PrescQIPP Community Interest Company

Commissioning medicines in service redesign – How to guide

This guide focuses on the inclusion of medicines in service redesign. It looks at how to ensure that services and care pathways include medicines which are safe, deliver improved patient outcomes, offer patient choice, a good patient experience and provide clinically effective and cost effective treatment.[1] In the context of this guide the term medicines also refers to devices, dressings and other healthcare products (such as oral nutritional supplements).

Much of this bulletin is based on documents produced by the NHS Specialist Pharmacy Service and this is gratefully acknowledged.

Recommendations

- Ensure that the supply and administration of medicines is considered in the early stages of the service redesign process.
- Consider how medicines included in the service will be supplied, for example; on an FP10; under a Patient Group Direction (PGD); direct supply of medicines or appliances to be personally administered.
- Ensure medicines supply systems are in place when a new service opens or starts.
- Medicines included in the service should comply with local formulary recommendations.
- Medicines services should be ratified by the local area prescribing committee if applicable.
- Consider any possible transfer of care issues. For example when medicines are initiated or stopped – how will this be communicated between different care settings.
- If the service requires any additional funding and/or a prescribing budget (also known as cost centre), consider how this will be funded (programme budgeting or prescribing budget top slice).
- Ensure information about the new service and the key contacts involved are communicated to wider stakeholders, for example community pharmacists.
- Develop processes to monitor and ensure medicines services are safe and appropriate.

Background

Medicines are the most common treatment intervention and are used in most services and care pathways.[2] Therefore early consideration of pharmaceutical requirements, governance requirements and logistical requirements relating to medicines is key to a successful service redesign.[3]

The King's Fund is an independent charity working to improve health and health care in England. They recommend that urgent action is needed to prepare the health and social care system for an ageing population and the increasing prevalence of long-term conditions.[4] In this rapidly changing NHS, reforms and service redesign are inevitable and will undoubtedly involve medications. The commissioners are responsible for ensuring services and pathways in which medicines are used are commissioned to standards that deliver cost effective use of resources, reduced risks associated with medicines use, improved patient outcomes and experience.[2]

NHS England has a useful guide for commissioners considering, and involved in, service reconfiguration to navigate a clear path from inception to implementation. It will support commissioners when considering how to take forward their proposals, including effective public involvement. It enables them to reach robust decisions on change in the best interests of their patients.[5] The guide "Planning, assuring and delivering service change for patients" is available here: www.england.nhs.uk/resources/resources-for-ccgs/#service-change

NHS England also gives Clinical Commissioning Groups (CCGs) practical support in gathering data, evidence and tools to help them transform the way care is delivered for their patients and populations. Commissioning for Value comprehensive data packs are of particular interest to CCG clinical and management leads with the responsibility for finance, performance, improvement and health outcomes; to NHS England regional team leads; and to commissioning support teams who are helping CCGs with this work.[6] The NHS Right Care is now part of NHS England; they are working with Public Health England to provide a suite of materials to support effective commissioning for value. This includes a range of comprehensive data packs and online tools.[6] More information, links to NHS Right Care resources and the data packs are available here: www.england.nhs.uk/resources/resources-for-ccgs/comm-for-value/

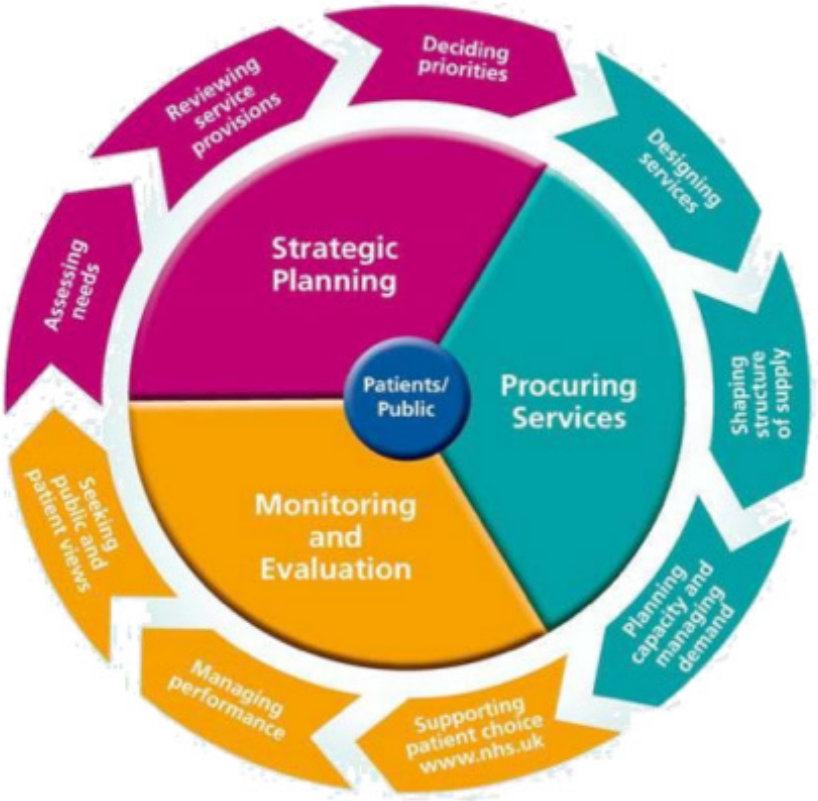
The East and South East England Specialist Pharmacy Services have produced two documents - The Medicines in Commissioning Checklist and Optimising Medicines Use in Care Pathways. These two resources are interlinked and help ensure that high quality, cost effective, accessible medicines management services are commissioned and provided within new and redesigned patient services. The resources emphasise the delivery of QIPP and the NHS Outcomes Framework and, above all, demonstrate how to maximise patient outcomes through medicines optimisation.[1]

The resources have been developed by senior pharmacists to support both commissioners and service providers to help plan, secure and monitor aspects of services that involve medicines. They can be used to identify and address medicines-related issues in pathways and service specifications. This is to ensure compliance with both legal and quality standards such as Care Quality Commission (CQC) Standards. The checklist supports the components of the commissioning cycle.

Figure 1: The commissioning cycle Reproduced from Specialist Pharmacy Services medicines in commissioning checklist document https://www.sps.nhs.uk/wp-content/uploads/2014/11/Meds_in_Commissioning_Checklist_Vs5.1_Nov14_JW.pdf

Strategy Planning
Assess Needs and Provision Review Impact on local Pharmaceutical Needs Assessment
Deciding Priorities and Investments What are the risks if current services are to be de-commissioned?
Patient Safety and Governance Are key performance indicators & outcome measures that support the governance of medicines built into the specification?
Funding Aspects Has funding been identified for medicines, supply & storage systems, and any training needs for staff?
Legal Aspects Would the service comply with NHS regulations?
Patient Experience How will choice, information needs and access to medicines be addressed?

Monitoring and Evaluation
Patient Safety and Governance Is there a robust Medicine Policy and are Standard Operating Procedures or protocols in place for all processes involving medicines?
Legal Aspects Are the arrangements for prescription, supply and administration of medicines within the law?
Staff training and competency What training and competencies are required for staff who will be delivering the service?
Funding Aspects Has funding been identified to ensure the service has safe systems & equipment for optimal medicines management?
Patient Experience Are medicines prescribed for which regular monitoring is essential for patient safety?



Procuring Services
Assess Needs and Provision Review Have all aspects of medicines use been addressed in the service specification?
Patient Safety and Governance Is there a designated person with lead responsibility for the safe and cost effective use of medicines?
Funding Aspects Has funding been identified for all aspects of medicines use?
Legal Aspects Should any other legislation be considered e.g. VAT, Human Rights, Waste Regulations?
Service Delivery Will medicines be administered as part of the service and how will they be sourced?
Staff training and competency Are there enough staff to deliver the service?

Patients and the Public
Assess Needs and Provision Review Who are the potential providers?
Patient Safety and Governance Is there a clear communication process about current medication & recent changes to medication wherever care is delivered to the patient
Legal Aspects Are the staff that will be employed to provide the service appropriately qualified, competent, and registered for the activity being commissioned?
Service Delivery How will patients access medicines?
Patient Experience Do patients and/or their carers have their medicines explained to them? Do they know how to access advice and information after they have left the care setting?

The other supporting medicines in commissioning resources can be found on the Specialist Pharmacy Services website at: https://www.sps.nhs.uk/articles/medicines-in-commissioning-resources/

Medicines supply and administration in service redesign

To get medicine use right, it is important that the supply and administration of medicines is considered in the early stages of the service redesign or pathway commissioning process. To help identify the extent to which medicines are involved in the service or pathway consider the following questions (taken from SPS mecicines in commissioning checklist for further information see https://www.sps.nhs.uk/wp-content/uploads/2014/11/Meds_in_Commissioning_Checklist_Vs5.1_Nov14_JW.pdf):

Will the proposed service/pathway involve:

- Treatment with medicines?
- Prescribing of medicines?
- Supply/dispensing of medicines?
- Procurement of medicines?
- Administration of medicines to patients?

If the answer is "yes" to any of these questions seek assistance from the Medicines Management Team.[2]

If medicines use is not considered early in the commissioning process, it can result in several outcomes including the following examples:

- Service provision delayed because of failure to allocate time for the development of Patient Group Directions (PGDs).
- Service provision delayed because the service did not comply with the National Patient Safety Agency requirements for delivery of Anticoagulant Services.
- Service had to be withdrawn from a provider who was found to be operating illegally.[2]

Once it has been identified that medicines use will be involved in the service redesign or pathway it is important to consider how the medicines will be supplied. Will the medicine be supplied to the patient on an FP10 NHS prescription form; will it be given to the patient under a PGD; will pre-packed medicines be supplied directly; or will the medicine be personally administered to the patient? It is important that, no matter how the medicines are to be supplied to the service users or patients in the pathway, that the supply systems are in place for when the service is launched to avoid delaying service provision.

FP10 prescription

If NHS FP10 prescription forms are to be used as part of the service or pathway, it is important to remember that the cost of providing this NHS service is recharged to the organisation who provided patients with the prescription. The patient presents this prescription to a pharmacy (or appliance dispensing contractor) to obtain the medicines (or appliances) required. The NHS Prescription Services (part of the NHS Business Services Authority) invoices either the service provider, or local authority for the prescription costs incurred by this service on a monthly basis.[7] Therefore as part of service redesign it is important to consider who will prescribe; how will prescribing be monitored; how will this be funded, where the budget for this prescribing will come from.

The NHS Prescription Services website has a wide range of useful information on remuneration and reimbursement and is available here: www.nhsbsa.nhs.uk/PrescriptionServices.aspx

The Local Authority and Provider Welcome pack available here: www.nhsbsa.nhs.uk/PrescriptionServices/3879.aspx has information for new organisations providing a service which involves the supply of medicines and appliances using NHS pharmacy services.

The pack contains information on how to obtain and maintain prescribing codes for your organisation and prescribers. To use NHS FP10 prescription forms as part of a service or pathway, an organisation needs an Organisational Data Service (ODS) code to link their prescribers. ODS codes can be issued to

either the commissioner or the provider of the prescribing service, depending on who has responsibility for managing the costs of the service.[7]

It is the role of the authorised signatories within commissioner and provider organisations to set up a new cost centre and to notify NHS Prescription Services of organisational and prescriber changes so that prescribing costs can be attributed to the correct prescriber and prescribing budget, and can then provide accurate and detailed prescribing information.[7] The senior authorised signatory will usually be the Head of Medicines Management/Chief Pharmacist/Director or equivalent within each organisation.[8] The pack contains links to various forms which the authorised signatory can use to set up new cost centres; inform NHS Prescription Services of a doctor or non-medical prescriber joining a cost centre or request a spurious code. A spurious code is needed when:

- A hospital doctor does not have a Doctor Index Number (DIN)
- An additional prescribing code is needed for a GP working in more than one practice/cost centre (so that prescribing in each practice/cost centre can be monitored)
- A generic prescribing code is sufficient because prescribing data is not required at individual prescriber level.[7]

The NHS Prescription Services can only charge the cost of a prescription back to the correct prescriber and prescribing budget if they have been notified of the link between that prescriber and prescribing budget.[7] The pack also has information on how to order FP10 prescription forms; how to reconcile invoices and how to access data about prescribers and services.[7]

Other points to consider if FP10 prescription forms are to be used as part of the service or pathway are:

- Will the service or pathway be using Electronic Prescription Service (EPS)?
- Will the service or pathway involve repeat prescriptions, if so will just one prescription be issued and then prescribing passed back to the patients usual GP?
- Will the service or pathway involve medicines which require titrating? If so how could this be managed?
- Will the service or pathway involve prescriptions for controlled drugs which could require additional governance around the supply, storage and record keeping?
- Will the service or pathway require any shared care protocols?
- What governance will be required for the service or pathway, for example governance arrangements for prescription pads, fitness to practice etc.?

Patient Group Directions (PGDs)

PGDs provide a legal framework that allows some registered health professionals to supply and/or administer a specified medicine(s) to a pre-defined group of patients, without them having to see a doctor (or dentist). However, supplying and/or administering medicines under PGDs should be reserved for situations in which this offers an advantage for patient care, without compromising patient safety.[9] The Specialist Pharmacy Services website has information, resources and examples of PGDs and is available here: https://www.sps.nhs.uk/category/services/guidance-and-governance/patient-group-directions/

If the service or pathway might involve the supply or administration of medicines to patients under a PGD, then the tool "To PGD or not to PGD" is intended for use in the first stage of the process to help consider whether a PGD is appropriate.[10] The aim of this tool is to ensure that patients receive safe and appropriate care and timely access to medicines, in line with legislation.[10] The tool also has links which signpost to legislation, national guidelines and other NHS PGD resources. The tool is available from: https://www.sps.nhs.uk/articles/to-pgd-or-not-to-pgd-that-is-the-question/

If it is considered that a PGD would be appropriate for the service or pathways then other points to consider include:

- Who will write the PGD?
- Who will authorise the PGD in line with legalisation requirements?
- Who will use the PGD?
- How will the PGD be maintained? Who will review and update it?

The National Institute for Health and Care Excellence (NICE) has produced a guideline which provides good practice recommendations for individual people and organisations involved with PGDs, which is available here: www.nice.org.uk/guidance/mpg2

Direct (non FP10) supply of medicines or appliances

The Medicines Act 1968 restricts who can supply medicinal products to patients; only a registered retail pharmacy is permitted to supply non General Sales List (GSL) medicines, i.e. Pharmacy only medicines (P) and Prescription Only Medicines (POM). If a wholesaler were to supply direct to patients this would be classed as a retail transaction and would not be permitted.[11] However there are two exceptions, one where the patient has an immediate need for the medicine (e.g. out of hours supply) and where the doctor administers the medicine themselves (e.g. flu vaccine).[11] In fact the NHS (General Medical Services Contracts) Regulations 2004 Part 4 52 (2) states that a GMS contractor may provide to a patient any drug, medicine or appliance, not being a Scheduled drug, which he or she personally administers or applies to that patient.[11] Therefore it would be acceptable for a contractor working under the GMS regulations to supply a drug, medicine or appliance which is being administered to a patient, for example a nurse supplying a dressing which they are going to personally apply.[11] More information is available in an FAQ from The Pharmaceutical Services Negotiating Committee (PSNC). Although this FAQ has now been archived and some of the terms used are no longer relevant (e.g. PCT) it contains some useful information and is available here: archive.psnc.org.uk/pages/pct_direct_supply_of_medicines_and_appliances_.html

There are some services or pathways where the direct supply route maybe suitable, for example, oral nutritional supplements or wound care. In April 2012 The National Prescribing Centre published "Prescribing of Dressings – Guiding principles for improving the systems and processes for the supply and prescribing of wound dressings".[12] This document describes ten guiding principles for wound management products and wound care pathways. Principle 3 recommends that local health economies should understand their local procurement and prescribing arrangements for dressings across primary, secondary and social care. Historically dressings have been prescribed in primary care on FP10 prescriptions for individual patients. Increasingly, organisations are looking at whether this is the most cost effective and patient centred approach; this has resulted in a number of alternative procurement options.[13]

Table 1. Summary of non-FP10 procurement options and their key features[13]

Taken from SPS Systems and Processes of Wound Care - A QIPP resource of good practice. Procurement and Prescribing Options for Dressings https://www.sps.nhs.uk/articles/optimising-systems-and-processes-of-wound-care-a-qipp-resource-of-good-practice/

Procurement option	Key features
In house purchase using organisation's ordering portal	The organisation purchases the dressings directly from either: 1. One or more community pharmacies. 2. The NHS supply chain. 3. A wholesaler. Whichever route is used the organisation orders and invoices through the trust's existing purchasing system. This system is independent of the dressing product manufacturers. Reporting systems may be basic. Adherence to a formulary will not be built into the system as the system may not restrict product choice.
Online ordering system provided by wound care product manufacturer	Manufacturers online ordering systems. These allow organisations to set up an online ordering system with either: 1. One or more community pharmacies. 2. The NHS supply chain. 3. A wholesaler. The systems are all described as user friendly and similar to on-line grocery shopping. They allow a number of lists to be set up to allow for different products to be used by different practitioners within the organisation. All have suites of reports that can be produced by the company for the organisation. These can be tailored to the needs of the organisation. There may or may not be a requirement to have a number of the company's products on the list of dressings. The most cost effective company may be the one that has most of its dressings on the organisation's formulary
Online ordering system provided by NHS Supply Chain	NHS Supply Chain has its own on line ordering system for dressings called SOLO. It works very similarly to the ordering systems described above but using NHS Supply Chain as the only supplier. Case studies can be found at: www.supplychain.nhs.uk/casestudies The NHS Supply Chain price is used but additional discounts may be available. This system is independent of the dressing product manufacturers. Does not use community pharmacy.

There are some issues that would need to be considered when procuring dressings via the non-FP10 route. Taken from SPS Systems and Processes of Wound Care - A QIPP resource of good practice. Procurement and Prescribing Options for Dressings. https://www.sps.nhs.uk/articles/optimising-systems-and-processes-of-wound-care-a-qipp-resource-of-good-practice/

- The effect on relationships with community pharmacies and Local Pharmaceutical Committees.
- The non FP10 route will attract VAT and will not benefit from the claw back of national average

discount (approximately 7.5%).

- Is there is a requirement to go out to tender? What resources are required for implementation? If invoicing will be direct; what is the administrative burden for this?
- Items dispensed on FP10 are the property of the patient and can only be used by or on that patient. Dressings procured via the non- FP10 route are the property of the organisation so they can be used as a 'stock' items.
- Consider deliveries (frequency, location and who will manage) and storage of products.
- Resources and staff required for stock control and ordering.
- Consider how to ensure formulary adherence, how this could be monitored, how non-formulary items can be accessed for specific patients if required and how anticipated savings are realised.
- Any nurse (including non prescribers) can order dressings for use on a patient. They are accountable so may need to increase their knowledge of the products on the formulary.
- How will data be monitoring and reported?
- Each organisation will have their own policy and procedure for working with industry partners. However dressing choice must be made independently of commercial considerations.
- Implementation of the service in care/residential homes requires careful consideration. It will require robust monitoring arrangements, possibly visits to the care home, possibly a narrower formulary and could have cross-border CCG implications.[13]

Other points to consider in service redesign

In addition to how medicines will be supplied and possibly administered, there are many other points to consider which concern medicines in service redesign.

The medicines in commissioning checklist can be used by commissioners and service providers to ensure that all medicines related issues are considered in service redesign. The checklist is available at: https://www.sps.nhs.uk/articles/medicines-in-commissioning-resources/ Below is a summary of the key points from this checklist.

1. Does the service or pathway comply with current legislation and NHS regulations?

For example does it comply with CQC standards, NHS and non-NHS provider regulations? Will the service require licences, a medicines policy, Standard Operating Procedures (SOPs), processes or PGDs? Does it comply with controlled drug (CD) safe handling requirements, waste and VAT regulations if necessary?

2. Does the service or pathway comply with current evidence and best practice guidance?

For example does it comply with The Royal Pharmaceutical Society standards, national NICE guidelines, the local formulary and prescribing guidelines? Does the service require ratification by the local area prescribing committee? Is a risk register required? Is there a process for reviewing and reporting adverse reactions and medication errors? Is a Medication Safety Officer required? Are there processes in place to allow safer transfer of care relating to medicine issues? The PrescQIPP webkit: www.prescqipp.info/transfercare can be used to support transfer of care processes.

3. Will the service or pathway result in a need to decommission services?

How will the transition period and staff transfer be managed?

4. Will the service or pathway have cost implications for the way in which medicines are used compared to current arrangements?

Will prescribing occur in primary or secondary care? How will you ensure prescribing is cost effective?

How will funding be calculated? How will funding be transferred to the new service or pathway? Will additional funding and/or a prescribing budget be required? How will this be funded (programme budgeting or prescribing budget top slice)? Who will be responsible for funding, the CCG or NHS England?

5. Will the service or pathway be provided by staff adequately trained in the activities required?

Will staff require professional registration? Will they need to undertake revalidation? Will you need a designated person responsible for the safe use of medicines? Are clinical governance framework and/or competency frameworks required?

6. Will the service or pathway enhance patient safety, understanding of medicines and overall experience?

Have potential providers got the capacity and capability to deliver the service or pathway. Is patient involvement in service redesign required? How will providers deal with complaints? Who is responsible for checking patients' understanding and adherence to treatment? Are there systems to support self-administration? Who do patients contact for information about their medicines? Will this information be written? If so who will be responsible for timely updates of this information? Do you need to hold patient information and if so who is responsible for completing the records?

7. Will the service or pathway require Key Performance Indicators (KPIs) and outcome measures to monitor performance?

How will the service be monitored - activity measures, quality measures, performance against budget, audit or local Commissioning for Quality and Innovation (CQUINS)? www.institute.nhs.uk/commissioning/pct_portal/cquin.html

8. Will the service or pathway require access to or advice from a specialist pharmacist?

Are complex or specialist medicines (e.g. biologicals) or vulnerable patients involved? Is access to pharmaceutical advice and medicines information services required?

9. Will the service or pathway require clear lines of responsibility and accountability to be defined?

For example responsibility and accountability for legal liability, clinical governance, financial governance, professional ethics and codes of practice, employment contracts or inter- organisation responsibilities.

It is important to think about medicine optimisation when redesigning a service or pathway and to consider how the new service/pathway will fit in with other services or pathways already in place. It is vital to have a holistic approach to patient care by considering the patient as a whole and not focusing on one aspect of their treatment. Different clinicians and health care staff see the patient in different ways, all of them correct, but by not seeing the whole patient pathway, their understanding is limited. Make sure you understand the entire process/patient pathway before starting any improvement project.[14]

Consider what challenges might be received from stakeholders and identify possible issues which might occur when redesigning a service or pathway. It is prudent to set up a risk log, an issue log and a lessons learned log. These logs should be updated throughout the service/pathway redesign process. This will allow reflection and the lessons learned log will aid future projects.

To support commissioners when undertaking service redesign for services or pathways that include medicines a project planning tool is available here: https://www.prescqipp.info/resources/category/311-commissioning-medicines-in-service-redesign This tool can also be utilised to help plan how information about the new service or pathway will be communicated. This is to key contact and stakeholders, for example community pharmacists.

Summary

Medicines are the most common treatment intervention and used in most services and pathways.[1] Therefore it is vital that services and care pathways which include medicines are safe, deliver improved patient outcomes, offer patient choice, a good patient experience and are clinically effective and cost effective treatment options.[1] It is important that how the medicine will be supplied and administered is considered in the early stages of the service redesign process to ensure that supply systems are in place for when a new service opens or starts. If medicines are included it is advisable to seek assistance from the Medicines Management team and consider the following:

- Does the service or pathway comply with current legislation and NHS regulations?
- Does the service or pathway comply with current evidence and best practice guidance?
- Will the service or pathway result in a need to decommission services?
- Will the service or pathway have cost implications for the way in which medicines are used compared to current arrangements?
- Will the service or pathway be provided by staff adequately trained in the activities required?
- Will the service or pathway enhance patient safety, understanding of medicines and overall experience?
- Will the service or pathway require KPIs and outcome measures to monitor performance?
- Will the service or pathway require access to or advice from a specialist pharmacist?
- Will the service or pathway require clear lines of responsibility and accountability to be defined?

Above all it is important to think about medicine optimisation and to have a holistic approach to patient care. This can be done by considering the patient as a whole and not focusing on one aspect of their treatment.

There are several useful tools available to support commissioning medicines in service redesign on the SPS website. https://www.sps.nhs.uk/articles/medicines-in-commissioning-resources/

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Additional PrescQIPP resources

 Briefing

 Data pack

 Planning tool, templates

Available here: https://www.prescqipp.info/resources/category/311-commissioning-medicines-in-service-redesign

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Contact help@prescqipp.info with any queries or comments related to the content of this document.

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