder	The essential feature is a cluster of cognitive, behavioural and physiological symptoms indicating that the individual continues using the substance despite significant substance-related problems.	Bloodshot eyes, pupils larger or smaller than usual, deterioration of physical appearance, sudden weight loss or gain, tremors, slurred speech, impaired cognition, lack of motivation, sudden mood swing, increased irritability, appearing fearful, paranoid or anxious <sup>82</sup>
Trauma and stress-related disorders	Post-traumatic stress disorder, acute stress disorder	Presence of psychological distress following exposure to a traumatic or stressful event.	Re-experiencing symptoms such as flashbacks, bad dreams, intrusive thoughts, or avoidance of places or objects that are reminders of the traumatic event, trouble recalling the event, derealisation symptoms, hypervigilance (e.g., being intensely startled by stimuli that resemble the trauma) <sup>83</sup>

### 3.1 Screening for mental illnesses

Stigma can be a major challenge for patients living with mental illness and cause them to delay seeking medical advice.<sup>84</sup> Moreover, many individuals with mental illnesses do not actually recognise their symptoms and know what resources exist to support them.<sup>85</sup> Although the ability of pharmacists to screen patients with depression has proven to be effective and feasible in community pharmacy settings, whether screening affects clinical or economic outcomes is not yet clear.<sup>86</sup> Despite this, there is a clear opportunity for pharmacists to leverage their accessibility to identify potential signs and symptoms of mental illness in their patients and refer patients for diagnosis and treatment if needed.<sup>87</sup>

Therefore, pharmacists should be equipped with the knowledge and skills to adequately perform this role. To participate in screening for mental illnesses, pharmacists should be acquainted with appropriate validated screening tools (scales) as well as know how to use them, when to use them and how to interpret results.

Examples of these tools include the General Health Questionnaire, the Generalised Anxiety Disorder Assessment, the Insomnia Severity Index, the Patient Health Questionnaire (PHQ) for Depression, and the Depression, Anxiety and Stress Scale.<sup>88</sup> The PHQ-9 (the nine-question version of the PHQ), in particular, has been identified as the tool with the best validity and reliability for primary care settings.<sup>89</sup> However, this list of tools is not exhaustive as there are many existing tools and questionnaires pharmacists can use depending on the condition they are screening for. Pharmacists are encouraged to seek out opportunities to educate and train themselves on how to appropriately use screening tools in their practice setting.

One tool that is commonly used to assess wellbeing is the WHO-5 Well-Being Questionnaire. This tool consists of five questions that patients respond to using a Likert scale to identify how they have been feeling over the past two weeks.<sup>90</sup> This questionnaire has been translated into more than 30 languages and has been used globally.<sup>91</sup> A systematic review of this tool has shown that it has been successfully and accurately used as a depression screening tool as well as a tool to assess wellbeing over time or compare well-being between different groups of people (see Table 3).<sup>91</sup>

Table 3: WHO-5 Well-Being Questionnaire<sup>90</sup>

Over the last two weeks	All the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
I feel cheerful and in good spirits	5	4	3	2	1	0

Over the last two weeks	All the time	Most of the time	More than half of the time	Less than half of the time	Some of the time	At no time
I feel calm and relaxed	5	4	3	2	1	0
I feel active and vigorous	5	4	3	2	1	0
I wake up feeling fresh and rested	5	4	3	2	1	0
My daily life is filled with things that interest me	5	4	3	2	1	0

**Scoring:** The raw score is calculated by adding the numbers selected for each of the five questions. The raw score can range from 0 to 25, with 0 representing the worst quality of life and 25 representing the best.

**Interpretation:** If the raw score is below 13 or the patient answers 0 to any of the questions, it is recommended they take the Major Depression (ICD-10) Inventory. A score below 13 indicates poor well-being and is an indication for testing for depression using ICD-10. \*

**Monitoring change:** If the standardised percentage changes by 10%, that is considered a significant change and may require additional care or referrals.

\*The ICD-10 can be found in Annex 2 in the WHO publication “Wellbeing measures in primary health care”.<sup>90</sup>

Another tool is the Mental Health America [Take a Mental Health Test](#) website, which includes online assessments for depression, anxiety, bipolar disorder, post-traumatic stress disorder, eating disorders, addiction, postpartum depression and psychosis.<sup>92</sup> The NHS in the UK has also developed a [Depression and Anxiety Self-Assessment Quiz](#) that can be accessed online.<sup>93</sup> [Here to Help](#) is a project of the British Columbia Partners for Mental Health and Substance Use Information and its website includes screenings for mental well-being, depression, anxiety and substance use.<sup>94</sup> Finally, [Help Yourself. Help Others](#) is another free online screening tool developed by MindWise Innovations in the US that includes screenings for a wide variety of conditions, including anxiety, depression, gambling addiction, alcohol use disorder, opioid misuse, bipolar disorder, and more.<sup>95</sup> These four websites are examples of free online screening tools and there are many other tools and resources pharmacists can leverage to identify potential mental illnesses in their patients. It is important to note that these assessments cannot diagnose a mental illness and only indicate that additional assessments or care may need to be provided to a patient. If pharmacists are encouraging patients to take these assessments, they should also make sure they have referral and follow-up pathways in place to support patients should their assessment indicate they need additional assessments or care.

Beyond obtaining knowledge and skills about signs and symptoms of mental illness and mental health screening tools, pharmacists need to establish a trusting therapeutic relationship with their patients (see Chapter 6), provide a quiet and private environment to screen and counsel patients, and encourage their referral to primary care providers, psychologists, psychiatrists or other mental healthcare professionals.

## 4 Responding to mental health crises

Given the frequency of interaction that pharmacists have with their patients, they are well situated to identify potential signs of mental health crises. Thus, it is important for pharmacists to know what these signs are and how to best respond to ensure their patients receive appropriate, immediate care when experiencing a mental health crisis.

According to the National Alliance of Mental Illness (NAMI), a mental health crisis is “any situation in which a person’s behaviour puts them at risk of hurting themselves or others and/or prevents them from being able to care for themselves or function effectively in the community”.<sup>96</sup> A mental health crisis can be triggered by many different situations, including changes in relationships with others, conflicts with loved ones, death or estrangement of loved ones, trauma or exposure to violence, work or school stressors, starting new medication, missing doses of a medicine, using drugs or alcohol, etc. However, this is not an all-encompassing list and there is significant variability in what situations or experiences may cause or contribute to a mental health crisis in an individual. Additionally, mental health crises may not be triggered by anything and may just be part of the individual’s mental illness.<sup>96</sup> According to NAMI, the following may be warning signs of an imminent mental health crisis:<sup>96</sup>

- Inability to perform daily tasks like bathing, brushing teeth, brushing hair, changing clothes;
- Rapid mood swings, increased energy level, inability to stay still, pacing; suddenly depressed, withdrawn; suddenly happy or calm after period of depression;
- Increased agitation, verbal threats, violent, out-of-control behaviour, destroys property;
- Abusive behaviour to self and others, including substance use or self-harm (cutting);
- Isolation from school, work, family, friends;
- Loses touch with reality (psychosis) — unable to recognise family or friends, confused, strange ideas, thinks they are someone they are not, does not understand what people are saying, hears voices, sees things that are not there; and
- Paranoia (or excessive feelings of distress and feeling of blame).

Another significant concern for those who may be experiencing, or at risk of experiencing, a mental health crisis is suicide, which is a mental health crisis in itself. Suicide can be prevented so it is imperative to be aware of common warning signs of suicide and to know how to directly assess for suicidal ideation, as well as where to refer patients should they be at risk. And while suicide can be prevented, it is important to note that it can often be very difficult to predict given that it is a multifaceted issue and signs can manifest in many different ways. However, it is still important to be aware of common warning signs as outlined by NAMI:<sup>96</sup>

- Giving away personal possessions
- Talking as if the person is saying goodbye or going away forever
- Taking steps to tie up loose ends, like organising personal papers or paying off debts
- Making or changing a will
- Stockpiling pills or obtaining a weapon
- Preoccupation with death
- Sudden cheerfulness or calm after a period of despondency
- Dramatic changes in personality, mood and/or behaviour
- Increased drug or alcohol use
- Saying things like “Nothing matters anymore”, “You’ll be better off without me” or “Life isn’t worth living”
- Withdrawal from friends, family and normal activities
- Failed romantic relationship
- Sense of utter hopelessness and helplessness
- History of suicide attempts or other self-harming behaviours
- History of family/friend suicide or attempts



When these symptoms are seen in patients, pharmacists have an opportunity to speak to them, assess for suicide directly and refer them to appropriate mental health care services so they can receive the care they need. There are many existing tools and frameworks that can assist pharmacists in navigating these difficult conversations. First, the Substance Abuse and Mental Health Services Administration (SAMHSA) in the US has developed practice guidelines that include core elements for responding to mental health crises. Within these guidelines are 10 essential values that should be incorporated into any response or conversation with an individual experiencing a mental health crisis (Table 4). While pharmacists will not be the primary healthcare provider treating someone experiencing a mental health crisis, it is possible that they might be the first point of contact that an individual has with the healthcare system so they should attempt to incorporate these values as much as possible and as appropriate.

Table 4: SAMHSA 10 essential values for responding to a mental health crisis<sup>97</sup>

Essential value	Description
Avoiding harm	An appropriate response to mental health crises considers the risks and benefits attendant to interventions and, whenever possible, employs alternative approaches, such as controlling danger sufficiently to allow a period of “watchful waiting”. In circumstances where there is an urgent need to establish physical safety and few viable alternatives to address an immediate risk of significant harm to the individual or others, an appropriate crisis response incorporates measures to minimise the duration and negative impact of interventions used.
Intervening in person-centred ways	Appropriate interventions seek to understand the individual, his or her unique circumstances and how that individual’s personal preferences and goals can be maximally incorporated in the crisis response.
Shared responsibility	An appropriate crisis response seeks to assist the individual in regaining control by considering the individual an active partner in — rather than a passive recipient of — services.
Addressing trauma	It is essential that once physical safety has been established, harm resulting from the crisis or crisis response is evaluated and addressed without delay by individuals qualified to diagnose and initiate needed treatment. There is also a dual responsibility relating to the individual’s relevant trauma history and vulnerabilities associated with particular interventions; crisis responders should appropriately seek out and incorporate this information in their approaches, and individuals should take personal responsibility for making this crucial information available (for instance, by executing advance directives).
Establishing feelings of personal safety	Assisting the individual in attaining the subjective goal of personal safety requires an understanding of what is needed for that person to experience a sense of security (perhaps contained in a crisis plan or personal safety plan previously formulated by the individual) and what interventions increase feelings of vulnerability (for instance, confinement in a room alone). Providing such assistance also requires that staff be afforded time to gain an understanding of the individual’s needs and latitude to address these needs creatively.
Based on strengths	An appropriate crisis response seeks to identify and reinforce the resources on which an individual can draw, not only to recover from the crisis event, but to also help protect against further occurrences.
The whole person	An individual with a serious mental illness who is in crisis is a whole person, whose established psychiatric disability may be relevant but may — or may not — be immediately paramount.
The person as credible source	An appropriate response to an individual in mental health crisis is not dismissive of the person as a credible source of information — factual or emotional — that is important to understanding the person’s strengths and needs.
Recovery, resilience and natural supports	An appropriate crisis response contributes to the individual’s larger journey toward recovery and resilience and incorporates these values. Accordingly, interventions should preserve dignity, foster a sense of hope, and promote engagement with formal systems and informal resources.
Prevention	An adequate crisis response requires measures that address the person’s unmet needs, both through individualised planning and by promoting systemic improvements.

In order to ensure these values are incorporated into a crisis response, the SAMHSA practice guidelines also outline principles for enacting the essential values, which are listed below and discussed in more detail in the [guidelines](#).<sup>97</sup>

- Access to supports and services is timely
- Services are provided in the least restrictive manner
- Peer support is available
- Adequate time is spent with the individual in crisis
- Plans are strength-based
- Emergency interventions consider the context of the individual's overall plan of services
- Crisis services are provided by individuals with appropriate training and demonstrable competence to evaluate and effectively intervene with the problems being presented
- Individuals in a self-defined crisis are not turned away
- Interveners have a comprehensive understanding of the crisis
- Helping the individual to regain a sense of control is a priority
- Services are congruent with the culture, gender, race, age, sexual orientation, health literacy and communication needs of the individual being served
- Rights are respected
- Services are trauma-informed
- Recurring crises signal problems in assessment or care
- Meaningful measures are taken to reduce the likelihood for future emergencies

## 4.1 Mental health first aid

Pharmacists can equip themselves with skills to appropriately address mental health crises in the pharmacy by partaking in mental health first aid (MHFA) training. MHFA was developed in 2000 in Australia as a course that aims to “empower and equip individuals with the knowledge, skills, and confidence needed to support [those] experiencing a mental health problem or experiencing a crisis, such as being suicidal”.<sup>98</sup> This programme has since expanded outside Australia. It is now being provided in 24 countries and has trained over four million people.<sup>98</sup>

There is considerable evidence that shows MHFA training has positive effects. MHFA USA has compiled a summary of research conducted throughout the world, including studies from the US, Australia, India, Canada, Japan, the United Kingdom, Sri Lanka, Pakistan and Sweden. These studies show that MHFA training increases knowledge of mental illnesses and increases trainees' confidence in helping individuals who are experiencing a mental health crisis.<sup>99</sup> A meta-analysis of MHFA training supports these claims and shows that there are also increases in intentions to provide MHFA as well as increases in the amount of help provided to people experiencing a mental health crisis.<sup>100</sup> The benefits of MHFA training have also been recognised by academic institutions and it is increasingly being incorporated into pharmacy curricula around the world.<sup>101, 102</sup> For more information on the impact of MHFA training, the research summary developed by MHFA USA can be reviewed in its 2021 research summary.<sup>103</sup>

In MHFA training, participants are taught about the MHFA Action Plan (ALGEE). The ALGEE acronym can be a helpful tool to guide conversations with individuals experiencing a mental health problem or crisis. The action plan can be applied to many different situations a pharmacist may encounter when speaking with patients. MHFA USA provides a helpful example of how this action plan can be used if an individual is experiencing a panic attack. Symptoms of a panic attack can include sweating, shaking, numbness, dizziness, heart palpitations, chest pain, abdominal distress, shortness of breath, fear of “going crazy” or dying, or chills or hot flashes. Table 5 describes the ALGEE Action Plan as well as an example of how to apply this model if an individual experiencing symptoms of a panic attack is encountered.<sup>104</sup>

Table 5: MHFA Action Plan (ALGEE)<sup>104-108</sup>

Action plan steps (ALGEE)	Description	Examples responses for a patient experiencing a panic attack
<b>A</b> Approach the person, assess, and assist with any crisis	Look for signs of suicidal thoughts and behaviours, non-suicidal self-injury, or other harm. When assessing a person's risk, keep privacy and confidentiality in mind. If the person does not want to confide in you, encourage them to speak with someone they trust. If someone's life is in immediate danger, seek emergency help as soon as possible.	Ask the patient if this has happened before and if they think they are having a panic attack now. If they have not had one before or do not think they are having one now, call for emergency assistance immediately as these symptoms may also indicate a person is having a heart attack. If this is something they are familiar with and they think they are having a panic attack, ask them if they would like help. If they do, introduce yourself if they do not already know you.
<b>L</b> Listen and communicate non-judgementally	Let the person share without interrupting them and follow these five tips: (i) reflect on your own state of mind; (ii) adopt an attitude of acceptance, genuineness and empathy; (iii) use verbal skills to show that you are listening; (iv) maintain positive body language (e.g., open body posture, comfortable eye contact); and (v) recognise cultural differences.	Ask the patient directly what they think might help them (e.g., sitting down, moving away from crowds). Do not assume you know what is best for them.
<b>G</b> Give support and information	After someone shares their experience and emotions, be ready to provide hope and useful facts. Approach conversations with respect and dignity and do not blame the individual for their symptoms.	Remain calm and reassure the person that they are most likely experiencing a panic attack and that it is not dangerous. Explain that while what they are feeling is frightening, the symptoms will pass. As you talk, use short sentences and speak in a clear, firm manner. Be patient and stay with them throughout the attack.
<b>E</b> Encourage the person to get appropriate professional help	The earlier someone receives help the better their chances are of recovery, so offer to help the person learn more about their options, including referrals to physicians, social workers, counsellors, etc. If possible, have a list available of local and national resources.	When the panic attack is over, provide the person with information related to panic attacks if they do not know about them or do not know where to acquire relevant resources. If they seem concerned, explain that there are effective treatments for panic attacks and that there is help available to them.
<b>E</b> Encourage other supports	Help the person identify their support network and programmes within the community, and help them create a personalised emotional and physical self-care plan. Self-care can help people contribute to their own recovery and can include exercise, relaxation and meditation, self-help books based on cognitive behavioural therapy, or engaging with family, friends, faith and other social networks.	Encourage the person to tap into other support sources, like family, friends or any communities they are a part of. Support groups of people who also experience panic attacks could be useful, as well.

In addition to the MHFA ALGEE framework, NAMI provides some general techniques that can be used to de-escalate a mental health crisis:<sup>96</sup>

- Keep your voice calm
- Avoid overreacting
- Listen to the person
- Express support and concern
- Avoid continuous eye contact
- Ask how you can help
- Keep stimulation level low
- Move slowly
- Offer options instead of trying to take control
- Avoid touching the person unless you ask permission
- Be patient
- Gently announce actions before initiating them
- Give them space, do not make them feel trapped
- Do not make judgmental comments
- Don't argue or try to reason with the person

For additional resources, pharmacists can refer to MHFA Australia's free [guidelines for providing mental health first aid](#). This website includes guidelines for providing MHFA to individuals with depression, panic attacks or eating disorders, and those who have experienced traumatic events. There are also guidelines for providing MHFA to those from immigrant and refugee backgrounds and providing MHFA in Asian countries (including guidelines for India, Japan, the Philippines and Sri Lanka).<sup>109</sup> Additional guidelines have been developed by MHFA that are specific to [suicidal thoughts and behaviours](#).<sup>109, 110</sup>

Ultimately, there are many resources pharmacists can use to help educate themselves on how to appropriately respond to a mental health crisis. By pursuing these resources, pharmacists will be well-prepared to help support their patients with mental illnesses and ensure anyone they encounter who is experiencing a mental health crisis receives the support and care they need.

There is also a need for pharmacy educators to incorporate MHFA topics into their curricula in order to prepare pharmacy students to respond to mental health crises in their future careers. While this is being done in some countries, including the US, the UK and Australia, there is a need for this training to be expanded globally.<sup>101,</sup>

<sup>102, 111-113</sup>

## 5 Suicide prevention and medication-related means restrictions for suicide risk mitigation

The role of pharmacy teams in suicide prevention is beginning to be realised. Since 2012, a growing body of research, predominantly from Canada, Australia, the US and the UK, highlights the role and aspirations of pharmacy teams in suicide prevention, and the associated training needs.<sup>58, 114-117</sup> This work is almost exclusively relating to community pharmacists, with other sectors less explored, and while some studies consider the input of the wider pharmacy team<sup>58,115</sup> others focus on pharmacists.<sup>114,116</sup> The role of pharmacists and their teams in suicide prevention can be broadly conceptualised as two, overlapping roles: (i) social, medical and holistic role; and (ii) means restriction.<sup>117</sup> These align with two of the four evidence-based interventions recommended by the WHO in its “Live life” guidance, namely, “Early identify and support anyone affected” and “Limit access to means of suicide”.<sup>118</sup>

### 5.1 Social, medical and holistic role

Pharmacists and their teams talk to people about suicide,<sup>58, 114-116</sup> with up to 85% having had at least one interaction with a person at risk of suicide.<sup>116</sup> In the UK, Canada and Australia the accessibility of community pharmacy teams was cited as a facilitator to conversations about suicide.<sup>58, 114</sup> The inclusion of pharmacists in a patient’s “circle of care” is a real opportunity for suicide prevention,<sup>117</sup> and for effective triage and referral.<sup>58, 114</sup> To support safe and effective conversations with people about suicide prevention, evidence-based gatekeeper training has been called for.<sup>58, 114</sup> A review of pharmacist suicide prevention training identified pockets of bespoke training in the US, with training mandatory for pharmacists registered in Washington state from 2018.<sup>119</sup> In England in 2021, 72,000 patient-facing pharmacy staff completed Zero Suicide Alliance training as part of the Pharmacy Quality Scheme.<sup>120</sup> For guidance on how to approach conversations with patients regarding their mental health, see Chapter **Error! Reference source not found.**

### 5.2 Means restriction in pharmacy

The most prevalent method of suicide varies by geographic region and is influenced by demographic factors.<sup>121</sup> Medicine poisoning features in self-harm/suicide attempts and is a common method of suicide in some countries, particularly in women.<sup>122, 123</sup> Pharmacists and medicines go hand-in-hand, therefore it seems natural that pharmacists might have a role in medicines means restriction for suicide prevention.<sup>124</sup> Pharmacists in Canada and Australia reported identifying people at risk of suicide and subsequently triaging based on explicit or implicit comment when requesting medicines.<sup>114</sup> In a US survey, 21.6% of community pharmacy staff had responded to a request for a medicine at a potentially lethal dose.<sup>115</sup> In the UK, there was little focus on medicines from pharmacists although there were examples where prescription quantities were restricted, yet pharmacists had often not been told by the prescriber that this was done to limit access to medicines due to perceived suicide risk.<sup>58</sup> This seems a pragmatic approach although there is limited evidence to support this. Recent concerns have been raised in the USA about blanket transfer to 90-day prescriptions where smaller quantities might be more suitable.<sup>125</sup> When paracetamol (acetaminophen) pack sizes were restricted to 32 from pharmacies (maximum 100 per transaction) and 16 in non-pharmacy outlets (maximum 32 per transaction), deaths involving paracetamol poisoning reduced by 43%.<sup>126</sup>

Currently, we know little about the contribution to poisoning of medicines that are borrowed from others or obtained illegitimately, including from the internet. The evidence of the role of pharmacists and their teams in suicide prevention is from high-income countries. It is important to note that pesticide poisoning accounts for 20% of poisonings worldwide,<sup>118</sup> and pharmacies are often one provider of pesticides in low- and middle-income countries. For example, Sniper is a pesticide identified for its potential to be misused or abused in Nigeria,<sup>127</sup> and this is available in pharmacies. This brings another dimension to the role of pharmacy teams in means restriction, which has been incompletely explored.

## 6 Establishing and maintaining a therapeutic relationship

The goal of pharmaceutical care is to achieve what is best for patients and improve their overall quality of life (patient-centeredness of care). Individualised care plans utilise patients' medication experiences and preferences to achieve these goals. The cycle of care, as well, requires timely follow-up to evaluate actual patient outcomes because of this plan. This can be made possible when the patient understands, agrees with, and actively participates in the treatment regimen, thus optimising each patient's medication experience and clinical outcomes.<sup>128</sup> Thus, establishing a therapeutic relationship is a crucial element of pharmaceutical care practice, as it will dictate the quality of care provided.

This relationship should be built on trust, mutual respect, open communication, cooperation and shared decision making around therapeutic goals. The key to building a therapeutic relationship is to create an environment for the patient that fosters communication, and this can be achieved through displaying empathy, positive regard and congruence.<sup>5</sup> For patients with mental health issues, the therapeutic relationship is regarded as the foundation of mental health practice,<sup>129</sup> as a positive therapeutic relationship has been found to be associated with better therapy outcomes in terms of adherence to medication,<sup>130</sup> clinical improvement, duration of hospital stay, rehospitalisation rates and patient satisfaction.<sup>131</sup> In contrast, a negative therapeutic relationship was shown to be linked to poorer therapy outcomes and increased risk of violence.<sup>129, 132</sup>

Establishing and maintaining a clinician-patient therapeutic relationship in psychiatric practice was recently described by Skodol and Bender.<sup>133</sup> They proposed that patients with mental health issues have two components of their personalities: a pathological component that might hinder a clinician's attempts to establish therapeutic relationship, along with an adaptive (healthier) element that is amenable to treatment. In long term psychotherapy, forming a therapeutic alliance is pivotal for the success of therapeutic relationships and consists of three stages: (i) initial agreement on therapy goals, and the role of patient and clinician in achieving them; (ii) the empathic stage where the clinician or therapist is regarded as caring and genuine by the patient; and (iii) the cognitive stage in which the patient joins the therapist as credible collaborator.

Establishing a therapeutic relationship can, however, be challenging, especially in acute psychiatric settings.<sup>129</sup> The involuntary admission of patients and forcing of medication may lead to a perceived coercion by patients and loss of autonomy, which adversely affects the therapeutic relationship. In addition, increasing severity of symptoms in those settings is negatively correlated with the quality of the therapeutic relationship. These barriers might not be similarly encountered in long-term psychotherapeutic settings and more investigations should be directed toward this area.

Moreover, all studies about therapeutic relationships in mental health patients focused on clinicians and nurses. Although pharmacists in different areas of the world showed positive attitudes towards maintaining a trusting therapeutic relationship, the current practice of this role is still quite far from optimal.<sup>134, 135</sup> Nevertheless, there are no studies which evaluate the impact of establishing a pharmacist-patient therapeutic relationship on the efficacy and safety of psychotropic medicines, medication adherence or therapeutic goals in people experiencing mental illness. These gaps in practice create huge opportunities for pharmacists to improve this area of their pharmaceutical practice by emphasising interdisciplinary work with other healthcare providers, focusing on the continuous follow-up of patients to maintain a stable therapeutic relationship beyond acute settings, and training on their verbal and non-verbal communication skills with special attention to mental health patients.

In order to support the development of positive therapeutic relationships, pharmacy educators may wish to incorporate opportunities for pharmacy students to interact with those experiencing mental illnesses in a classroom setting. One meta-analysis found that face-to-face meetings with those with serious mental illnesses do more to improve attitudes and behavioural intentions and reduce stigma towards those with mental illnesses than education alone.<sup>136</sup> Specific to pharmacy students, a systematic review found that incorporating patients into the curricula provides benefits for students and for the patients themselves. Students benefit by developing increased confidence, communication skills and knowledge, and patients benefit by experiencing personal satisfaction, empowerment and knowledge.<sup>137</sup> Thus, if people with mental

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illnesses are invited into the classroom, pharmacy students have an opportunity to speak with them in a safe place, ask questions and gain a deeper appreciation for their experiences with their mental illness.

## 7 Referral and interprofessional collaboration to support patients' mental health

Mental illnesses and their consequences are increasingly gaining interest globally.<sup>138, 139</sup> In spite of that, there is a shortage of trained healthcare professionals who can deal with these issues.<sup>43, 140, 141</sup> A representative survey from 21 countries showed that there is an under-treatment of major depressive disorder, even in high income countries.<sup>140</sup> Yet, pharmacists are not practising their full scope of practice in mental illness and addictions care,<sup>142</sup> although they have high willingness to contribute to the care continuum.<sup>135, 143</sup>

As mentioned before, pharmacists are known to be the most accessible healthcare professionals for the management of minor ailments, as well as chronic diseases.<sup>43</sup> In addition, medicines are one major modality in the management of mental illnesses,<sup>139</sup> hence, pharmacists have a crucial role in counselling patients about their medicines, so as to increase efficacy and minimise side effects, as well as enhancing patients' adherence to treatments. They also play an important role in making recommendations to optimise a patient's therapy. Thus, the integration of pharmacists into the mental health care team is pivotal to help achieve therapeutic goals and potentially help offset increasing issues related to access to care. It may also contribute to recovery-oriented systems of care for individuals with serious mental illness.

In summary, pharmacists alongside psychiatrists have been shown to have a significant role in the care of patients with mental health issues. Pharmacists' integration in the medical team would lead to an improvement in a patient's illness, a decrease in the frequency of side effects and, ultimately, would improve patients' quality of life. In patients with depression or post-traumatic stress disorder, a vast body of literature showed that there was a significant improvement in clinical outcomes when the medical team included a clinical pharmacist, compared with standard care.<sup>144</sup> A study in the US revealed that incorporating a psychiatric pharmacist into primary care produced positive treatment outcomes and it even expanded access to depression treatment modalities.<sup>144</sup> The degree of this integration can vary based on the country. For example, in the UK, community pharmacists have the right to access patients' clinical data, therefore, they should have and should look for more collaboration with mental health care providers, so that this access can be extended to patients' mental health data.<sup>145</sup> The latter will ultimately ease the integration of pharmacists into the healthcare team. The question now is what are the roles that pharmacist can perform as an integral part of the healthcare team providing care to people with mental illness.

Beyond integration into the healthcare team, pharmacists also have an important role to play in referring patients to other healthcare providers. Given that community pharmacists may be the first point of contact that someone has with the healthcare system, it is important for pharmacists to consider how they will manage referrals for their patients. Pharmacists should ensure they have a referral pathway in place to support patients who need emergency care (i.e., those experiencing a mental health crisis, as described in Chapter **Error! Reference source not found.**) and those who need additional assessments or follow-up care from a mental health care provider.<sup>49</sup> Where a patient is referred will vary by country, so it is important for pharmacists who wish to engage more in providing mental health care services to understand what options exist in their communities for their patients and how they will go about connecting their patients with these services.

### 7.1 Interprofessional collaborative care models — literature overview

Medicines for mental illnesses are highly effective yet many patients are still not treated successfully and, as a result, they do not reach complete remission and can have serious adverse events.<sup>146, 147</sup> In this context, medical doctors and other healthcare professionals (e.g., pharmacists, nurses) should follow treatment guidelines, check medication adherence, and take steps to optimise their patients' treatment. Adherence to evidence-based guidelines for depression and anxiety disorders is very low in primary care, as was described in a cross-sectional study of Dutch primary medical care centre.<sup>148</sup> In this study, it was found that only 27% of patients with anxiety disorders and 42% of patients with a depressive disorder received guideline-consistent care and the severity of symptoms experienced by patients did not influence guidelines adherence.<sup>148</sup> Another



study published by Kessler *et al* found similar results in the US primary care settings, with only 21.7% of major depressive disorder cases being adequately treated over the past 12 months.<sup>149</sup>

Schizophrenia is even more challenging to manage due to disease progression, low treatment response and adverse events. Approximately 50% of patients do not respond to antipsychotic treatment and 75% suffer treatment relapse.<sup>150</sup> Psychotropics also present concerns in terms of potential drug-drug interactions, which is another area where pharmacists can contribute their expertise as part of an interprofessional team.

As can be seen from these examples, there are many potential opportunities for pharmacists to contribute to the interprofessional healthcare team to help improve treatment outcomes among those with mental illnesses. Pharmacists are particularly well-suited to improve adherence to treatment guidelines and address drug-drug interactions.

Adler *et al* evaluated the impact of clinical pharmacist interventions in depression treatment (n=533). In this study, clinical pharmacists performed consultations in-person and by telephone to assist the primary care provider and patient with selecting a medicine, dose and regimen, in accordance with depression guidelines. The authors evaluated the impact on several different outcomes. Six-month antidepressant uses rates for intervention patients exceeded controls (57.5% vs. 46.2%, P=0.03). Furthermore, the intervention effectively improved antidepressant uses rates for patients not on antidepressants at enrolment (32.3% vs 10.9%, P=0.001). The pharmacist intervention proved equally effective in subgroups traditionally considered difficult to treat, including those with chronic depression and dysthymia. Patients taking antidepressants had better modified Beck Depression Inventory (BDI) outcomes than patients not taking antidepressants (-6.3 points change, vs -2.8, P=0.01). Still, the outcome differences between intervention and control patients were not statistically significant (17.7 BDI points vs 19.4 BDI points, P=0.16). This study shows an important impact on different outcomes, although not on treatment remission.<sup>151</sup>

A similar study was published by Finley *et al*. They checked changes in the severity of depressive symptoms and their impact on overall health care costs for employers and beneficiaries.<sup>152</sup> Of the 151 beneficiaries referred to the programme, 130 (82%) remained under pharmacist care for a minimum of one year and were included in the aggregate analysis. Statistically significant improvements were observed for Patient Health Questionnaire-9 scores from baseline to endpoint ( $11.5 \pm 6.6$  to  $5.3 \pm 4.7$  [mean  $\pm$  SD], P<0.0001). The clinical response rate was 68%, with a 56% remission rate. In the economic subgroup analysis (n=48), annual medical costs decreased from USD 6,351 per enrollee to USD 5,876, which was lower than the projected value (USD 7,195). Total health care costs to the employer increased from USD 7,935 per enrollee to USD 8,040, which was lower than the projected value (USD 9,023).<sup>152</sup>

In a second study, Finley *et al* checked the impact of a collaborative care model on depression treatment in a primary care setting (75 patients in the intervention group and 50 patients in the control group).<sup>153</sup> After six months, the authors reported that the intervention group demonstrated a significantly higher drug adherence rate than that of the control group (67% vs 48%, odds ratio 2.17, 95% confidence interval 1.04–4.51, P=0.038). Patient satisfaction was significantly greater among members randomly assigned to pharmacists' services than among controls, but the outcome difference was too small to be statistically significant.<sup>153</sup> The pharmacists were also allowed to prescribe ancillary drugs (e.g., trazodone for sleep), but if a change in antidepressant drugs was indicated, approval from the primary care provider was needed.<sup>153</sup>

Stuhec *et al* conducted three different studies that included elderly patients with mental illnesses and polypharmacy.<sup>154-156</sup> The first study was a prospective non-randomised study, including nursing home patients with different mental illnesses.<sup>154</sup> The clinical pharmacist provided interventions in a medication review form (non-prescriber), and general practitioners and psychiatrists made final acceptance decisions. Twenty-four patients were included (mean age=80.6, SD=6.8). The mean number of medicines per patient before the medical review was 12.2 (SD=3.1) and decreased to 10.3 (SD=3.0) at the end of the study period (P<0.05). At the end of the study period, potential type X and D drug-drug interactions had decreased significantly by 33.3% and 42.6%, respectively (P=0.004). The total number of drug-related problems was 165, of which 8% (n=165) were expressed, and the other was identified as potential. With the intervention, the clinical pharmacist reduced the number of risk factors by 16 (29.1%, n=55). In 13 patients, benzodiazepines were taken for several years despite their association with adverse drug reactions, especially falls. Only three of 18 patients indicated receiving antipsychotics (schizophrenia and delusional disorders). Other antipsychotics were used for restlessness, behavioural and psychological symptoms in dementia, delirium and insomnia, all without an approved indication for antipsychotics (except risperidone for behavioural disorders in dementia).<sup>154</sup> This study shows a

significant impact of pharmacists on deprescribing in a real clinical setting because minimum excluding criteria were used (e.g., non-randomised study).

In their second study, the researchers included 49 patients treated with antipsychotics who were older than 65 years and treated with at least 10 medicines (e.g., excessive polypharmacy). A clinical pharmacist with five years of experience in psychiatry provided recommendations via medication review and psychiatrists approved or disapproved these recommendations. The authors found that patients' number of medicines decreased after the clinical pharmacist's interventions (15.4 medicines before; 12.0 after,  $P < 0.05$ ). Accepting the clinical pharmacist's recommendations, but not age, improved antipsychotic treatment guidelines' adherence ( $P = 0.041$ ).<sup>155</sup> This study shows a positive association between intervention acceptance and clinical pharmacist recommendations, identifying clinical pharmacists as important partners in better treatment adherence and lower polypharmacy rates in patients with excessive polypharmacy.

Their third study evaluated the long-term impact of clinical pharmacist interventions in a primary care setting (e.g., primary care clinic) in Slovenia.<sup>156</sup> The study included 48 patients (79.4 years,  $SD = 8.13$ ). The number of medicines decreased by 9.5% after the medication review provided by a clinical pharmacist. The clinical pharmacist proposed 198 interventions related to psychotropics, of which the general practitioners accepted 108 (55%). All accepted interventions (99.1%) except one were still maintained six months later. This led to a significant decrease in the total number of medicines, potentially inappropriate medicines (PIMs), and potential type X drug-drug interactions (pXDDIs) ( $p < 0.05$ ) and improved depression, anxiety, insomnia and schizophrenia treatment guidelines adherence.<sup>156</sup> This study is important because results show that almost all accepted interventions were continued for six months, and clinical pharmacists can improve treatment guidelines adherence significantly (e.g., 40% in depression, 25% in insomnia, 19% in anxiety and 18% in schizophrenia).<sup>156</sup>

Another study that highlights the impact pharmacists can have on mental health outcomes is a 12-month study conducted in Scotland that includes a clinical pharmacist as an independent prescriber in primary care settings. In this study, pharmacists could practise autonomously by initiating and altering medication without necessarily referring to general practitioners. Results were positive and showed that Patient Health Questionnaire-9 and General Anxiety Disorder-7 scores were reduced by 50%.<sup>157</sup> According to these results, there is potential to translate these results into sustained pharmaceutical services and therefore further evaluations are needed.

Some studies have also been conducted in mental health hospitals (e.g., psychiatric hospitals), where clinical pharmacists' interventions are made in different forms (e.g., part of the team, discharge consultations, medication review).<sup>158-161</sup> In a Slovenian study conducted in a small psychiatric hospital, the retrospective observational pre-post study examined the impact of clinical pharmacist recommendations in an interdisciplinary medical team during psychiatric hospital rounds.<sup>161</sup> The clinical pharmacist made 315 recommendations for a total of 224 participants (average age mean=59.4, median=56). Psychiatrists accepted 295 (93.7%) of the recommendations. After the recommendations, the number of expressed and potential drug-related problems decreased in 166 (93.8%) and 129 (93.8%) interventions, respectively. Three months after discharge, 222 accepted recommendations were continued (70.5%).<sup>161</sup> The psychiatrists' acceptance rate was very high because pharmacists could communicate within the team on each occasion. These results show that clinical pharmacists are very important members of a multidisciplinary team on the ward in daily rounds.<sup>160, 161</sup> Clinical pharmacist interventions can also reduce antipsychotic polypharmacy, as shown by Goren et al. In their study, initially 5.9% of patients were prescribed three or more antipsychotics at discharge. However, after a clinical pharmacist's interventions, that figure was reduced to 2.5% and then to 0.0%.<sup>158</sup> A 2020 systematic review ( $n = 64$ ) found that incorporating psychiatric pharmacists into interprofessional healthcare teams was the most common pharmacist practice in psychiatric settings and was associated with significant improvements in patient-level outcomes.<sup>160</sup>

In all, through these studies, it can be seen that pharmacists should be integral members of the interprofessional mental health care team. With their medicines expertise, they can provide a unique skillset to the team and can contribute to improving treatment outcomes for those with mental illnesses.

## 8 Optimising psychotropic medicines use

### 8.1 Patient counselling on medicines use for mental illnesses

Patients living with mental illnesses still face stigmatisation; therefore, it is important for pharmacists to be aware of the language and non-verbal cues they use when counselling, with a particular focus on using destigmatising language and being empathetic.<sup>162</sup> For example, “you suffer from depression” puts the mental illness in a negative light, as opposed to “you are experiencing the symptoms of depression” which is much less stigmatising. When approaching any counselling session with an individual with mental illness, pharmacists should ensure they are prepared to use person-centred language, which is language that highlights that an illness is only one part of a person’s life, not their primary identity. For example, the term “schizophrenic” should be replaced with “person with schizophrenia”. Words used should also be neutral and not imply a positive or negative judgement. For example, suicide attempts should not be classified as successful or unsuccessful, instead the phrase “survived a suicide attempt” should be used.<sup>163</sup> Pharmacists who are unsure if they are using the correct terms are encouraged to seek out resources that can assist. For example, the [Mental Health Language Guide](#) developed by Well Beings initiative in the US or the [Language Guide](#) developed by the Mental Health Complaints Commissioner in Australia.

Counselling patients with mental illness is similar to counselling those with physical health conditions, but there are some additional points that should be addressed, including: (i) latency to onset of action in antidepressants and long-acting injectable antipsychotics; (ii) the lack of addiction with all drug classes, except benzodiazepines and Z-drugs; and (iii) the lack of a change in personality when taking antidepressants, antipsychotics or mood stabilisers. These three items are important factors that often concern patients and can influence treatment initiation and adherence.<sup>164</sup> In addition, pharmacists should ensure patients are aware that antidepressants might worsen their symptoms after medication initiation (e.g., within the first and second week). This is extremely important as this is a main reason why higher suicidality (i.e., suicidal thoughts, plans, and actions, suicide attempts, and completed suicide) can be seen in studies with antidepressants compared with placebo.

Pharmacists may wish to follow-up frequently with their patients who have newly initiated an antidepressant and ask about their symptoms. As there is an abundance of information on the internet, it can be valuable to start a counselling session with the open question “What have you already read on the internet?”. With that question, pharmacists can learn about the patient’s fears (e.g., particular side effects), can correct false information and can put those fears into perspective.

Shared decision-making is very important in mental health care. Therefore, patients need a lot of information in order to make decisions regarding whether or not to take medicines. Important questions a patient and their healthcare professional might ask themselves may be:

- Why should I take this medicine?
- How do medicines help me in the long-term?
- How can I deal with worsening symptoms? (These are usually seen within 10 days, e.g., receptor desensitization.)
- How do I take it and when?
- What are the most common side effects? What can I do to minimise these side effects (e.g., take it with a meal, taking sedating drugs before bedtime, sugar free gum for dry mouth etc.)?
- What is my prognosis if I take the medicine vs if I decide not to take it? (It is advisable to look up these numbers in the current national or international guideline for the disease e.g., the relapse rate, recovery rate, remission rate.)
- What other treatment options do I have?
- What parameters need to be monitored while I’m taking the medicine and how often should they be measured (electrocardiogram, laboratory tests, blood pressure, etc.)?
- What if I want to discontinue the medicine?
- What is the overall risk-benefit ratio in my individual case (with all comorbidities etc.)?

- What non-prescription medicines do I need to avoid due to possible drug interactions while I take this medicine?
- What habits can have an impact on treatment effectiveness and tolerability (e.g., smoking and CYP induction, grapefruit juice on CYP inhibition, low salt intake on lithium levels)?

During the counselling session, pharmacists can obtain information on the patient that may influence their adherence, their willingness to take a medicine, the individual benefits, and the intolerable side effects that would lead them to discontinuation. Sometimes this leads to a pharmaceutical recommendation to the prescribing physician to choose a different medicine. It is possible that a patient might prefer to tell the pharmacist about their fears and willingness to take a drug as opposed to a physician because the pharmacist is not the prescriber in most cases. This emphasises the role of pharmacists in mental health care, both in primary care settings (direct contact with healthcare providers who prescribe psychotropic drugs) and secondary and tertiary care settings, as they are able to retrieve patient information that has an influence on the selection of the drug.

Pharmacists can provide medication reviews in all settings and, through them, they can suggest changes in pharmacotherapy because of poor outcomes (e.g., no remission) and medication-related problems (e.g., adverse events, drug-drug interaction, inappropriate dosing). It is important that physicians and pharmacists work closely together to ensure optimal patient outcomes. Ultimately, the pharmacist can play a very important role and should therefore become active in performing medication reviews and patient counselling.

In the hospital setting, group counselling, also known as psychoeducational groups, is a time-efficient way to counsel on drug classes, e.g., antidepressants, antipsychotics, mood stabilisers, anti-craving drugs, anxiolytics, sleeping aids. During these group sessions of 25–60 minutes (depending on the acuteness of the diseases of the patients that are attending the group), the pharmacist can explain the mechanism of action, side effects, important drug interactions, how and when to take the medicine, and how long to take it for. Also, it is important to address the effect of drug therapy versus psychotherapy and other non-pharmacological therapies.

Another consideration in patient counselling is the relatives, carers, case managers, etc of the patient. Family concepts of a relative's illness are an important part of the coping process and reveal the cultural construction of the experience of illness. Thus, family members have an influence on the patient's medication adherence. Specific psychoeducational groups for patients and their family members have been developed and implemented successfully.<sup>165</sup> A pharmacist can lead those groups in the hospital or ambulatory care setting, but also counsel patients with their family members in counselling sessions individually.

The ultimate goal of individual or group counselling is to educate patients and provide them with the necessary knowledge to participate in shared decision making with their healthcare providers.

## 8.2 Clinically important treatment outcomes — implications for pharmacist counselling

In order to adequately counsel and support people being treated for mental illnesses, it is important for pharmacists and patients to have an understanding of the desired and expectable treatment outcomes and the time that different treatment options may take to produce a perceivable effect. This will contribute to understanding the treatment process, managing expectations and, ultimately, supporting adherence to treatments.

Mental illness treatment outcomes include short-term (e.g., four weeks) and long-term outcomes (e.g., up to 20 years). In psychopharmacological treatments, the main short-term outcomes are defined by treatment response, relapse and remission.

In their interactions with people being treated for mental illnesses, pharmacists may ask about subjective perceptions of the effects of treatment and symptom evolution. However, different validated scales are used in clinical practice and studies to measure treatment response (e.g., the Hamilton Depression Rating Scale). Treatment response is a crucial step towards remission and successful long-term outcomes. Full remission means the complete absence of symptoms and is the main goal of short-term treatment.<sup>146</sup> Another short-term

outcome measured in mental health illnesses, particularly in the context of randomised clinical trials, is the statistical concept of standardised mean difference (SMD). The SMD allows for comparison between experimental and control groups in a clinical research context.<sup>166</sup>

Long-term outcomes are focused on the prevention of relapse, a lower number of hospitalisations and lower mortality. Although short-term outcomes are important, especially in the acute phase of treatment, long-term outcomes impact disease progression. Examples of treatment outcomes in depression, generalised anxiety disorders, and schizophrenia are summarised in Table 6. The following sections provide further details of selected studies of the measurement of treatment outcomes, and their implications for mental healthcare, including pharmacy practice.

Table 6: Examples of treatment outcomes in depression, generalised anxiety disorder and schizophrenia.

	Depression	Generalized anxiety disorders	Schizophrenia
Short-term outcomes	Remission and preventing relapse Acceptability and tolerability Standardised mean difference (SMD)	Remission SMD	Acceptability and tolerability SMD
Long-term outcomes	Treatment remission, long-term remission	Relapse prevention	Response, the better chance for remission, effectiveness (e.g., time to discontinuation), tolerability rehospitalisations, mortality
Scale for outcome measurement	Hamilton Rating Scale for Depression	Hamilton Anxiety Rating Scale	Positive and Negative Syndrome Scale

### 8.2.1 Outcomes in depression and anxiety treatments — literature overview

Treatment response and remission are key short-term outcomes in depression and anxiety disorders treatment. In depression treatment, the Hamilton Rating Scale for Depression (HAM-D-17) is used as a gold standard for measuring treatment response and remission. Treatment response is defined as a minimum of 50% improvement on the HAM-D-17 scale (e.g., 50% fewer points), while remission is defined as 7 points or less on the HAM-D-17 scale. The HAM-D-17 scale should not be used as a diagnostic instrument. Assessment time is approximately 20 minutes per patient. HAM-D-17 can be used by healthcare professionals, including pharmacists. Translations are available in different languages.<sup>146, 167</sup>

The Sequenced Treatment Alternatives to Relieve Depression (STAR\*D) study is a key naturalistic study where clinical outcomes (remission as the main outcome) in treatment for major depressive disorder were measured.<sup>168</sup> Over seven years, the authors enrolled over 4,000 patients from 23 psychiatric and 18 primary care sites in the US. Pharmacists can use these outcomes in conversations with patients about treatment efficacy after first and second episodes. This has been the largest and most consequential antidepressant study conducted to date.<sup>168</sup> This study consisted of four stages of treatment:<sup>169</sup>

- **Stage 1** — Patients with depression were treated aggressively with citalopram for 12–14 weeks. Approximately 33% of participants reached remission and around 10–15% responded to therapy but did not reach remission.
- **Stage 2** — Patients who were intolerant to citalopram or did not reach remission in stage 1 were either switched to other treatment options (sertraline, bupropion, venlafaxine, cognitive therapy), or had another option added to their therapy (bupropion, buspirone, cognitive therapy). Of those who switched medicines, 25% became symptom-free. Of those who added-on to their treatment, around 33% became symptom free.
- **Stage 3** — Patients who were intolerant of stage 2 treatment or did not reach remission were included in stage 3. Patients were again asked to either switch to another medicine (mirtazapine or

nortriptyline) or add on to their existing treatment (lithium or triiodothyronine). Approximately 12–20% of participants became symptom-free.

- **Stage 4** — Patients who did not respond to any of the treatments in stages 1–3 were taken off all other treatments and randomly assigned to either tranylcypromine or the combination of venlafaxine extended release with mirtazapine. Approximately 7–10% of patients became symptom-free.

In all, around 50% of participants became symptom-free after two stages of treatment and around 70% after four stages. The STAR\*D trial also showed no significant differences among different strategies used after the first unsuccessful treatment with citalopram (even if they switched them to a similar or different medicine). All strategies showed similar remission rates.<sup>146</sup>

Building on this, combination antidepressant treatment was compared with monotherapy in a 2016 meta-analysis published by Henssler *et al*, which included 8,688 articles and 38 studies, involving 4,511 patients.<sup>170</sup> This study showed that combination treatment was significantly superior to monotherapy, although more long-term studies are needed.<sup>170</sup>

Finally, recognising that treatment for depression in those over the age of 65 years has been increasing, a systematic review of randomised controlled trials aimed to evaluate the efficacy and tolerability of antidepressants in this patient population. The review evaluated remission rates, treatment responses and emergent adverse events. The authors found that selective serotonin reuptake inhibitors (SSRIs) were not superior to placebo in achieving remission or response, but they were superior in preventing relapse. Duloxetine was found to be superior to placebo in achieving remission and response, but also increased the risk of adverse events. Ultimately, the study emphasises the importance of closely monitoring antidepressant usage in older adults and working to prevent and manage potentially dangerous adverse events.<sup>171</sup>

Similarly to depression, anxiety disorders are also treated with psychotherapy and pharmacotherapy. The efficacy of psychological and pharmacological approaches is similar in the acute treatment of anxiety disorders.<sup>147</sup> The Hamilton Anxiety Rating Scale (HAM-A) is often used to assess treatment improvement in both clinical practice and trials. After two weeks (HAM-A score  $\geq 20\%$ ), the onset of efficacy is strongly predictive of remission. If the beginning is not seen after four to six weeks of treatment, the response is low. SSRIs are considered the first-line treatment, and serotonin and norepinephrine reuptake inhibitors and pregabalin are often used for generalised anxiety disorder (GAD).<sup>147</sup>

Different medicines were compared for GAD treatment in short-term trials and effect sizes were calculated. Twenty-one randomised clinical trials were included with a duration of eight to 24 weeks, and with a total of 5,935 participants. Effect sizes (SMD) were from 0.50 for pregabalin to 0.17 for buspirone, which shows low to moderate effect sizes.<sup>172</sup> Long-term studies show that many different medicines have been tested (paroxetine, escitalopram, duloxetine, venlafaxine and quetiapine) in trials (16–52 weeks), and results were positive in terms of relapse prevention.<sup>148</sup> Pharmacists can use this information to provide education to patients focused on usually necessary time to response and remission and treatment efficacies (e.g., short and long-term).

## 8.2.2 Outcomes in schizophrenia treatment — literature overview

Schizophrenia is a progressive mental illness, and the main outcomes are focused on the short- and long-term outcomes. Short-term outcomes have been measured in multiple meta-analyses.<sup>173, 174</sup> In the latest meta-analysis, Huhn *et al* compared 32 different antipsychotics in 402 different studies, including 53,463 participants. They showed that antipsychotics reduced overall symptoms more than placebo (although this was not statistically significant for six drugs), with SMDs ranging from  $-0.89$  for clozapine to  $-0.03$  for levomepromazine. The authors found some efficacy differences between antipsychotics, but most are gradual rather than discrete.<sup>174</sup>

A similar meta-analysis focusing on elderly patients with schizophrenia has also been published and showed that, in terms of the overall symptoms, olanzapine was significantly superior to haloperidol.<sup>175</sup> A similar result was observed in adult patients with schizophrenia.<sup>173</sup> A placebo-controlled study including paliperidone showed no significant difference.<sup>175</sup> All meta-analyses have several important limitations because patients with polypharmacy and several comorbidities were excluded, and the impact on remission was not checked (only SMDs). Most studies with schizophrenia used the Positive and Negative Syndrome Scale (PANSS) for

treatment improvement measurement. The PANSS is a relatively brief interview, requiring 45 to 50 minutes to undertake.<sup>176</sup>

Long-term outcomes in schizophrenia treatment were calculated in different registry studies (e.g., cohort studies).<sup>177, 178</sup> In the first registry cohort study, patients in inpatient settings from 1972 to 2014 in Finland (cohort of all persons with schizophrenia) were included. Results show that antipsychotic treatment leads to a lower hospitalisation risk than no treatment.<sup>177</sup> Researchers checked if a long-term antipsychotic treatment leads to lower mortality in the latest long-term study on this topic. Inpatient care was included between 1972 and 2014 in Finland (n=62,250), with up to 20 years of follow-up. The cumulative mortality rates during a maximum follow-up of 20 years were 46.2% for no antipsychotic use, 25.7% for any antipsychotic use, and 15.6% for clozapine use. The results showed that clozapine has the highest impact on lower mortality in long-term treatment.<sup>178</sup>

Long-term remissions have also been tested in key prospective studies, including CATIE (Clinical Antipsychotic Trials for Intervention Effectiveness), EUFEST (European First Episode Schizophrenia Trial) and SOHO (Schizophrenia Outpatient Health Outcomes), as was summarised by Citrome *et al.*<sup>179</sup> Citrome *et al* showed that antipsychotic efficacy was much lower in chronic schizophrenia patients than in first-episode patients with schizophrenia, which means that early treatment can improve outcomes (e.g., remission). After 12 months' of treatment, approximately 60% of patients with first-episode schizophrenia remitted, compared to only 30% patients with chronic schizophrenia. All studies indicate that differences in efficacy and tolerability exist between the antipsychotics.<sup>179</sup>

Non-response to treatment is frequent because approximately 50% of patients do not respond to antipsychotics and 75% suffer treatment relapse. Clozapine as a first-line treatment for treatment-resistant schizophrenia is delayed in many countries, and therefore multidisciplinary collaboration is needed to improve prompt diagnosis and treatment follow-up of this condition.<sup>150</sup> Antipsychotic polypharmacy has been used often before clozapine, although different guidelines offer different recommendations.<sup>180</sup> Antipsychotic polypharmacy is associated with several adverse events, including metabolic problems and increased rates of metabolic syndrome (50.0% vs. 34.3%,  $P=0.015$ ) and ratio of triglycerides to HDL-cholesterol TG/HDL (50.7% vs. 35.0%,  $P=0.016$ ).<sup>181</sup> Late clozapine use means lower possible clozapine efficacy and poorer treatment, and therefore appropriate strategies are needed to improve clozapine management in schizophrenia treatment.<sup>182</sup>

Pharmacists can use these outcomes in conversations with patients (e.g., efficacy of treatment, adverse events and their monitoring, long-term mortality with treatment and without treatment). Pharmacists should also monitor adverse events and give all necessary information to patients (e.g., how to minimise antipsychotic adverse events) and provide charts at each appointment.

## 8.3 Using adherence as an indicator of need

Adherence is an indicator that correlates with prognosis. Low adherence acts as a signal to the pharmacist and treatment team that the individual has higher health care needs than a person who has the ability to take their medicines as prescribed. This latter person may be more responsive to medication with fewer adverse effects. They may also have better organisational skills, cognition and other close supports that align with their better prognosis and treatment outcomes. They are more likely to have good insights into their illness, a less severe illness and fewer comorbidities (mental and physical). Adherence may be low with one medicine and better with another, for a range of reasons. Response to medication is difficult to predict and can be different over time. To argue that the problem is poor adherence is to ignore the many factors that contribute to it.

An important role of the pharmacist is to help people who are in need of their care for whom pharmacotherapy may be a first- or second-line treatment option, many of whom have low medication adherence, and also for those who are fully adherent but not responding to or tolerating their current regimen. Sometimes, but not always, simply improving adherence to psychotropic medication substantially improves the health and wellness of the individual. Other times, improving adherence leads to worse outcomes — psychotropic medicines can be associated with a high adverse effect burden and serious adverse effects. A focus on improving treatment adherence with the idea that doing so will lead to a better chance for treatment response can cause a pharmacist to miss what the patient needs.

Thinking of adherence as an indicator of a patient's prognosis and health needs helps to set the pharmacist up for prioritising and supporting them to meet their needs. People with low adherence to their psychotropic medication have reduced rates of treatment response and remission. Improving these rates takes more than simply increasing pill-taking regularity. It is important that the pharmacist listens to patients who are not taking their medicines as prescribed. What patients say usually clarifies the reasons and their rationale. The issue of low adherence may relate to a patient's experience with their illness (e.g., lack of insight), attitude toward the medicine (e.g., concerns of long-term harms), and experiences with the medicine (e.g., burdensome adverse effects, insufficient treatment benefit). Learning about and addressing a patient's concerns may lead to improved medication adherence, but it is just as likely to lead to a change in the management strategy, which includes stopping the medicine, modifying the dosing schedule, switching to another medicine, or adding a different medicine to manage ongoing symptoms or adverse effects. Taking a categorical approach to changing a patient from "poor adherence" to "good adherence" to their prescribed medication focuses on the indicator rather than the patient. The goal needs to focus on treatment concordance, which indicates an agreement between the patient's health team and the patient that respects the patient's beliefs and wishes in determining which, when and how medicines are to be taken.<sup>183</sup>

Patient autonomy and patient-centred care should be the priorities for engendering a long-term therapeutic relationship with a patient living with a mental illness. This needs to be kept in mind when recognising low adherence and attempting to understand and respond to it. The first step toward understanding low adherence is to listen to the patient. Without judgment, questions to support the discussion can include:

- What might make it hard for you to take your medicine as prescribed?
- Are you finding that it is helping you?
- Are there side effects that you are experiencing that we can talk about?
- What do you know about this medicine that concerns you?

Responses to these and other questions can be used to identify and discuss options that address low adherence that are specific to the patient's values and wishes. Aligning changes to the care plan with the patient's interests, whether it be in assessment and follow-up only or changes to the medication regimen, will improve patient satisfaction with their care and adherence to the overall care plan.

## 8.4 Evaluating and resolving medicines-related problems

Medication use reviews, medication reviews and drug-drug interaction checks can identify medicines-related problems. Of course, the more information the pharmacist has on a particular patient, the better the pharmaceutical intervention can be. Direct patient contact is more time-consuming than a chart review, so finding a balance and defining factors that lead to direct patient counselling in the hospital setting needs to be implemented (e.g. polypharmacy, number of comorbidities, severe adverse drug reactions). In community pharmacy, direct counselling is always possible, but reimbursement for longer counselling sessions (e.g., medication reviews) is lacking in many countries. Also, communication paths to prescribing physicians have to be established in both settings. Confidentiality has to be observed at all times. Transparency is also very important when working with psychiatric patients, so they should always be informed when one healthcare professional is interacting with other healthcare professionals. Nevertheless, overwhelming the patient with drug interaction warnings might endanger adherence. A dialogue between patient, physician and pharmacist is ideal.<sup>184, 185</sup>

Political efforts should be undertaken to achieve reimbursements for those often time-consuming interventions. In some countries (e.g., USA, UK, Slovenia) clinical pharmacists work in primary care clinics and they provide a medication review, which is reimbursed by national or private insurance systems.<sup>186</sup> In Germany, the reimbursement by national health insurance of medication reviews in community pharmacy began in 2022 as well.

As part of these medication reviews, clinical pharmacists consult each patient and can suggest medication initiation, medicine switching and discontinuation, and can monitor patients, including clinical outcomes measurement (e.g., ask for a second appointment). Thus, it is important to advocate the reimbursement of these services so patients can benefit from the addition of a medicines expert on their healthcare team.



### 8.4.1 Drug interactions

Due to the wide receptor binding profile, and the CYP-inhibitory and CYP-inducing potential of many psychotropic drugs, a drug interaction check is of utmost importance in psychiatric patients to ensure drug therapy safety. The pharmacist can give recommendations about a different drug therapy to physicians if necessary to avoid drug-drug interactions (DDIs). On an acute ward, a clinical pharmacist was able to reduce the number of relevant DDIs by 78%.<sup>187</sup>

Therapeutic drug monitoring can be used to assess the severity of pharmacokinetic drug interactions in which the psychotropic drug is the victim drug. However, psychotropic drugs are often the perpetrator drugs (inhibitors or inducers) and therapeutic drug monitoring does not exist for all drugs or even drug classes, so avoidance or close monitoring for signs for non-efficacy or toxicity is needed.

Sometimes a patient is taking drugs that are not on the prescriber's medication list. To specifically ask for more drugs than are on the list (e.g., contraceptives, herbals, food supplements) can detect drug interactions that led to drug-related problems. Also, grapefruit juice, a strong inhibitor of CYP3A4, can cause severe drug interactions. Questions on dietary habits and changes to them can reveal drug-related problems.

There are many drug interactions, especially where polypharmacy of psychotropic drugs is concerned, that can lead to sedation, anticholinergic side effects due to a high anticholinergic burden, QTc prolongation, hyponatraemia and many others. Specific charts like the QTc-risk charts at [www.crediblemeds.org](http://www.crediblemeds.org) or the anticholinergic burden score at [www.abccalc.com](http://www.abccalc.com) can help to identify DDIs that the drug interaction databases do not identify.

Using databases for DDI-checks is essential in polypharmacy patients. The selection of the best database is difficult though, because they differ from each other.<sup>188</sup> For example, using American databases may not allow the pharmacist to enter national drugs that are not approved in the US. Some databases provide more information on particular drug classes. Especially for psychotropic drugs, there is a lack of "hits" in the databases for severe drug interactions. Using CYP-charts additionally might help to detect or even avoid severe pharmacokinetic drug interactions. DDIs in elderly patients have been also described in different sources, such as Priscus or Beers and therefore they can also be useful resources in daily practice. DDIs are a leading reason why psychiatrists actively consult pharmacists; thus, pharmacists should be aware of resources that can help them to identify and address DDIs in their patients.<sup>189</sup>

### 8.4.2 Therapeutic drug monitoring

Therapeutic drug monitoring is a useful tool in psychiatry as therapeutic drug levels and dose-related reference ranges are defined for all psychotropic drugs.<sup>190</sup> Pharmacokinetic knowledge as well as analytical skills enable the pharmacist to help detect errors in the preanalytical steps (correct sampling tube, time of blood drawing, transport), but also can help to interpret the results. Therapeutic drug monitoring is an excellent tool to detect medication-related problems like non-adherence, drug interactions and absorption problems (e.g., in bariatric patients).

### 8.4.3 Adverse effects

Standardised side effect rating scales can be used to assess side effects. The most prominent is the UKU (Udvalg for Kliniske Undersogelser) side effect rating scale. The Glasgow antipsychotic side effect scale, the Neuroleptic side effect rating scale, the antidepressant side effects checklist, the Toronto side effect scale and others can be used to systematically assess side effects at stated times as defined by the monitoring plan. Managing side effects is crucial to maintaining adherence. Guidelines and publications give specific recommendations how to manage side effects of particular drugs or drug classes.<sup>191-195</sup>

### 8.4.4 Pharmacogenomics testing

Genetic polymorphisms have a significant effect on drug levels (Cytochromes (CYP), UDP-glucuronosyltransferase (UGT)) and drug distribution via P-glycoprotein (pg-P) and adverse drug events (human leukocyte antigens HLA-A and HLA-B). Genetic polymorphisms differ between ethnic groups, but nevertheless cannot be predicted just by ethnicity as within populations there is substantial distribution on every continent.<sup>196</sup>

Pharmacogenomics testing was established decades ago to help avoid adverse drug events and increase response rates in psychiatry.<sup>197</sup> A lot of evidence has been gathered in the past decades for many psychotropic drugs. The most prominent expert-consensus guidelines and databases are provided by the Clinical Pharmacogenetic Implementation Consortium ([www.cipicpgx.org](http://www.cipicpgx.org)), the Pharmacogenomic Knowledgebase ([www.pharmGKB.org](http://www.pharmGKB.org)) and the Dutch Pharmacogenetic Working Group (<http://upgx.eu>). Specific guidelines are published for many psychotropic drugs on the websites of the societies (e.g., antidepressants, antipsychotics, mood stabilisers.)

The decision of whether to pre-emptively test or test only after a treatment failure is still up for debate among experts. However, this tool can help to increase the remission rates and decrease adverse event rates. Therefore, patients who did not respond to a maximum dose or showed intolerable side effects after a starting dose are good candidates for pharmacogenomics testing.

Pharmacists can conduct pharmacogenomics testing. Buccal swabs are primarily used so collection of blood by the physician is not needed. The interpretation of pharmacogenomics results is challenging as not only drug-drug-interactions, but also drug-gene interactions, drug-drug-gene and drug-gene-gene interactions change the pharmacokinetic profile of the patient. Drug selection based on pharmacogenomics results can avoid not only side effects, overdosing and toxicity but also inefficacy of drug therapy. The hospitalisation time in patients with depressive disorders can be decreased by using pharmacogenomics in a collaborative approach of physicians and pharmacists.<sup>198</sup> Patients' perception of pharmacogenomics testing is good and therefore patients might request it or at least information about it.<sup>199</sup> Therefore, pharmacists should make themselves aware of the availability of these services.

## 8.5 Developing treatment and monitoring plans

The effectiveness, tolerability and safety of psychotropic medicines are wide ranging and unpredictable. The most experienced specialist, with or without the use of the most advanced pharmacogenomic technologies, will not be able to accurately predict which medicine will be optimal for treating their patient's depression, anxiety, psychosis or other psychiatric condition. The burden of living with unremitted symptoms despite ongoing treatment and the risk for adding to that burden with medication-related adverse effects and safety concerns, with acute and chronic use, behoves all health care providers involved in the prescribing and dispensing of medications to establish a rational and responsive treatment and monitoring plan.

The more efficiently the treatment and monitoring plan is communicated the more likely the goals of improved health and adverse events avoided will be achieved. As such, first and foremost in the implementation of planning a patient's care it to ensure that communications are open, efficient and shared. This is often not the experience of the pharmacist. However, working toward changing this, at the local, regulatory and international levels, is a common goal that all pharmacists can support and benefit from.

There is usually a minimum of three critical team members involved in developing treatment and monitoring plans for medicines to be used in the treatment of mental illness — the patient, the prescriber and the pharmacist. Often there are others who play very important roles, including family members and other health care providers (e.g., nurses, personal care workers, therapists). The most important individual on the team is the patient (or legal representative), who needs to be involved in the planning of treatment and its monitoring. Treatment acceptance and satisfaction are increased when patients are involved in care planning for the short- and long-term.

Pharmacists play a range of roles in care planning. Some work directly with specialists directing pharmacotherapeutic options to be discussed with the patient, for example, within established mental health services. Others work in primary care and consult on selected patient cases to recommend new medicines or changes to existing regimens to respond to untreated conditions, address partial response or treatment-related issues (e.g., adverse effects, access problems), or guide treatment discontinuation. Most pharmacists work directly with their patients but not with the rest of the patient's health care team, which can set up what are usually surmountable challenges, especially regarding team communications.

Regardless of the pharmacist's level of specialisation or work setting, the pinnacle priority of the pharmacist's role applies, which is to support achievement of optimal health outcomes of their patients through the judicious use of medicines and other health interventions that are within their scope of practice. In this context, judicious use involves selecting, starting, modifying, maintaining and stopping medication. Much of this is done by the direct and frequent assessments and communications with their patients and timely collaborations with other members of the patient's health care team, especially the prescriber.

Monitoring of medication-related outcomes is a team activity: it starts when the patient is first dispensed the medicine and the shared activity continues thereafter. A community-dwelling patient typically takes on much of the responsibility of monitoring from the outset. Regardless of the directions on the prescription label, they are the ultimate decision maker, determining whether and when to start the medication and what dose to take, when to take it, how often, and for how long. It should not be assumed that the patient took the medicine as prescribed and their reasons for not doing so need to be understood, validated and incorporated into the ever-evolving care plan.

### 8.5.1 The pharmacist's patient care plan

Though often not officially recognised this way, the pharmacist's patient care plan should be seen as a component of the patient's overall care plan, contributed to by all members of the patient's health care team. The pharmacist's patient care plan needs to align with the goals of the overall care plan and any deviations need to be communicated and agreed upon via team consensus. In reality, this works with a variety of role-based assumptions, usually to good effect and without causing issues. For example, the prescriber may assume that the pharmacist will modify the care plan by advising the patient on how to manage psychotropic-induced adverse effects such as constipation, orthostatic hypotension, sedation or dry mouth without the need for direct communications with any team members other than the patient. When the interventions recommended by the pharmacist do not resolve the issue, the assumption is that the pharmacist, or patient, will consult the prescriber or other members of the health care team to explore further assessments and changes to the pharmaceutical care plan. Additionally, the pharmacist assumes that they will be informed, by the patient or prescriber, of changes to the plan, especially when involving medicines, such that they can maintain a comprehensive perspective of the patient's medicines use and the associated expected and potential desired and undesired outcomes.

There can be a problem with an approach that is based on such assumptions, however. This quickly becomes apparent when there is more than one prescriber involved, for example, a psychiatrist and a family physician, and when the patient has limited capacity for reliable and timely communications, including patients with poor insight into their mental illness or cognitive problems. Similarly, where there is more than one pharmacy involved, this type of assumptions can emerge very quickly. Under conditions such as these, more intensive communications among treatment team members along with documentation and, in some cases, the overt establishment of a communication plan are required to assure that the health system is working optimally in the patient's best interest.

From the pharmacist's perspective, the treatment and monitoring plan needs to be purpose-built to fit the patient and their medication regimen. Patients are unique in terms of their illness and treatment experiences. Treatment options for one patient experiencing a recurrence of a major depressive episode may not include any of the same or may include all of the same options for another patient with the same diagnostic presentation and mood disorder history. Similarly, the monitoring plan will need to be developed based on the patient's illness and medication experiences. A general rule, for example, to follow-up with a patient after one-week of starting a new antidepressant may not be the right plan for all patients. A patient with a history of worsening anxiety and ruminating thoughts that onset almost immediately after starting a previous antidepressant should be contacted earlier, possibly several times during the first week. Another patient who stopped treatment weeks ago due to nuisance adverse effect who is currently remitted and stable may be given information for what to monitor during the start of therapy of a different antidepressant and to contact the pharmacy directly if any concerns are identified within the first two weeks. Clinical practice guidelines provide clear recommendations for treatment planning and monitoring that, when applied, improve the quality of patient care guided by the best evidence. These illness-specific guidelines should be used to inform care planning and monitoring with the caveat that modifications that meet patient needs are important and intended by these guidelines.

Just as care plan development needs to be specific to the individual, it also needs to be specific to the medication regimen. This is evident based on the recommendations for monitoring patients taking different antipsychotics and applies to different monitoring needs when taking various mood stabilisers and antidepressants.<sup>200, 201</sup> For example, regular discussions around types of food preferred and to be avoided are critical to patient safety when treated with monoamine oxidase inhibitors, but are mostly irrelevant with other psychotropic medicines, other than those with issues of absorption on an empty stomach and appetite increase as a prevailing medication-related effect.

### 8.5.2 Longitudinal care

There are two common approaches to the timing of assessments within the pharmacist’s patient care plan. One is based on convenience, which is mostly dictated by the prescription’s dispensing interval and unplanned pharmacy visits. The other is based on patient need, which most often does not align with the dispensing interval. To transition from a convenience-based schedule to the preferred patient-centred plan requires innovation and changes to workflow processes within the pharmacy, for example, scheduled follow-up encounters in person or by telephone.<sup>202, 203</sup>

In recent decades, psychotropic dispensing intervals have lengthened due to improvements in medication overdose safety. This is most apparent with the change from tricyclic antidepressants to selective serotonin reuptake inhibitors (SSRIs) and serotonin and noradrenaline reuptake inhibitors (SNRIs) as first-line therapies for the treatment of anxiety, depressive and other psychiatric disorders. This has facilitated the change from weekly to monthly doses of medicines dispensed early in the course of therapy. However, overdose risks were not the only consideration for seeing the patient early in follow-up after starting an antidepressant. Sharing accurate information about antidepressants, learning and responding to patient concerns, assessing treatment response, tolerance and acceptance, and revisiting what to expect (desired and undesired) from antidepressants is an ongoing process that requires multiple discussions over several patient encounters. These visits should occur at a higher frequency at the start of therapy to identify and address early-onset adverse effects, respond to treatment questions and concerns, offer support, reminders and resources, and identify any specific safety concerns.

Pharmacists place a lot of focus on counselling patients starting new courses of treatment; new starts of psychotropic medicines are no exception to this practice pattern. Recurring follow-up encounters need to be planned and taken advantage of. Only focusing on helping patients get started with a new therapy is not a well-suited approach to this therapeutic area, where a chronic disease management approach is needed.

Longitudinal care is a holistic, dynamic, and integrated plan that documents important disease prevention and treatment goals and plans, is patient-centred, reflects a patient's values and preferences, and is dependent upon bidirectional communications.<sup>204</sup> Longitudinal follow-up, as the default approach, is needed considering that most patients do not have a robust or even satisfactory response to their first course of treatment and that the medicines carry many burdensome adverse effects early in the course of therapy that can prematurely derail the treatment plan and the potential for serious, possibly irreversible adverse effects with long-term use. Table 7 illustrates activities and their content during different phases of a treatment course, including before the treatment course starts and during its early and stabilisation, or relapse prevention, phases. Also included are suggestions for these encounters during treatment termination. Pharmacists also support patients in ways that extend beyond medication management. Table 7 also lists examples of these non-pharmacological activities provided by pharmacists.<sup>202, 205</sup>

**Table 7: Longitudinal follow-up — example for an adult with a major depressive episode treated with a standard antidepressant**

Phase	Patient assessment and education
<b>Prior to start of treatment</b> Week 0 and before	Acceptance/concordance: <ul style="list-style-type: none"> <li>Determine patient attitude toward course of therapy</li> <li>Discuss options and proceed when treatment concordance achieved</li> </ul> Response: <ul style="list-style-type: none"> <li>Discuss target symptoms (including self-harm)</li> <li>Educate about expected timeline of symptom improvement and probability of non-, partial, and full or near-full response</li> <li>Discuss minimal planned duration of treatment</li> </ul>

Phase	Patient assessment and education
	<ul style="list-style-type: none"> <li>Inform patient of follow-up assessment and education plans</li> </ul> Tolerance/safety: <ul style="list-style-type: none"> <li>Ask about concerns before starting treatment</li> <li>Anticipate and educate about common nuisance adverse effects and uncommon/rare serious adverse effects</li> <li>Identify avoidable safety concerns (drug-drug and drug-disease interactions, overdose risk)</li> </ul>
	Non-pharmacological activities: <ul style="list-style-type: none"> <li>Establish who are the patient's care team members and personal supports</li> <li>Discuss other forms of therapy and how to access them</li> <li>Suggest community resources and supports</li> <li>Ask about and support the use of self-help strategies for mental health</li> </ul>
<b>Early treatment phase</b> Weeks 1 to 12	Acceptance/concordance: <ul style="list-style-type: none"> <li>With each patient encounter, inquire about medicines use, including dose and timing</li> <li>With dose titration, verify patient readiness for dosage changes and work towards achieving concordance if changes to the plan are needed</li> <li>If adherence is low, investigate reasons and respond with options</li> </ul> Response: <ul style="list-style-type: none"> <li>Assess achievement of treatment goals:               <ul style="list-style-type: none"> <li>&lt;3 weeks: early improvement</li> <li>3–8 weeks: symptom reduction continues</li> <li>9–12 weeks: remission or near remission</li> </ul> </li> </ul> Tolerance/safety: <ul style="list-style-type: none"> <li>Assess development of adverse effects and safety concerns using a mix of medication-specific and open-ended questions:               <ul style="list-style-type: none"> <li>&lt;1–2 weeks: assess acute tolerability problems</li> <li>3–12 weeks: set up regular encounters to support early identification and response to tolerability and safety issues</li> </ul> </li> </ul>
	Non-pharmacological activities: <ul style="list-style-type: none"> <li>Follow-up on previous discussions about personal and community supports as well as other forms of therapy</li> <li>Refer to higher level of care if patient is experiencing a mental health crisis</li> <li>Continue to encourage self-help approaches that enhance overall mental health</li> </ul>
<b>Stabilisation and relapse prevention phase</b> Weeks 12 to months or years	Acceptance/concordance <ul style="list-style-type: none"> <li>Revisit previous discussions of planned duration of therapy; modify as needed</li> <li>Continue to inquire about medicines use and investigate and respond to reasons if adherence is low</li> <li>Continue to work toward achieving treatment concordance long-term</li> <li>Revisit previously discussed and engage in new pharmacotherapy education topics, including relapse risk with treatment continuation versus termination and self-monitoring for late onset adverse effects.</li> </ul> Response: <ul style="list-style-type: none"> <li>Regularly assess targets of pharmacotherapy, including symptoms and functioning, including self-harm</li> <li>Be prepared to offer treatment recommendations if suboptimal response or symptom relapse is evident</li> </ul> Tolerance/safety <ul style="list-style-type: none"> <li>Continue to regularly monitor for the development of adverse effects and safety concerns using a mix of medication-specific and open questions</li> <li>Provide the patient and other team members with advice on adverse effect mitigation strategies</li> </ul>
	Non-pharmacological activities: <ul style="list-style-type: none"> <li>Validate patient's personal successes and accomplishments (e.g., social, occupational, recreational)</li> <li>Inquire about and encourage self-help strategies for mental health improvement</li> <li>Support access to health services; advocate when necessary to increase timely access to services</li> </ul>
<b>Termination phase</b>	Acceptance/concordance <ul style="list-style-type: none"> <li>Prepare and discuss a treatment termination plan that is acceptable to the patient and limits the risk for illness relapse and medication-withdrawal</li> <li>During regular encounters, ask about any issues experienced during the termination process or deviations from the plan</li> <li>Collaborate with the patient and other team members to respond to issues identified</li> </ul> Response: <ul style="list-style-type: none"> <li>Educate about changes in risk for illness recurrence with treatment termination</li> <li>Monitor for symptom recurrence and functional decline during dose reduction phase and, importantly, following treatment termination</li> </ul>

Phase	Patient assessment and education
	Tolerance/safety: <ul style="list-style-type: none"> <li>• Educate about optimal method for terminating treatment</li> <li>• Provide treatment team with suggested dose reduction plan based on medication and patient considerations</li> <li>• Educate the patient about withdrawal symptoms during dose reduction phase and after treatment termination with agreed upon instructions for how to respond to them should they develop</li> <li>• Establish a plan for regular encounters during the termination phase</li> </ul>
	Non-pharmacological activities: <ul style="list-style-type: none"> <li>• Revisit self-care and other therapeutic interventions that support long-term recovery and optimal mental health</li> <li>• Offer ongoing communications and support, especially during the first-year, high-risk period of relapse after treatment termination</li> </ul>

### 8.5.3 Caring for the whole patient

It is uncommon that a patient who is otherwise completely healthy will present to their health care provider with a single mental health issue. The norm is that the patient has a history of multiple health issues, some directly affecting their functioning and quality of life, others not currently active, and all relevant and important to the patient's health and medication journey.

It is important to emphasise the importance of caring for the whole patient, which starts with understanding their current health and medication priorities during early meetings. The value of the pharmacist as a critical member of the patient's health care team becomes most apparent when the pharmacist is aware of and actively involved in the management of the patient's physical health and mental health problems (including substance use disorders).

Pharmacists working in clinical settings co-located with other members of the patient's health care team and having direct access to patient charts have an advantage over community pharmacists. They can more easily gather information about the patient's current health issues and collaborate in real time about health priorities and treatment options. They also often have more time to spend with their patients to gather specific information needed for supporting medication management decisions. Although these work environments are the exception rather than the rule for pharmacists, they demonstrate the potential offered by pharmacists to play a critical role in developing and implementing care plans that encompass the whole patient, inclusive of physical and mental health priorities.

The Bloom Programme has demonstrated that this can also be accomplished by community pharmacists.<sup>203, 206</sup>

Patients living with one or more mental illnesses and experiencing at least one medication-related problem are eligible for the six-month programme. Programme enrolment involves a description of the programme and a comprehensive assessment that includes a review of physical, mental, and substance use problems as well as medication experiences, past and present related to current health issues. While the programme is for patients with mental illnesses, the purpose of enrolling a patient into the programme is to help them achieve the health and medication goals they prioritise along with their health care team. For example, an enrolled patient with generalised anxiety disorder, diabetes mellitus, recurrent migraines, insomnia and a relatively unhealthy diet may prioritise improving glucose management through changes to their diet and diabetes medication regimen before taking steps to address concerns about their medicines for anxiety and insomnia. Achieving successful outcomes related to these health issues can take months of working closely together, even when supported by an efficient collaborative working relationship between the pharmacist and prescriber. It may be that the recurrent migraines were related to the other health conditions and deprescribing of migraine prevention therapies or reduced use of acute medication interventions may become a priority for the patient after the other issues have been addressed. Pharmacy programmes that target single specific conditions (e.g., depression) or high priority medicines (e.g, clozapine) have limited potential to broadly impact the health and quality of life of the patient compared with those that are designed to be holistic, especially when longitudinal care is an inherent feature.

## 8.6 Stopping psychotropic medicines

Practice guidelines recommend treatment durations that vary depending on the mental illness and patient experiences with the illness and its treatment. For example, it is recommended that first-episode psychosis be treated in a specialised early psychosis programme, where available, and that antipsychotic therapy be maintained for a minimum of three years before considering its discontinuation.<sup>207</sup> Treatment is to be continued if there are ongoing symptoms, recent illness instability or evidence of psychotic relapse with recent dose reduction attempts. For depression, the minimum duration of treatment is six to nine months after experiencing symptom remission. For people with multiple depressive episodes, recent severe episodes, or serious suicide attempts, duration recommendations range from a minimum of two years to the patient's lifetime. For other conditions, such as anxiety disorders and insomnia, guidelines recommend that the use of specific medicines, particularly sedative-hypnotic medicines such as benzodiazepine receptor agonists (e.g., lorazepam, zopiclone), are to be limited to four weeks or less. As such, planning for the end of treatment is an important issue for all psychotropic medicines for all mental illnesses, even those typically considered to be serious and persistent.<sup>208-211</sup>

With few exceptions, ending a long-term treatment course involving a psychotropic medicine should be done gradually. There are two main reasons for this, namely, to reduce the risk for early relapse and to limit or avoid withdrawal symptoms. Notoriously difficult psychotropic medicines to stop are SSRI and SNRI antidepressants (with the exception of fluoxetine due to its unusually long half-life) and benzodiazepine receptor agonists. Rapid dose reduction and treatment termination of antipsychotics can also lead to early relapse and withdrawal effects, including withdrawal dyskinesias, cholinergic rebound phenomena and dysphoria.<sup>212, 213</sup> Whereas medicines such as bupropion and lithium do not appear to cause withdrawal symptoms when stopped abruptly, doing so may be associated with an avoidable premature return of symptoms. This phenomenon has been most well established with the gradual vs. rapid reduction of lithium in people with bipolar disorder who have been stable and episode-free for many years. Most will relapse within a few months to two years with abrupt lithium cessation whereas up to 20% may be spared any relapse even five years after gradually stopping lithium over several weeks.<sup>214</sup>

Pharmacists are the most logical team members for proposing a gradual dose reduction plan of a psychotropic medicine due to their intimate knowledge of drug pharmacokinetics, receptor dynamics, medication withdrawal syndromes, dosage strengths, formulation options and strategic therapeutic substitutions needed when withdrawal experiences are severe and recalcitrant to usual dose reduction methods.<sup>215, 216</sup> With appropriate training and experience, a highly valued service that pharmacists can offer is the planning, implementation and monitoring of psychotropic treatment discontinuations. This service needs to ensure collaboration with prescribers and planning and monitoring with patients.

## 8.7 Ensuring optimal psychotropic pharmacotherapy

"Is this the best medicine for me?" is a common question asked of pharmacists who care for patients taking psychotropic medicines. The question can be a reflection of the patient's uncertainties about taking a medicine for a mental health problem, concerns of harm or losing control over their own thinking, or feeling overwhelmed by choice and uncertainty. The pharmacist is being asked for their opinion, in this case a second opinion, on the pharmacotherapy of mental illness. This is one of several ways that pharmacists are directly engaged in optimising psychotropic pharmacotherapy for their patients.<sup>46</sup> Others range from independent or delegated prescribing authority to providing detailed treatment recommendations as part of an elicited or spontaneous pharmacotherapy consultation, for example, following a medication review.

Pharmacists are trained in mental illness and its pharmacotherapeutic management. This training starts during their professional degree and continues when they are licensed practising pharmacists through continuing professional development activities, consultations with peers and colleagues and, most importantly, experience through direct patient contact. On any given day in almost all pharmacies, pharmacists meet patients taking psychotropic medicines and offer education, advice and resources that support patient autonomy and the treatment plan. These interactions often lead to modifications in the patient's pharmacotherapy, for which the pharmacist has the opportunity to assess the impact of their advice (whether offered as a recommendation or, less commonly, as a pharmacist's prescription).

The role of the pharmacist in guiding psychotropic choice, dosing and treatment duration is not well recognised outside the profession. In many contexts, this common activity is invisible to external health service planners. For example, a community pharmacist identifies a medication-related issue during a routine medication review (i.e., inadequate response to current pharmacotherapy), they then contact the physician and share their assessment and recommendations verbally, the physician agrees with the pharmacist's assessment and suggested changes in the pharmacotherapeutic regimen, the prescription is modified officially by the physician, the pharmacist and patient work together to implement the changes in the medication regimen, and the pharmacist follows up the patient several times before the patient sees the prescriber again. From an external perspective, the pharmacist dispensed the medicine that reflected the changes in the prescription written by the physician. There is no record, other than their own documentation, to indicate the role of the pharmacist other than as dispenser.

Though not widely recognised externally, the pharmacist's role in optimising patient health outcomes via medication management is a service eagerly sought by patients. This was evident in the Bloom Programme pilot project in Nova Scotia, Canada.<sup>217</sup> Participants living with a mental illness were eligible for enrolment if they met any of the following criteria: (i) treatment optimisation required due to suboptimal response to current pharmacotherapy; (ii) experiencing adverse effects affecting functioning or quality of life; (iii) polypharmacy/inappropriate therapy; (iv) difficulties withdrawing from treatment; or (v) low or non-adherence. The main reason for enrolling in the community pharmacy-based mental health programme was for treatment optimisation, with 81% of participants indicating this as their primary reason. In contrast, only 11% enrolled due to issues of non-adherence. Patients were looking to their community pharmacists for guidance on how to change their medication regimen to achieve their health priorities. With four out of five identified health problems reported by the patient as resolved or improved upon discharge from the programme, the Bloom Programme demonstrated the ability of pharmacists to provide this service.

Pharmacists have the knowledge and skills to work with their patients and other members of the health care team to guide pharmacotherapeutic interventions that improve patient mental well-being. This can be achieved by pharmacists working in community pharmacies as well as those in primary care and specialised mental health service environments. Enhancing the recognition of this role and the opportunities to optimise it need to be explored further.



## 9 Pharmacists' roles at transitions of care

Transitions of care or the coordination of healthcare service delivery from one setting to another plays a critical role in the overall quality of patient outcomes. It has been noted that gaps in transitions of care can contribute to high hospital readmission rates and higher healthcare spending. To address some of these challenges, there is need to engage healthcare providers across different specialties to understand the scope of care, expected outcomes, and build consensus on responsibilities during transitions of care. Ultimately, ineffective transitions of care occur as a result of breakdowns in communication, breakdowns in patient education and breakdowns in accountability.<sup>218</sup>

Integrating pharmacists in transition-of-care programmes helps to bridge the gap in care especially around medicines use. Pharmacists have the opportunity to clarify patient concerns around their medicines, collaborate with physicians in reviewing patient treatment plans to address medication errors, and reduce readmissions overall.<sup>219</sup>

Pharmacists have multiple and varied roles in transitions of care especially with a focus on mental health care. Pharmacists are positioned to deliver primary mental health care services ranging from preliminary screening and diagnosis, to psychosocial counselling and referral services. They can also support patients living with mental illness through medicines dispensing, medicines reconciliation and medication therapy monitoring, among others. On a policy and health systems management level, pharmacists serve as academicians, policy makers and systems thinkers who develop policies, frameworks and guiding documents as well as the training of the next generation of healthcare practitioners. Anchored on the basis of pharmacy practice being to deliver quality healthcare service to patients to reduce suffering and ensure positive health outcomes, it is important to acknowledge that transitions in care happen at the following interfaces:

- Primary healthcare facilities, including community pharmacies to specialized hospitals or referral facilities, both inpatient and outpatient'
- Inpatient facilities to home-based care, including at discharge post admission in hospitals; and
- Specialist health facilities to general physicians, moving towards self-care.

Cognisant of these transitions, there are various roles that need to be performed and pharmacists are poised to perform many critical roles to support patients as they make transitions in care.

### 9.1 Signposting to mental health facilities

Upon screening or diagnosis of patients, pharmacists can refer them to specialist or higher-level facilities, including for inpatient care when there is need for close monitoring. Referral services by pharmacists should go beyond triaging and issuing a referral note to the next health facility, and encompass comprehensive and personalised transition of care support to the next level of care. This should include:

- Structured and comprehensive patient notes based on primary health services discharged to the patient, patient response and differentials necessitating the referral.
- In-person transfer of patient from the pharmacist to the next service provider at the next station of care including agreed upon starting care plan with patient involvement to ensure optimal outcomes in care. Often, it is noted that upon referral, due to mistrust by patients, they fail to comply with the new care plan at the next health facility, thus compromising the quality of care.
- An assignment of roles and responsibilities to a specified practitioner in the next facility with clear handover notes to guide further care.

### 9.2 Care at discharge and patient follow up

At the point of discharge from hospital care, in most healthcare settings the last point of contact for patients is the pharmacist. This presents pharmacists with an ideal opportunity to take up responsibility in ensuring the patient does not relapse and has all the knowledge necessary to successfully adhere to their treatment plan after being discharged. Pharmacists in transitions of care roles can therefore take responsibility to:

- Review and optimise patient discharge medicines in collaboration with the discharging physician and nurse to ensure the patient has the best discharge care plan, is able to adhere to their care plan, and has an enabling supportive framework for their recovery upon discharge. It has been noted that patients with mental illnesses often are faced with social challenges which may contribute to their relapse, e.g., loneliness, abusive social environment, among others.
- Optimise the patient care plan post-discharge. Considering that mental illnesses call for extended periods of care, there is need to have a clear plan of care for the patient, including how they will obtain their prescription refills, how they will receive psychosocial counselling, and more. At the point of discharge, the pharmacist can initiate contact with primary care providers to ensure they are able to support the patient in their local settings upon discharge. This can involve collaboration with social workers in the patients' locality who will be the patients' first point of contact in case of need, local community pharmacies or primary healthcare facilities where prescription refills will be done, and an emergency contact in case the patient has any concerns later after discharge.
- Schedule clinic follow ups with the patient and their physicians to ensure that the patient does not lose contact with the health facility upon discharge and, most importantly, to ensure continuity of care.
- Review and make accessible the transitions of care notes for other healthcare providers who will support the patient in their ongoing treatment after discharge. This can be a primary healthcare facility, the social worker, or even the community pharmacy identified to support continuity of care. This should have clear guidance on the patient care plan, warnings and precautions on what to and what not to do, as well as where to seek guidance or counsel in case of need.

## 9.3 Framework to support transitions of care

Pharmacists working in health systems and policy acknowledge the importance of transitions of care in healthcare service delivery. They also have an opportunity to envision, design and operationalise frameworks to guide transitions of care. These may include policy documents, service charters for the different practice settings, and strategies to coordinate transitions of care with a special focus on the role of the pharmacist, and key performance metrics for the same. Considering the challenges experienced in transitions of care include breakdowns in communication, patient education and accountability, there is need to have clear guidance frameworks on these with specific performance criteria for pharmacists in their respective spaces. These will include:

- Standard operating procedure detailing:
  - What information needs to be captured at transitions of care;
  - Who needs to lead the transition of care;
  - How handovers will take place;
  - Where the actual transition of care needs will take place, i.e., referring facility or receiving facility; and
  - When transition of care is considered complete.
- A checklist detailing the information to be provided and certified by both the referring and receiving healthcare provider (pharmacist).
- Key performance indicators for monitoring and evaluation of transitions of care pegged on patient outcomes and quality of care discharge with an incentive model.

In the effective performance of responsibilities of pharmacists in transition of care, there are key imperatives that need to be met, including:

- Access to patient medical records to inform decision making and facilitate transfer of care;
- Robust institutional frameworks which involve standing agreements between different levels of care and facilities, e.g., community pharmacy and a specialised psychiatric hospital and rehabilitation facility for seamless patient transition;
- An effective and responsive remuneration scheme that compensates pharmacists for their work in transitions of care to incentivise operational excellence in their work; and
- Recognition of transitions of care as a specialty of practice for pharmacists and integration into healthcare service delivery models and specialists' categories by relevant professional bodies.

There is a growing case for pharmacists' role in transitions of care with evidence of impact which needs to be sustained, targeted and advanced by more pharmacists taking an active role in transitions of care, especially in mental health care.<sup>220</sup>

## 10 Measuring outcomes: metrics for mental health services

When implementing mental health services, pharmacists must ensure they are gathering data to evaluate the impact of these services, especially if they are being newly implemented in their practice setting. By collecting these data, pharmacists will be able to participate in continuous quality improvement and develop an evidence base that can be used to advocate reimbursement of services, advanced scope of practice and effective treatment that can ensure long-term outcomes (e.g, long-term remission).

To measure the impact of new services, there are three general categories of measures that can be evaluated: outcomes, process, and balancing measures. Outcomes measures evaluate the impact of services on the patient. Process measures evaluate the performance of the system that is delivering the services. Balancing measures evaluate whether changes in one part of a system are having unintended negative effects in another part of the system. Generally, process measures tend to be leading measures and outcomes measures tend to be lagging measures, meaning that impacts of changes will first be reflected in process measures. Thus, positive changes in process measures should indicate positive changes in outcomes measures.<sup>221</sup> Some examples of these measures in the context of mental health care include:<sup>222</sup>

- **Outcomes** — Functioning, symptoms, quality of life, patient satisfaction with services
- **Process** — Percentage of patients who have been screened for a mental health condition, percentage of patients receiving appropriate doses of psychotherapy, average number of patients served, average visit length, percentage of patient referred to a mental health care provider
- **Balancing** — Does implementing new mental health services affect the ability of the pharmacist to fulfil other responsibilities in the pharmacy?

While the specific measures that will be selected within each of these categories will vary depending on the intervention, it is best to ensure that each of these categories is represented when evaluating the impact of mental health services.<sup>223</sup>

Similarly, pharmacists can develop measures to evaluate their services based on the six domains of health care quality as outlined by the Institute of Medicine.<sup>224, 225</sup> These six domains highlight important concepts that should be incorporated into any mental health services or interventions that pharmacist may provide (see Table 8).

Table 8: Institute of Medicine’s six domains of health care quality<sup>224, 225</sup>

Domain of health care quality	Description
Safe	Avoiding harm to patients from the care that is intended to help them.
Effective	Providing services based on scientific knowledge to all who could benefit and refraining from providing services to those not likely to benefit (avoiding underuse and misuse, respectively).
Patient-centred	Providing care that is respectful of and responsive to individual patient preferences, needs, and values and ensuring that patient values guide all clinical decisions.
Timely	Reducing waits and sometimes harmful delays for both those who receive and those who give care.
Efficient	Avoiding waste, including waste of equipment, supplies, ideas and energy.
Equitable	Providing care that does not vary in quality because of personal characteristics such as gender, ethnicity, geographic location and socioeconomic status.

Within mental health care, there are many different measures pharmacists can select to evaluate the impact of their services. Globally, there is limited agreement on which measures are most appropriate and effective for evaluating mental health services and there is limited evidence as to what is validated in community pharmacy settings. However, there are currently efforts being made through the Common Measures in Mental Health Science Initiative to address the “fragmented landscape of mental health data” by adopting common

measures that should be used globally to allow for mental health research to be more straightforward to “compare, communicate and interpret”.<sup>226</sup>

While still in the early stages of work, this initiative has agreed upon six measures for adults, and strongly recommends collecting each of these data points (see Table 9), in addition to age and sex at birth, when conducting mental health research:<sup>226, 227</sup>

Table 9: Data points recommended by the Common Measures in Mental Health Science Initiative<sup>226, 227</sup>

Scale	Description
<a href="#">DSM-5 Level 1 Crosscutting Assessment</a>	This assessment evaluates mental health domains that are important across psychiatric diagnoses. It addresses 13 psychiatric domains, including depression, anger, mania, anxiety, somatic symptoms, suicidal ideation, psychosis, sleep programmes, memory, repetitive thoughts and behaviours, dissociation, personality functioning and substance use. <sup>228</sup>
<a href="#">WHODAS 2.0</a>	The WHO Disability Assessment Schedule 2.0 is a generic assessment for health status and disability that can be used for all diseases. It addresses six domains of functioning: cognition, mobility, self-care, getting along, life activities and participation. <sup>229</sup>
<a href="#">PHQ-9</a>	The Patient Health Questionnaire is a self-administered questionnaire for assessing depression. The PHQ-9 includes nine questions which can be used to assess and monitor the severity of depression. <sup>230</sup>
<a href="#">GAD-7</a>	The Generalized Anxiety Disorder Scale is a self-administered questionnaire for assessing anxiety. The GAD-7 includes seven questions which can be used to diagnose GAD as well as screen for panic, social anxiety and post-traumatic stress disorder. <sup>230</sup>

There is little guidance on validated outcomes metrics that should be used in a pharmacy setting. However, a recent systematic review of 64 publications analysed the impact of pharmacists on outcomes for those with psychiatric or neurologic disorders. In this paper, Werremeyer *et al* found that having pharmacists involved in mental health care can contribute to improved patient outcomes in both inpatient and outpatient settings as well as general and specialty settings.<sup>160</sup>

- **Hospital** — Pharmacists’ involvement leads to fewer medication errors and fewer repeat hospitalisations.
- **Outpatient, primary care, specialty clinics** — Pharmacists’ involvement leads to improved medication safety (including improved appropriateness of treatment), greater likelihood of reaching therapeutic goals (including fewer symptoms and hospitalisations).
- **Community** — Pharmacists’ involvement allows for improved access to long-acting injectable antipsychotics, improved adherence and increased satisfaction with medicines.
- **Substance use disorder treatment settings** — Pharmacists’ involvement allows for increased access to medicines to treat substance use disorder, as well as naloxone.

Pharmacists have been shown to have an impact on a wide variety of outcomes metrics, but there is still limited guidance regarding the most appropriate outcomes metrics for pharmacy-based studies.

# 11 Practice-based research on pharmacists' roles in mental health

Pharmacists who wish to implement mental health services in their practice or conduct practice-based research on pharmacists' roles in mental health care should consider a variety of factors when developing their programmes or research plans. Ideally, pharmacists will develop their programmes in a stepwise manner, from planning to implementation to evaluation, that allows them to fully consider the needs of their community and develop a comprehensive programme implementation and evaluation plan.

## 11.1 Identifying a health issue

Pharmacists who wish to address mental health in their community should take time to analyse local and national data related to mental health in order to fully understand the needs of their community. It is important for pharmacists to understand the incidence and prevalence of certain conditions as this may highlight a specific area where pharmacists' efforts may be most impactful. To obtain these data, pharmacists may wish to explore the WHO [Global Health Observatory](#), the [World Bank](#), [Our World in Data](#), or other local or national data sources.

Beyond quantitative data, pharmacists may also wish to consider qualitative data. This may be found in studies conducted by other researchers or could be obtained by the pharmacists themselves. Qualitative data may shed light on opportunities for intervention that are not readily apparent in quantitative data. For example, pharmacists could conduct interviews or focus groups with certain patients to identify barriers they face in accessing mental health care or what services they would be most receptive to receiving from a pharmacist. Pharmacists wishing to conduct research among their patients will need to ensure proper ethical approvals are in place before beginning.

According to the [Community Toolbox](#), a free, online resource that includes numerous toolkits to support individuals in implementing programmes, the following items should be addressed when assessing the needs and resources of a community:<sup>231</sup>

- Describe the makeup and history of the community to provide a context within which to collect data on its current concerns;
- Describe what matters to people in the community;
- Describe what matters to key stakeholders;
- Describe the evidence indicating whether the problem or goal should be a priority issue; and
- Describe the barriers and resources for addressing the identified issue(s).

Once the pharmacist has an understanding of the needs of their community, they can identify the specific condition, risk factor, etc. they would like to address through their programme or intervention.

### 11.1.1 Identify existing community resources

When identifying a focus for their programme or intervention, pharmacists should also endeavour to conduct an environmental scan. An environmental scan requires that pharmacists identify the services or programmes that already exist in their community to address the issue they have selected. By doing this, pharmacists will be able to ensure they are not duplicating work that is already being done by others. They may also identify opportunities to support existing programmes, expand their reach or fill gaps. As part of this environmental scan, it may be helpful to meet local stakeholders to learn more about their experiences of addressing mental health in their communities and where they might see opportunities for pharmacists to make an impact.

Once pharmacists have an understanding of the current efforts being conducted in their communities to address the issue they have identified, they can begin to plan their programmes. Substantial time should be dedicated to the programme planning process to ensure their programme or intervention is successful.

## 11.2 Planning a programme

### 11.2.1 Literature review

Programme planning is essential to ensuring the success of a programme or intervention and pharmacists should endeavour to spend substantial time planning their programme. Pharmacists may wish to begin the planning process by conducting a literature review to identify interventions with the greatest potential to address the issue they have selected. For those implementing novel programmes or approaches, literature may be limited, but reviewing research conducted in other fields (e.g., medicine, psychiatry, social work, etc.) will likely still be relevant. Reviewing the literature may also provide insights into barriers others have faced when implementing similar programmes and will allow the pharmacist to pre-emptively make plans to avoid these barriers.

### 11.2.2 Stakeholder collaboration

When planning a programme, it is important to ensure that work is not done in a silo. Therefore, stakeholders who will be affected by the programme or intervention, including patients and other healthcare providers, should be invited to participate in the planning process. As outlined by the Community Toolbox, the following are considerations for promoting stakeholder engagement:<sup>232</sup>

- Determine why you need or want other people to get involved;
- Identify those who need to be involved in order to accomplish your group's objectives;
- Plan to recruit participants and members from diverse backgrounds and viewpoints;
- Review representation from different sectors of the community as a way to identify who should be involved and who is not. Consider representation from different sectors;
- Create conditions that will allow the greatest diversity of people and organisations to participate. Consider how to address barriers including language, childcare, transportation, time, etc; and
- Create an atmosphere that fosters continued participation.

If a team of stakeholders is developed, a programme or intervention can be co-designed by all involved, which should help to promote acceptability and sustainability of the programme.

### 11.2.3 Programme objectives and goals

When developing a programme plan, pharmacists, in collaboration with programme stakeholders, should develop goals and objectives that will guide the implementation of their programme. As outlined by the US Centers for Disease Control and Prevention, a goal is a “broad statement about the long-term expectations of what should happen as a result of your programme (the desired result)”. Objectives, on the other hand, are “statements describing the results to be achieved, and the manner in which they will be achieved”. Objectives should be clearly defined and it is often recommended that they follow SMART criteria – specific, measurable, achievable, relevant and time-bound.<sup>233</sup> Chapter **Error! Reference source not found.** includes additional details and considerations for selecting outcomes metrics.

### 11.2.4 Planning tool: RE-AIM framework

One tool that may be helpful as pharmacists are developing their programme plan is the RE-AIM framework. RE-AIM is an acronym for Reach, Effectiveness/efficacy, Adoption, Implementation and Maintenance. This tool has been used widely in both programme planning and evaluations contexts. An interactive online tool is [available](#) that uses the RE-AIM framework to outline important questions that should be asked when developing a programme (see Table 10).<sup>234</sup>

Table 10: RE-AIM framework and programme planning questions

RE-AIM framework	Questions
<b>Reach</b>	Who will the initiative appeal to? How and where will you reach them? How will you know if those who participated are representative of the intended beneficiaries?
<b>Effectiveness/efficacy</b>	What are the most important outcomes you expect to see? How likely is it that your initiative will achieve its key outcomes? Will your programme be effective for those most in need? What unintended consequences might there be?
<b>Adoption</b>	What settings or organisational types are you targeting? How many of these settings and organisations do you estimate will use the programme? Who will deliver the programme and do they have the skills and time?
<b>Implementation</b>	How will the initiative be delivered, including adjustments and adaptations? To what extent will the key aspects of the programme be delivered as intended? What are some of the possible obstacles to consistent implementation? What costs and resources (including time and burden, not just money) need to be considered?
<b>Maintenance</b>	What will happen over the long-term? Can organisations sustain the initiative over time and are there plans to leave trained staff in place? How likely is your initiative to produce lasting effects for individual participants? How will you get the word out about your intervention and lessons learned? How will you be able to follow your initiative for an extended period of time? What are likely modifications or adaptations that will need to be made to sustain the initiative over time

### 11.2.5 Planning tool: logic models

Another tool pharmacists may wish to use to assist with programme planning and implementation is a logic model. A logic model is an illustration of how a programme aims to achieve its intended outcomes. It outlines the relationship between the resources a programme needs, the activities a programme will implement and their associated short and long-term impacts. Logic models allow for team members and stakeholders to discuss and agree upon a shared vision for their programme. It also allows for discussion to ensure the programme team has the necessary resources to complete activities that will lead to their long-term goal(s). Logic models often consist of five sections: resources/inputs, activities, outputs, outcomes and impact (see Table 11). However, there are many different ways a logic model can be depicted.<sup>235</sup>

Table 11: Logic model template (adapted from the W.K. Kellogg Foundation)<sup>235</sup>

Resources/inputs	Activities	Outputs	Outcomes	Impact
Identify the resources that will be needed to implement the programme (e.g., staff, funding, infrastructure, equipment, etc.)	Identify the activities or actions your programme plans to implement (e.g., services, development of educational materials, etc.). These can include services, products and infrastructure.	Identify the direct outputs from your activities. (e.g., number of screenings provided, number of patients served). These typically describe the size or scope of services provided.	Identify the short-term impacts of your programme (e.g., changes in attitude, behaviours, knowledge, skills, status, level of functioning). These should generally be individual level outcomes.	Identify the long-term impacts of your programme. This should be the overall goal of your programme and should generally be organisational, community and system level changes.



Once a logic model is developed, it can be updated and adapted as programme implementation progresses and programme plans change. However, it should serve as a reminder to the programme team of the ultimate goal they are trying to accomplish through their efforts.

By taking the time to develop a comprehensive programme plan, pharmacists can ensure they are well prepared to implement it.

## 11.3 Implementing a programme

While preparing for programme implementation, pharmacists must also consider a variety of factors to ensure implementation is successful. These factors can also be incorporated into a logic model and include:

- **Staffing** — Do you or your staff need additional training to provide the intervention? If so, where and when will be this obtained?
- **Logistics** — How will the programme fit into your current workflow? When will the intervention be provided? Every day, or only certain days or times?
- **Regulations** — Are there any regulatory barriers you might face when implementing the programme? Have you obtained the necessary ethical approvals?
- **Budget** — What will the programme or intervention cost? Where will the money come from? Are there grants you could pursue? Are you able to be reimbursed for services provided?
- **Resources** — Are there any new resources you might need to implement the programme?
- **Data** — What metrics are you evaluating? How will you collect and manage data? Who will oversee data collection? How often will data be collected? Where will data be stored? For how long will you be collecting data?
- **Documentation** — Where will you document services provided? Who will document these services and when?

Beyond these factors, the WHO has developed an implementation research toolkit which outlines several contextual factors that should be considered when implementing an intervention and may require adaptations to be made to the implementation plan. These factors include socio-economic, stakeholder, health system, institutional, physical, political and cultural factors.<sup>236</sup> These factors should be analysed in order to determine if they will influence the implementation of a programme and, if so, adjustments will need to be made to the implementation plan.

## 11.4 Evaluating a programme

Another important aspect of participating in practice-based research or implementing a new programme is determining how the programme or intervention will be evaluated. Ideally prior to implementation, pharmacists should develop a programme evaluation plan. Pharmacists will need to determine how they want to analyse the data they have collected and when they want to analyse it. They should also consider how they might change their programme in response to the data collected.

The RE-AIM framework (see section 11.2.4) can also be used to guide programme evaluation. Questions to ask include:<sup>237</sup>

- **Reach** — What percentage of potentially eligible participants were excluded or took part, and how representative were they?
- **Effectiveness** — What impact did the intervention have on all participants who began the programme, on process intermediate and primary outcomes, and on both positive and negative (unintended) outcomes, including quality of life?
- **Adoption** — What percentage of settings and intervention agents within these settings (e.g., medical offices/physicians, pharmacies/pharmacists) were excluded or participated, and how representative were they?
- **Implementation** — To what extent were the various intervention components delivered as intended (in the protocol), especially when conducted by different (non-research) staff members in applied settings?

- **Maintenance (individual level)** — What were the long-term effects (minimum of six to 12 months following intervention)? What was the attrition rate? Were drop-outs representative? How did attrition impact conclusions about effectiveness?
- **Maintenance (setting level)** — To what extent were different intervention components continued or institutionalised? How was the original programme modified?

To further support programme evaluation, the WHO has developed an Evaluation Practice Handbook which includes many practical considerations for developing an evaluation plan. The WHO outlines several evaluation criteria and related questions (see Table 12).

Table 12: WHO evaluation criteria and related questions<sup>238</sup>

Criterion	Measure	Sample questions
<b>Relevance</b>	The extent to which the objectives of an intervention are consistent with the requirements of beneficiaries, country needs, global priorities and the policies of partner organisations and donors. Retrospectively, questions related to relevance may be used to evaluate whether the objectives of an intervention or its design are still appropriate given changed circumstances.	To what extent are the programme objectives justified in relation to needs? Can their <i>raison d'être</i> still be proved? Do they correspond to local, national and global priorities?
<b>Efficiency</b>	How economically resources and inputs (funds, expertise, time, etc.) are converted to outputs and results. Comparison of the results obtained or, preferably, the outputs produced, and the resources spent. In other words, are the effects obtained commensurate with the inputs?	Have the objectives been achieved at the lowest cost? Could better effect be obtained at the same cost?
<b>Effectiveness</b>	The extent to which the programme or initiative's objectives were achieved or are expected to be achieved, taking into account their relative importance. Effectiveness is also used as an aggregate measure of (or judgement about) the merit of worth of an activity — i.e. the extent to which a programme has achieved, or is expected to achieve, its major relevant objectives and have a positive institutional impact. Whether the objectives formulated in the programme are being achieved, what the successes and difficulties have been, how appropriate the solutions chosen have been and what the influence is of factors external to the programme.	To what extent has the outcome or impact been achieved? Have the intervention and instruments used produced the expected effects? Could more results be obtained by using different instruments?
<b>Sustainability</b>	The continuation of benefits from an intervention after major assistance has been completed, the probability of continued long-term benefits, the resilience to risk of the net benefit flows over time. The extent to which the results and outputs of the intervention are durable. Evaluations often consider the sustainability of institutional changes as well as public health impacts.	Are the results and impacts, including institutional changes, durable over time? Will the impacts continue if there is no more public funding?
<b>Impact</b>	Grouping of the positive and negative, primary and secondary long-term effects produced by a development intervention, directly or indirectly, intended or unintended.	Are the results still evident after the intervention is completed?

The Community Toolbox also provides valuable insight into the evaluation process and recommends that an evaluation plan include, at a minimum:<sup>239</sup>

- Key evaluation questions on planning and implementation issues, assessing attainment of objectives, impact on participants, and impact on community;
- Type of evaluation measures to be used to answer them (i.e., what kind of data you will need to answer the question);
- Type of data collection (i.e., what evaluation methods you will use to collect these data); and

- Experimental design (a way of ruling out threats to the validity, e.g., believability, of your data. This would include comparing the information you collect with data from a similar group that is not doing things exactly the way you are doing things.)

Finally, any evaluation that is completed should be shared with programme stakeholders to ensure their continued engagement in the programme.

### 11.4.1 Quality improvement

When programme evaluation occurs and pharmacists analyse data collected through their programmes, they may also wish to participate in quality improvement to refine the services they are providing. One common quality improvement model that is often used is the [Model for Improvement](#), which includes two different components. The first part of the model consists of three questions pharmacists should ask themselves when developing a new service or intervention, namely:<sup>240</sup>

- What are we trying to accomplish?
- How will we know that a change is an improvement?
- What change can we make that will result in an improvement?

These three questions then feed into the second component of the model: the Plan-Do-Study-Act (PDSA) cycle. The PDSA cycle is a method by which changes are implemented, measured and then changed or adapted based on the data collected. This is an iterative process that involves developing a plan to implement an intervention based on the three questions, implementing the intervention, studying the intervention using appropriate pre-determined measures, and acting on the data collected by making adjustments to the intervention to prepare for the next iteration of the cycle.<sup>240</sup> By using this process, pharmacists will be able to integrate new services into practice and continuously evaluate and improve them for the ultimate benefit of their patients.

The steps outlined in this chapter are not inclusive of every consideration pharmacists will make when implementing a programme or participating in research, but highlight the main factors pharmacists should be considering. With opportunities for pharmacists to engage in mental health care growing every day (as outlined throughout this handbook), there is a need for more pharmacists to engage in practice-based research in order to demonstrate the significant impact pharmacists can have on mental health and well-being. As research in this area grows, pharmacists can use the data to help advocate policy and reimbursement changes which will further support the integration of pharmacists in mental health care.

## 12 Supporting the mental health of pharmacy teams

Not only is it important for pharmacists to address the mental health concerns of their patients, but it is equally important that they consider their own mental health and that of their pharmacy colleagues. The issue of mental health and burnout among pharmacy teams has become more widely recognised in recent years, particularly during the COVID-19 pandemic. Burnout has been widely documented among many different facets of the profession and it is essential that efforts are made to address this issue. While burnout itself is not a mental health diagnosis, it can increase the risk of developing a mental illness, so this is an important issue to address.<sup>241</sup>

According to the WHO, burnout is an “occupational phenomenon” that is caused as a result of chronic stress in the workplace and is usually characterised by the following three symptoms:<sup>242</sup>

- Feelings of energy depletion or exhaustion;
- Increased mental distance from one’s job, or feelings of negativism or cynicism related to one’s job; and
- Reduced professional efficacy.

Burnout can have far-reaching implications and can affect not only the individual experiencing it, but also their patients. Burnout has been associated with a greater risk for hypercholesterolemia, type 2 diabetes, coronary heart disease, musculoskeletal pain, prolonged fatigue, gastrointestinal issues, respiratory problems, and much more. Experiencing burnout can also contribute to insomnia, depressive symptoms, use of psychotropic and antidepressant medicines, and hospitalisation for mental illnesses.<sup>241</sup>

Regarding impacts on patients, there has been research that shows higher levels of burnout are related to worse patient safety and lower quality of care.<sup>241, 243-245</sup> In studies focusing specifically on nurses and surgeons, burnout was shown to be associated with worse safety and quality of care as well as reduced patient satisfaction.<sup>246, 247</sup>

Given the consequences that burnout has on individual healthcare providers as well as their patients, it is important to address this issue within the pharmacy profession. The prevalence of burnout in the profession varies depending on the practice setting, country and many other factors. However, studies have shown considerably similar rates of burnout in a variety of countries. For example, a study in Saudi Arabia showed a burnout prevalence among pharmacists of around 60%, in France the prevalence was 56%, in Japan it was around 50%, and in the United States it was around 61%.<sup>248-251</sup> While burnout has long been a concern in the healthcare field, it became an even greater issue during the COVID-19 pandemic. During the pandemic, pharmacists were found to have increased job demands, including new roles like providing COVID-19 tests and vaccinations, coupled with reduced resources, including lack of personal protective equipment and medicines shortages, which led to high levels of burnout among the profession.<sup>252, 253</sup>

Beyond examining prevalence of burnout, many studies have aimed to explore the underlying factors that contribute to these high burnout rates within the profession as well as risk factors that increase the likelihood of an individual developing burnout. Studies that have evaluated burnout among the pharmacy profession have found that younger age and fewer years of experience are common risk factors for burnout.<sup>248, 250, 251, 254-256</sup> Work environment, including longer work hours, an unsupportive work environment, and stress frequency at work are also risk factors.<sup>250, 251, 254, 255, 257.</sup>

Beyond these risk factors, studies differ in their evaluations of whether certain factors increase risk or not. For example, some studies show that being female increases the risk of burnout, whereas other studies show that males are more susceptible to burnout.<sup>249, 251, 256-258</sup> Pharmacists should keep these factors in mind but should be aware that anyone, including themselves, can develop burnout and it is important to be aware of the symptoms so it can be quickly addressed.

There are many strategies that can be taken to help prevent and address burnout. The WHO has provided the following recommendations to prevent occupational stress, burnout, and fatigue:<sup>259, 260</sup>

- Set clear and consistent goals for staff;
- Provide frequent training to increase role effectiveness and coping strategies;
- Provide work-focused consultations to staff who are experiencing job stress;
- Encourage the development of support groups and resource exchange networks;
- Maximise staff autonomy and participation in decision-making;
- Organise work to reduce job strain by optimising workload and working time, ensuring safe staffing levels, encouraging regular breaks and having flexible schedules;
- Optimise shift lengths to avoid fatigue, giving preference to shift rotation in a forward direction; and
- Provide accommodation for health workers during emergency operations, with access to food services, sanitary facilities and recreational opportunities.

Similarly, the Institute for Clinical Systems Improvement (ICSI) has developed a resource that outlines steps that should be taken to promote healthcare workers' well-being from a systems perspective. Through its analysis, the ICSI identified five foundational elements for supporting the wellbeing of the healthcare workforce:<sup>261</sup>

- **Relationship-based culture** — Foster a culture where positive relationships between staff at all levels are the cornerstone of the organisation.
- **Coordinated infrastructure** — Coordination of expertise and services that may traditionally operate in silos with the aim of supporting staff.
- **Bi-directional communication** — Develop a strong internal communications strategy that enables direct and frequent “top-down” as well as “bottom-up” engagement to support your staff.
- **Ongoing needs assessment** — Continually evaluate the needs of staff, paying attention to particular stressors of different work units.
- **Responsive solutions** — Offer systems-driven interventions (e.g., policies, protocols, and programmes) and staff self-directed interventions (e.g., podcasts, apps), and have an ongoing plan for evaluation.

## 12.1 Mental health resources for the pharmacy workforce

Beyond systems-level changes, there are also steps that can be taken at an individual level. First, every member of the pharmacy team has an opportunity to contribute to an environment and work culture that is supportive of discussing mental health concerns and providing assistance as needed. Mind, a mental health charity in the UK, has developed many [resources](#) that can be used by pharmacists to help support the mental health of their team members.<sup>262</sup> One [resource](#) outlines the steps that should be taken to support staff who are experiencing a mental health problem, including guidance on how to create a culture where mental health concerns can be openly discussed, how to have conversations about mental health, how to support someone who has a mental health concern, and how to manage someone's time off and their return to work.<sup>263</sup> Mind, with support by the Mental Health at Work Leadership Council, has also developed the [Mental Health At Work](#) website, which includes a variety of toolkits and resources to help promote mental health in the workplace.<sup>264</sup>

Additionally, there are individual behaviours that members of the pharmacy team can adopt to promote their own well-being. However, these behaviours cannot replace the care provided by trained mental health care professionals, and pharmacy team members should seek care as soon as possible should they have concerns about their mental health.

First, pharmacy team members should take steps to develop a self-care plan. According to Mental Health First Aid (MHFA), self-care includes “activities and practices that you can engage in on a regular basis to reduce stress and maintain your short- and longer-term health and wellbeing”.<sup>265</sup> According to MHFA, a self-care plan should include:<sup>265</sup>

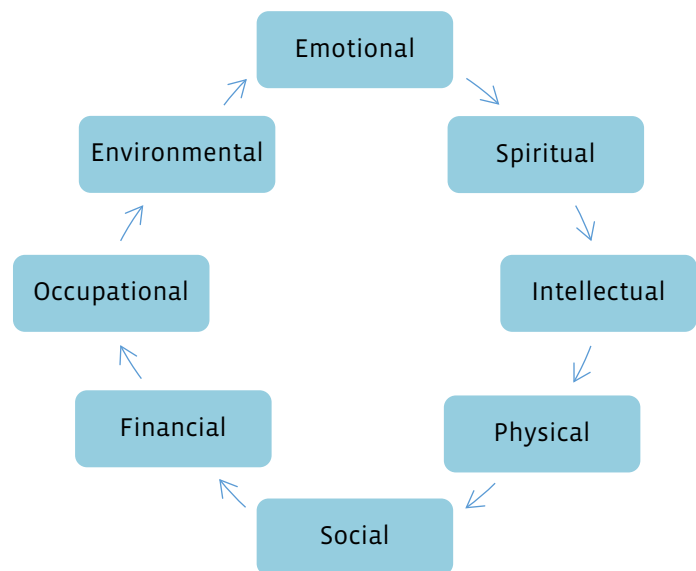
- Taking care of physical and psychological health;

- Managing and reducing stress;
- Recognising emotional and spiritual needs;
- Fostering and sustaining relationships; and
- Achieving balance in different areas of life.

Further, given the added stress of working in the healthcare field, SAMHSA (the Substance Abuse and Mental Health Services Administration in the US) has developed a [resource](#) for healthcare professionals to assist with coping with stress and compassion fatigue. Within this [resource](#) are self-care activities that can be included in a self-care plan. These include being physically active, sleeping and eating well, not increasing alcohol or drug use, staying in contact with family and friends, and looking to colleagues for support at work. Some additional activities that are recommended as potential stress reducers are: visualisation, progressive muscle relaxation, mindful movement (e.g., yoga), meditation, breathing exercises, humour, journal writing or drawing, and spiritual or religious practices.<sup>266</sup> Ultimately, a self-care plan is highly individualised and should be tailored to the needs and interests of the individual developing the plan.

According to SAMHSA, there are eight dimensions of wellness that contribute to an individual's overall wellbeing (see Figure 2). It is important to assess each of these dimensions in one's own life and identify opportunities to improve wellness in that area. For example, improving physical wellness may include eating a healthier diet, participating in more physical activity, sleeping more, or reducing or eliminating use of alcohol or tobacco. Social wellness, on the other hand, may include meeting new people, reconnecting with friends, or ensuring there is sufficient time being spent with family. Within the [SAMHSA guide](#), individuals can make a plan to build their wellness in each of these areas in order to improve their overall mental health and wellbeing.<sup>267</sup>

Figure 2: SAMHSA's eight dimensions of wellness



Pharmacists can also consider developing a Wellness Action Plan. This tool, as outlined by Mind, is used to identify what an individual needs to be well at work and how they can support their mental health and wellbeing. It is also used to identify an individual's working style as well as their stress triggers and responses. The Wellness Action Plan [template](#) developed by Mind includes key questions individuals should ask themselves so they can then have conversations with their team members or managers about their responses in order to facilitate a supportive work environment that is understanding and accepting of mental health challenges. For example, one question is "what actions would you like to be taken if any . . . early warning signs of poor mental health are noticed by your manager or colleagues?"<sup>268</sup>

In some countries, there are also pharmacy-specific support services that pharmacists may wish to pursue. For example, in Australia, there is Pharmacists' Support Services, which is a charity that offers a 24-hour anonymous support line for pharmacists. In the UK there is Pharmacist Support, which is a charity that provides support services and aims to promote well-being among pharmacists and their families, former pharmacists and pharmacy students.

Finally, there are many additional resources available online that can support pharmacists, or others, who are struggling with their mental health. While each country will have their own specific resources, there are also international resources that can be used. For example, the [International Association for Suicide Prevention](#) provides information on international helplines and crisis centres. [Find a Helpline](#) is a free, online tool that connects people to helplines in over 50 different countries.

It is essential that pharmacy teams support one another and look after their own mental health as well as that of their team members. It is also important to advocate systems-level changes that can further promote mental health and well-being and reduce the risk of burnout among pharmacists.

## 13 Ethical considerations

When providing patient care services to individuals with mental illnesses, it is important to be aware of the many different ethical concerns that may arise and have an idea of how to navigate potentially complex ethical situations. Broadly, these concerns can be organised around the four main ethical principles of non-maleficence, beneficence, autonomy and justice (see Table 13).<sup>269</sup>

Table 13: Overview of the four main ethical principles<sup>270</sup>

Ethical principle	Description
<b>Non-maleficence</b>	Providers should do no harm to the patient or society and should ensure they are not intentionally creating harm or injury. This principle also requires that any risks or potential harms should not outweigh the benefits of a certain medical decision (i.e., treatment, intervention, etc.)
<b>Beneficence</b>	Providers should always endeavour to benefit patients and society. Contrary to non-maleficence, beneficence is not only concerned with avoiding harm, but also providing benefits.
<b>Autonomy</b>	Providers should ensure a patients' beliefs and wishes are followed, even if it is not always in their best interest. This principle encompasses other important concepts, including privacy, confidentiality and informed consent. This principle is one that is commonly contemplated when treating those with mental illnesses.
<b>Justice</b>	Providers should ensure the equitable distribution of resources and ensuring all receive fair, appropriate healthcare services.

While these four main ethical principles will present in a variety of ways when caring for patients with mental illnesses, there are some common ethical situations that may arise. These are discussed below.

When considering issues related to patient autonomy, it is likely that situations will arise related to informed consent, privacy and confidentiality. It is also possible that situations may occur that require providers to weigh the importance of autonomy with other ethical principles, such as beneficence and non-maleficence.

**Informed consent** — Informed consent requires that patients are able to understand and voluntarily decide for themselves whether to receive a certain treatment or procedure. However, this concept becomes complicated when caring for those with mental illnesses. To provide informed consent, patients must be presented with all necessary information about a particular treatment. The process of informed consent also requires active communication and dialogue between a provider and patient, and allows patients to get all their questions answered. Broadly, the consent process should include the following information:<sup>271</sup>

- Purpose of the treatment and why it is being proposed;
- Specifics of the treatment, including frequency, mode of administration, etc;
- Benefits and risks of the treatment;
- Potential alternatives to the proposed treatment;
- Side effects or other potential effects the treatment may have on a patient's daily life;
- Cost of the treatment or insurance coverage;
- Consequences of forgoing the proposed treatment; and
- Who will be providing the treatment.

Given all of the information required to obtain informed consent, it is important to note that it requires more than a patient simply signing a form: it requires communication. Consent also requires an ongoing conversation and patients must be allowed to withdraw their consent at any time.<sup>271</sup>

Informed consent becomes more complicated when the mental capacity or competency of the patient is in question due to effects of their mental illness. The terms "mental capacity" and "competency" have different legal definitions in different countries, but the concept remains the same — patients must have the mental capacity to consent to treatment. Capacity or competence are often determined by assessing the four following areas for each patient:<sup>272</sup>



- **Communicating choices** — Patients must be able to communicate whether they accept or decline a particular medical treatment. It is also required that patients are able to maintain their decision and are not constantly changing their mind. However, if a patient changes their mind, that alone does not indicate a lack of ability to communicate choices. However, frequent decision changes can indicate a lack of ability in this area, especially if they can be linked to a particular mental illness a patient might have.
- **Understanding relevant information** — Patients must be able to comprehend the information that is shared with them about a potential medical treatment. This can be assessed by having the patient repeat back or rephrase information that was shared with them about the treatment. However, healthcare providers should ensure they are sharing information using easy-to-understand words and phrases.
- **Appreciating a situation and its consequences** — Patients must not only comprehend the information that is shared with them about a medical treatment, they must also appreciate how this information may affect them as an individual. This is particularly important when considering the benefits and risks of a potential medical treatment and their likelihood of occurring. Patients should be able to interpret these risks and understand the potential implications on their life. To assess this aspect, healthcare providers should ask patients to explain their understanding of their illness, their need for treatment, the likely outcomes and the motives of those involved.
- **Manipulating information rationally** — Patients must be able to rationally assess information and use reasoning to come to a decision. While appreciating a situation requires that a patient understands how a decision will affect them, reasoning requires that a patient is able to weigh information to make a decision. This aspect evaluates how a patient arrives at their decision; thus, to assess this in patients, providers should evaluate the patient's mental process for making their decision.

This information will typically be assessed by a patient's mental health care provider, but it is important for pharmacists to be aware of these factors and consider how they might influence their approach to care. If a patient is not able to provide consent, healthcare providers should try to follow what the patient may have expressed prior to becoming incapable of providing consent. These wishes may take the form of a legal document, such as a living will, or may be conveyed by a designated individual or proxy. If the patient has not previously indicated their wishes, efforts should be made to find an individual, such as a family member or partner, who can act in the best interests of the patient and make decisions for them.<sup>271</sup>

**Privacy and confidentiality** — Given the stigma that surrounds mental illness, ensuring privacy and confidentiality for all patients is imperative. This is especially important in public spaces such as pharmacies. When discussing mental health with a patient, pharmacists should always endeavour to provide a private space where conversations cannot be overheard by others. This is an extremely important consideration and is often identified as a primary concern among patients regarding receiving mental health care services in a pharmacy setting.<sup>273</sup> However, beyond this, there are several other considerations pharmacists should be aware of.

While laws concerning patient privacy will vary in every country, it is generally expected that information related to a patient's diagnosis, treatment, prognosis, etc, be kept confidential and not shared with anyone the patient has not explicitly approved. According to the World Psychiatric Association's Code of Ethics for Psychiatry, "except in emergencies, including an imminent threat to harm other people, or under proper legal compulsion, [practitioners] do not release information regarding patients without patients' consent". And, even if practitioners have obtained consent, they should only release the most limited information necessary. Therefore, pharmacists must take steps to ensure they are not sharing confidential information and they should also be aware of what kinds of situations would require they share confidential information.<sup>274</sup> For example, if a patient credibly threatens to harm themselves or others, reporting should be considered. If a patient references child or elder abuse, this information is often required to be reported. If other situations occur, pharmacists should use their best professional judgement regarding whether to break patient confidentiality and report. However, if the patient or another person is at risk of being harmed, reporting the information to the relevant authorities is justified.<sup>275</sup>

**Involuntary treatment** — Another issue related to informed consent and privacy is that of involuntary treatment. At times, it may be necessary for patients to receive treatment against their wishes. This is often done when public safety is at risk, there is significant risk to the patient should they not receive treatment, or

the patient lacks the capacity to fully understand the implications of their decisions. This is a difficult situation as it requires reflection on the discrepancies between the principles of autonomy, beneficence and non-maleficence. According to the American Psychiatric Association, involuntary treatment should “ensure the least restrictive clinically appropriate alternative and, to the extent possible, respect the informed consent process and the patient’s decision-making capacity”. Generally, involuntary treatment takes the form of hospitalisations, court-ordered treatment or medication.<sup>275</sup>

**Justice** — Finally, within the concept of justice, it is important to ensure equal and fair care is provided to all patients. This includes providing culturally appropriate and responsive care. One example of how culture might manifest in treatment for mental illness is the culture surrounding giving and receiving gifts. In some cultures, it is highly frowned upon to accept gifts from patients, regardless of how small or large they are, as this may damage the therapeutic relationship between a provider and patient. However, in other cultures, rejecting the gift may damage the therapeutic relationship. Thus, it is important to interpret these situations in terms of the community and cultural context in which care is being provided. Another issue that pharmacists may face is that of the role of traditional and herbal medicines in the treatment of mental illnesses. Some cultures may place a higher value on these than on conventional pharmacological treatments. Thus, pharmacists should consider the interplay of all four ethical principles (see Table 13).<sup>276</sup> When faced with these situations, pharmacists can ask themselves the following questions to help navigate the interplay of these ethical principles:<sup>277</sup>

- How severe is the patient’s illness? Is it acute or chronic?
- Can their condition be cured or managed with conventional treatments?
- How invasive or toxic is the conventional treatment? What are the side effects?
- What is the quality of evidence regarding the safety and efficacy of the traditional medicine?
- How well does the patient understand the risks and benefits of taking the traditional medicine?
- Does the patient voluntarily accept the risks associated with the traditional medicine?
- How strong is the patient’s desire to take the traditional medicine? How persistent are they?

In order to provide equitable, fair healthcare services, a patient’s culture and identity should be taken into account. Pharmacists should take steps to educate themselves on the culture of their patients so they ensure they are providing the highest quality care possible.

# 14 Barriers and facilitators to providing mental health care services

## 14.1 Barriers

### 14.1.1 Structural and systems-level barriers

Pharmacists' involvement in providing mental health care services is often hindered by many structural and systems-level barriers, including:

- **Limited time** — Pharmacists have many daily responsibilities and may not have the time or capacity to implement new mental health services in their practice setting, particularly if they are short-staffed. As pharmacists continue to take on more and more new roles in patient care (ranging from vaccinations to point-of-care testing to enhanced roles in medication therapy management), their ability to provide additional new services is reduced.<sup>273</sup> This has also been identified as a barrier by patients, who view pharmacists as too busy to discuss concerns related to their mental illness.<sup>278</sup>
- **Remuneration** — In most countries, pharmacist-provided mental health services are not reimbursed. This lack of proper remuneration, coupled with existing high job demands, makes it difficult for pharmacists to provide sustained mental health care services to patients.<sup>279</sup>
- **Lack of access to medical records** — Pharmacists, particularly those who practise in a community setting, typically do not have access to a patient's medical records. This prevents pharmacists from having a clear understanding of the health status of the patient and prevents them from identifying potential areas for intervention. Thus, their ability to provide care for those with mental illnesses is limited.<sup>280</sup>
- **Privacy concerns** — Patients have identified a lack of privacy and busy pharmacy environment as a significant barrier to receiving mental health care services in a pharmacy setting. Therefore, even if patients are receptive to receiving mental health care services from their pharmacists, they may not wish to receive these services if they cannot be provided in a quiet, private place.<sup>281</sup>
- **Models of care** — Pharmacists' involvement in mental health care services is reduced as a result of existing models of care. In particular, there are many challenges that exist when trying to integrate pharmacists into a multidisciplinary mental health care team and, as a result, pharmacists can often be overlooked when it comes to providing team-based care to an individual with a mental illness. This can be due to a variety of factors, including perceptions that a pharmacist is not going to be useful to the team or concerns that pharmacists are trying to expand their scope of practice too far. However, these barriers are typically faced among those who have not previously collaborated with pharmacists.<sup>49</sup>

### 14.1.2 Attitudes and stigma

A barrier to increasing pharmacists' engagement in mental health care services is the stigma associated with people with mental illnesses.<sup>142, 282, 283</sup> Such stigma is widespread and, as a result, pharmacists may have reservations about providing mental health services as they might believe these individuals are violent or too difficult to speak with.<sup>273, 282</sup> While some studies have found that pharmacists have positive attitudes towards those with mental illnesses, others have found that stigma and negative views still exist. Negative attitudes towards those with mental illness may also stem from a lack of education about mental illness and its impact on individuals. Thus, pharmacists who were not exposed to mental health topics or provided with training specific to mental health may hold negative attitudes towards those with mental illnesses.<sup>49</sup> Patients often share that stigma is a major factor that holds them back from receiving care for their mental illness. In fact, some studies have found that those with mental illnesses have received less counselling, monitoring and follow-up from pharmacists than those with physical health conditions.<sup>273</sup> Stigma and negative attitudes towards those with mental illnesses is a significant barrier to pharmacists providing mental health care services but, with increased training and education, this barrier can be addressed.

### 14.1.3 Training

A significant barrier to increasing the availability of pharmacist-provided mental health care services is a lack of training, which can lead to a lack of confidence in providing mental health care services.<sup>273</sup> If topics related

to mental health are not adequately covered in pharmacy schools, pharmacists will graduate without the necessary skills to provide these services to their patients. This leads to a shortage of trained pharmacists who are able to provide services to those with mental illness.<sup>140, 141</sup>

## 14.2 Facilitators

Given the prevalence of mental illnesses globally, there is a need for pharmacists to increase their engagement in mental health care service provision. Despite the challenges, there are steps that can be taken on both individual and systems-level to overcome barriers and increase pharmacists' participation in mental health care.

### 14.2.1 Increased training opportunities

Training and education focused on mental health care should be integrated into pharmacy curricula globally. In order to prepare pharmacy students to engage with this patient population upon graduation, they should be educated on the topics discussed throughout this handbook and given opportunities to develop key skills in practice. Pharmacy students should have opportunities to pursue elective courses focused on mental health, Mental Health First Aid training and experiential rotations focused on mental health care. Additionally, in-person contact with those experiencing mental illness has been shown to reduce stigma and improve attitudes towards those with mental illnesses.<sup>273</sup>

Practising pharmacists should also seek continuing professional development opportunities that will allow them to further build their knowledge and skills in this area, including Mental Health First Aid or suicide prevention training. As pharmacists continue to seek out training in these areas, their confidence in providing mental health care services will continue to grow.<sup>284</sup> FIP has concurrently published the "[FIP knowledge and skills reference guide: A companion to the mental health care handbook](#)" to support pharmacists' professional development in the area. The guide outlines the knowledge and skills for roles and interventions in mental health by pharmacists, and is intended to be useful to pharmacists, educators and CPD providers.

### 14.2.2 Accessibility of pharmacists

As one of the most accessible healthcare providers, pharmacists have an opportunity to interact with individuals with mental illnesses more than others in the healthcare system. Pharmacists can leverage this accessibility and the relationships they have with their patients to provide mental health care services. Studies found that positive relationships between patients and the pharmacy team reduced perceptions of stigma among patients and made them more willing to discuss mental health concerns with the pharmacist.<sup>278, 285</sup> And because privacy was an often-cited concern for patients, pharmacists should consider how they wish to address this concern, either through creating a private space in their pharmacy or providing mental health services over the telephone.<sup>278</sup> Finally, pharmacists can also leverage their accessibility to increase awareness of the roles they are able to play in mental health care. While patients are likely unaware of the many ways pharmacists can contribute to their mental health care, awareness campaigns can be an effective method to increase interest in their services.<sup>286</sup>

### 14.2.3 Policy

Policies need to capture the critical role of pharmacists in mental health care service delivery in order to help facilitate the integration of pharmacists' services into the mental health practice realm. Failure to implement such policies may lead to sporadic and piecemeal involvement of pharmacists in mental health care. Further, policies should be implemented in order to ensure pharmacists are compensated for the services they provide. Finally, pharmacy associations and groups should work to develop policies and resources to encourage pharmacists in their jurisdictions to increase their engagement in mental health care service provision.

## 15 Conclusions

As the global burden of mental illness continues to grow, there is an urgent need for pharmacists worldwide to increase their engagement in providing mental health care services. This handbook has outlined the many different ways that pharmacists can contribute to improving mental health among their patients, including by screening for mental illness, responding to mental health crises, referring patients to additional care, working as part of interprofessional teams, optimising the use of psychotropic medicines and participating in transitions of care services.

Beyond these roles, it is also important for pharmacists to consider their own mental health, and the mental health of their pharmacy team, and take steps to ensure they are receiving the necessary care and resources to support their mental health and well-being.

In summary, despite the barriers that exist to implementing some of these services, there are numerous opportunities for pharmacists to increase their engagement in mental health care service provision and, ultimately, improve mental health in their communities.

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