

## Commissioning medicines in service redesign – How to guide

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

### Recommendations

- Ensure that the supply and administration of medicines and other treatments are considered in the early stages of the service redesign process.
- Consider how medicines and other treatments 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 supply systems are in place for medicines and other treatments before a new service opens or starts.
- Medicines and other treatments included in the service should comply with local formulary recommendations.
- Any new medicines or medicines used for new indications used in the proposed new services or pathways 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. Or if a medicine is classified as specialist/hospital only prescribing but through shared care is transferred to primary care, how would this work in practice.
- If the service requires any additional funding and/or a prescribing budget (also known as a cost centre), consider how this will be funded (programme budgeting, prescribing budget top slice or does the funding need to move with the service from one location to another).
- 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 used in proposed new services or pathways are safe and appropriate.

### Background

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

In a rapidly changing NHS, reforms and service redesign are inevitable and will undoubtedly involve medicines and other treatments. The commissioners are responsible for ensuring services and pathways

in which medicines and other treatments are used are commissioned to standards that deliver cost effective use of resources, reduced risks associated with medicines use, improved patient outcomes and experience.<sup>2</sup> The King's Fund is an independent charity working to improve health and health care in England. They recommend that planning and implementation of major service redesign must be as evidence based as possible and that moving towards a more community-based service does not always deliver significant savings.<sup>4</sup> A separate report looks at the redesign of community services and highlights the most promising possibilities demonstrated by Sustainability Transformation Partnerships (STPs) and Accountable Care Systems (ACSSs).<sup>5</sup>

NHS England published a useful guide to assist commissioners considering, and involved in, service reconfiguration to navigate a clear path from inception to implementation in March 2018. It will support commissioners when considering how to take forward their proposals, including effective public involvement and effective alignment with local STP plans and investment priorities. It enables them to reach robust decisions on change in the best interests of their patients. The guide "Planning, assuring and delivering service change for patients" is available here: <https://www.england.nhs.uk/wp-content/uploads/2018/03/planning-assuring-delivering-service-change-v6-1.pdf>

NHS Improvement also provide a range of tools to support the process of service redesign. <https://improvement.nhs.uk/resources/quality-service-improvement-and-redesign-qsir-tools/>

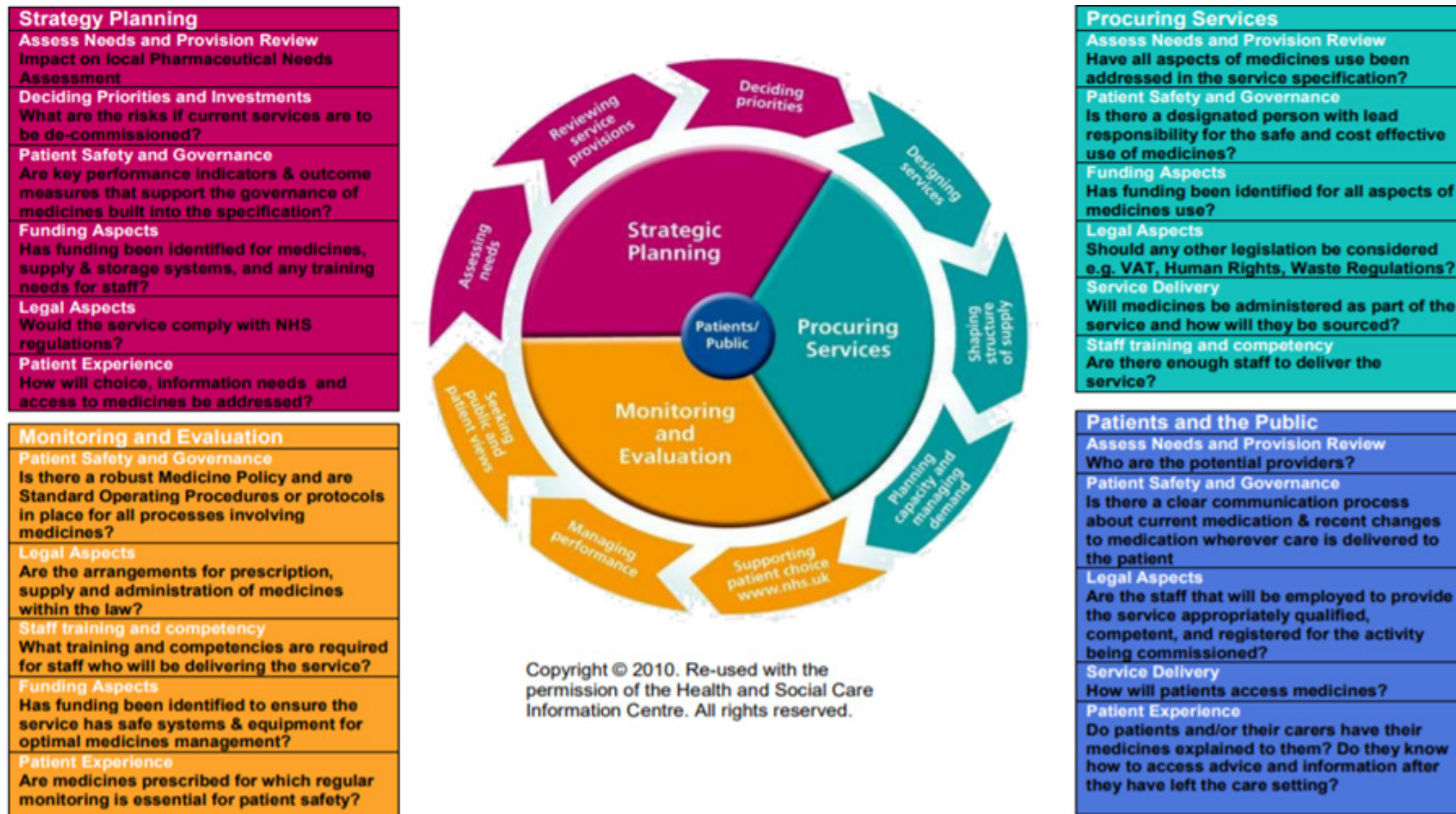
NHS England gives Clinical Commissioning Groups (CCGs) practical support in gathering data, evidence and tools to help them transform the way care is delivered for their patients and populations. NHS RightCare Intelligence is of particular interest to CCG clinical and management leads with the responsibility for finance, performance, improvement and health outcomes; NHS England regional team leads; STP Leads and commissioning support teams who are helping CCGs and STPs with this work. NHS Right Care is part of NHS England and together with Public Health England they provide a suite of materials to support effective commissioning. These include 'where to look' packs, focus packs, equality and health inequality packs, long term condition packs and mental health conditions packs along with intelligence tools and online support as well as examples of best practice through casebooks.<sup>6</sup> Depending on the service being considered, other medicines related NHS England resources may inform some specific types of redesign such as:

Medicines not reimbursed through national prices and directly commissioned by NHS England. <https://www.england.nhs.uk/wp-content/uploads/2017/04/NHS-England-drugs-list-v15-2020-2021.pdf>

Conditions for which over the counter medicines should not routinely be prescribed in primary care. <https://www.england.nhs.uk/wp-content/uploads/2018/03/otc-guidance-for-ccgs.pdf>

In November 2014, the East and South East England Specialist Pharmacy Services produced two interlinked documents - the Medicines in Commissioning Checklist and Optimising Medicines Use in Care Pathways. These resources help ensure that high quality, cost effective, accessible medicines optimisation 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.<sup>1</sup>

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 appropriate legislation and the fundamental standards of care as regulated by the Care Quality Commission (CQC). The checklist in figure 1 below supports the components of the commissioning cycle.

Figure 1: The commissioning cycle reproduced from Specialist Pharmacy Services medicines in commissioning checklist document<sup>2</sup>

## Medicines supply and administration in service redesign

To get medicine and other treatments use right, it is important that the supply and administration of medicines and other treatments is considered in the early stages of the service redesign or pathway commissioning process. To help identify the extent to which medicines and other treatments are involved in the service or pathway consider the following questions.<sup>2</sup>

Will the proposed service/pathway involve:

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

If the answer is “yes” to any of these questions seek assistance from the Medicines Optimisation Team or equivalent team in your organisation.<sup>2</sup>

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 National Patient Safety Alert requirements.
- Service had to be withdrawn from a provider who was found to be operating illegally.<sup>2</sup>

Once it has been identified that medicines and other treatments use will be involved in the service redesign or pathway, it is important to consider how medicines and other treatments will be supplied. Will the medicine or other treatment 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 and other treatments are to be supplied to the service users or patients in the pathway, that the supply systems are in place in advance of when the service is launched to avoid delaying service provision.

## FP10 prescription

If FP10 NHS prescriptions are to be used as part of the service pathway, it is important to allocate a budget to cover prescribing costs and dispensing fees where applicable. The prescription is sent to a pharmacy (or appliance dispensing contractor) to obtain the medicines (or appliances) required. This is done either electronically through the Electronic Prescription Service (EPS) or by the patient or their representative presenting the prescription to the pharmacy. 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.<sup>7</sup> Therefore as part of service redesign it is important to consider who will prescribe; how will prescribing be monitored; how will this be funded and 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: [www.nhsbsa.nhs.uk/PrescriptionServices.aspx](http://www.nhsbsa.nhs.uk/PrescriptionServices.aspx)

Information for new organisations developing a service which involves the supply of medicines and appliances using NHS pharmacy services can be found on the NHS Business Services Authority website.<sup>7</sup> A welcome pack for local authorities and providers, details how to obtain and maintain prescribing codes for your organisation and for its 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.<sup>8</sup>

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.<sup>8</sup> The senior authorised signatory will usually be the Head of Medicines Optimisation/Chief Pharmacist/Director or equivalent within each organisation. 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.<sup>8</sup>

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. 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.<sup>8</sup>

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)? Is EPS available in the setting and do all potential prescribers have access to the EPS system? Further information on EPS can be found at <https://digital.nhs.uk/services/electronic-prescription-service>.
- Will the service or pathway involve repeat prescriptions, if so, will just one prescription be issued and then prescribing passed back to the patient's 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 prescribing, 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.?
- Will the prescribed drugs be in accordance with national recommendations (e.g. NICE) and with local formulary guidance?

## 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 the need for a prescription. 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.<sup>9</sup> The Specialist Pharmacy Service website has information, resources and examples of PGDs:

<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. The aim of this tool is to ensure that patients receive safe and

appropriate care and timely access to medicines, in line with legislation.<sup>9</sup> The tool also has links which signpost to legislation, national guidelines and other NHS PGD resources.

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 legal 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:

[www.nice.org.uk/guidance/mpg2](http://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). Doctors are also allowed to supply medicinal products to their own patients. If a wholesaler were to supply direct to patients this would be classed as a retail transaction and would not be permitted. 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). 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. 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 that they are going to personally apply.<sup>10</sup>

There are some services or pathways where the direct supply route may not be the most suitable in terms of cost effectiveness, quality assurance or patient convenience, for example, oral nutritional supplements or wound care. A number of alternative procurement and supply options have therefore been explored in these specialist areas.<sup>11,12</sup> Table 1 summarises different ways of procuring dressings.

**Table 1. Summary of non-FP10 procurement options for dressings and their key features<sup>11</sup>**

Procurement option	Key features
In house purchase using organisation's ordering portal	<p>The organisation purchases the dressings directly from either:</p> <ol style="list-style-type: none"> <li>1. One or more community pharmacies.</li> <li>2. The NHS supply chain.</li> <li>3. A wholesaler.</li> </ol> <p>Whichever route is used, the organisation orders and invoices through their existing purchasing system.</p> <p>This system is independent of the dressing product manufacturers.</p> <p>Reporting systems may be basic.</p> <p>Adherence to a formulary may not be built into the system as the system may not restrict product choice.</p>

<p>Online ordering system provided by wound care product manufacturer</p>	<p>Manufacturers online ordering systems. These allow organisations to set up an online ordering system with either:</p> <ol style="list-style-type: none"> <li>1. One or more community pharmacies.</li> <li>2. The NHS supply chain.</li> <li>3. A wholesaler.</li> </ol> <p>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.</p> <p>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.</p> <p>There may or may not be a requirement to have a number of the manufacturer's products on the list of dressings.</p> <p>The most cost-effective company may be the one that has most of its dressings on the organisation's formulary.</p>
<p>Online ordering system provided by NHS Supply Chain</p>	<p>The NHS Supply Chain has its own online ordering system for dressings called SOLO. It works very similarly to the ordering systems described above but using the NHS Supply Chain as the only supplier.</p> <p>Case studies can be found at: <a href="http://www.supplychain.nhs.uk/casestudies">www.supplychain.nhs.uk/casestudies</a></p> <p>The NHS Supply Chain price is used but additional discounts may be available. This system is independent of the dressing product manufacturers. It does not use community pharmacy.</p>

There are some issues that need to be considered when procuring dressings via the non-FP10 route.<sup>11</sup>

These include:

- The effect on relationships with community pharmacies and Local Pharmaceutical Committees.
- The non-FP10 route attracts VAT and will not benefit from the claw back of national average discount (approximately 7.5%).
- Is there a requirement to go out to tender? What resources are required for implementation? Non-FP10 procurement options will be invoiced direct. The administrative burden for this will need to be factored into the cost of the service. 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 the named patient. Dressings procured via the non-FP10 route are the property of the organisation so they can be used as a 'stock' item. This can be useful if the dressing may require testing and it would not be cost-effective to request a full box.
- Consider deliveries and storage of products (frequency, location and who will manage the receipt and put stock away).

- Consider the resources and staff required for stock control and ordering.
- Consider transport of dispensed items to the patients location or any satellite clinics.
- Consider how to ensure formulary adherence, how this could be monitored, how non-formulary items can be accessed for specific patients if required, the process for this and its monitoring and how anticipated savings are realised.
- Any nurse (including non-prescribers) can order dressings for use on a patient. They take responsibility for the choice of product and are accountable for their actions so they may need to increase their knowledge of the products on the formulary to maintain competence.
- How will data be monitored and reported? How will the formulary be updated?
- 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.

## 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 the commissioning checklist can be used by commissioners and service providers to ensure that all medicines related issues are considered in service redesign.<sup>2</sup> 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 fundamental standards of care for 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 bulletin 178 can be used to support best practice when transferring between care settings. <https://www.prescqipp.info/our-resources/bulletins/bulletin-178-care-homes-transferring-patients-between-care-settings/>

In addition, there are several shared examples in the PrescQIPP Community resources e.g. Transfer of Care around Medicines (TCAM) (2019) and Optimising Transfer of Care to improve safety in diabetes care (2019). The links for these are here:

<https://www.prescqipp.info/community-resources/innovation-and-best-practice/winner-transfer-of-care-around-medicines-tcam-2019/>

<https://www.prescqipp.info/community-resources/innovation-and-best-practice/optimising-transfer-of-care-to-improve-safety-in-diabetes-care-2019/>



### 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 you ensure continuity of prescribing for patients?

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 the 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 accessible, e.g. different languages, large print, pictorial, braille? 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 and keeping them safe and in line with current guidance?

### 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 the local Commissioning for Quality and Innovation framework (CQUIN)?

<https://www.england.nhs.uk/nhs-standard-contract/cquin/>

### 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. Consider appointing a project manager to oversee the whole process.

It is important to think about medicine optimisation as early as possible 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.<sup>13</sup>

Consider what challenges might be received from stakeholders and identify possible issues that might occur when redesigning a service or pathway. It is prudent to set up a risk log, an issues 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 in attachment 1. This tool can also be utilised to help plan how information about the new service or pathway will be communicated to key contact and stakeholders, for example community pharmacists.

## Summary

Medicines are the most common treatment intervention and used in most services and pathways. 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.<sup>1</sup> 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 essential to seek assistance from the medicines optimisation team (or equivalent local team) and consider as early as possible in the process 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.

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 Briefing	<a href="https://www.prescqipp.info/our-resources/bulletins/bulletin-273-commissioning-medicines-in-service-redesign/">https://www.prescqipp.info/our-resources/bulletins/bulletin-273-commissioning-medicines-in-service-redesign/</a>
 Implementation tools	

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