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Department of Health & Social Care

NHS

Novel coronavirus (COVID-19) standard operating procedure

Running a medicines re-use scheme in a care home or hospice setting

This guidance is correct at the time of publishing. However, it is subject to updates so please use the hyperlinks to confirm you are accessing the most up-to-date information.

NHS England and NHS Improvement

Contents

1. Purpose

This standard operating procedure (SOP) supports timely access to essential prescribed medicines during the COVID-19 pandemic for patients who are being cared for in a care home[1] or hospice setting.[2] In England, care homes can offer nursing and personal care or personal care only. The latter may not employ any registered nurses. This guidance is applicable in England and for use during the COVID-19 pandemic only.[3]

Care homes and hospices in Northern Ireland, Scotland and Wales should refer to guidance and SOPs produced by the governing bodies and regulators in their devolved administration.

2. Background

COVID-19

Public Health England has issued guidance on managing COVID-19 in a residential care setting.

Managing medicines

NICE has issued good practice for managing medicines in care homes. The guidance promotes safe and effective use of medicines in care homes by advising on processes for prescribing (including remote prescribing), handling and administering medicines. It also recommends how medicines (including controlled drugs) should be received, stored and disposed of within a care home setting. That guidance includes a recommendation that care home providers must ensure that medicines prescribed for a resident are not used by another resident.

Although this remains good practice, this new Standard Operating Procedure is designed to help providers manage situations where, during the COVID-19 pandemic, the best interest of patients mean that it is not appropriate to follow this recommendation.

Recycling/re-use of unused medicines

The Human Medicines Regulations 2012[4] are the legislation that underpins the dispensing and supply of medicines, supplemented in the case of controlled drugs by the

[1] The Care Standards Act 2000 defines a 'care home' as accommodation that provides nursing or personal care.
[2] Hospice care aims to improve the quality of life and wellbeing of adults and children with a life-limiting or terminal condition. It helps people live as fully and as well as they can to the end of their lives, however long that may be.
[3] The up-to-date status of the COVID 19 pandemic is confirmed at https://www.gov.uk/coronavirus
[4] http://www.legislation.gov.uk/uksi/2012/1916/contents/made

Misuse of Drugs Regulations 2001. Part 12 of the Human Medicines Regulations 2012 limits the supply of prescription-only medicines (POMs) to supply in accordance with a prescription of an authorised prescriber, subject to various exceptions including supply under a patient group direction (PGD).

Provided that a supply is, in fact, in accordance with the prescription, for the specific purposes of Part 12 of the Human Medicines Regulations 2012, it will generally not be relevant how that medicine is sourced.

Accordingly, if at each stage of the supply chain the legal requirements relevant to that stage have been adhered to, the possibility exists that providers may have in their possession medicines that they are lawfully entitled to have in their possession for one purpose which they may be able to use for another purpose. This new guidance is to support making appropriate use of that recognised possibility in care homes and hospices.

When a patient is prescribed a medicine, once the final supply of the medicine is completed and it is in the patient's safe keeping, it is their property (although not their exclusive responsibility). If the medicine is still in the safe custody of the care home or hospice care provider, whether or not the final supply to the patient has been completed is the subject of differing legal views. Some would say that it becomes the patient's property as early as when it leaves the pharmacy.

This guidance does not seek to resolve these complex legal issues. Rather, it presents an agreed line through them, in the current very unusual circumstances, and that agreed line is strictly for the limited purposes which the guidance addresses.

Under usual circumstances, the re-use or recycling of another patient's medicine is not recommended by the Department of Health and Social Care (DHSC) as the quality of any medicine that has left the pharmacy cannot be guaranteed. Any unused medicines would normally be disposed of by returning them to a contracted external company or community pharmacy.

However, there are increasing concerns about the pressure that could be placed on the medicines supply chain during the peak of the COVID-19 pandemic. A medicines re-use scheme for care homes and hospices could potentially ease some of that pressure in the coming weeks.

Medicines re-use schemes already operate successfully in NHS hospitals across the UK. In addition, hospices and care homes generally have good procedures in place to store

medicines in an appropriate way. We can therefore be more confident of the quality of any unused medicines in these settings.

Due to the current unprecedented impact of COVID-19, DHSC and NHS England and NHS improvement are recommending a relaxation of previous recommendations and the NICE recommended good practice guidance to accommodate re-use of medicines, under very specific circumstances and only in a crisis situation as outlined.

First and foremost, the quality, integrity and safety of medicines are paramount and the best way to assure this is for pharmacies to supply medicines obtained through the regulated supply chain, appropriately labelled for individual patients.

However, in the unprecedented COVID-19 situation, DHSC and NHS England and NHS Improvement recognises that the re-use of medicines may be appropriate in certain circumstances. It is recommended that medicines should only be re-used in accordance with a medicines re-use scheme, set out in a SOP.

This SOP has been developed to support care home and hospice providers. It offers a framework to run a safe and effective medicines re-use scheme that is in the best interest of patients.

3. Medicines re-use scheme SOP for care homes and hospices

When would this apply?

This is time limited and would only apply during this period of emergency. i.e. during the COVID-19 pandemic.

What might constitute a crisis?

Each individual care home or hospice must carry out a risk assessment on an individual medicine basis.

Three key indicators should inform the risk assessment and the subsequent decision:

- No other stocks of the medicine are available in an appropriate timeframe (as informed by the supplying pharmacy) and there is an immediate patient need for the medicine.
- No suitable alternatives for an individual patient are available in a timely manner i.e. a new prescription cannot be issued, and the medicine(s) supplied against it in the conventional manner quickly enough.
- The benefits of using a medicine that is no longer needed by the person for whom it was originally prescribed or bought, outweigh any risks for an individual patient receiving that unused medicine.

Is a medicine suitable for re-use?

The medicine must be checked against the criteria in Tables 1 to 3 (see below) by a registered healthcare professional.[5]

Where no registered healthcare professional is on site (eg in a care home that only offers personal care and has no registered nurses on site), registered healthcare professionals (eg pharmacists, pharmacy technicians, general practitioners, community nurses) from other local organisations, such as clinical commissioning groups, general practices or community settings, can perform that check (this may be done virtually) and confirm that the medicine is suitable for re-use.

All medicines no longer needed by the person for whom they were originally prescribed and intended for re-use must be under the supervision of a registered healthcare

[5] A healthcare professional should be registered with one of the UK's professional regulatory bodies regulated by the Professional Standards Authority.

professional and appropriate records should be kept, including details of the registered healthcare professional who performed the check on suitability for reuse.

If the medicine suitable for re-use is a controlled drug, then it must remain in the control (possession) of an organisation authorised to do so. Further information from the Home Office can be found here. Appropriate records (e.g. controlled drugs register) **must** be maintained in respect of controlled drugs.

This SOP applies to medicines that have been supplied to patients while in a care home or a hospice, have not been removed from that setting (other than for short periods e.g. an outpatient appointment) and have been stored in accordance with good practice guidance on storing medicines in a managed setting. It applies to all medicines, including liquid medicines, injections (analgesics, insulin), creams and inhalers, that are in sealed or blister packs and when the criteria in Table 1 are met.

Providers should also consider, in the case of medicines that they have had difficulty accessing, whether the normal assumption of allowing patients to keep their own supplies of medicines for self-administration is appropriate, or whether other storage arrangements would better facilitate their re-use, if that patient no longer needs them.

Re-use should only be within a single care home/hospice setting; medicines identified for re-use should not be transferred to another care home or hospice, even those within the same parent organisation.

Tables 1 to 3 below provide supporting prompts to assist the registered healthcare professional with their decision making. It is advised that medicines for re-use are pro-actively assessed prior to them being needed in an emergency situation.

Table 1: Criteria to be considered before the medicine can be reused

	Yes	No	Notes
Is the medicine in an unopened pack or blister that has not been tampered with?			In an unopened, unadulterated and sealed pack (including sub-pack) or blister strip. If any doses have already been used, the remainder of that blister strip should be destroyed. If the contents (including blister strips and sealed individual units such as ampoules) are completely intact, then as long as they match the description on the packaging

			they were retrieved from (including check of batch numbers) they can be considered for re-use.
Is it in date?			Medicines should be in date. If expired, they will need to be returned to a pharmacy to be safely destroyed.
Has it been stored in line with the manufacturer's instructions, including any need for refrigeration?			Any medication that requires refrigeration, or that has a reduced shelf-life once removed from refrigerated storage, should be destroyed if it has not stored appropriately. Medicines left in unsuitable conditions (eg direct sunlight, near radiators) or where appropriate storage cannot be confirmed, should be destroyed.
Is the medicine a licensed medicine that has either been prescribed by a registered healthcare professional with prescribing rights or bought 'over the counter'?			For some medicines, 'homely remedies' are an option in care homes and should be considered in line with guidance: https://www.sps.nhs.uk/articles/rmoc-guidance-homely-remedies/

If the answer to all of the above questions is **yes,** then the risk of reuse may be judged to be minimal. If the answer to **any question** is **no** then the medicine should not be re-used. If doubt remains, discuss with appropriate registered healthcare professionals and local networks to get a wider perspective on the decision.

Table 2: Minimise risk of cross-contamination

	Yes	No	Notes
Is the medicine from a patient with a diagnosis of COVID-19 or showing symptoms of COVID-19?			Ensure that adequate infection prevention and control precautions have been taken. Medicine that has been retrieved from a patient infected with COVID-19 should be sealed (double bagged) and quarantined for three days. A do not process before date should be fixed to the bag before the bag is stored safely and away from any other medicines.

Table 3: Ensuring permission is obtained and patients, families and/or carers are fully involved

	Yes	No	Notes
If a medicine is thought to be suitable for re-use, permission should, if possible, be obtained for re-use from the patient for whom it was prescribed or (if the patient lacks capacity) from a person with power of attorney, or (if the patient has died) from their next of kin.			If the patient has become responsible for the safe keeping of the medicine, it is the property of the patient (although not their exclusive responsibility), but if the medicine is still in the safe custody of the care home or hospice care provider, whether the final supply to the patient has been completed is the subject of differing legal views. Reflecting this uncertainty, if possible, ensure the patient or their next of kin agrees for the medicine to be reused. **See Annex B.**

To ensure re-use of medicines is an option that can be used as flexibly as possible we suggest that care homes and hospices proactively seek written permission from all patients for:

- their medicines (if no longer needed) to be made available for other patients and/or
- them to receive a re-used medicine, provided they are deemed safe for re-use.

Further information to inform discussions is available in Annex B.

Once a decision has been made to re-use a medicine, then the following processes (summarised in the flow chart in Section 4 of this SOP) should be followed:

All medicines

1. A log should be maintained of re-used stock. The log should include the generic drug name, batch number, strength, formulation, expiry date quantity and details of the registered healthcare professional who assessed the medicine, as a minimum. When the stock is re-used, the quantity used should be entered. An example log returns sheet is given in Annex B.

2. Any medicines that might be re-used should be placed in a sealed container and marked as 'patient returns', to make it clear that the stock should only be re-used when stock cannot be obtained from the legitimate supply chain. The additional obligations in respect of storage of controlled drugs must be adhered to.
3. Once a medicine has been assessed as being suitable for re-use, the usual processes and governance, as recommended by NICE guideline SC1: Managing medicines in care homes, apply.

4. Any re-used medicine would need to be administered according to the direction of a relevant prescriber[6] and recorded by care home or hospice staff in the relevant administration chart.

5. Unless the product is being supplied under a PGD or a patient specific direction, a new prescription must be obtained prior to supply to the new patient. If it is for a controlled drug, the extra requirements in relation to controlled drugs prescriptions must be satisfied. New remote prescriptions should be scanned and emailed before the first dose is given, and a copy of the prescription kept with the patient's records in line with current processes.

6. The administration chart (paper or electronic) should be updated by the care home or hospice, in line with the direction from the prescriber (in most cases this would be the prescription). The new record should be checked for accuracy and signed by a second trained and skilled member of staff before it is first used. The prescriber does not need to sign the MAR chart.

Controlled drugs

7. Any stock of medication Schedule 2 or 3 controlled drugs should only be retained if it can be stored securely with controlled and limited access (in line with safe

[6] This can be a verbal direction initially with a written prescription to follow either by email or hard copy

storage requirements for controlled drugs). Lawful possession of such drugs is generally predicated on a prescription or direction being in place, so continuity of prescriptions is important for these particular products, having regard to the normal timeframes for safe disposal of these products where they are no longer needed.

8. Any Schedule 2 controlled drugs must be entered into a separate section of the controlled drugs register and then an entry made when they are re-used, as is usual practice.

Records

9. All records (CD register entries and returned medicines stock, risk assessments) must be kept in line with legislation.

Prescribers

10. When medicines are out of stock and there is an immediate need for them, an alternative preparation should be prescribed and dispensed, as is usual practice where possible.

11. Where stock is not available, the supplying pharmacy will contact the care home or hospice to establish whether a medicines re-use scheme is in place and stock of the required medicine is available in the home.

12. Re-used medicines may be administered to residents in a care home or hospice under the direction of a prescriber, and in line with this SOP, where an appropriate medicines re-use scheme is in operation.

13. In this situation, the direction would normally be in the form of a prescription. If a prescription is issued remotely, it should be scanned and emailed to the care home by the prescriber (for known medicines shortages) or the community pharmacy as appropriate in each individual case.

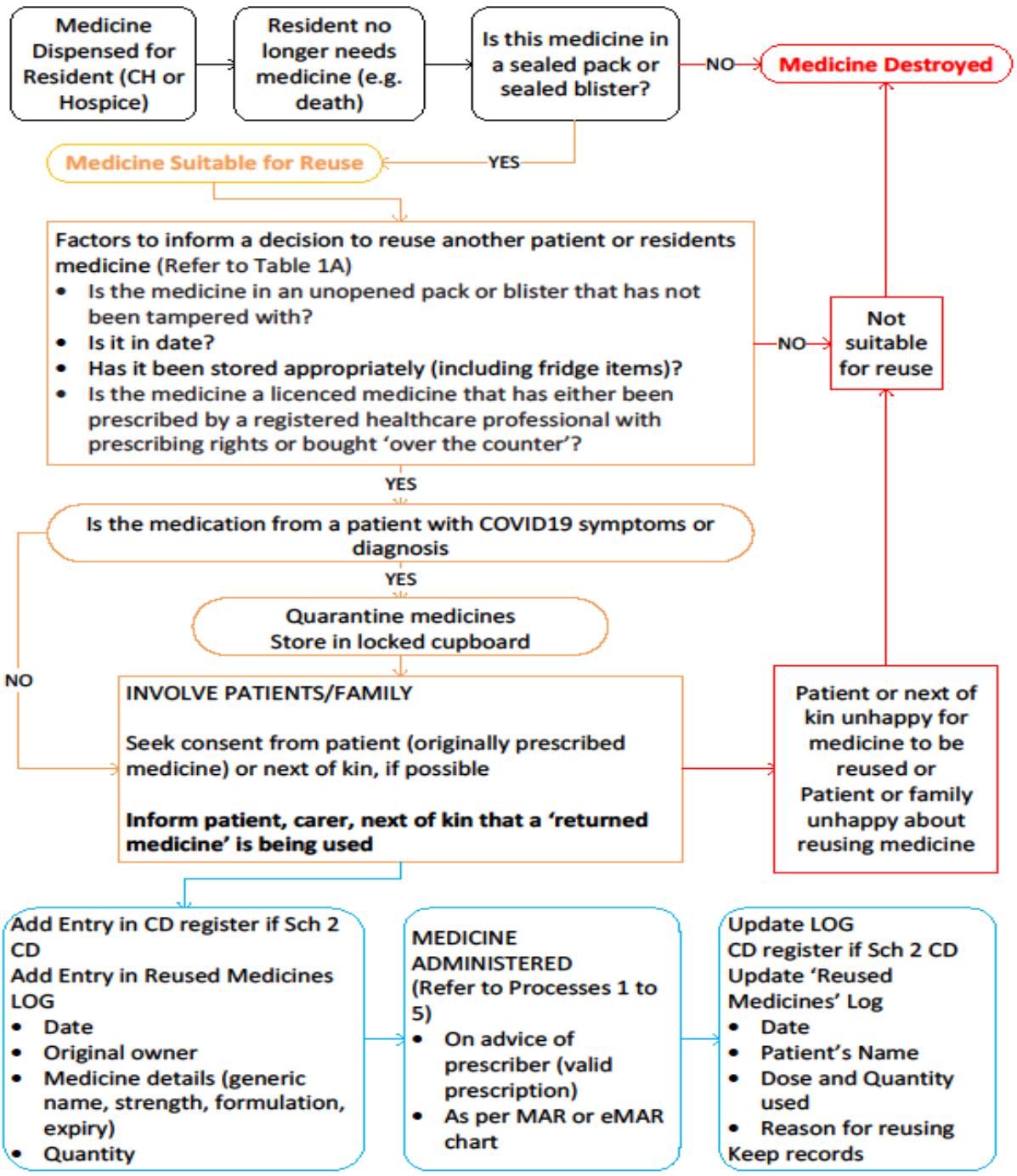
Community pharmacy

14. When medicines are out of stock and there is an immediate need for them, an alternative preparation should be prescribed and dispensed, as is usual practice where possible.

15. Where there is no suitable alternative or a prescription cannot be written for the alternative medicine (eg out of hours), the community pharmacy team should ask the care home or hospice whether they run a medicines re-use scheme and whether they have any stock of the required medicine.

16. If stock of a re-used medicine is available in the care home or hospice, the community pharmacy team must share a copy of the prescription for that medicine with the home and update the corresponding MAR chart as necessary. The supply of the medicine by the care home or hospice will need to be in accordance with that prescription. They cannot rely on a report of its contents.

4. Medicines re-use pathway



Pharmacovigilence
- Report all adverse events and problems to CCG, COVID19 Trimverate
- Report clinical adverse via Yellow Card Scheme (note that medicine was reused)
- Log all errors via NRLS or equivalent