

# Overview Report on the COVID-19 Operational Standards for Pharmacies

17 June 2021

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## About the PSI – The Pharmacy Regulator

The Pharmaceutical Society of Ireland (PSI), the pharmacy regulator, is a public body established under the Pharmacy Act 2007 to protect the health, safety and wellbeing of patients and the public by regulating pharmacists and pharmacies in Ireland. There are 6,749 pharmacists, and 277 pharmaceutical assistants registered with the PSI. In addition, there are 1,970 pharmacies on our register.

### Our ongoing responsibilities to the public

Our principal purpose as a regulator is to ensure patient safety and public protection. We are committed to carrying out our work independently, ethically, and transparently. The Pharmacy Act 2007, as amended, establishes the statutory role of the PSI as the pharmacy regulator. Under this legislation and all other applicable legal and public policy frameworks, the PSI must ensure that, on an ongoing basis, we:

-  operate fair, transparent, and efficient registration procedures for all registrants (pharmacists, pharmaceutical assistants, and retail pharmacies), and maintain the statutory registers,
-  evaluate, for accreditation purposes, programmes of education leading to qualifications appropriate for practice as a pharmacist in Ireland,
-  oversee the effective implementation of the mandatory system of CPD for pharmacists,
-  promote and support professional practice by pharmacists and share information for the benefit of patients and the wider health system,
-  communicate and engage with the public, the pharmacy profession, and our many other stakeholders to ensure our work is understood and informed by these stakeholders,
-  assure the public of the quality and safety of community pharmacy services through ongoing programmes of quality assessment and oversight of compliance with essential safety requirements,
-  undertake investigations into matters of serious concern regarding the actions of pharmacists and/or pharmacies and initiate enforcement actions, including prosecutions, where appropriate,
-  manage the professional complaints process in accordance with the law, natural justice, and fair procedures,
-  contribute to the ongoing review of new and existing pharmacy and medicines legislation, and contribute to public policy developments relating to our regulatory remit,

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 comply with our own external compliance obligations and with the Code of Practice for the Governance for State Bodies, which provides assurance that the PSI acts in accordance with best practice in the management and governance of public bodies, and
- 
 operate prudent financial management practices and continue to steward all PSI funds so as to maximise the pool of financial resources available to deliver on our statutory functions.

## Our Vision, Mission and Values

Our vision, mission and values that underpin our work in the PSI are set out in the diagram below. Additional information about our role and the work that we do is available on our website at [www.psi.ie](http://www.psi.ie).



## Introduction

As we are all aware, the onset of the COVID-19 pandemic in early 2020 presented considerable challenges to health and social care services. The pressure to respond to the immediacy of the pandemic was enormous while the range of issues to be addressed was unprecedented. All types of healthcare services were required to adapt to a rapidly changing situation where immediate responses were necessary to save lives and prevent the spread of the virus. Healthcare staff of all backgrounds were asked to step forward and work selflessly to protect the vulnerable and care for the sick. All this while, justifiably, also concerned about their safety and that of their loved ones. We all owe our healthcare staff, including pharmacists working across all types of healthcare settings, an enormous debt of gratitude.



This gratitude also extends to staff working in community pharmacies across the world who stayed working in their pharmacies to ensure patients and the public had continued access to medicines and advice, as well as reassurance. Community pharmacy teams in Ireland too, throughout 2020, demonstrated their commitment to patients and the public by continuing to provide medicine services despite the many pressures and anxieties caused by the pandemic. This commitment continues during 2021 as we all work to overcome the impact of the pandemic and to support the national vaccination programme.

As the pharmacy regulator, PSI worked to support the public health response during 2020. As part of this, we were conscious of the need to support community pharmacies in continuing to operate safely during the pandemic. One of the important steps we took was to develop our [COVID-19 Operational Standards for Pharmacies](#). This report describes why and how we developed these Standards and how we encouraged community pharmacies to engage with the Standards through a 'use and learn' approach.

Part of the 'use and learn' approach involved visiting a small sample of pharmacies (remotely and in-person) to assess how the Standards were working in practice and see how the pharmacies in the sample were coping with the pressure of the pandemic. This report sets out some important observations and findings from these initial assessments. We will follow up on these findings as part of our strategic objective of evolving a more effective regulatory model for community pharmacies.

We thank everyone who participated with us in developing the Standards, particularly the members of our Safety Collaborative, and those pharmacies and pharmacy teams who volunteered to be part of our initial assessments. Given the pressure these people were all under, we are gratified that they would take the time to assist us in our work and play an important role in helping PSI achieve its public interest mission of assuring public trust in pharmacy through effective regulation.

Niall Byrne

Registrar & Chief Officer

June 2021

# Section One: Developing the Standards

## 1.1 Ensuring continuity of pharmacy-delivered care during COVID-19

### Pharmacies

Pharmacies are a critical part of our healthcare system, providing essential access to medicines, medical devices and other healthcare services such as vaccinations and healthcare advice. There are 20+ million visits to pharmacies in Ireland each year, and 80+ million items are dispensed annually. As with all healthcare services, it is important that the public can trust pharmacies to provide safe and reliable healthcare services at all times.

The onset of the COVID-19 pandemic placed unprecedented, urgent demands on community pharmacies to ensure continuity of supply of medicines and treatment and to protect the public, patients, and pharmacy teams. Pharmacies rose to these significant challenges by responding professionally and quickly adapting their work practices providing medicines, other healthcare services and counselling to patients.

In particular, those in governance and leadership roles in community pharmacies<sup>1</sup> stepped forward and showed strong leadership over the last year. Their role in ensuring that their pharmacies protect the vulnerable and that patients and staff are supported through uncertainty has been critical. Effective governance, good planning and ongoing management of risks have been the hallmarks of community pharmacy leadership during this crisis. They will continue to be essential as the challenges presented by the COVID-19 pandemic continue. As the regulator, PSI is very clear that we must encourage and support good governance and effective leadership in community pharmacy, both during the pandemic and after.

### PSI – The Pharmacy Regulator

In response to the challenges presented to community pharmacies by COVID-19, PSI, decided that we should support those in governance positions in community pharmacies by developing relevant and necessary guidance in the form of our COVID-19 Operational Standards for Pharmacies.

We convened a multi-stakeholder Safety Collaborative consisting of representation from those in governance and leadership roles in community pharmacies, as well as from the Health Service Executive (HSE), Department of Health (DoH), Health Protection Surveillance Centre (HPSC) and the Irish Pharmacy Union (IPU). We consider the Safety Collaborative to be an excellent example of responsive regulation in action. We believe that it demonstrates how a regulator can play an important and relevant role during a crisis by bringing together

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<sup>1</sup> Those in governance and leadership roles include superintendent and supervising pharmacists, and pharmacy owners.

a group of key people to work effectively and efficiently to develop practical support for those they regulate. We also believe that this work demonstrates PSI's commitment to creativity and innovation in delivering on our public interest mission and our public protection functions.

## 1.2 Development of the COVID-19 Operational Standards for Pharmacies

### 1.2.1 Why develop Standards?

By developing standards, we align pharmacy regulation with how healthcare settings, more generally, are regulated. Regulatory standards are an effective, flexible and non-prescriptive means for regulating healthcare services. Standards are intended to indicate 'what a good quality healthcare service looks like' while leaving it to those in governance and leadership positions to decide how exactly they deliver a good quality service in their settings. In keeping with this intention, PSI developed our COVID-19 Operational Standards to indicate to those in governance and leadership positions in community pharmacy what PSI as the regulator, expects from pharmacy leaders in continuing to ensure safe services and a safe environment for patients, the public and their staff, during the COVID-19 pandemic.

The Standards are also intended to inform patients and the wider public about what they can expect from their pharmacy and to provide assurance that their pharmacy is, indeed, a safe and supportive healthcare environment despite the risks arising from COVID-19.

We are committed to supporting pharmacies to meet the Standards, and the relevant statutory requirements, as part of our ongoing mission to assure the public that pharmacies and pharmacists can be depended upon for safe and reliable healthcare. We expect that there will be a high degree of voluntary compliance with the Standards and that pharmacies will positively engage with the Standards, recognising that the overall aim of the Standards is to deliver the best outcomes for patients and the public while the risks of COVID-19 remain present in our communities.





## 1.2.2 How were the Standards developed?

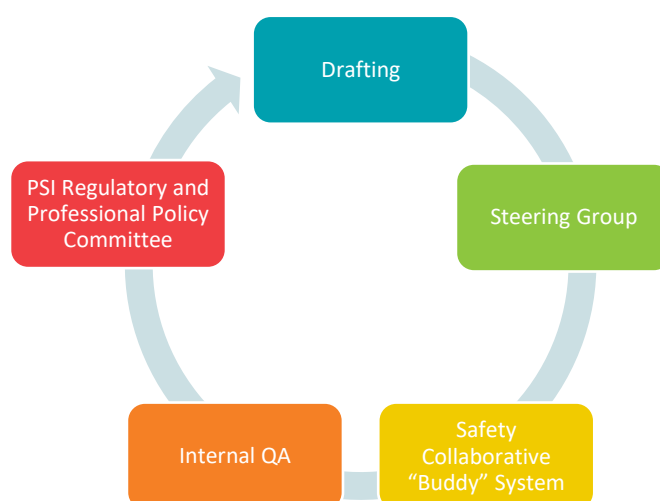
To undertake the rapid process of co-designing the COVID-19 Operational Standards for Pharmacies with stakeholders, we convened a multi-stakeholder Safety Collaborative, as described earlier.

Collaboratives such as this are widely used to enhance health care systems and to improve patient safety and quality by bringing together experts who share evidence on best

practices<sup>2</sup>. Collaboratives involve working across traditional disciplines and sectoral boundaries, to share key knowledge and experiences, to impact patients and service users positively.

While the Standards' development was informed by the good practice approaches published by the Health Information and Quality Authority (HIQA)<sup>3</sup>, the Safety Collaborative used a modified version of this methodology, having regard to the need to publish the Standards quickly in response to the COVID-19 pandemic. The Standards reflect the national public health advice in place to manage the COVID-19 pandemic and were also informed by approaches adopted both nationally and internationally<sup>4</sup>.

Having come through the internal governance processes of PSI, the Standards were approved by the PSI Council on 23 July 2020 and published on 7 August 2020 on the [PSI website](#).



<sup>2</sup> Zamboni, K., Baker, U., Tyagi, M., Schellenberg, J., Hill, Z., & Hanson, C. (2020). How and under what circumstances do quality improvement collaboratives lead to better outcomes? A systematic review. *Implementation Science*, 15, 1-20.

<sup>3</sup> [International Review of methodologies for developing standards \(higa.ie\)](#)

<sup>4</sup> A number of resources and guidance from pharmacy and non-pharmacy regulatory bodies were examined both nationally and internationally, as well as resources from the International Pharmaceutical Federation (FIP).

### 1.2.3 What do the Standards cover?

There are five [Standards](#) covering four domains with **Quality** and **Safety** being the overarching principles.

The four domains are:

1. Good governance
2. The pharmacy team
3. The pharmacy setting
4. The pharmacy services

Each standard is equally important and each is outcome-focused. The Standards mutually inform and cross-reference each other.



### 1.2.4 How are the Standards being implemented?

As standards are an evolution in how we regulate community pharmacies, we are adopting a learning and engagement approach to implementation through a 'use and learn' period. The 'use and learn' period will continue until the end of 2021.

### 1.2.5 How is PSI supporting the implementation of the Standards?

We have developed a number of helpful resources to support pharmacy teams in engaging with the Standards during the 'use and learn' period. These include:

- An [introductory video](#) which is available to view on the PSI website,
- A one-page [summary poster](#) setting out the five Standards, which can be printed and displayed in the pharmacy
- A designated email address for registrants' feedback on the Standards.

In addition, information concerning the Standards is available on the [PSI website](#) and has been included in the regular PSI newsletters, as well as through a webinar which we hosted in November 2020.



## Webinar

To provide information and support to pharmacies, we held a webinar on the COVID-19 Operational Standards on 18 November 2020. [View the presentation from the webinar.](#)

The webinar, entitled ‘Supporting safety & leadership in pharmacies during COVID-19’ was the first time PSI engaged with the profession via this platform. The webinar aimed to emphasise to pharmacists what is expected during the ‘use and learn’ period.

The Registrar & Chief Officer, PSI representatives and two practising pharmacists who are members of the Safety Collaborative shared their insights and learnings in relation to using the Standards in practice during the webinar. Feedback from attendees was very positive.

### 1.2.6 Engagement with other regulators

To develop our approach for fieldwork testing<sup>5</sup> and learn from other regulators who use standards to assure the quality and safety of healthcare services, we held several collaboration and engagement meetings with other national and international healthcare regulators across health and social care. These meetings, held between October 2020 and February 2021, allowed us to learn from these regulator’s experience in developing, publishing and assessing performance against healthcare standards.

This included engagement with the Health Information and Quality Authority (HIQA), the Mental Health Commission (MHC) and the General Pharmaceutical Council (GPhC). During these engagement meetings a range of areas was explored including:

- Approaches to outcomes-focused inspections/assessments
- Gathering evidence against standards during assessments
- Making evidence-based judgements against standards
- Publication of reports
- Training of inspection and assessment staff

## 1.3 Regulating pharmacies through standards

### 1.3.1 How do the Standards fit within the existing regulatory framework?

The Pharmacy Act 2007 and the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended) are the principal pieces of legislation governing the regulation of community pharmacies. While these statutory provisions, which are focused on conformance with requirements, continue to apply, we are now supplementing these with outcome-focused standards intended to define what good performance looks like in pharmacies.

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<sup>5</sup> By ‘fieldwork testing’ we mean testing the Standards in practice, in collaboration with the community pharmacy sector, and learning from their experience of using the Standards.

In international settings, it is recognised that the development and implementation of regulatory standards, and the monitoring of performance against standards, have a real impact on driving improvement in quality and safety in healthcare, and in supporting good governance and strong leadership across healthcare settings<sup>6</sup>. By introducing our COVID-19 Standards, we are aligning pharmacy regulation in Ireland with how healthcare settings, more generally, are regulated.

Under our previous [PSI Corporate Strategy 2018 to 2020](#), we had already commenced the development of Governance and Accountability Standards for Pharmacies. As part of this project, we held interactive workshops about governance and accountability in pharmacies with superintendent pharmacists at 11 regional seminars during springtime 2018. The response to the proposal that regulatory standards form part of how we regulate community pharmacies was, generally, very well received. More information about this particular piece of work is available on the [PSI website](#).

Our prior experience commencing the development of Governance and Accountability Standards enabled us to rapidly develop the COVID-19 Operational Standards for Pharmacies, in response to the challenges presented by the pandemic.

### Our vision - regulatory reform using standards

Although the COVID-19 Operational Standards for Pharmacies are not currently underpinned by specific legislation, the rapid onset of the pandemic was both a reason, and an opportunity, to move into this area as a matter of urgency. Our experience with our COVID-19 Standards to date is that regulatory standards are of value and that they should play an important role in how PSI regulates community pharmacies into the future.

We consider that providing a statutory basis for standards is, among other matters, an important legislative reform issue which we are keen to progress under our current Corporate Strategy 2021 – 2023. Our strategic goal is to work with the Department of Health and other stakeholders, to see the COVID-19 Operational Standards, and other relevant standards, operating on a statutory basis. We are also keen to see our Standards being adopted by the community pharmacy sector because the standards support good practice, allow innovation and help create assurance for the public that pharmacies are championing safety and quality. Fundamentally, our ongoing work with stakeholders is all directed towards building awareness among the public of the quality of service expected by all who receive healthcare advice and treatment in a community pharmacy.

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<sup>6</sup> Schaefer, C., & Wiig, S. (2017). Strategy and practise of external inspection in healthcare services—a Norwegian comparative case study. *Safety in Health*, 3(1), 1-9.

## Section Two: Fieldwork Testing Methodology

During the 'use and learn' period, we are conducting fieldwork testing of the Standards in cooperation with a small number of pharmacies. Our testing (virtual and on-site) commenced in October 2020. We initially visited pharmacies where members of our Safety Collaborative were involved in governance and leadership roles. The testing work was later extended to other pharmacies that had volunteered to participate through an expression of interest, issued to pharmacies in December 2020.

In total, we have conducted 41 visits, of which physical onsite visits accounted for 13 visits and the remaining 28 visits were conducted virtually due to Government public health advice relating to the ongoing COVID-19 pandemic. While this is a small sample of all community pharmacies, we learned a lot from our engagement with the leaders and staff involved. We very much appreciate the time and commitment of all who engaged with us in the testing process.

### 2.1 What was the aim of fieldwork testing?

The aim of the fieldwork testing was to:

- ✓ Learn how well the Standards were working in practice,
- ✓ Gather feedback on how the Standards could be improved, and
- ✓ Inform us as to how best to monitor performance against the Standards when the 'use and learn' period ends
- ✓ Gain experience using data triangulation in community pharmacies (i.e., **talking** with pharmacy staff, **observing** practices, workflows and interactions, and **reading** relevant documentation).

Our findings from this testing process are presented in this Chapter. All of our findings to date will inform the further development of a monitoring framework and an associated judgement framework, which will assist us in assessing performance against the Standards, once the 'use and learn' period has concluded.

### 2.2 How was fieldwork testing carried out?

To ensure consistency in our approach during the fieldwork testing, we developed key areas of focus (see figure 1. below) under each Standard to guide our assessment staff during the fieldwork testing. These were informed by approaches adopted by other healthcare regulators, adapted to the community pharmacy context, together with input from the members of our Safety Collaborative. It is expected that these key areas of focus will later

inform our key lines of enquiry (KLOE)<sup>7</sup>, when we move later to the assessment of community pharmacies' performance against the standards.

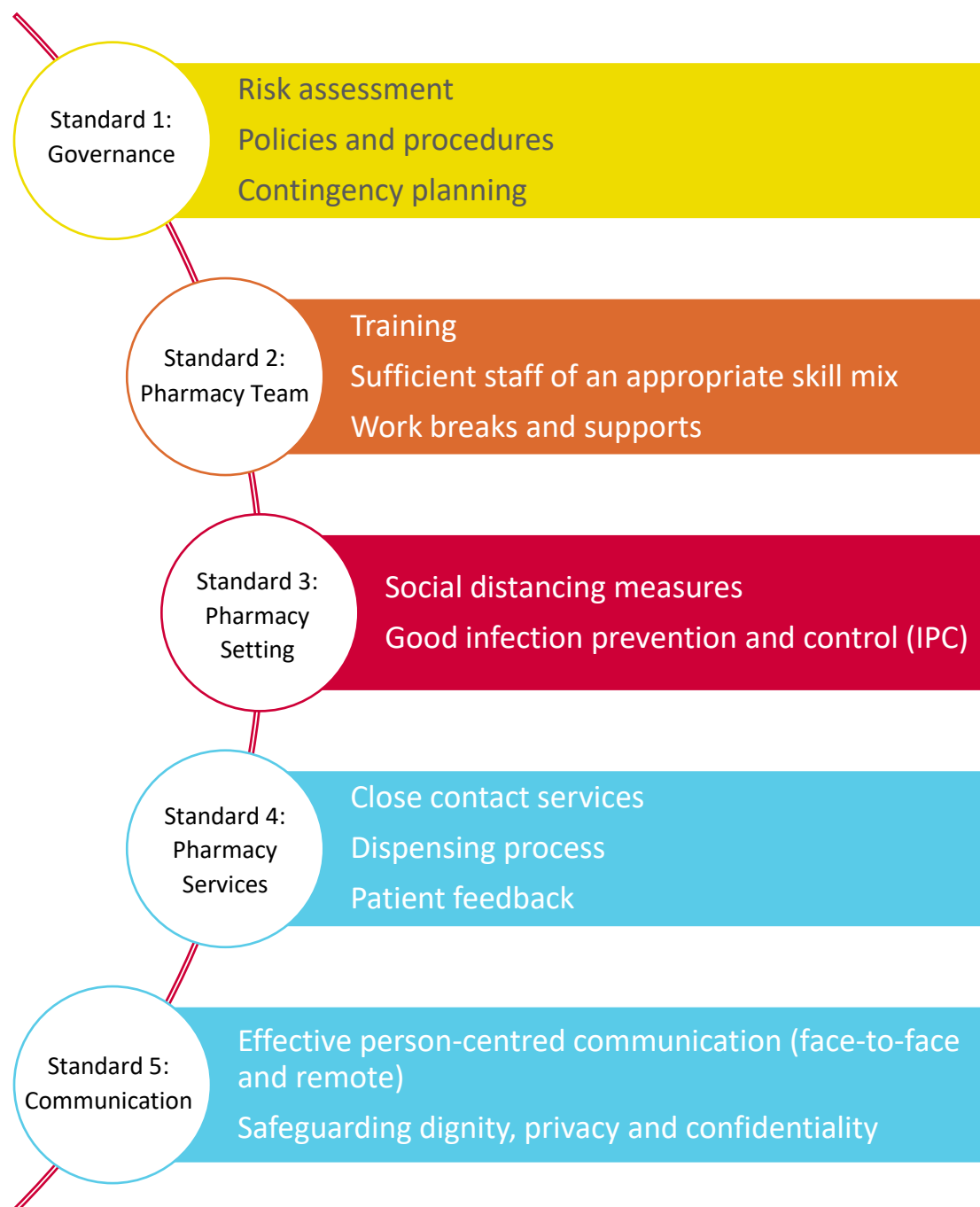
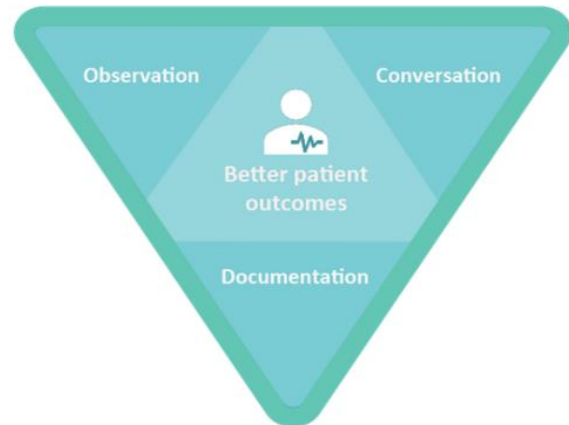


Figure 1: Key Areas of Focus

<sup>7</sup> Boyd, A., Addicott, R., Robertson, R., Ross, S., & Walshe, K. (2017). Are inspectors' assessments reliable? Ratings of NHS acute hospital trust services in England. *J Health Serv Res Policy*, 22(1), 28-36.  
<https://doi.org/10.1177/1355819616669736>

In addition, during the fieldwork testing period we used the process of data triangulation. Using data triangulation during assessments, including quantitative and qualitative data, increases the robustness and reliability of the findings<sup>8</sup>, and is considered best practice in terms of how to monitor performance against healthcare standards. We acknowledge that virtual visits have some limitations in terms of the ability to triangulate sources of information fully.



Data triangulation involves looking at three types of supporting evidence of implementation:

- Observation of premises and practices
- Conversation with those in governance and leadership roles and their teams
- Reading and reviewing relevant documentation

The process of data triangulation involves more of a focus on what we see and what staff tell us instead of relying heavily on documentation when assessing healthcare quality.

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<sup>8</sup> Benning, A., Ghaleb, M., Suokas, A., Dixon-Woods, M., Dawson, J., Barber, N., ... & Lilford, R. (2011). Large scale organisational intervention to improve patient safety in four UK hospitals: mixed method evaluation. *Bmj*, 342.

## Section Three: Observations and findings

### Observations & findings: Standard 1



#### Standard 1.

A clear and effective governance structure is in place which promotes a culture of quality and safety in your pharmacy.

Under this standard, those in governance roles fully embrace their leadership responsibilities in the interests of patients, the public and their staff during the COVID-19 pandemic. Clear lines of accountability are in place between the pharmacy owner, superintendent pharmacist and supervising pharmacist across all aspects of service provision. An environment is established where responsibilities are clear and transparent, particularly for risk assessment and contingency planning. The focus of leadership is on delivering safe and reliable patient care despite the presence of COVID-19 in our communities.

### Standard 1: Key areas of focus

#### Risk assessment

Given the extra pressures on pharmacies and the many changes in pharmacy services and practices during the pandemic, risk assessment is of primary importance. Those in governance and leadership positions have a critical responsibility to identify, record, audit and manage the risks associated with providing pharmacy services during the pandemic to reduce the risk of transmission of COVID-19 and protect staff, patients and members of the public.

#### What good practices were observed?

It was positive to find that pharmacies had taken measures to identify, record, and manage COVID-19 risks, and that actions had been implemented to reduce the risks identified.

Pharmacies that were particularly strong in this area regularly audited their assessed risks and made changes to reflect updated public health advice.



## What could be improved?

Some of the pharmacies visited did not have a formalised risk assessment process, in that the risk assessment was not documented. Lack of documentation made it difficult for assessors to determine what controls had been put in place in response to the assessed risks associated with COVID-19.

In addition, while many pharmacies had made a strong effort at the outset of the pandemic to assess and manage risks related to COVID-19, their assessments were not always updated or reviewed as the pandemic progressed to reflect updates to the public health advice.

## Policies and procedures

Policies and procedures play a fundamental role in continuous quality assurance. Their implementation helps to ensure quality and consistency of service to patients, ensures that the expertise of the pharmacy team is used effectively and enables the delegation of appropriate tasks to trained members of the pharmacy team. Policies and procedures facilitate good communication and teamwork which are essential in providing high quality and safe services to patients.

## What good practices were observed?

In the pharmacies we visited, it was positive to see in many cases that policies and procedures had been re-assessed and adapted or re-developed in the context of COVID-19.

Changes to policies and procedures which we saw included:

- changes to dispensing processes in response to changes in relevant prescription legislation and the introduction of the National Electronic Prescription Transfer System (Healthmail)
- changes to how close contact services are provided during the COVID-19 pandemic
- management of delivery services
- use of the patient consultation area,
- changed housekeeping and cleaning practices, and
- disposal of patient-returned medicines, where this service was provided

Pharmacies that were particularly strong in this area also had arrangements in place to ensure that policies and procedures were reviewed and updated to reflect any changes made to public health advice.

## What could be improved?

Some pharmacies had not re-assessed and adapted or developed their policies and procedures in the context of COVID-19. Although changes had been made to procedures and workflows, we found in some cases during conversations with staff that the overview of processes as described by staff varied between staff members.

## Contingency planning

Business contingency planning is about planning to anticipate, as far as possible, and manage challenges that may arise, for example in dealing with changes in demand and capacity caused by the COVID-19 pandemic. Patients and the public rely on the continued availability of their pharmacies. It is vital that pharmacy owners, together with superintendent and supervising pharmacist(s), regularly review their business contingency plans in accordance with guidance from the HSE/PSI<sup>9</sup> and ensure that all staff are familiar with the contingency plan and trained appropriately in their roles.

### What good practices were observed?

In the pharmacies we visited, it was positive to see that many pharmacies had prepared a contingency plan in the event of closure or reduced staffing levels related to COVID-19 which reflected up-to-date PSI and HSE guidance. In most cases, these contingency plans were kept under regular review due to the changing nature of the COVID-19 pandemic.

Pharmacies that were particularly strong in this area had a 'buddying' arrangement in place with one or more local pharmacies, which they could refer their patients to or work with, should their pharmacy have to close temporarily due to the impact of the pandemic.

### What could be improved?

In some pharmacies we visited there was no contingency plan in place or, during conversations with staff, it was apparent that staff were not aware of what the contingency plans were or how to deal with a temporary closure of the pharmacy due to reduced staffing levels arising in the context of COVID-19.

In other cases, while there was a contingency plan, arrangements were not in place to ensure that all staff were familiar with the contingency plan or trained appropriately in their roles relating to the contingency plan.

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<sup>9</sup> [https://www.thepsi.ie/Libraries/COVID/Continuity\\_Planning\\_for\\_Pharmacy\\_Covid\\_19\\_Version\\_2.sflb.ashx](https://www.thepsi.ie/Libraries/COVID/Continuity_Planning_for_Pharmacy_Covid_19_Version_2.sflb.ashx)

## Observations & findings: Standard 2



### Standard 2.

The pharmacy team is supported and enabled to provide safe and high-quality patient care.

The pharmacy team is likely to be under additional pressures and anxieties due to the COVID-19 pandemic and changing work practices. Pharmacy owners, superintendent and supervising pharmacists provide leadership to the pharmacy team and promote a supportive and safe work environment which meets the requirements set out in the Government's Return to Work Safely Protocol: COVID-19 Specific National Protocol for Employers and Workers.

## Standard 2: Key areas of focus

### Training

Regular training keeps staff up to date on changing work practices during the COVID-19 pandemic. This promotes a supportive and safe work environment for staff and enables them to provide safe and high-quality patient care.

#### What good practices were observed?

In the pharmacies we visited, it was very positive to see that staff training had been taken seriously. Great efforts were made to ensure that all staff were trained and up-to-date in infection prevention and control measures, changes to service delivery and changes to relevant prescription and dispensing legislation introduced in response to the COVID-19 pandemic.

Pharmacies that were particularly strong in this area had good internal auditing and monitoring systems in place to ensure that the training provided is embedded in the day-to-day operation of the pharmacy.

#### What could be improved?

In some pharmacies we visited, through conversations with staff, we found no system in place for auditing or monitoring of training by those in governance and leadership roles, to ensure that the training provided is embedded in the day-to day operation of the pharmacy.

## Sufficient staff of appropriate skill mix

By continually monitoring and reviewing staffing levels throughout the COVID-19 pandemic those in governance and leadership roles ensure that staffing levels remain adequate and ensure that sufficient staff of an appropriate skill mix are available to provide safe and high-quality patient care. It is a requirement of the Government's Return to Work Safely Protocol: COVID-19 Specific National Protocol for Employers and Workers to appoint a lead worker representative to ensure that COVID-19 measures are strictly adhered to in their place of work. The role of the lead worker representative is to work collaboratively with the employer to assist in the implementation of measures and monitor adherence to the measures to prevent the spread of COVID-19.

### What good practices were observed?

Pharmacies that were particularly strong in this area had an up-to-date contingency plan in place that clearly outlined the critical activities of the pharmacy and the inputs (e.g. staffing levels and skill mix) required to maintain them.

In the pharmacies we visited it was positive to see that a least one lead worker representative had been appointed to assist those in governance roles to oversee the implementation, monitoring, evaluation and communication of risk controls implemented in response to COVID-19.

### What could be improved?

In some pharmacies we visited we found it was not always clear how those in governance and leadership roles had planned and managed staffing levels to ensure that there was enough staff with the right knowledge and skills available at all times to meet the identified needs of patients, and, thereby, to ensure the effective delivery of safe and high-quality patient care.

In some cases, through conversation with staff members, it was established that the lead worker representative was an individual in a governance or leadership role at the pharmacy. This is not consistent with the information set out in the Governments Return to Work Safely Protocol: COVID-19 Specific National Protocol for Employers and Workers.

## Work breaks and supports

Breaks are an important welfare issue for staff in all healthcare settings, including pharmacies. For pharmacists, work breaks are also a significant patient safety issue. It is imperative that pharmacists do not become overly fatigued during their working day and that they are consistently able, and supported by those in governance and leadership positions, to provide a safe and professional service to their patients, whether at the start of their day or the end. Pharmacists working long hours, dispensing and checking prescription medicines and providing safety-critical advice to patients and other healthcare

professionals, without clear and scheduled breaks, presents avoidable risks for pharmacists and patient safety. We have previously issued information on our position on work breaks in our PSI newsletter [Issue 2: July 2020](#).

The provision of appropriate breaks, particularly during this ongoing pandemic, where the implementation of infection, prevention and control measures and significant changes to services and work practices have placed considerable further demands on each individual, requires serious attention and action from those in governance and leadership positions.

### What good practices were observed?

In the pharmacies we visited, it was positive to see that non-pharmacist staff were provided with the opportunity to take an appropriate work break(s) to support their welfare and to enable them to provide safe and high-quality patient care.

It was also positive to see that structures and processes were in place to support staff with work-related stress and anxiety, which has been a significant issue for frontline staff across all health services during the COVID-19 pandemic.

### What could be improved?

While a small number of pharmacies we visited had introduced safe practices whereby pharmacists could take appropriate work breaks, through for example closing the pharmacy for lunch or by having arrangements in place to ensure that alternative pharmacist cover was provided, we were very concerned to see that, in a significant number of pharmacies we visited, those in governance and leadership roles had not ensured the pharmacist on duty had the opportunity to avail of an appropriate work break during the working day.

## Observations & findings: Standard 3



### Standard 3.

A safe environment is provided for patients and staff to minimise the risk of spread of COVID-19 and other infections in the pharmacy.

To ensure the safe and efficient operation of pharmacy services during the COVID-19 pandemic, it is important that a safe and clean physical environment is provided where there is a focus on key infection prevention and control (IPC) practices in line with public health advice and best practice for the prevention and control of COVID-19. This includes appropriate environmental control and staff protection. IPC practices are maintained to as high a standard as possible, and in a visible manner which instils staff and patient confidence.

## Standard 3: Key areas of focus

### Social distancing measures

To minimise the risk of spread of COVID-19 it is essential to ensure that all staff and visitors to pharmacies follow social distancing according to current public health advice where possible and public health advice on the wearing of surgical masks or face coverings (as appropriate). In addition, it is necessary to increase ventilation within pharmacies insofar as possible.

#### What good practices were observed?

It was reassuring to see that all pharmacies visited had made great efforts to optimise and adapt their layouts to minimise the risk of the spread of COVID-19 and other infections, while continuing to be accessible to patients and members of the public.

We observed a range of good practices regarding how pharmacies supported staff, patients and the public to practice social distancing and supported the wearing of surgical masks for staff and the wearing of face coverings for patients and members of the public. In addition, we observed some good practices concerning increasing ventilation.

#### What could be improved?

In many of the pharmacies we visited, we noted that improvements could be made in terms of increasing ventilation, by increasing outdoor air entry using intermittent or partial

window/door opening, as much as possible in line with updated HPSC [Interim guidance to minimise the risk of transmission of COVID-19 infection in pharmacies](#).

In addition, in isolated cases, we observed pharmacy staff wearing face coverings instead of surgical masks. This is not acceptable and all pharmacy staff should wear surgical masks in line with current HPSC guidance [Current recommendations for the use of Personal Protective Equipment \(PPE\) for Possible or Confirmed COVID-19 in a pandemic setting](#).

## Good infection prevention and control practice

Good infection prevention and control practices are essential in minimising the risk of COVID-19 and other infections in the pharmacy as the virus that causes COVID-19 can be spread indirectly, by a person touching infected surfaces (e.g. table, door handles) and then touching their eyes, nose or mouth. Regular cleaning of frequently touched hard surfaces and hands helps to reduce the risk of infection.

### What good practices were observed?

In the pharmacies we visited, it was positive that significant efforts had been made in infection prevention and control practices to minimise the risk of the spread of COVID-19 and other infections in the pharmacies.

We observed a range of good practices in this area regarding how pharmacies had adapted their cleaning processes in response to COVID-19, to ensure that good infection prevention and control was based on up-to-date public health advice and embedded in the day-to-day operation of the pharmacies.

Through conversations with staff, we established that they had a clear understanding of their individually assigned responsibilities related to cleaning and decontamination of the pharmacy environment and the importance of performing good hand hygiene technique regularly throughout the working day.

### What could be improved?

In some cases, we noted a lack of documentation to support infection prevention and control practices, e.g., cleaning rotas or cleaning records. This would provide greater assurance that regular cleaning and decontamination is being undertaken in the pharmacy throughout the working day.

## Observations & findings: Standard 4



### Standard 4.

Pharmacy services are delivered safely, effectively and to a consistently high standard.

Despite changing circumstances and resource challenges to COVID-19, it is essential that pharmacy services continue to meet high standards of patient safety and person-centred care. Services must be managed and delivered to achieve the best possible health outcomes for patients, with minimal close contact but without compromising on patients' dignity, confidentiality and continuity of care.

## Standard 4: Key areas of focus

### Close contact services

COVID-19 has meant that pharmacies have had to make changes to how they provide close contact pharmacy services. Close contact services must be effectively planned and managed so that staff know how to provide them safely and effectively, consistently.

### What good practices were observed?

In the pharmacies we visited, it was positive to see that the pharmacies had planned, managed and delivered close contact services to achieve good health outcomes for patients, in line with relevant legislation, guidance and public health advice. We observed a range of good practices in this area where pharmacies listed the services they were providing, including any relevant changes to the normal operation of these services, on their websites or social media pages.

In addition, we observed cases where pharmacies had adapted their services to provide certain aspects of the service online, limiting the time patients needed to spend in the patient consultation area when they arrived at the pharmacy for the service, e.g., influenza vaccination or emergency hormonal contraception.



## What could be improved?

In some pharmacies, we noted that changes to the normal operation of services were not clearly indicated to patients via the pharmacies' websites or social media pages. In these cases, it would not always be clear to patients and members of the public which services are currently operating in these pharmacies and how to access these safely.

## Dispensing process

Significant changes were made to relevant prescription legislation during the COVID-19 pandemic to ensure continuity of care and access to treatment for patients and reduce the burden on prescribers and the broader healthcare system. These changes included the introduction of the National Electronic Prescription Transfer System (Healthmail), changes to the maximum validity period of prescriptions, changes to the provisions for repeating prescriptions and changes to the emergency supply provisions. All these changes placed significant obligations on pharmacists to use their professional judgement to ensure continuity of safe care to patients.

## What good practices were observed?

In the pharmacies we visited, it was positive to see that good efforts had been made to ensure that all patients, including those who may not wish to physically access the pharmacy, received effective, equitable, person-centred care.

Good practices included changes to dispensing practices in response to legislative amendments introduced to ensure continued access to medicines for patients during the COVID-19 pandemic and the use of the National Electronic Prescription Transfer System (Healthmail) to reduce footfall into the pharmacy.

Many pharmacies expanded their existing delivery services to ensure patients could still access their medicines and used phone calls and/or video calls to ensure patients received effective counselling on their medicines. Many pharmacies took steps to ensure vulnerable patients were regularly contacted to remind them that a delivery service is available and to check medicines levels and prescriptions held on file to ensure continuity of care. In addition, pharmacies used local volunteers and community groups to expand their delivery services in line with PSI/HSE Guidance on the [Home delivery of medicines by public servants and volunteers during the COVID-19 pandemic.](#)

## What could be improved?

Some pharmacies indicated that there was often an expectation that if the prescriber had sent a prescription to the pharmacy, it was automatically ready for collection. Clear public messaging about the necessity to order medicines from pharmacies in advance of arriving at the pharmacies would potentially reduce unnecessary footfall, having regard to the ongoing COVID-19 pandemic.

## Patient feedback

Patient feedback, if it is listened to and acted upon, with the support of those in governance, can be a valuable resource for providing insights and learnings into care quality, identifying strengths in, and improvements to, patient services as well as potential patient safety risks or gaps in patient care. All forms of patient feedback can be useful, whether formal or informal, positive or negative – the key issue is that feedback is not just collected but is used to improve care.

### What good practices were observed?

It was good to see that in some pharmacies we visited, they actively encouraged patient feedback and used it to improve their service delivery. Some pharmacies used online surveys/questionnaires to gather patient feedback regularly. This feedback was then used to make changes to service delivery or the layout and physical arrangements of the pharmacy during COVID-19.

### What could be improved?

We noted that in many pharmacies we visited, they did not have any formal structures or processes for gathering patient feedback regularly during the COVID-19 pandemic. In these cases, while feedback would be collected informally, usually verbally, it was not always recorded and/or used effectively to drive service improvements.

## Observations & findings: Standard 5



### Standard 5.

There is effective communication with patients both face-to-face and remotely.

There are more barriers than usual in terms of ensuring good communication with patients, with infection prevention and control procedures and other essential safety measures in place to protect both patients and staff.

In addition to extra pressures on staff, patients themselves may feel anxious to visit the pharmacy, but it is important that patients understand how to take their medicines correctly and safely and have an opportunity to ask questions.

Pharmacies must continue to respect patient confidentiality and privacy, while also abiding by infection prevention and control and social distancing measures. Patient counselling that is carried out remotely should insofar as possible meet the same standards of care as face to face counselling.

## Standard 5: Key areas of focus

### Effective person-centred communication (both face to face and remote)

There are many extra barriers to good communication due to the use of face coverings/surgical masks and COVID-19 social distancing measures. Good communication is vital for patient-centred care and patient dignity, privacy and confidentiality.

#### What good practices were observed?

In the pharmacies we visited, it was very reassuring to see that good efforts had been made in many cases to ensure that patients are provided with the opportunity to discuss their medicines and healthcare needs with a pharmacist, either remotely or in person. We noted innovative practices used to overcome communication barriers presented by Personal Protective Equipment (PPE) and social distancing; these included the use of online tools and

platforms to provide patient counselling and the use of the consultation tools and techniques recommended by the National Healthcare Communication Programme<sup>10</sup>.

### What could be improved?

In some pharmacies we visited, it was not always clear whether all patients were given the same opportunity on every occasion their medicines were dispensed, to discuss their medicines and healthcare needs with the pharmacist. In some cases, through conversations with staff, it was established that there was no procedure in place to check with patients if they would like to speak with the pharmacist when they were collecting their medicines.

## Safeguarding dignity, privacy and confidentiality

Principle 3 of the [statutory Code of Conduct for pharmacists](#) is 'Communicate effectively'. It states that pharmacists must respect patients' rights to privacy and confidentiality and ensure all staff maintain those rights, except where disclosure is legally required. The [PSI Patient Charter](#) outlines that patients can expect their pharmacist to respect their privacy at all times.

### What good practices were observed?

It was positive to see that many pharmacies had taken reasonable steps to safeguard and maintain patient dignity, privacy and confidentiality, while also abiding by infection prevention and control and social distancing measures. We observed innovative and good practices in this area, where pharmacists were able to discuss confidential matters with patients in the patient consultation area, while also abiding with social distancing requirements and safeguarding the patients' dignity, privacy and confidentiality.

### What could be improved?

We heard from pharmacies that one of the effects of the reduction in footfall to pharmacies is that conversations with the pharmacist at the counter were often more private. As public health restrictions begin to be relaxed over the coming months and footfall to pharmacies increases, we would remind pharmacies of the need to be mindful of encouraging patients to use the patient consultation area to discuss sensitive matters in private with the pharmacist.

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<sup>10</sup> <https://www.hse.ie/eng/about/our-health-service/healthcare-communication/nhcp-covid19-response-toolkit.pdf>

## Summary of observations and findings

In summary, the fieldwork testing gave us valuable insights into how the Standards are working in practice. It allowed us the opportunity to see the many good practices and innovative measures that pharmacy teams have put in place to protect their patients, communities and staff, while continuing to deliver essential healthcare services despite the risks and challenges presented by COVID-19.

### Significant areas of concern identified

A number of areas requiring improvement are identified in this Chapter, and these were raised with pharmacy teams on an individual basis during each visit. However, it is also important to note that there are three particular aspects of pharmacy operation which we have noted as giving rise to significant concern. As the regulator, we intend to place a particular focus on these areas over the coming months to work with the community pharmacy sector to drive focused improvements in these key areas.

#### 1. Work breaks for pharmacist staff

As noted earlier, fatigue is a well-recognised risk issue in healthcare environments, including pharmacies. Pharmacists working long continuous hours without breaks has been identified as a contributing cause of medication errors<sup>11</sup>. It is imperative that pharmacists do not become overly fatigued during their working day and that they are consistently able to provide a safe and professional service to their patients, whether at the start of their day or the end.

Based on our findings from our fieldwork testing, we are very concerned to see that in many cases pharmacists are not receiving appropriate work breaks during the working day. We regard this as an important patient safety issue which must be addressed by the community pharmacy sector.

#### 2. Patient counselling & professional communication

The safe use of medicines is dependent on patients understanding how to take their medicines and being supported by their pharmacist to self-manage their health at home. Pharmacists have a key role in counselling patients on the safe and appropriate use of their medicines. This requirement is set out in the Regulation of Retail Pharmacy Businesses Regulations 2008 (as amended). The professional obligations on pharmacists regarding communication with patients are set out in the statutory Code of Conduct for Pharmacists.

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<sup>11</sup> Jacobs, S., Johnson, S., & Hassell, K. (2018). Managing workplace stress in community pharmacy organisations: lessons from a review of the wider stress management and prevention literature. *International Journal of Pharmacy Practice*, 26(1), 28-38.

From our fieldwork testing, we are concerned that due to the measures implemented to reduce the spread of COVID-19 in pharmacies (social distancing measures, PPE and virtual consultations), counselling of patients on their medicines has been significantly impacted. We regard this as a significant safety issue which we will continue to pursue as a priority area of quality improvement for the community pharmacy sector.

### 3. Patient Feedback

Patient feedback, if it is listened to and acted upon with support by those in governance, can be a valuable resource for providing insights and learnings into care quality, identifying strengths in, and necessary improvements to, patient services as well as potential patient safety risks or gaps in patient care. All forms of patient feedback can be useful, whether formal or informal, positive or negative, however it is important that it is not just collected but used to improve care.

Based on our findings from our fieldwork testing, we are concerned about the lack of structures and processes in place in pharmacies to capture patient feedback on the quality of care they receive. Encouraging patients to share their experience will allow pharmacy teams to address any issues, risks, or problems identified, thus improving the quality and safety of services. We will be looking at this area over the coming months to learn more about good practices in use and encourage wider adoption.

## Conclusion

### What are our next steps?

We developed the COVID-19 Operational Standards for Pharmacies to support and guide those in governance and leadership roles in pharmacies, in continuing to provide safe and high-quality pharmacy services during the COVID-19 pandemic. We appreciate that standards are a new regulatory approach for the retail pharmacy sector, however we also believe that they have real benefits in supporting pharmacies to be more focused on achieving good outcomes for patients and the public. Standards allow for adaptation to the local context and acknowledge that not all pharmacies are the same, while assisting those in governance and leadership roles to use their professional judgement and autonomy to empower pharmacy professionals to provide safe, high-quality care to patients and the public. We consider that incorporating standards into our existing regulatory framework will allow us to focus on what really matters to patients and the public.

The fieldwork testing provided us with a valuable and important opportunity to test our assessment approaches in practice. Our learnings to date will inform the development of a monitoring and an associated judgement framework that will assist us in carrying out assessments of performance against the standards once the 'use and learn' period has concluded at the end of 2021. A further report will be issued after this period.

During the extended 'use and learn' period over the coming months, it is our intention to conduct additional fieldwork testing in a wider cohort of pharmacies. It is expected that the fieldwork testing will comprise physical or virtual visits and/or hybrid visits. However, this will depend on the prevailing public health situation and the guidance issued by the Government, having regard to the ongoing COVID-19 pandemic. Additional fieldwork testing will enable us to test and refine our assessment approaches more widely over the coming months to ensure these are valid before being used to assess community pharmacies' performance against the standards once the 'use and learn' period has concluded.

If you would like to get involved in facilitating a visit to your pharmacy during the 'use and learn' period or if you have any queries, comments or concerns about any aspect of the COVID-19 Operational Standards for Pharmacies or this report you can send us an email to [covid19standards@psi.ie](mailto:covid19standards@psi.ie).

## A message of thank you

During our fieldwork testing, we were reminded of the creativity and professionalism of pharmacy professionals and their dedication to their patients. It was a privilege to see, first-hand, how seriously all involved took their responsibilities in helping to reduce the spread of COVID-19 in our communities.

We wish to thank all the pharmacy teams that volunteered to participate in our fieldwork testing and who did so under the pressure of providing pharmacy services during the pandemic. We are very grateful to everyone who took part for their valuable contribution to the development of the Standards and for their input in helping us develop a method of assessing performance against the standards in a fair and effective way.

We also wish to thank our colleagues who joined us on the Safety Collaborative to rapidly develop the COVID-19 Operational Standards for Pharmacy; for their input and expertise in developing our fieldwork testing approach and volunteering some of their pharmacies for fieldwork testing.

In addition, we would like to acknowledge the engagement and collaboration of other regulators, including HIQA, the GPhC and the Mental Health Commission, for sharing their knowledge and experience of using healthcare standards with us.