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Consultation on the proposal for the supply and administration of medicines using patient group directions by operating department practitioners across the United Kingdom

October 2020

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please email england.cpomedicinesmech@nhs.net.

A patient and public summary of this consultation guide is available.

Equality and Health Inequalities Statement

Promoting equality and addressing health inequalities are at the heart of NHS England and NHS Improvement's values. Throughout the development of the policies and processes cited in this document, we have:

- Given due regard to the need to eliminate discrimination, harassment and victimisation, to advance equality of opportunity, and to foster good relations between people who share a relevant protected characteristic (as cited under the Equality Act 2010) and those who do not share it; and

- Given regard to the need to reduce inequalities between patients in access to, and outcomes from healthcare services and to ensure services are provided in an integrated way where this might reduce health inequalities

Contents

1 Introduction to the consultation

1.1 What are we consulting on?

This consultation is on the proposal to enable Operating Department Practitioners (ODPs) to use Patient group Directions (PGDs).

ODPs are currently able to use patient specific directions (PSDs) to administer or supply a medicine. A PSD is a written instruction to administer a medicine to a named patient who has been assessed by the authorised prescriber who then prescribes the medicine.

This UK-wide consultation is being led by NHS England and NHS Improvement on behalf of the four nations and relates to the proposal to enable ODPs to use patient group directions (PGDs) to supply and administer medicines directly to patients in the course of their professional practice.

PGDs are written instructions for medicines, including certain controlled drugs, to be supplied and / or administered by groups of health professionals to certain groups of patients without a prescription or patient specific direction[1]. PGDs are a supply or administration mechanism and are NOT a form of prescribing. Further detail about the mechanism can be found in appendix C.

There are two options for consideration in this consultation:

Option 1: no change.

Option 2: enabling the supply and administration of medicines using patient group directions by operating department practitioners

The proposed changes require amendment to both the Human Medicines Regulations 2001 and the Misuse of Drugs Regulations 2001. The Human Medicines Regulations apply UK-wide so subject to the agreement of Ministers, changes to them will apply across the four countries. The Misuse of Drugs Regulations apply only to England, Wales and Scotland; the Misuse of Drugs (Northern Ireland) Regulations 2002 will need to be amended separately and this will be undertaken by the Department of Health in Northern Ireland.

Should legislation be amended, the changes would apply throughout the UK, in any setting in which ODPs work and PGDs are permitted including the NHS, independent and voluntary sectors.

The consultation will run for 8 weeks and will close on **10th December 2020**.

You can find a glossary of terms used in this consultation guide in section 9

1.2 Why are the proposed changes being considered?

The proposed use of PGDs by ODPs to supply and administer medicines would bring many benefits to patients, commissioners and providers by facilitating the redesign of services which are focussed on enhancing the quality of patient care whilst also increasing capacity through effective use of the workforce.

[1] NICE (2017) *Patient group directions: medicines practice guideline*

- A greater number of patients would be able to receive the care and medicines they need from the ODP undertaking their care, without having to also see a prescriber.
- Patient outcomes would be improved through timely access to the medicines they need and thereby reducing delays in diagnosis and treatment.
- Patient experience would also be greatly improved by reducing the number of duplicated appointments or additional appointments with other healthcare professionals to access medicines required.
- Improved patient safety by reducing delays in perioperative care and creating clear lines of responsibility for decisions made regarding medicines.

Further information about the benefits of this proposal is presented in section 4.3. Potential risks and measures in place to manage the risks can be found in section 4.5.

1.3 Who has been involved?

This consultation guide has been developed in partnership with Department of Health and Social Care; the Medicines and Healthcare products Regulatory Agency; the Northern Ireland Department of Health; the Scottish Department of Health and Social Care; and the Welsh Department of Health and Social Services.

The College of Operating Department Practitioners (CODP) and the Association for Perioperative Practice (AfPP), the professional bodies that represent ODPs in the UK, have also collaborated in the development of this consultation guide and the supporting documents that accompany it.

1.4 Supporting documents

There are several national resources published by the National Institute of Clinical Excellence (NICE) to support the health professionals involved in the writing, reviewing and authorisation of PGDs and those who operate under them. ODPs would be expected to comply with these as national guidance. These include:

- *Patient Group Directions: Medicines Practice Guideline*[2]
- *Competency framework: For people developing and / or reviewing and updating patient group directions*[3]
- *Competency framework: for people authorising patient group directions*[4]
- *Competency framework: for health professionals using patient group directions*[5]

1.4.1 Consultation Stage Impact Assessment

Impact assessments are an integral part of the policy making process; the purpose of an impact assessment is to focus on why the proposed intervention is necessary, what impact the policy change is likely to have and the highlighting of costs, benefits and risks. The *Consultation Stage Impact Assessments* contains evidence of the actual (where available) and estimated costs and benefits associated with the proposal. The consultation is an opportunity to gather additional evidence to further inform the costs, benefits and risks of the proposal.

[2] NICE (2017) *Patient group directions: medicines practice guideline*
[3] NICE (2017) *Patient group directions: tools and resources*
[4] NICE (2017) *Patient group directions: tools and resources*
[5] NICE (2017) *Patient group directions: tools and resources*

1.5 The questions being asked

Question 1
Should amendments to legislation be made to enable ODPs to supply and administer medicines to their patients using patient group directions?

Question 2
Should amendments to legislation be made to enable ODPs to supply and administer controlled drugs to their patients using patient group directions?

Question 3
Do you have any additional information on any aspects not already considered as to why the proposal to enable ODPs to supply and administer medicines using patient group directions SHOULD go forward?

Question 4
Do you have any additional information on any aspects not already considered as to why the proposal to enable ODPs to supply and administer medicines using patient group directions SHOULD NOT go forward?

Question 5
Does the *Consultation Stage Impact Assessment* give a realistic indication of the likely costs, benefits and risks of the proposal?

Question 6
Do you think that this proposal could impact (positively or negatively) on any of the protected characteristics covered by the Public Sector Equality Duty set out in section 149 of the Equality Act 2010 or by section 75 of the Northern Ireland Act 1998?

Question 7
Do you feel that this proposal could impact (positively or negatively) on health inequalities experienced by certain groups?

You will also be asked questions about yourself and / or your organisation so that the views of different groups can be better understood.

2 Background

2.1 Context

The Chief Professions Officers' Medicines Mechanisms (CPOMM) programme is set in the context of the current direction of the NHS which puts patients and the public at the heart of everything we do. The Five Year Forward View[6] sets out the vision for the future of the NHS in England, a future in which access to health care is intuitive and simplified. The NHS Long Term Plan[7] envisions integrated care systems for England; within which redesigned services can enable a future where care can be personalised when people need it and can be joined-up with fewer appointments with health professionals to receive it.

NHS England and NHS Improvement are leading a number of key programmes of work which aim to put in place the infrastructure to make the vision a reality. The programmes include the Medicines Value Programme, which has been set up to improve health outcomes from medicines and ensure that the NHS in England gets the best value from the NHS medicines bill. Whilst the Medicines Value programme is focused on the NHS in England, similar types of work are taking place in Scotland, Wales and Northern Ireland.

The CPOMM programme aims to enable the selected professions to maximise their ability to improve the patient's care, experience and safety. Optimising medicines and improving access to the right medicines whilst maintaining safety for patients would also be consistent with the government's policy to focus on improved outcomes for all and to transform the way the NHS provides care. The CPOMM programme also supports the achievement of a number of current ambitions across the UK:

In Scotland: supports the delivery of *Achieving Sustainable Quality in Scotland's Healthcare: A '20:20' Vision*[8]*, Health and Social Care Delivery Plan 2016*[9] and *Realising Realistic Medicine 2015/16*[10]

In Wales: supports the achievement of ambitions set out in *Taking Wales Forward 2016-2021*[11], *Prosperity for All: the national strategy*[12] and *A Healthier Wales: our Plan for Health and Social Care*[13]

In Northern Ireland: supports the delivery of *Health and Wellbeing 2026: Delivering Together*[14] and the *Medicines Optimisation Quality Framework*[15]

2.2 Programme of work

In 2016 NHS England undertook a scoping project to determine the need for prescribing, supply and / or administration of medicines responsibilities to be extended to a number of regulated health professionals. The resultant report indicated the legal mechanism of

[6] NHS England (2014) *Five year forward view*
[7] NHS England (2019) *The NHS long term plan*
[8] NHS Scotland (2011) *Achieving sustainable quality in Scotland's healthcare: a 20:20 vision*
[9] The Scottish Government (2016) *Health and social care delivery plan*
[10] The Scottish Government (2017) *Realising realistic medicine: Chief Medical Officer's annual report 2015-16*
[11] Welsh Government (2016) *Taking Wales forward 2016-2021*
[12] Welsh Government (2017) *Prosperity for all: the national strategy*
[13] Welsh Government (2018) *A healthier Wales: our plan for health and social care*
[14] DoH Northern Ireland (2016) *Health and wellbeing 2026: delivering together*
[15] DoH Northern Ireland (2016) *Medicines Optimisation Quality Framework*

administration, supply or prescribing that best fits the professions considered, and prioritised certain professions based on current NHS priorities.

The CPOMM Programme of work commenced on 1 April 2017 to take forward the identified priorities. A programme board was established to oversee this work (see appendix A) and a working group was also founded to support the development of this work (see appendix A).

We are leading consultations on behalf of the four nations on proposals which include changes to medicines responsibilities for eight regulated health professions as follows:

- enabling **dental hygienists** and **dental therapists** to supply and administer specific medicines under exemptions within medicines legislation
- enabling **biomedical scientists**, **clinical scientists** and **operating department practitioners** to supply and administer medicines using patient group directions
- amending the current lists of controlled drugs that **podiatrist** and **physiotherapist** independent prescribers are legally able to prescribe
- amending the list of medicines that **paramedics** can administer using exemptions

All the proposals share the same aim: to make it easier for people to get the medicines they need when they need them and avoiding the need for people to see additional health professionals just to receive medicines.

Views are sought on the proposed changes for each of the eight professions separately because of the differences between the professions, any unique characteristics which apply to them and the changes being proposed for them. Furthermore, changes to medicines legislation need to be considered independently for each profession. However, only one consultation guide has been developed for both dental therapists and dental hygienists due to the similarity of the professions; although we will still be seeking views on these two professions separately.

All of the consultations can be found on the NHS England consultation hub website.

3 Introduction to the operating department practitioner profession

3.1 The role of the operating department practitioner (ODP)

ODPs are statutory regulated healthcare professionals. There are currently 14,540[16] ODPs registered with the Health and Care Professions Council (HCPC) in the UK. The term 'operating department practitioner' is a protected title in law, and all ODPs, whether working in the NHS, private or voluntary sectors, must be registered with the HCPC.

The core scope of practice for all ODPs is the provision of safe, effective care to perioperative patients through the assessment, planning, delivery and evaluation of perioperative care as a key member of the surgical team. Whilst ODPs practise across all areas of perioperative care, there are three identified areas of practice which support the definition of the scope of practice[17]:

Surgical phase- in order to care effectively for the patient, the ODP applies a robust understanding of aseptic technique, wound management and infection control; in addition to the technical skills of surgical care. In the surgical role, the ODP is required to have detailed knowledge of the surgical procedure, related anatomy and potential complications to ensure that appropriate care is delivered in a timely manner.

Anaesthetic phase- the ODP ensures the wellbeing of the patient throughout the anaesthesia by working effectively as part of the anaesthetic team. To deliver care the ODP uses a robust understanding of anaesthetic techniques, physiology and the pharmacological interventions as part of the induction and maintenance of anaesthesia.

Post-anaesthetic care phase- the ODP receives the patient and plans and delivers individualised care, using extensive knowledge of normal and altered physiology and the process of initial recovery from anaesthesia. The ODP monitors and assesses the patient and makes clinical decisions related to these observations including the assessment and management of both pain and post-operative nausea and vomiting.

Most ODPs will work across all three areas of practice, some across just two, depending on organisational policy and need.

3.2 Where ODPs work

The scope of practice for ODPs has extended beyond the operating department as increasingly their transferable knowledge and skills are recognised in other departments. ODPs now apply the core scope of practice to the different settings, including:

- the emergency department where ODPs assess, triage, and deliver care to patients, particularly in trauma and resuscitation
- intensive care and high dependency units where ODPs care for patients as part of the team. Some ODPs have additional training as Advanced Critical Care Practitioners

[16] Health and Care Professions Council *registrants by profession & route & gender* September 2020
[17] College of Operating Department Practitioners (2009) *Scope of practice*

- pre-assessment units where ODPs assess patients prior to admission for surgery including referring the patient for additional diagnostic investigations
- endoscopy units, both in hospital and community settings where ODPs plan and deliver care for patients undergoing endoscopy. Some ODPs have undertaken additional training and can undertake endoscopy procedures
- pre-hospital care where ODPs may undertake a range of roles, for example solo responder or off-shore health professional
- transplant and retrieval teams, including transplant co-ordinator roles and live donor programme leads where ODPs will care for the patient in theatre and support the family to organise the retrieval process
- attending both intra- and inter-hospital patient transfers. ODPs will care for ventilated or critically ill patients who are being transferred between hospitals in an ambulance or between different hospital departments
- hospital resuscitation teams, both as key members of the teams and delivering training to others
- imaging units, providing anaesthesia support during interventional radiology and imaging procedures needing anaesthesia such as computed tomography (CT) and magnetic resonance imaging (MRI)

Individual ODPs have also extended their scope of practice to a number of advanced roles, where they undertake duties that would have been traditionally performed by doctors, including:

- ODP endoscopist - involving the autonomous undertaking of endoscopic procedures in community or hospital settings
- acute pain practitioner - as a part of the acute pain team, planning and implementing acute pain management strategies
- surgical first assistant[18]- providing direct assistance to the surgeon during the surgical procedure e.g. holding retractors, cutting sutures

3.3 The professional bodies

The College of Operating Department Practitioners (CODP) and the Association for Perioperative Practice (AfPP) are the professional bodies representing ODPs in England, Scotland, Wales, Northern Ireland and the Channel Islands. The role of the professional bodies is summarised in appendix B for information.

3.4 Professional regulation

The purpose of professional regulation is to protect the public. All ODPs, whether working in the NHS, private or voluntary sectors, must be registered with the HCPC. The HCPC sets the standards that all registrants must meet in relation to their education, proficiency, conduct, performance, character and health. These are the standards that the HCPC considers necessary for safe and effective practice. Registrants must meet all these standards and meet the standards relevant to their scope of practice to stay registered. They must complete a professional declaration every two years thereafter, to confirm they have continued to practise and continue to meet these standards. Registrants must also ensure that they have appropriate indemnity in place to cover all of their work. This

[18]Perioperative Care Collaborative (2012) *Position statement: surgical first assistant*

indemnity may be provided through an employer, a professional body or by private arrangement.

3.5 How operating department practitioners are trained

There are currently 34 HCPC-approved programmes leading to registration in operating department practice in the UK, which are delivered by 24 higher education institutions (HEIs). Two types of pre-registration ODP programmes are offered within the UK, a diploma in higher education and a degree programme. The first degree-level curriculum was published in 2011 and there has been a transition to degree level education across the country with 17 HEIs currently offering the degree. The degree programme is of 3 years duration and the diploma 2 years; both programmes include clinical placements within operating theatres within NHS and / or independent hospitals to ensure a standard of proficiency is achieved which enables graduates to be eligible to apply for HCPC registration.

Graduates from all pre-registration programmes must meet the HCPC *Standards of Proficiency: operating department practitioners*[19] as the baseline for safe and effective practice and the standards against which ODP programmes are approved. Education and training related to medicines is a key component of the pre-registration curriculum. The CODP curriculum[20] for degree-level study specifies that each student must demonstrate a comprehensive and evidence-based understanding of the pharmacokinetic and pharmacodynamic effects of medicines encountered within the practitioner's scope of practice. All programmes include learning and assessment, through practice and / or simulation, on the administration of prescribed medicines and fluids via a range of routes.

3.6 Continuing professional development (CPD)

Once registered, ODPs must undertake CPD and demonstrate that they continue to practise both safely and effectively within their scope of practice in order to maintain their registration. For the duration of their career, registrants are required to maintain a continuous, up-to-date and accurate record of their CPD activities, which must demonstrate a mixture of learning activities relevant to current or future practice. Their CPD activities must contribute to both the quality of their practice and service delivery, and benefit service users.

When the members of a profession renew their registration, the HCPC audits the CPD activities of 2.5% of registrants chosen at random from that profession. Those registrants who are chosen for audit must submit a CPD profile to show how their CPD meets the minimum standards of the regulator. A failure to submit or complete successfully an audit leads to administrative removal from the register.

[19] HCPC (2014) *Standards of proficiency: operating department practitioners*

[20] CODP (2011) *bachelor of science (hons) in operating department practice – England, Northern Ireland and Wales, bachelor of science in operating department practice – Scotland curriculum document*; London: CODP

4 Case for change

4.1 Identification of viable options

The report of the 2015 NHS England scoping project indicated the legal mechanism of administration, supply or prescribing that best fits the professions considered, and prioritised certain professions based on current NHS priorities. The report recommended that further work should be undertaken to enable ODPs to be able to supply and administer medicines using PGDs. This is because, whilst ODPs are able to supply and administer medicines that have been prescribed, usually by doctors (also known as patient specific directions or PSDs), they often need to refer patients to doctors to receive the medicines they need.

Two options have been considered during the development of this proposal.

Option 1- no change
There would be no change to legislation; ODPs would continue to use PSDs to supply and administer medicines to their patients.

Benefits
For some patients the scope of the existing legislation works well for those patients whose medicines needs can be anticipated in advance of their treatment or where a prescriber is always available.

Limitations
Existing arrangements may not best support the needs of patients who need a different medicine because they experience more pain or nausea than expected, for example. The full impact of this option and the limitations of the current mechanism available to ODPs are outlined in section 4.2

Option 2: proposal to enable ODPs to supply and administer medicines using PGDs.

Benefits
Patients who are treated by ODPs would be able to receive the treatment they need without additional appointments or delays to see a prescriber to receive their medicines. Further information about the anticipated benefits can be found in section 4.3.

Limitations
Should legislation be amended, the limitations of the PGD mechanism[21] may mean that some of the patients that ODPs see may not benefit from the proposed changes to legislation, such as those requiring medicines with variable dosing.

In summary, there are two options for consideration in this consultation:

- **Option 1**: no change
- **Option 2:** legislation is amended to enable ODPs to be able to supply and administer medicines using PGDs.

[21] NICE (2017) *Patient group directions: medicines practice guideline*

4.2 Limitations of the current use of medicines mechanisms by ODPs

4.2.1 Patient specific direction (PSD)

ODPs are currently able to use PSDs to administer and supply medicines. A PSD is a written instruction to supply or administer a medicine to a named patient who has been assessed on an individual basis by the authorised prescriber who then prescribes the medicine[22]. The PSD then enables an ODP to administer or supply the medicine to the patient. ODPs use this mechanism extensively to administer a number of medicines to patients including antiemetics (to treat or prevent nausea and vomiting), analgesics (to treat pain) and controlled drugs as part of a peri-operative regimen. Hence, medicines knowledge and administration techniques is included in pre-registration education and supported through CPD.

PSDs are useful in many care settings; they are individually tailored to the needs of a single patient, wide-reaching and can encompass controlled drugs. However, there are certain limitations to their use:

- they require direct input from an independent prescriber
- they can be restrictive when access to a prescriber is problematic or if the service provided is non-prescriber led
- organisations may limit locally who is authorised to supply and / or administer medicines using PSDs

Avoidable delays in patient care occur when ODPs are unable to supply or administer appropriate medicines under existing arrangements. This often results in patients needing to wait for another health professional, to receive the medicines required.

4.3 Benefits of the proposal

Although use of PSDs has improved patient care, the impact of the use of PGDs for the supply and administration of medicines is anticipated to bring many benefits to patients, commissioners and providers.

4.3.1 Provision of best care, first time, in the right place

Appropriate access to medicines through the proposed use of PGDs by ODPs will enable patients to access the medicines they need in a timely and effective manner. Timely administration or supply of medications using PGDs will result in improved patient outcomes and experience; for example, the prompt provision of appropriate analgesia will reduce patients' pain and distress in addition to facilitating a timely discharge from the perioperative environment.

[22] Specialist Pharmacy Service (2018) Questions about patient specific directions

4.3.2 Improved outcomes

The proposed use of PGDs by ODPs would improve patient outcomes through ensuring that they receive the right treatment at the right time without delay. Timely access to medicines through the proposed use of PGDs by ODPs would help avoid the risks associated with delayed treatment such as pain and nausea. Additionally, some diagnostic and treatment procedures which require the administration of a medicine would not be delayed because of the absence of a prescription.

4.3.3 Clearer lines of clinical responsibility and accountability

Under current legislation, when delivering patient care, ODPs frequently need to request an independent prescriber to prescribe medicines for the patients they are caring for. The prescriber is unlikely to be as familiar with the patient and their clinical history as the ODP caring for that patient. The proposed use of PGDs would therefore enable ODPs to take responsibility for their decisions to administer medicines in accordance with the written PGD and would provide clearer lines of accountability.

4.3.4 Reduced resource usage and cost effectiveness

If PGDs were in place as proposed, ODPs could administer the medicine without requiring the intervention of doctors and other health professionals, therefore increasing efficiency of service delivery by maximising appropriate use of all professionals in the team. This is pertinent in pre-assessment units where medicines are frequently administered using PGDs following the assessment of the patient. An example is administration of neomycin-chlorhexidine cream for MRSA decolonisation prior to elective procedures that involve implant surgery.

4.3.5 Medicines optimisation

Medicines optimisation looks at how patients use medicines over a period of time. It may involve stopping some medicines as well as starting others, and considers opportunities for lifestyle changes and non-medical therapies to reduce the need for medicines. The proposed use of PGDs by ODPs could enable patients to get the best use of their medicines in line with the principles of medicines optimisation[23].

- PGDs must contain information and directions to the health professional administering or supplying the medicine, such as any onward referral or follow up actions to be taken[24].
- PGDs are written and authorised by multidisciplinary groups of health professionals including doctors and pharmacists and should be evidence-based.
- They must be reviewed every two to three years as a minimum and in a timely way following the publication of any new NICE guidance regarding the management of infections.
- They should be discontinued if no longer clinically relevant therefore preventing the medicine being used.

[23] Royal Pharmaceutical Society (2013) *Medicines Optimisation: Helping patients to make the most of medicines- good practice guidance for healthcare professionals in England*

[24] Human Medicines Regulations 2012

4.4 Use in clinical practice

The scenarios below demonstrate how ODPs might use PGDs to administer or supply medicines within clinical practice and the benefits to be gained from this proposal. These are only illustrative examples; decisions about the medicines included in PGDs will require local agreement.

Scenario 1: 1% tetracaine eye drops

Nationally there is an increasing need to improve the provision of services for patients requiring eye surgery such as repair of cataracts in order to shorten waiting times. Currently, most eye surgery sessions do not have an anaesthetist allocated to a list of patients. This is because eye surgery is predominately performed by local anaesthetic blocks[25] following the administration of 1% tetracaine local anaesthetic drops onto the surface of the eye; anaesthetists mainly see patients that require general anaesthesia for their surgical procedures.

ODPs contribute to the delivery of care to patients undergoing eye surgery, such as repair of cataracts. The majority of these procedures are performed under local anaesthetic block and as an initiative to improve efficiency some ODPs have been trained to administer the local anaesthetic. All the medicines for the local anaesthetic are prescribed on a PSD however there are occasions where a second dose of the 1% tetracaine eye drops is needed. As the prescription is often for one administration only, sometimes the ODP must find a doctor who can write another prescription. This can result in delays to the both the local anaesthetic block and the surgery procedure as the patient must wait for the additional medicine to be administered.

Allowing ODPs to administer medicines under a PGD to patients who meet the criteria, would limit delays to the delivery of anaesthesia and thus allow the eye surgery to proceed in a timely way. This will also maximise the capacity of the operating list, which is in line with the national initiative to improve the service provision of eye surgery.

Scenario 2: salbutamol

Some ODPs work within emergency departments across the UK. As part of this role, ODPs work in the resuscitation room where they frequently care for patients attending with acute exacerbations of asthma. Patients who present to the emergency department with an acute shortness of breath may bypass an initial triage assessment if they are too unwell to wait to be seen. They are admitted directly to the resuscitation room where care may be provided by an ODP. If bronchospasm is diagnosed on examination, this requires immediate treatment.

In line with national guidelines[26] the initial treatment would be a salbutamol nebuliser. Currently the ODP must ask a prescriber to see the patient and prescribe the nebuliser which can delay the care. If the ODP could administer this using a PGD, then prompt intervention would prevent further deterioration and unnecessary stress for the patient. As ODPs often work in the resuscitation room, enabling them to use PGDs allows them to provide a better service in this area. This would allow the prescribers to see other patients that need their attention more and thus improve the efficiency of the ED overall and potentially reduce waiting times.

[25] Royal College of Anaesthetists, Royal College of Ophthalmologists (2012) *Local anaesthesia for ophthalmic surgery*.
[26] British Thoracic Society, Scottish Intercollegiate Guidelines Network (2016) *Asthma guidelines*

Scenario 3: midazolam and flumazenil

Endoscopy is type of diagnostic procedure that examines the inside of a body cavity using a scope which has a camera at one end. Demand for the endoscopy service is high; in response to demands such as 2-week cancer waits and the programmes for monitoring patients at risk following the treatment of bowel cancer, colonic polyps, Barrett's oesophagus and inflammatory bowel disease[27]. This is part of the UK-wide NHS bowel screening programme which is likely to be expanded to offer a one-off bowel scope screening to all patients in England over 55[28], thus further increasing demand. To help address the increased demand, and maximise the use of the ODP endoscopy workforce, procedures such as using colonoscopy (using a flexible scope to look inside the bowel) are increasingly being performed by ODPs who have successfully completed an approved endoscopy course.

Endoscopic procedures are often performed by doctors however other trained, competent staff, including ODPs, may also perform them. These procedures are usually undertaken while the patient is awake, using sedation to help them relax. Local trust guidelines state that titrated doses of intravenous midazolam is recommended for conscious sedation. Flumazenil must also be available to reverse the effects of the midazolam in the unlikely event that patients become so deeply sedated that breathing is impaired[29]. PGDs in the department for both midazolam and flumazenil enable other health professionals currently able to use PGDs to administer the medicines to patients requiring endoscopy, in the absence of a gastro-intestinal consultant.

Allowing ODPs to administer the medicines under PGDs to patients who meet the criteria would limit delays to the delivery of sedation, increase safety and subsequent performance of the procedure. Similarly, reducing delays reduces the risk of heightened anxiety for patients waiting longer than necessary. Improved efficiency of the endoscopy service overall results in an increased capacity and hence improved opportunities to detect polyps and cancers in patients in a timely fashion.

Scenario 4: buccal prochlorperazine

Patients requiring day surgery in the UK are admitted and discharged on the same day which offers a number of advantages to both the patient and the efficiency of the service provided. As such the NHS Modernisation Agency identified day surgery as one of the 'high impact changes' with the intention that day surgery would become the "norm for elective surgery"[30]. In order to discharge patients in a timely manner, it is essential that post-operative nausea and vomiting (PONV) is managed; however medicines to prevent sickness and nausea are not routinely prescribed unless there is a significant risk factor for PONV[31].

ODPs will care for patients in the post-operative recovery area in the day surgery unit and this will include assessment of both pain and nausea. PONV is very distressing for patients and as such is identified as the one of the most common reasons for dissatisfaction after anaesthesia; and while serious complications resulting from PONV are rare, it can delay discharge and increase the risk of day surgery patients requiring overnight admission[32]. As a result it is important that the ODP is able to treat PONV promptly to minimise patient distress and optimise recovery. In a number of day surgery units, PGDs enable other eligible health professionals to use PGDs to administer antiemetic medicines in the absence of a prescriber. For example, buccal prochlorperazine is commonly included in a PGD for administration in day surgery units for patients over 16. As ODPs cannot use PGDs they must obtain a prescription from a doctor

[27] British Society of Gastroenterologists (2005) *Non-medical endoscopists*

[28] Public Health England (2018) Guidance: *Our approach to bowel cancer screening standards*

[29] National Patient Safety Agency (2008) *Rapid Response Report: reducing risk of overdose with midazolam injection in adults*

[30] NHS Modernisation Agency (2011) *10 High Impact Changes for Service Improvement*

[31] AAGBI (2011) *Day Case and Short Stay Surgery*

[32] Pierre S, Whelan R (2011) Nausea and vomiting after surgery, *Continuing Education in Anaesthesia Critical Care and Pain*, 13 (1): 28-32

(usually an anaesthetist) and so there will usually be a delay as they will usually be caring for another patient in the operating theatre.

Allowing ODPs to administer a medicine to prevent sickness and nausea to treat PONV using a PGD to patients who meet the criteria will reduce the delay in receiving the treatment and will improve the recovery time for the patient. Reducing these delays will improve the patient experience and reduce the risk of the patient requiring overnight admission, and is therefore important in optimising the overall service.

4.5 Management of potential risks associated with the proposal

Whenever there is an extension of medicines supply, administration and prescribing responsibilities to regulated health professions there will be associated risks. Identification of the risks informs the development of governance and patient safety measures that are necessary to maintain patient safety.

There are a number of potential risks to the proposal to enable ODPs to supply and administer medicines using PGDs. The risks perceived are not unique to ODPs; they are the same as those for other professions that use PGDs to supply and administer medicines. As such, they can be mitigated against by the governance and patient safety measures described in section 5. The potential risks perceived of the proposal, and a summary of the mitigating actions that can be taken are included in table 1 below.

Table 1: Potential risks and governance measures already in place to manage them

Potential risk	Potential solution
ODPs may supply or administer a medicine using a PGD without having undertaken either nationally available (CPPE) or locally provided training to use PGDs resulting in an increased risk of error.	• ODPs are required to only supply and administer medicines within their scope of practice and competence and the HCPC has the powers to remove individuals from their register if the person falls below the standards required. • NICE guidance strongly recommends training and refers to local PGD policy and governancerequirements. • Organisations should ensure that ODPs have undertaken relevant training prior to using PGDs. • Local governance arrangements for the use of PGDs will include ODPs.
PGD authorising bodies in NHS organisations may not approve PGDs to be used by ODPs therefore patients seeing the ODPs employed by the organisation will not benefit from any change to legislation.	• As part of implementation, NHS England and NHS Improvement and the devolved administrations, together with professional bodies and other key stakeholders, will raise awareness of any changes in legislation, in order to inform local decision-making and promote consistency.

The limitations of the PGD mechanism[33] may mean that not all the patients that ODPs see will benefit from the proposed changes to legislation, such as those requiring medicines with variable dosing.	• Although there are some limitations to the PGD mechanism, scoping has identified that PGDs are the best fit for the profession currently.
The time taken for development, approval and review of PGDs in order that ODPs can administer and supply medicines using the mechanism can be lengthy which may delay the benefits for patients.	• The time saved by removing the necessity for the writing of PSDs for frequently used medicines will provide some balance to this at an organisational level. • Exemplar PGDs could be shared on the PGD website, hosted by the Specialist Pharmacy Service which could be accessed across the UK. • Some of the PGDs that ODPs will need may already be in use by nurses in the same services in organisations. Whilst the PGD will be reviewed at the same time as adding ODPs to the PGD, this process takes less time than completely writing the PGD.
If the legislation is amended to enable ODPs to supply and administer medicines using PGDs but not to supply and administer the controlled drugs that most other professions can using PGDs, this could lead to confusion within organisations, inconsistency for patients seeing different health professionals who are providing the same type of care, and increased risk of error.	• Information could be provided on the Specialist Pharmacy Service website and the training package updated to make the position clear. • Separate profession-specific PGDs would need to be written for services where the same type of care is provided to patients by ODPs and other professions who can supply and administer controlled drugs.

[33] NICE (2017) *Patient group directions: medicines practice guideline*

5 Governance and patient safety

The following governance and patient safety measures are already in place in organisations which employ health professions that can use PGDs to supply and administer medicines. Some of the measures are statutory and some are mandated by organisations.

5.1 Safe use of PGDs

The preferred way for patients to receive the medicines they need is for a prescriber to provide care for an individual patient on a one-to-one basis. If there is a prescriber in the care pathway, they should prescribe for the patient.

The National Institute of Clinical Excellence (NICE) provides guidance on the writing, authorising, implementation and use of PGDs[34] [35] and provides a suite of tools for organisations, services and individuals to structure training and governance, and a set of standards against which organisations can monitor their performance. This guidance applies to England and Wales; however, the principles may be applicable in Scotland and Northern Ireland.

Although the service is commissioned by NHS England, the NHS Specialist Pharmacy Service team is also commissioned by NICE to provide expert pharmaceutical support and guidance relating to all aspects of the use of PGDs by online information and example PGDs[36]. The information offered is publicly available and in line with NICE guidance. it is therefore applicable to England and Wales, but may also be applicable to Scotland and Northern Ireland. For detailed information regarding the safe use of PGDs by all eligible health professionals, see appendix C.

5.1.1 Local governance

PGDs are locally written and locally governed. Organisations already have governance arrangements in place for other professions who use PGDs and ODPs would be expected to comply with these. Arrangements include:

- involvement in the writing and authorisation
- implementation of PGDs at service level
- expectation and provision of training
- assurance of competence to supply or administer the medicine(s) included in the PGD by the service lead
- oversight of PGDs in the organisation in which staff are using them
- audits of use and impact

5.1.2 Role of Controlled Drugs Accountable Officer (CDAO)

PGDs can be written to include only certain controlled drugs for administration by any eligible health profession (see appendix C). All aspects of controlled drugs management are overseen by a CDAO in each organisation who is accountable for the governance where controlled drugs are used. This includes being familiar with the PGDs for controlled drugs, should any be in place in the organisation. The CDAO is usually the chief pharmacist or other senior person in the organisation; the roles and responsibilities and the

[34] NICE (2017) *Patient group directions: tools and resources*
[35] NICE (2017) *Patient group directions: medicines practice guideline*
[36] Specialist Pharmacy Service website

requirement to appoint a CDAO are governed by legislation[37] [38] [39]. The responsibilities of the CDAO include:

- ensuring that the organisation has a controlled drugs policy that includes use of PGDs
- ensuring that the organisation has a set of standard operating procedures covering all aspects of controlled drug handling and use including PGDs
- ensuring that processes for monitoring compliance are in place
- being a member of a local intelligence network which shares concerns and oversees management of controlled drugs

Should legislation be amended, all ODPs who will be administering controlled drugs using PGDs must know who the local CDAO is and comply with any local monitoring and / or inspection requests that the CDAO may make including the reporting of any incident or issue related to controlled drugs.

5.1.3 Professional accountability

ODPs must ensure they provide evidence-based care within their scope of practice and competence. Should legislation be amended, when using PGDs to supply or administer medicines, they will be professionally accountable for their decisions, including actions and omissions. This also means that, should legislation be changed, even though ODPs could supply or administer a medicine legally, they are not obliged to do so and must always work within their HCPC *Standards of Conduct, Performance and Ethics*[40]. ODPs must have due regard to patient safety information and should be aware of change and update their practice accordingly, which may include not using a PGD until it is amended or reviewed in light of the guidance.

5.1.4 Adverse drug reactions (ADRs), interactions and errors

If an error in supply or administration occurs whilst using PGDs, ODPs must take immediate action to manage the effects on the patient, prevent potential side effects to the patient and must report the error as soon as possible according to local protocols. The reporting of errors must be in an open and transparent way, in order that anything learned from the incident is shared as appropriate.

If a patient experiences an adverse reaction to a medication- once the required treatment has been undertaken, this should be recorded in the patient's notes and, if indicated, the Medicines and Healthcare products Regulatory Agency should be notified via the Yellow Card Scheme[41]. ODPs are expected to be able to recognise common side effects and adverse reactions to the medicines they administer, and to know when there is a potential risk of an interaction.

[37] *The Controlled Drugs (Supervision of Management and Use) Regulations 2013*
[38] *The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (No 3239) (W. 286)*
[39] *The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009*
[40] HCPC (2016) *Standards of Conduct, Performance and Ethics*
[41] MHRA *Yellow Card Scheme*

5.2 Eligibility and training to use PGDs

Should legislation be amended, all HCPC registered ODPs would be eligible to supply and administer medicines using the PGD mechanism. However, it would be for local organisations to agree appropriateness for the use of PGDs within a clinical service using the national guidelines[42] and local governance to inform the decision.

Whilst formal accreditation is not mandatory, ODPs should be trained in the use of PGDs as strongly advised by NICE and part of good practice in organisational governance and is currently encouraged for all health professionals legally able to use the mechanism (see appendix D). Competency frameworks[43] set out the skills and knowledge expected by those who undertake the writing, reviewing, implementation and use of PGDs and should inform the curriculum for training programmes. Locally written training programmes may be provided by organisations for their own staff, the e-learning package written by the Centre for Postgraduate Pharmacy Education[44] is freely available and endorsed by the Specialist Pharmacy Service (see section 5.1).

5.3 Communication of decisions to supply and administer medicines using PGDs

It is not expected that the communication relating to the proposed use of PGDs by ODPs would require any changes to the current processes that they currently follow in relation to the use of PSDs. If able to use PGDs to supply and administer medicines to patients, ODPs will have access to comprehensive medical records and will also obtain additional information from the patient and other health professionals as required. This may include current medicines being taken including over-the-counter, previous side effects experienced to any component of the medicine to be supplied or administered, current and past medical history and any other information that may affect the patient's response to the medicine. The ODP must record in the medical record that this information has been scrutinised and that the medicine is suitable for the patient.

Any medicines supplied or administered by ODPs must be recorded within the patient's medical notes. Subject to legislative change, if PGDs are used, a statement that the medicine has been supplied or administered using a PGD should also be included within the patient's record.

This information would also be communicated to appropriate registered health professionals when the ODP is conducting the handover of the patient's care. The medicines administered will predominantly be part of the patient's overall hospital care of which the GP will be informed in line with information governance procedures. However, if any medicines are supplied using PGDs to the patient to take at home then the GP will also be informed in line with good information governance procedures. ODPs already undertake these processes when using PSDs.

[42] NICE (2017) *Patient group directions: medicines practice guideline*
[43] NICE (2017) *Patient group directions: tools and resources*
[44] Centre for Postgraduate Pharmacy Education *PGD e-learning package*

5.4 Antimicrobial resistance

Where supply or administration of antimicrobial medicines using PGDs is indicated, ODPs will be required to work within their scope of practice and the *Antimicrobial Prescribing and Stewardship Competencies*[45] in line with the requirements of antimicrobial stewardship[46], as well as their role in the prevention of infection in order to remove the need for avoidable antimicrobial use[47]. Effective prevention of infection must be part of the everyday practice of ODPs as preventing infections helps to reduce the need for antimicrobials. When administering or supplying antimicrobials using PGDs, ODPs must work within local antimicrobial guidelines which take into consideration local resistance patterns. ODPs are expected to be familiar with the requirements of their role in antimicrobial stewardship[48] and to use readily available resources including education programmes[49].

PGDs should only be written for those antimicrobial medicines which are included in local formularies and best practice guidelines, and written and authorised by multidisciplinary groups of health professionals[50]. They must be reviewed every three years as a minimum or in a timely way following the publication of any NICE guidance related to the management of infections and should be discontinued if no longer clinically relevant. PGDs must be written with the involvement of a pharmacist and those for antimicrobials should be discussed with a microbiologist and an antimicrobial stewardship pharmacist also. They would advise on aspects such as the decision to include the antimicrobial in a PGD, the conditions it would be used for (which may be fewer than its manufacturers' authorisation indicates), the duration of the course and the criteria of the ODPs for whom the PGD is intended. The antimicrobial should be supplied for as short a treatment duration as possible and in line with local antimicrobial policy and guidelines.

5.5 Use of PGDs by private practitioners

Few ODPs work in private practice. Where they do, their roles may vary widely. If working in independent hospitals, their roles are usually the same as when working within NHS settings. If working as independent practitioners, they could be undertaking such diverse work as aesthetics (cosmetic procedures) or as an off-shore practitioner e.g. providing care to workers on oil rigs.

As HCPC-regulated health professionals, ODPs working in private practice are governed and regulated by the same standards as those working in the NHS, and the standard of care expected is the same. Should PGDs be permitted within this clinical setting (see Appendix C), the PGDs must be written, authorised and implemented in line with all the relevant national and local governance requirements including the NICE Medicines Practice Guidance[51]. Employers outside of the NHS have the same roles and responsibilities as those within the NHS and must implement the same standard of local governance arrangements related to the safe storage, supply and administration of medicines.

[45] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies*
[46] NICE (2015) *Guidance NG 15: antimicrobial stewardship: systems and processes for effective antimicrobial medicine use*
[47] Department of Health (2008) *The Health and Social Care Act: Code of Practice on the prevention and control of infections and related guidance*
[48] Public Health England (2015) *Antimicrobial stewardship: Start smart - then focus*
[49] Health Education England (2017) *Antimicrobial resistance- a training resources guide*
[50] NICE (2017) *Patient group directions: medicines practice guideline*
[51] NICE (2017) *Patient group directions: medicines practice guideline*

In addition, their practice or clinic must also be registered and regulated by one of the following, depending on the location of the practice:

- in England, the Care Quality Commission - the independent regulator of health and adult social care service providers in England
- in Wales, Healthcare Inspectorate Wales - the independent inspectorate and regulator of healthcare in Wales
- in Northern Ireland, the Regulation and Quality Improvement Authority - responsible for inspecting the availability and quality of health and social care services
- in Scotland, Care Inspectorate Scotland - responsible for regulating independent healthcare services.

6 Equality and health inequality considerations

We have undertaken an *Equality and Health Inequalities Screening Tool* in accordance with NHS England requirements. A review of the screening tool by the specialist NHS England team indicated that a full Equality and Health Inequalities assessment is required alongside the consultation to collate responses.

During the consultation we will assess if the proposal will make it easier for people to get the medicines they need when they need them, avoiding the need for people to see additional health professionals just to receive medicines. This may remove or minimise disadvantages suffered by vulnerable people when accessing medicines.

6.1 Public sector equality duty

Public bodies within England, Scotland and Wales have legal obligation under the Equality Act 2010[52], and are required to have due regard to the aims of the Public Sector Equality Duty[53] (PSED) set out at section 149 of the Equality Act 2010, in exercising their functions, such as when making decisions.

There are three aims to the PSED and public bodies must, in exercising their functions, have due regard to them all. They are the need to:

- eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010
- advance equality of opportunity between persons who share a relevant protected characteristic and persons who do not share it
- foster good relations between persons who share a relevant protected characteristic and persons who do not share it

The PSED covers the following protected characteristics:

- age
- disability
- gender reassignment
- pregnancy and maternity
- race (includes ethnic or national origins, colour or nationality)
- religion or belief (includes lack of belief)
- sex
- sexual orientation
- marriage and civil partnership (but only in regard to the first aim of the PSED- eliminating discrimination and harassment)

As this is a UK-wide consultation, due regard has also been given to the requirements of section 75(1) of the Northern Ireland Act 1998[54] which requires all public authorities in carrying out their functions relating to Northern Ireland to have due regard to the need to promote equality of opportunity between:

- persons of different religious belief, political opinion, racial group, age, marital status and sexual orientation
- men and women generally

[52] Equality Act 2010
[53] Public Sector Equality Duty 2011
[54] Northern Ireland Act 1998

- persons with a disability and persons without
- persons with dependants and persons without

Furthermore, section 75(2) of the 1998 Act requires public authorities without prejudice to their obligations under subsection (1) to have regard to the desirability of promoting good relations between persons of different religious belief, political opinion and racial group.

6.2 Health inequality duties

Health inequalities have been defined as 'differences in health status or in the distribution of health determinants between different population groups' by the World Health Organisation. The National Health Service Act 2006 as amended by the Health and Social Care Act 2012[55] established specific legal duties on NHS England and NHS Improvement to 'have regard' to the need to reduce inequalities between patients in access to, and outcomes from, healthcare services and in securing that services are provided in an integrated way.

The Act does not define a list of groups impacted by the duties, any group experiencing health inequalities is covered. This means that NHS England and NHS Improvement must consider the whole of the population for which they are responsible, identify inequalities within that population group and have regard to the need to reduce inequalities when exercising their functions.

The consultation process provides a further opportunity to consider the potential positive and negative impact of the proposed changes on equality and health inequalities and to seek the views of responders. We and the devolved administrations will give due regard to responses received and we will be developing a fuller Equality and Health Inequalities impact assessment alongside the consultation.

[55] Health and Social Care Act 2012

7 Consultation format

7.1 Who can respond to this consultation?

Everyone is welcome to respond. We hope to hear from the public, patients, patient representative groups, carers, voluntary organisations, healthcare providers, commissioners, dentists, doctors, pharmacists, operating department practitioners, other allied health professionals, nurses, regulators, the Royal Colleges and other representative bodies.

We are grateful to individuals and organisations who take the time to respond to this consultation.

7.2 How to respond

If you would like to respond to this consultation you can do so by:

- completing the online questionnaire
- requesting a paper copy of the consultation response form to be posted to you by contacting: england.cpomedicinesmech@nhs.net

  Please complete this form and return it to:

  CPOMM Programme Team
  NHS England and NHS Improvement
  5W06 Quarry House
  Quarry Hill
  Leeds
  LS2 7UE

Responses should be sent to arrive no later than 10th December 2020.

This consultation remains open for eight weeks and will close on **10th December 2020**.

7.3 Alternative formats

- A patient and public summary version of this consultation guide is available; it can be made available in alternative formats, such as large print and easy read, and may be available in alternative languages, upon request. Please contact england.cpomedicinesmech@nhs.net
- A paper copy of the patient and public summary consultation guide is available on request. Please contact england.cpomedicinesmech@nhs.net

7.4 Engagement events

Engagement events will be held online during the consultation period. These will provide an opportunity for those attending to find out more about the proposals and the consultation process.

To register or find out more information about any of these events please go to: https://www.england.nhs.uk/medicines-2/chief-professions-officers-medicines-mechanisms-programme/.

7.5 How we will use your responses

Following close of the consultation, we will review, analyse and consider all responses received. A summary of the responses will be published on the NHS England website.

Under the General Data Protection Regulation, NHS England and NHS Improvement will be data controller for any personal data you provide as part of your response to the consultation. NHS England and NHS Improvement have statutory powers they will rely on to process this personal data which will enable them to make informed decisions about how they exercise their public functions.

If you respond as an individual, we will anonymise your response but we may publish your response in part or full unless you tell us not to. If you respond on behalf of an organisation, we will list your organisation's name and may publish your response in full unless you tell us not to. If you would like any part of your response to stay confidential, you should explain why you believe the information you have given is confidential. We may need to disclose information under the laws covering access to information (usually the Freedom of Information Act 2000). If you ask us to keep part or all of your response confidential, we will treat this request seriously and try to respect it but we cannot guarantee that confidentiality can be maintained in all circumstances.

7.6 Next steps

The proposed changes to medicines legislation and the findings of the consultation will be presented to the Commission on Human Medicines who make recommendations to Ministers regarding changes to the Human Medicines Regulations. Subject to the agreement of Ministers, the Medicines and Healthcare products Regulatory Agency (MHRA) will make the necessary amendments. The Human Medicines Regulations are co-signed by the Secretary of State and the Minister of Health in Northern Ireland and apply UK-wide so changes to them will apply across the four countries.

As this proposal is also in relation to controlled drugs, changes to the Misuse of Drugs Regulations are also required. The proposed changes to medicines legislation and the findings of the consultation will be presented to the Advisory Council on the Misuse of Drugs who makes recommendations to Ministers regarding changes to the Misuse of Drugs Regulations. Subject to the agreement of Ministers, the Home Office will then make the necessary amendments.

The Misuse of Drugs Regulations apply only to England, Wales and Scotland; the Misuse of Drugs (Northern Ireland) Regulations 2002 will need to be amended separately and this will be undertaken by the Department of Health in Northern Ireland.

If all elements of the proposal are approved and all relevant organisations are in a position to complete their elements of the work at the earliest possible point without delay, the proposed changes to the Human Medicines Regulations and the Misuse of Drugs Regulations could come into force in 2021.

Each nation is responsible for making amendments to the NHS Pharmaceutical regulations in their own country. The NHS regulations in that country must be amended before the changes can be implemented. The resultant focus and pace of this in each respective country are matters for each nation.

8 Appendices

8.1 Appendix A: Contributors

8.1.1 Chief Professions Officers' Medicines Mechanisms Programme Board

Name	Organisation	Organisational Role
Professor Martin Stephens (Chair)	University of Portsmouth/NHS England and NHS Improvement	Visiting professor/Local Pharmacy Network Chair
Suzanne Rastrick (SRO)	NHS England and NHS Improvement	Chief Allied Health Professions Officer
Shelagh Morris (until 30.6.18)	NHS England and NHS Improvement	Deputy Chief Allied Health Professions Officer
Fiona Carragher (until 31.12.18)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Angela Douglas (from 1.4.19)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Janet Clarke	NHS England and NHS Improvement	Deputy Chief Dental Officer
Dr Bruce Warner	NHS England and NHS Improvement	Deputy Chief Pharmaceutical Officer
Helen Marriott (until 31.12.18)	NHS England and NHS Improvement	Programme Lead
Dianne Hogg (until 30.9.19)	NHS England and NHS Improvement	Programme Manager (until 13.1.19) Programme Lead (from 14.1.19)
Lois Quayle (from 1.10.19)	NHS England and NHS Improvement	Programme Lead
Claire Potter	Department of Health and Social Care	Medicines Regulation & Prescribing
Graham Prestwich	NHS England and NHS Improvement	Patient & Public Representative
Bill Davidson	NHS England and NHS Improvement	Patient & Public Representative
Anne Ryan	Medicines and Healthcare products Regulatory Agency	Policy Division
Katherine Gough	NHS Dorset CCG	Head of Medicines Management
Dr Joanne Fillingham	NHS Improvement	Clinical Director Allied Health Professions, Deputy Chief AHP Officer
Professor Iain Beith	Council of Deans for Health	Head of a multidisciplinary Health and Social Care School
Graham Mockler	Professional Standards Authority	Head of Accreditation
Samina Malik	Health Education England	Senior Education and Training Policy Manager
Jan Beattie	Scottish Government	Allied Health Professions Officer for Primary Care
Dr Rob Orford	Welsh Government	Chief Scientific Adviser (Health)
Dr Mark Timoney (until 7.12.18)	Northern Ireland Government	Chief Pharmaceutical Officer
Hazel Winning (from 1.1.19 – 1.9.19)	Northern Ireland Government	Lead Allied Health Professions Officer
Steven Sims	NHS England and NHS Improvement	Programme Coordinator
Victoria Ryan (until 11.12.18)	NHS England and NHS Improvement	Programme Administrator

8.1.2 Patient group directions project working group

Name	Organisation	Organisational Role
Fiona Carragher (chair) (until 31.12.18)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Angela Douglas (chair) (from 1.4.19)	NHS England and NHS Improvement	Deputy Chief Scientific Officer
Shelagh Morris (until 30.6.18)	NHS England and NHS Improvement	Deputy Chief AHP Officer
Thomas Kearney (from 1.12.18)	NHS England and NHS Improvement	Deputy Chief AHP Officer
Helen Marriott (until 31.12.18)	NHS England and NHS Improvement	Programme Lead
Dianne Hogg (until 30.9.19)	NHS England and NHS Improvement	Programme Manager (until 13.1.19) Programme Lead (from 14.1.19)
Lois Quayle (from 1.10.19)	NHS England and NHS Improvement	Programme Lead
Karen Stewart	Scottish Government	Healthcare Science Officer
Professor Ian Young	DoH Northern Ireland	Healthcare Science Officer
Dr Rob Orford	NHS Wales	Chief Scientific Adviser (Health)
Tracy Rogers	Specialist Pharmacy Service	PGD specialist advice
Jo Jenkins	Specialist Pharmacy Service	PGD specialist advice
Hannah Abbott	College of Operating Department Practitioners	President
Tracey Williams	The Association for Perioperative Practice	AfPP trustee & vice-president
Dr Jane Needham	Institute of Biomedical Science	Haematology advisor
Denise Cook	Institute of Biomedical Science	Microbiology advisor
Catherine Ross	The Society for Cardiological Science & Technology	President
Dr Jagjit Sethi	British Academy of Audiology	Immediate past president
Manoj Mistry	NHS England and NHS Improvement	Patient & public representative
Ayath Ullah	NHS England and NHS Improvement	Patient & public representative
Steven Sims	NHS England and NHS Improvement	Programme Coordinator

Victoria Ryan (until 11.12.18)	NHS England and NHS Improvement	Programme Administrator

8.2 Appendix B: Role of the professional bodies

8.2.1 The College of Operating Department Practitioners (CODP)

CODP is the only professional body dedicated to representing ODPs and has approximately 6000 members. The College sets the standards of education for the profession and promotes the enhancement of knowledge and skills in the development of the profession through regional, national and international networks. The College works on behalf of the profession in the context of the multidisciplinary team and as such collaborates with other perioperative organisations.

8.2.2 Association for Perioperative Practice (AfPP)

AfPP was established as the National Association for Theatre Nurses in 1964 and changed its name in 2005 to be able to offer full membership to other perioperative staff including ODPs. AfPP is a membership organisation and a registered charity that works to enhance skills and knowledge within operating departments, associated areas and sterile services departments.

8.3 Appendix C: Best practice use of PGDs

The Human Medicines Regulations require that PGDs are signed by a doctor (or dentist) and a pharmacist, and on behalf of an authorising body. It is good practice that a member of the healthcare profession working under the PGD is also involved in the development of the PGD. The person signing on behalf of the authorising body is often the clinical governance lead who has designated responsibility for signing PGDs on behalf of the authorising body. This responsibility may be delegated by the committee responsible for clinical governance within the organisation. NICE provides guidance on the writing, authorising, implementation and use of PGDs[56].

The legislation also specifies which registered health professionals can use PGDs to supply and administer medicines. Student health professionals are not allowed to work under a PGD unless they are already on the appropriate register; for example, a student health visitor may already be a registered nurse, so would be allowed to work under a PGD.

Healthcare practitioners working under a PGD will need to ensure they have met the training and competency requirements that are detailed in the PGD. They cannot work under a PGD whilst acquiring these skills; for example, a physiotherapist undertaking training in intra-articular injection technique cannot do this under a PGD, unless they have been assessed as competent and authorised to practise by their manager

A health professional working under a PGD is not permitted to delegate the work to another member of staff under the PGD.

Which medicines can be supplied and / or administered under PGD?

Medicines fall into three legal categories, general sales list, pharmacy medicines, and prescription only medicines. PGDs are necessary to administer or supply prescription only medicines, they are required to supply a pharmacy medicine by authorised health professionals other than pharmacists, but are not needed to administer pharmacy medicines, or administer or supply general sales list medicines.

Where a PGD is not required it is good practice to use a written protocol. Some organisations choose to use a PGD in these situations as they value the rigorous governance arrangements that PGDs offer.

There are five schedules of controlled drugs, some of which can be included under a PGD. Table 2 below gives further details regarding the inclusion of controlled drugs within PGDs. Appendix D which lists the professions that are currently eligible to operate under PGDs shows that most of the professions can also use them to supply and administer controlled drugs.

[56] NICE (2017) *Patient group directions: tools and resources*

Schedule	Examples of controlled drugs	Which controlled drug can a PGD be used for?
Schedule 1	No therapeutic use e.g. LSD and you need a licence to produce, possess or supply	None
Schedule 2	Includes diamorphine, morphine, amphetamines, ketamine	Ketamine, by all eligible staff groups. Morphine and diamorphine in specific circumstances only by nurses and pharmacists
Schedule 3	Includes minor stimulants and other controlled drugs (such as buprenorphine, temazepam, midazolam)	Only midazolam, by all eligible staff groups
Schedule 4	Includes most of the benzodiazepines (except temazepam and midazolam) plus non-benzodiazepine hypnotics. Anabolic steroids and growth hormones	All controlled drugs except anabolic steroids and injectables used for treating addiction
Schedule 5	Certain controlled drugs (such as codeine, pholcodine and morphine) that are exempt from full control when present in medicinal products of specifically low strengths	All controlled drugs

Table 2: the inclusion of controlled drugs within PGDs

Restrictions to what can be supplied and / or administered under a PGD

- Abortifacients and radiopharmaceuticals cannot be administered under PGD
- Unlicensed medicines (medicines that do not have a UK marketing authorisation) cannot be given under PGD. This includes medicines that are specially prepared for a patient, sometimes called ‘specials’.
- Off-label or off-licence is defined as a medicine being used outside of the terms of its UK marketing authorisation (license), such as outside defined indications, doses or routes of administration. For example, when amitriptyline, which is licensed for the treatment of depression, is used for neuropathic pain. As long as this is clearly justified by best clinical practice it would be allowed under a PGD.
- Mixing one medicine with another will usually result in a new unlicensed product being created, unless one product can be described as a vehicle for the administration of the other e.g. as a reconstitution or diluting agent. An example is when ipratropium nebulising solution is mixed with salbutamol nebulising solution prior to administration, making a new unlicensed product; this cannot be administered under a PGD.
- Antimicrobials can be used in PGDs but only when it is clinically essential and clearly justified by best practice guidance, has been agreed by a local specialist in microbiology and their use is monitored and reviewed regularly (see section 5.4).

- Dressings and appliances cannot be supplied or administered under PGD as they are not medicines.

Clinical scenarios that PGDs should not be used in

NICE guidance states that PGDs should not be used in these clinical situations:

- when a medicine needs frequent dosage adjustments or frequent or complex monitoring in a PGD (for example, anticoagulants or insulin)
- when dose adjustments are required to a medicine supplied under a PGD when the medicine is already in the patient's possession
- management of long-term conditions, such as hypertension or diabetes
- when uncertainty remains about the differential diagnosis

Further considerations

- The medicine will need to be available at the time of supply or administration. When the medicine is supplied to the patient to take away then the medicine must be appropriately packaged and labelled. All medicines need to be suitably stored in medicine cupboards or medicine refrigerators which meet the safe storage requirements.
- Where medicines are supplied to a patient to take away there is a requirement to levy a prescription charge where applicable unless the medicine does not require a fee to be charged (e.g. contraceptives, treatment of STI or TB) or the patient is exempt. For convenience, some NHS organisations have introduced systems that avoid health professionals collecting the charges themselves. Examples include arranging for finance departments to invoice patients following treatment and installing pay machines which issue tokens with which patients pay their prescription charges.
- If an exemption exists in the Human Medicines Regulations that allow the medicine to be administered or supplied this mechanism should be used instead of a PGD. For example, adrenaline injection for anaphylaxis is exempt and a local protocol would be the preferred option.
- The authorisation of PGDs by independent healthcare providers is related to the services in which they are used, not the setting. Private services that are required to be registered with the Care Quality Commission in England, the Healthcare Inspectorate in Wales, the Care Inspectorate in Scotland, or the Regulation and Quality Improvement Authority in Northern Ireland are able to authorise PGDs to be used by that service. If the service provided by the independent provider does not require registration then a PGD cannot be used. If the service is commissioned by the NHS/public health the PGD must be authorised by the commissioner in addition to the provider. All NHS services including those purchased from independent providers must adhere to NICE guidance[57]. ODPs working in an appropriately registered service within an independent provider must ensure that the same level of governance is in place in the organisation before PGDs are used.
- PGDs are not transferrable from one organisation to another; this means that an ODP who works across two organisations cannot use the same PGD in both organisations unless both have authorised the PGD.

[57] NICE (2013) *Patient group directions: medicines practice guideline*

8.4 Appendix D: Registered health professions legally able to use PGDs

Profession	Date commenced using PGDs	Able use PGDs to supply and administer the controlled drugs listed in table 2
Dental hygienists	2010	
Dental therapists	2010	
Dietitians	2003	
Midwives	2000	√
Nurses	2000	√
Occupational therapists	2003	√
Optometrists	2000	√
Orthoptists	2000	√
Paramedics	2000	√
Pharmacists	2000	√
Physiotherapists	2000	√
Podiatrists/chiropodists	2000	√
Prosthetists and orthotists	2003	√
Radiographers - diagnostic	2000	√
Radiographers - therapeutic	2000	√
Speech & language therapists	2003	

8.5 Appendix E: Frequently asked questions.

1) Why is the use of PGDs proposed for ODPs?

There are many potential benefits for patients, commissioners and health care providers. The proposed use of PGDs by ODPs has the potential to improve patient safety by reducing delays in care, improving compliance with medicines; improving patient experience through increased access, convenience, choice and productivity within multi-disciplinary teams. and supporting clearer lines of professional responsibility. Enabling ODPs to use PGDs would ensure patients receive the appropriate medicines in a timely manner and thus optimise care.

2) Would all ODPs be able to use PGDs?

It is proposed that only ODPs who are currently registered by the HCPC to practise and who have an identified clinical need for PGDs within their scope of practice will be eligible to train to use PGDs. However, local organisations would decide whether a PGD is appropriate for use within a clinical service, in line with national guidelines and local governance.

3) What training would ODPs undertake, if permitted to use PGDs?

As part of the registration pre-requisites, ODPs must demonstrate a comprehensive understanding of the pharmacology of the medicines used within the ODP scope of practice. Under the current arrangements, ODPs complete both pre-registration education and mandatory training related to medicines within their employing organisation. NICE[58] strongly recommends that all health professionals who are required to use PGDs undertake training prior to use. Locally provided training or access to a national e-learning programme such as that provided for England by the Centre for Postgraduate Pharmacy Education could fulfil that requirement. Local governance arrangements will need to ensure that ODPs working under a PGD have met the training and competency requirements detailed within the PGD.

4) What assurances are there that it would be safe to enable ODPs to supply and administer medicines using PGDs?

Patient safety remains of paramount importance. All PGDs that are written for ODPs to use would have patient safety as their primary concern. If changes to legislation occur, ODPs would be expected to meet the requirements of the competency frameworks[59] before using PGDs. Additionally, ODPs are required to work within their employers' clinical governance frameworks and are accountable for their actions to both their employers and regulatory body.

5) Would ODPs be able to supply and administer medicines to children if permitted to use PGDs?

It is proposed that ODPs using PGDs would be authorised to supply and administer medicines to children within their paediatric scope of practice and competence. ODPs have experience in supply and administration of medicines for children via PSDs. In addition, local and national policies and procedures would be followed which address medicine management issues in paediatrics.

6) What assurances are there that the proposed use of PGDs by ODPs would not increase antimicrobial resistance?

All healthcare workers have a vital role to play in preserving the usefulness of antimicrobials by controlling and preventing the spread of microbes. It is proposed that ODPs who would

[58] NICE (2017) *Patient group directions: medicines practice guideline*

[59] NICE (2017) *Patient group directions: tools and resources*

be authorised to supply or administer antibiotics using PGDs must be familiar with the requirements of their role in promoting the appropriate use of these medicines (antimicrobial stewardship) and to use readily available resources including education programmes. They would be required to work within their scope of practice *Antimicrobial Prescribing and Stewardship Competencies*[60]. They would also be required to follow local policies for antimicrobial use.

7) What assurances are there that the proposed use of PGDs by ODPs would not contribute to oversupply of medication?

ODPs are professionally responsible for ensuring that they adhere to national and local standards of supply and administration of all medicines. Medicines supply and administration is not an activity that occurs in isolation, so it is proposed that ODPs using PGDs would communicate with other practitioners involved in the care of patients in order to ensure that medicines supply is not duplicated and is appropriate for the condition to be treated.

8) Would there be an increase in the use of medicines with increased associated costs to the system?

It is proposed that the medicines that ODPs would administer or supply using PGDs includes only those that would otherwise be prescribed for their patients. As additional appointments and intervention by other health professionals just to administer or supply a medicine will be prevented, it is expected that costs to the system would fall.

9) How would ODPs maintain their competency in the use of medicines if permitted to use PGDs?

ODPs are required to undertake CPD relevant to their practice to maintain and demonstrate continuing competence. To maintain registration with the HCPC, ODPs must sign a professional declaration once every two years to confirm that they continue to meet the HCPC's standards of proficiency for safe and effective practice, and that they meet the HCPC's standards for CPD.

Examples of CPD for ODPs include:

- formal training courses
- peer supervising and teaching
- attending professional symposium events
- recording self-reflection
- presenting at and / or attending conferences
- membership of professional committees or special interest groups

ODPs working within the NHS also require annual appraisals, of which medicines management will be a part.

10) Would ODPs working outside the NHS be permitted to use PGDs?

Yes, provided that the PGD is authorised in the organisation and that they are written, authorised and implemented in line with the governance requirements of the NICE Medicines Practice Guideline[61]. See section 5.5 for further information.

[60] Department of Health and Public Health England (2013) *Antimicrobial prescribing and stewardship competencies*

[61] NICE (2017) *Patient group directions: medicines practice guideline*

9 Glossary

Term	Explanation
Administration of medicines:	Process by which a medicine is introduced into, or applied onto, the patient's body.
Chief Professions Officers' Medicines Mechanisms (CPOMM) Programme:	An NHS England and NHS Improvement programme of work to extend the supply, administration or prescribing responsibilities to regulated health professions where there is an identified need and benefit to patients. The programme aims to make it easier for people to get the medicines they need when they need them, avoiding the need for people to see additional health professionals just to receive medicines.
Commission on Human Medicines (CHM):	Advises ministers on the safety, effectiveness and quality of medicinal products and on changes to medicines law.
Continuing professional development (CPD):	Activities which help health professionals continue to learn and develop throughout their career to keep their skills and knowledge up to date so they are able to practise safely and effectively.
Controlled drugs:	Controlled drugs are medicines that are classified in the UK-wide Misuse of Drugs Act 1971 based on their benefit when used in medical treatment and their harm if misused. Strict legal controls apply to controlled drugs to prevent them being misused, being obtained illegally or causing harm. The measures include how controlled drugs can be stored, administered, supplied and recorded.
Controlled Drugs Accountable Officer (CDAO):	Person responsible for all aspects of controlled drugs management within their organisation. The roles and responsibilities of CDAOs, and the requirement to appoint them, are governed by legislation[62] [63] [64].
Department of Health and Social Care (DHSC):	The central government department with responsibility for leading the nation's health and social care system to help people live more independent, healthier lives for longer.
Health and Care Professions Council (HCPC):	The regulator of 16 different health and care professions including operating department practitioners. It maintains a register of health

[62] The Controlled Drugs (Supervision of Management and Use) Regulations 2013
[63] The Controlled Drugs (Supervision of Management and Use) (Wales) Regulations 2008 (No 3239) (W. 286)
[64] The Controlled Drugs (Supervision of Management and Use) Regulations (Northern Ireland) 2009

Term	Explanation
	and care professionals that are fit to practise in the UK and is responsible for setting the standards of education, proficiency, conduct, performance, character and health for these professionals.
Human Medicines Regulations 2012:	Set out a comprehensive process for the authorisation of medicinal products for human use; for the manufacture, import, distribution, sale and supply of those products; for their labelling and advertising; and for pharmacovigilance. They also set out which health professionals can prescribe medicines, and which can use PGDs and exemptions to supply and administer medicines.
Independent prescriber:	A practitioner responsible and accountable for the assessment of patients with undiagnosed and diagnosed conditions and for decisions about clinical management, including the prescribing of medicines.
Licensed medicine:	A medicine must be granted a licence by the appropriate body before it can be widely used in the UK. A licence indicates all the proper checks have been carried out and the product works for the purpose it is intended for.
Medicines and Healthcare products Regulatory Agency (MHRA):	Responsible for regulating all medicines and medical devices in the UK by ensuring they work and are as safe as possible. They are also responsible for making changes to medicines legislation that have been agreed by government. The MHRA is a part of the DHSC.
Misuse of Drugs Regulations (MDR) 2001	Allow for the lawful possession and supply of controlled (illegal) drugs for legitimate purposes. They cover prescribing, administering, safe custody, dispensing, record keeping, destruction and disposal of controlled drugs to prevent diversion for misuse.
Mixing of medicines:	The combination of two or more medicinal products together for the purposes of administering them to meet the needs of a particular patient, where one is not the diluent of the other.
Patient Group Direction (PGD):	A written instruction for medicines to be supplied and / or administered by groups of

Term	Explanation
	health professionals to certain groups of patients. They contain information as to which health professionals can supply or administer the medicine, which patients they can see, and when they should involve a doctor or dentist.
Patient Specific Direction (PSD):	A prescriber's written instruction for medicines to be supplied and / or administered to a named patient after the prescriber has assessed the patient on an individual basis.
Prescription Only Medicine (POM):	A medicine that is generally subject to the requirement of a prescription written by an appropriate practitioner (prescriber) before it can be administered or supplied to a patient. There are several exceptions that allow POMs to be administered or supplied without a prescription, including PGDs and exemptions listed in legislation.
Supply of medicines:	The activities undertaken, in response to formal orders, when medicines are issued to the place where they will be used or supplied directly to the patient.
Unlicensed medicines:	Medicines that are used outside the terms of their UK licence or which have no licence for use in the UK. Unlicensed medicines are commonly used in some areas of medicine such as in paediatrics, psychiatry and palliative care.

This information can be made available in alternative formats, such as easy read or large print, and may be available in alternative languages, upon request. Please email england.cpomedicinesmech@nhs.net.

A patient and public summary version of this consultation guide is available.