

RPS guidance on ethical, professional decision making in the COVID-19 Pandemic

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*On behalf of the RPS short life working group
on Ethical, professional decision making in the
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Summary

There is a wide recognition that all pharmacists and pharmacy technicians, like other health professionals, are working under extreme pressures during the current pandemic. These are likely to get worse before they get better and may recur. Staff are already having to make prioritisation decisions and are planning for previously unseen situations.

Pharmacists and pharmacy technicians are often by their very nature perfectionists and strive to do their best. When we find ourselves in situations such as these, perfectionism is counterproductive. We recognise that safe and effective care – rather than ideal care – may be the best and right kind of care to provide, in the context of the COVID-19 challenge. Pharmacists and pharmacy technicians will need to make quicker, timelier decisions which may feel uncomfortable, have increased belief in their own experience, and draw upon experience around them. The guidance in this document is intended for utilisation by all sectors of the profession and by staff in both strategic roles and those in roles closer to patients.

DECISIONS WE MAKE SHOULD BE:

- based on the best evidence available at the time
- reasonable and proportionate in the circumstances
- made in accordance with the latest government, NHS, regulatory and professional guidance and should take account of employers' guidance
- made as collaboratively as possible, remembering that every decision made will impact on others, both patients and professionals
- designed to secure safe and effective patient care as far as practicable
- timely, recognising that pressure of time means that rather than striving for perfection, decisions may have to be "good enough for the circumstances"
- recorded, including the reasons why decisions were made to ensure accountability and understanding of prevailing circumstances at the time

In line with the principles above, any judgements on decisions and conduct during this pandemic will be based on all the prevailing circumstances at the time of the decisions and conduct, not with the benefit of hindsight. This is supported by the joint statement from the health and care professional regulatory bodies.¹

The latest guidance on issues relating to the COVID-19 pandemic can be found at <https://www.rpharms.com/coronavirus/> and <https://www.psni.org.uk/publications/covid19-regulatory-statements-and-information/>

¹ <https://www.pharmacyregulation.org/news/regulatory-approach-challenging-circumstances-gphc-and-psni-joint-statement> accessed 1 April 2020

Acknowledgement

This guidance has benefitted from stakeholder input from a wide variety of pharmacy experts as indicated on the contributions page. The Royal Pharmaceutical Society (RPS) are exceptionally grateful to all of those involved for giving up their time freely when time is more precious than ever. The RPS reserves the right to change and update this guidance as the pandemic progresses.

Introduction and Background

This document has been produced by a short life working group convened by the Royal Pharmaceutical Society (RPS) to provide guidance to pharmacists and registered pharmacy technicians to assist with difficult decisions being made in the exceptional circumstances presented by COVID-19. It contains some guidance on structured decision making and some more specific examples relevant to the current pandemic. The role *pharmacy technician* as described in this guidance document reflects those that hold a professional registration.

COVID-19 brings with it a pandemic of scale not seen in our lifetime in the UK. The NHS is already under significant pressure and the mortality and morbidity statistics are at the time of writing, rising at an alarming rate on a daily basis.

Currently there is no specific national ethical guidance relating to pharmacy. As the pandemic progresses, our knowledge and wisdom will change before this document is updated; bear this in mind when using it to support your decision making.

The RPS is an advocate for the profession and strongly supports the interests of pharmacists and the public. Principles in this document are intended to apply to everyone providing pharmacy services recognising the importance of the whole pharmacy team working as one.

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The purpose of this guidance is to provide support to pharmacists and pharmacy technicians to make decisions in these exceptional circumstances and to also provide some reassurance that uncomfortable decisions made are sound and defensible.

Professional Decision Making

Professional decisions are informed by the best available evidence and grounded in reason. Accountability is an important part of the covenant the profession holds with the public propagating the trust that we are gifted by them. When events or decisions do not bring the most desirable outcome pharmacists and pharmacy technicians often worry that they have done wrong and will be penalised because of a less desirable outcome. Under these circumstances especially, pharmacists and pharmacy technicians should focus on reasoned decision-making, which underpins the skills of a health professional.

The Medicines Ethics and Practice Guide² provides a model for decision making (Box 1). Having a systematic approach allows professionals to account for the decisions they make. In times of crisis, this approach is offered as a useful support tool to fall back on. Each of the factors listed below may be adapted to take account of the prevailing circumstances and the time available. The time available for making decisions may be significantly shortened because of a wide range demands including the needs of all patients in need of services, limitations on available resources and other pressures on the service.

Decision-making is often improved through collaborative discussion where possible and time allows. During this pandemic, pharmacists and pharmacy technicians in all areas may be experiencing similar issues and discussion often assists.

Pharmacists and pharmacy technicians should be reassured that should decisions be called into question at a later date, they will be judged according to the circumstances at the time of the decision, not with the benefit of hindsight.³

- 2 Royal Pharmaceutical Society (2019), Medicines, Ethics and Practice Guide Edition 43 available from <https://www.rpharms.com/publications/the-mep/mep-viewer-member>
- 3 <https://www.pharmacyregulation.org/news/regulatory-approach-challenging-circumstances-gphc-and-psni-joint-statement> Accessed 1 April 2020

1	IDENTIFY
	Identify the issue/dilemma
2	GATHER
	Gather relevant information. This will include legal, ethical, professional and clinical guidance
3	GENERATE
	Consider the range of options in the time available; what could I do?
4	COMPARE
	What are the risks and benefits of each option?
5	DECISION
	Make a reasoned decision based on the evidence gathered
6	RECORD
	Make a record of both the final decision and the facts that informed that decision
7	REVIEW
	As situations change, review the decision in light of information, altering practise as necessary and recording changes

Box 1. Adapted for emergency circumstances from Exercising Professional Judgment RPS Medicines, Ethics and Practice Guide⁴

4 Royal Pharmaceutical Society (2019), Medicines, Ethics and Practice Guide Edition 43 available from <https://www.rpharms.com/publications/the-mep/mep-viewer-member>

Ethical Framework for Decision Making

Every health profession defines its expectations through some form of code of ethics, although its nomenclature may vary. Pharmacists and pharmacy technicians must adhere to the Standards for Pharmacy Professionals issued by the regulators, the General Pharmaceutical Council⁵ and the Pharmaceutical Society NI.⁶

In times such as these, it is critical that individuals work flexibly with colleagues across different disciplines and sectors, sometimes beyond traditional professional boundaries, to ensure the best realistic outcomes for patients, taking account of the circumstances they are working in. On the public's behalf, the General Pharmaceutical Council (GPhC) and the Pharmaceutical Society NI (PSNI) expect pharmacists and pharmacy technicians to uphold their respective standards, recognising that how this is achieved may look very different in the context of the present challenge, compared to normal times. The guidance that follows is based on two key UK government documents. The first was produced in 2007 following the SARS outbreak, updated following the H1N1 influenza pandemic of 2009 and most recently updated in 2017.⁷ The second document was produced by the Department of Health and Social Care in March 2020 to support the wider adult social care arena.⁸ Using these as the basis of this guidance aligns pharmacy with not only other medical professionals but also key emergency planners supporting health workers.

The UK government influenza guidance detailed that there are 8 priority areas to be considered in these exceptional times and these are detailed in Box 2. In broad principle these reflect a just perspective under the philosophy that everyone matters and that everyone matters equally.

5 https://www.pharmacyregulation.org/sites/default/files/standards_for_pharmacy_professionals_may_2017_0.pdf accessed 30 March 2020

6 <https://www.psni.org.uk/psni/about/code-of-ethics-and-standards/> accessed 6 April 2020

7 <https://www.gov.uk/guidance/pandemic-flu#ethical-framework> accessed 30 March 2020

8 <https://www.gov.uk/government/publications/covid-19-ethical-framework-for-adult-social-care/responding-to-covid-19-the-ethical-framework-for-adult-social-care#respect> Accessed 30 March 2020

Equal respect	everyone matters and everyone matters equally, but this does not mean that everyone will be treated the same
Respect	keep people as informed as possible; give people the chance to express their views on matters that affect them; respect people's personal choices about care and treatment
Minimise the harm of the pandemic	reduce spread, minimise disruption, learn what works
Fairness	everyone matters equally. People with an equal chance of benefiting from a resource should have an equal chance of receiving it – although it is not unfair to ask people to wait if they could get the same benefit later
Working together	we need to support each other, collaborate and work flexibly, take responsibility for our own behaviour and share information appropriately
Reciprocity	those who take on increased burdens should be supported in doing so
Keeping things in proportion	information communicated must be proportionate to the risks; restrictions on rights must be proportionate to the goals
Flexibility	plans must be adaptable to changing circumstances
Open and transparent decision-making	good decisions will be as inclusive, transparent and reasonable as possible. They should be rational, evidence-based, the result of a reasonable process and practical in the circumstances

Box 2. Ethical values adapted from "Pandemic flu planning information for England and the devolved administrations, including guidance for organisations and businesses."⁹

⁹ <https://www.gov.uk/guidance/pandemic-flu#ethical-framework> accessed 30 March 2020

Guidance relating to specific issues

Maintaining patient safety

Pharmacists' key priorities are to protect patients and to make optimal use of medicines. Where resource especially human resource, is depleted all tasks should be reviewed for immediate necessity and prioritised. In a pandemic, it is acceptable to adhere to a patient's confirmed current prescribed therapy, where time spent on optimisation might prevent treatment of others. Continuity of medication therapy and patient safety will be prioritised over medicines optimisation. The opposite applies to therapies where stewardship is of paramount importance for example (but not limited to) use of antibiotics, opioid pain relief and high risk medicines.

Managing staff and workload wisely is key for effective pharmacy operations. Pharmacists and pharmacy technicians should ensure that work is effectively delegated where possible to allow greater oversight and support of operations. Workforce management should be optimised so that staff are employed at the upper end of their professional skills and experience. Caution should be exercised when contemplating the delegation of tasks, and proper account taken of relevant legal requirements designed to secure patient safety.

Patient safety incidents are often caused by human factors such as lack of rest breaks, poor nutrition and dehydration. Systems established to reduce human factor-related errors should continue to be employed whenever possible. Pharmacists and pharmacy technicians should ensure, as far as practicable, that breaks both physical and mental are part of workload planning and are not overlooked even in difficult times.

Maintaining the safety of staff and volunteers

In this pandemic there has already been abuse of pharmacy staff, especially in primary care.¹⁰ Pharmacists and pharmacy technicians should remember that they are the guardians of the nation's medicines and maintain confidence in their own abilities in handling these difficult situations professionally and assertively where necessary. Person-centred care means understanding patient preferences and incorporating them where practicable, it does not mean all patient demands must be met. When they cannot be met or cannot be met as promptly as in normal times, it is important to manage patient expectations.

The safety of the workforce is paramount. Without an effective healthcare workforce, there is no care. Risk assessments should be dynamic and under constant review. Where the safety of staff is called into question appropriate action should be taken.

Volunteers will become an important part of the pandemic response. The role volunteers carry out should be clearly defined and agreed with appropriate training and supervision as per other staff members. Reasonable regard must be had to their safety.

¹⁰ <https://www.bbc.co.uk/news/uk-wales-52033913> accessed 4 April 2020

Working outside normal areas of specialism and/or competence

In normal times, pharmacists and pharmacy technicians must recognise and work within the limits of their knowledge and skills, and refer to others when needed. During a pandemic all sectors will be impacted by increased workload with concurrent reductions in staffing and skill mix as staff and family members become unwell. Pharmacists and pharmacy technicians may need to develop competence rapidly in areas which are in demand. Early consideration should be given to additional upskilling, ensuring appropriate recording of training.

The immediate need to ensure that patients receive medication or other treatment may involve working in unfamiliar areas. It is necessary to balance the importance of meeting patients' immediate needs with the requirement to work within one's competence: the goal when working in unfamiliar territory is patient safety and wellbeing and ensuring patients will not be in unnecessary pain or put at risk if the medication or treatment is not provided. As demand outstrips supply, the maintenance of key services will be a priority. All staff, irrespective of seniority or role, should be flexible in order to support priority and depleted areas. Appropriate care and due diligence should be exercised in redeploying resource.

Pharmacist prescribers, for example, will be competent to prescribe in their own area of practice but should feel supported to broaden their prescribing practice to other appropriate areas as non-specialists, where they can still positively impact on patient safety. In situations such as these, pharmacist prescribers can provide important support to improve staff skill mix and effective management of patient case load and complexity.

Pharmacy Technicians may be deployed into areas to provide medicines administration, therefore they must ensure that they work as part of the multidisciplinary team, recognising their scope of practice and where they can safely add value.

Under the current exceptional circumstances, it is important that pharmacists and pharmacy technicians focus on meeting immediate needs rather than striving for perfection.

Allocating scarce supplies of medicines and devices

Shortages in the medicine supply chain are not uncommon and significantly exacerbated during surges of demand. Staff at all levels and in all settings may be asked to make difficult and time-pressurised decisions around which patients receive which medicines, although the form of these decisions will vary. In some cases, multidisciplinary decisions around treatment withdrawal may need to be taken. Critical care staff will be familiar with decisions around withdrawal of care; many others will not and will find them difficult¹¹ and be caused moral distress (see later). Should this be the case it is crucial that patients affected continue to receive compassionate care.¹²

Decisions should be made using the best evidence available at the time and in accordance with national and local guidance. All decisions around resource allocation will have wider impact. In primary care, decisions may have to be made alone in circumstances where the prescriber would normally have been contacted but is unavailable, or because the wellbeing of patients does not allow time for the prescriber to be contacted. If time permits and there is a head office, or other pharmacist who may be asked for a view, this should be considered.

All decisions should be discussed, ideally across the multi-professional team in secondary care, to gather wider professional guidance and understand the potential for unintended consequences and likely impact. The Royal College of Anaesthetists and others have produced helpful guidance on use of scarce intensive care medicines.¹³

Where decisions are made that would not be taken in normal circumstances, a brief record of the justifications and prevailing conditions should be made.

It is common and acceptable practice to operate a "First come, First served" queuing approach, until medicines availability becomes critical. At this point, pharmacists should use their discretion and professional judgement as to the apportionment of scarce medication. For example, it may be appropriate to apportion available stock amongst current patients to allow time for treatment options to be considered and potentially adjusted.

11 Wilkinson, D., and J Savulescu. 2012. A costly separation between withdrawing and withholding treatment in intensive care. *Bioethics* 26 (1):32-48. doi.org/10.1111/j.1467-8519.2012.01981.x

12 <https://www.bma.org.uk/media/2226/bma-covid-19-ethics-guidance.pdf> accessed 2 April 2020

13 <https://icmanaesthesiacovid-19.org/drug-demand-supply-guidance> accessed 2 April 2020

Following of legislative requirements

The law is a minimum standard to allow society to function. It is designed in such a way that it is read as being universally applicable without context. The circumstances being witnessed are exceptional. So long as a pharmacist is able to account for their decisions, some departure from strict legal requirements may be the right thing to do, for example to reduce the risk of death or reduce intolerable pain. Guidance from the GPhC¹⁴ highlights that professional judgment is acceptable and encouraged; for example, in the splitting of 100 tablet original packs of paracetamol. Examples where professionals have to exercise judgment might include missing prescription details, including controlled drug prescriptions, where due diligence has been exercised and the professional is confident that the prescriber's wishes are clear. Where a prescriber's wishes are less clear, a reasoned decision-making process should be followed, for example, a missing dose on a drug chart could be established by referring to the patient's summary care record, even if the patient has not consented to this. Emergency supply provisions should be used to their fullest to facilitate continuity of patient care.

By contrast, it can never be acceptable for corporate or organisational instructions or 'standard operating procedures' to seek to normalise illegality.

Record keeping

Accountability of professionals is an important part of our covenant with the public. To achieve this and to protect ourselves, we make records. Record keeping may be reduced to the absolute minimum necessary to facilitate safe care in these difficult circumstances. Pharmacists and pharmacy technicians are advised to make notes of all key decisions made including the environmental circumstances at the time the decisions were made and any key facts. Should a complaint be received at a later date, decisions relating to conduct will be made in the context of the prevailing conditions at the time.¹⁵ Such conditions might include urgency/time available to make decision, needs of other patients, availability of medicines, access to prescribers and other specialist colleagues, time at work, availability of rest/meal breaks, availability of resources, indicative competing demands (including personal circumstances), and staff to patient ratios.

14 <https://www.pharmacyregulation.org/standards/guidance/questions-and-answers-coronavirus> accessed 2 April 2020

15 <https://www.pharmacyregulation.org/news/regulatory-approach-challenging-circumstances-gphc-and-psni-joint-statement> accessed 1 April 2020

Direct and indirect discrimination in decision making

All patients irrespective of background matter equally. However, that does not necessarily mean that all will be treated the same. When making decisions, particular care should be given to ensuring that individuals are not discriminated against especially during decisions about treatment options, including availability or allocation. Decisions pertaining to protected characteristics that have no evidenced implication on likely survival/"capacity to benefit quickly" such as age, religious views, disability including mental or learning difficulties are likely to be unlawful. Decisions where survival/"capacity to benefit quickly" is likely to impact on outcomes such as patients with severe respiratory failure secondary to COVID-19 would be acceptable.

Guidance recently issued by the British Medical Association¹⁶ states: "although a 'capacity to benefit quickly' test would be indirect discrimination, in our view it would be lawful in the circumstances of a serious pandemic because it would amount to 'a proportionate means of achieving a legitimate aim', under s19 (1) of the Equalities Act – namely fulfilling the requirement to use limited NHS resources to their best effect."

When considering sales of medicines and health-related products, pharmacists and pharmacy technicians should not:

- make decisions that reduce access of these products to more vulnerable patients compared to the wider population
- supply or offer to supply chloroquine or hydroxychloroquine without establishing it is sought for a treatment for which it is licensed, as it is not licensed for the treatment of COVID-19
- sell any product or seek any fee at an inflated price that may be seen to be profiteering or taking advantage of the pandemic.

16 <https://www.bma.org.uk/media/2226/bma-covid-19-ethics-guidance.pdf> accessed 2 April 2020

Moral Distress

Pharmacists and pharmacy technicians, like other professionals, are not immune to the circumstances being witnessed in both primary and secondary care. This is further intensified by some patients' individual behaviour, often out of character when scared, as has already been observed in this crisis.¹⁷

Pharmacists and pharmacy technicians are reminded of the importance of taking care of their own wellbeing and that of those they manage. They should consider Post Traumatic Stress Disorder (PTSD) risk reduction using techniques such as mindfulness, debriefing and psychological support by discussing their experiences with others including colleagues, managers, family members, other sources of professional or spiritual support.

It is important to consider how the impact of continued high workload, tiredness and emotional state affects the quality of decision making. Ensuring that you manage your mental wellness, seek support from others and therefore manage 'human factors' is vital in times of high pressure and crisis.

Pharmacists and pharmacy technicians will need to be able to live with their decisions made during this crisis. Adopting an evidence based, fair, systematic approach will be key to maintaining personal pride and wellbeing.

Organisations may wish to consider setting up multidisciplinary "Ethical support units" as has been done in France.¹⁸ These groups of senior professionals are available as a rapid response support mechanism for frontline staff. These groups can support colleagues in both primary and secondary care.

Pharmacist Support can be contacted via its website <https://pharmacistsupport.org/how-we-can-help/> and for Northern Ireland <https://www.pfni.org.uk/pass/who-we-are/>. Pharmacy Technicians are encouraged to utilise the range of resources available free to healthcare workers via their employers

¹⁷ <https://www.bbc.co.uk/news/uk-wales-52033913> Accessed 2 April 2020

¹⁸ Covid-19: Can France's ethical support units help doctors make challenging decisions? 2020; 369:m1291 doi: <https://doi.org/10.1136/bmj.m1291> Accessed 3 April 2020

Managing patients remotely

Reduced staffing or safety concerns may mean that care has to be delivered from a distance in certain circumstances. This can be effective, even if not meeting perfection, and indeed may provide important input that might otherwise not be possible.

Guidance from NHSX details information on assumptions that can be made with respect to information governance and remote working.¹⁹

Procurement and distribution

When there are known shortages of medicines and devices there is a potential conflict between obtaining stock to meet the needs of regular patients and reducing stock available for patients elsewhere. To ensure fairness to all patients, pharmacists and pharmacy technicians should not stockpile. It is vital that knowledge regarding shortages is shared in a timely manner with all relevant professionals. This allows for better decision making all round, better care for patients, especially palliative patients, and can reduce stress.

Stockpiling of medicines in areas not in official supply pathways should be strongly discouraged such as doctor's bags, community hubs and care homes as such actions are likely to disrupt supply to those who need it most.

Pharmacists and pharmacy technicians in both primary and secondary care procurement and distribution, and in clinical care functions, may be faced with supply challenges. This may involve consideration of alternative suppliers or sources of medicines. Care should be taken to ensure use of approved suppliers and quality of medicines offered.

Normal procedures regarding deliveries and returns may need to become more flexible to take into account opening times, staff availability and minimise wastage.

Consideration of the practicalities of medicines supply should be reviewed and consideration given to "patient ready" medicines that can be distributed under guidance.

¹⁹ <https://www.nhs.uk/key-information-and-tools/information-governance-guidance/health-care-professionals> Accessed 3 April 2020

Leadership

Those in leadership positions should consider their additional responsibilities and demonstrate professional integrity, taking responsibility for making difficult but informed decisions. Organisationally, the most appropriate and experienced individuals should collaboratively make the key decisions, providing direction to more junior staff.

Those in leadership positions have a responsibility to share their experiences and decision making processes wherever possible, to increase engagement and transparency and to prevent unnecessary duplication and wasted time.

Research /Experimental treatments

During this pandemic, research and novel, unlicensed treatments may be requested by patients or colleagues. Pharmacists should collaborate and work in accordance with the latest evidence, putting patient safety at the forefront of their decision making. Any involvement in research should be in accordance with Good Clinical Practice (GCP) and trial protocols, ensuring that these have received relevant ethics committee approval. Pharmacists should consider their role in pharmacovigilance and the benefits this may bring to a team.

General advice is available from the RPS website www.rpharms.com/development/research-and-evaluation.

Repurposing of medicines

All pharmacists and pharmacy technicians should act to ensure the most prudent use of medicines.

Under no circumstances is it currently acceptable to supply patient-returned or date-expired medicines without further regulatory advice as this would be in contravention of section 64(1) of the Medicines Act 1968 if a patient is harmed by taking a medicine that is not of the nature or quality demanded.²⁰

Should the situation arise that key medicines become unavailable, it may be necessary to give consideration to the use of some patient returned medication (for example from end of life packs) or that which is recently expired. Subject to the availability of space and segregation from in-date stock, Pharmacists and pharmacy technicians should retain patient-returned medicines that are likely to be in short supply (taking account of the latest COVID-19 infection control guidance) as well as recently expired medicines that appear of suitable quality for triage and potential reuse in case they are needed for future supply should in-date stocks be declared exhausted.

Learning and improvement

Innovation and adapting to local circumstances will create learning and potentially improvement opportunities. It is vital that this learning is shared with other professional colleagues. Pharmacists and pharmacy technicians should actively seek to contribute to organisational and professional forums to communicate any learning in a timely manner. This may prevent valuable time being exhausted wrestling with similar challenges and may provide professional networking and support.

²⁰ <http://www.legislation.gov.uk/ukpga/1968/67/section/64> accessed 6 April 2020

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