Final service specification - New Medicine Service (NMS)

01 October 2011

Introduction

In England, around 15 million people have a long-term condition (LTC). LTCs are those conditions that cannot, at present, be cured, but can be controlled by medication and other therapies. Although it can be difficult for some people to adjust to life with a LTC, there is often a great deal that can be done to manage symptoms and maintain quality of life.

The prescription of a medicine is one of the most common interventions in healthcare. In England there were 813.3 million NHS prescriptions dispensed by community pharmacies in 2009-10. The optimal use of appropriately prescribed medicines is vital to the self-management of most LTCs, but reviews conducted across different disease states and different countries are consistent in estimating that between 30 and 50 per cent of prescribed medicines are not taken as recommended. This represents a failure to translate the technological benefits of new medicines into health gain for individuals. Sub-optimal medicines use can lead to inadequate management of the LTC and a cost to the patient, the NHS and society.

It is therefore clear that non-adherence to appropriately prescribed medicines is a global health problem of major relevance to the NHS. It has been suggested that increasing the effectiveness of adherence interventions may have a far greater impact on the health of the population than any improvement in specific medical treatments[1].

Non-adherence is often a hidden problem, undisclosed by patients and unrecognised by prescribers. People make decisions about the medicines they are prescribed and whether they are going to take them very soon after being prescribed the new medicine.

Proof of concept research[2] has shown that pharmacists can successfully intervene when a medicine is newly prescribed, with repeated follow up in the short term, to increase effective medicine taking for the treatment of a long-term condition.

Service description

This service will provide support to people who are newly prescribed a medicine to manage a long-term condition, which will generally help them to appropriately improve their medication adherence.

Aims and intended outcomes

The service should:

a) help patients and carers manage newly prescribed medicines for a LTC and make shared decisions about their LTC

b) recognise the important and expanding role of pharmacists in optimising the use of medicines

[1] Haynes R, McDonald H, Garg A, Montague P. (2002). Interventions for helping patients to follow prescriptions for medications. The Cochrane Database of Systematic Reviews, 2, CD000011.
[2] Clifford S, Barber N, Elliott R, Hartley E, Horne R. (2006). Patient-centred advice is effective in improving adherence to medicines. Pharm World Sci (2006) 28:165-170.

c) increase patient adherence to treatment and consequently reduce medicines wastage and contribute to the NHS Quality, Innovation, Productivity and Prevention (QIPP) agenda

d) supplement and reinforce information provided by the GP and practice staff to help patients make informed choices about their care

e) promote multidisciplinary working with the patient's GP practice

f) link the use of newly-prescribed medicines to lifestyle changes or other non-drug interventions to promote well-being and promote health in people with LTCs

g) promote and support self-management of LTCs, and increase access to advice to improve medicines adherence and knowledge of potential side effects

h) support integration with LTC services from other healthcare providers and provide appropriate signposting and referral to these services

i) improve pharmacovigilance

j) through increased adherence to treatment, reduce medicines-related hospital admissions and improve quality of life for patients.

Service outline

The service is split into three stages, which are outlined below:

- patient engagement
- intervention
- follow up.

Patient engagement

1. Following the prescribing of a new medicine[3] for the management of a LTC, patients will be recruited to the service by prescriber referral (which could include referral for medicines prescribed to the patient as a hospital inpatient or outpatient) or opportunistically by the community pharmacy. The patient may not have visited the pharmacy on a previous occasion.

2. The conditions/therapies included in the initial rollout of the service are:
   - asthma and COPD
   - diabetes (Type 2)
   - antiplatelet / anticoagulant therapy
   - hypertension.

   For each therapy area/condition, a list of medicines has been published (see appendix 3 or the NHS Employers and PSNC websites).

3. It is not generally appropriate for the service to be provided where there has been a formulation change. The rationale for this is that a change from one solid dosage form to another is unlikely to present major clinical issues for a patient and hence provision of the NMS in such circumstances would not provide value to the NHS. However there may be circumstances, where in the professional opinion of the pharmacist, they believe the patient would benefit from the provision of the NMS where they are moving from one formulation of a medicine to another. In this case the NMS can be provided and pharmacists should document their rationale for making such a professional decision.

[3] If more than one medicine covered by the service is prescribed at the same time, that instance of the service will cover all those medicines.

4. The new medicine will be dispensed in accordance with the Terms of Service, except in circumstances where the patient has been referred by a healthcare professional at the hospital that has already dispensed the new medicine.

5. Initial advice will be given to the patient about the medicine and its use in accordance with the Terms of Service. At this stage the pharmacist may also offer the patient opportunistic advice on healthy living / public health topics in line with the promotion of healthy lifestyles essential service. The intervention and follow up stages of the service will also be opportunities to offer the patient healthy lifestyle advice.

6. The pharmacy and patient will agree a method and time for the intervention (typically between seven and 14 days after patient engagement).

7. The patient will be given information on the service (for example in the form of a leaflet), which will include an explanation that information may be shared with their GP as necessary; with the primary care trust (PCT) or successor organisation as part of clinical audit; and with the PCT or successor organisation, the NHS Business Services Authority and the Secretary of State for Health to verify that the service has been provided by the pharmacy as part of the post-payment verification process.

8. The pharmacy will obtain written consent from the patient to confirm that they agree to information being shared. If the patient does not consent to share information then they are not able to use the service.

Intervention

9. The pharmacist and patient will have a discussion at the agreed time and via the agreed method. It is expected that this will normally be a face-to-face conversation but alternatively it could take place as a telephone conversation if the patient prefers this. If the discussion does not happen at the agreed time, the pharmacist will make at least one attempt to follow up with the patient.

10. At the start of the discussion, the pharmacist will confirm that the patient understands the information they were given during patient engagement and that they still agree to information being shared with their GP as necessary; with the PCT or successor organisation as part of clinical audit; and with the PCT or successor organisation, the NHS Business Services Authority and the Secretary of State for Health as part of post-payment verification. If the patient does not consent to share information then the intervention is not provided.

11. Face-to-face discussions with patients will take place in a consultation area. In order to deliver the service a pharmacy must have a consultation area which is at least at the level required for the provision of the Medicines Use Review service:
    a. The consultation area should be a designated area where both the patient and pharmacist can sit down together.
    b. The patient and pharmacist should be able to talk at normal speaking volumes without being overheard by other visitors to the pharmacy, or by pharmacy staff undertaking their normal duties.
    c. The consultation area should be clearly designated as an area for confidential consultations, distinct from the general public areas of the pharmacy.

12. Telephone discussions with patients should be conducted on the pharmacy premises and take place in circumstances where the telephone conversation cannot be overheard except by someone whom the patient wants to hear the conversation, for example a carer.

13. The pharmacist will assess the patient's adherence to the medicine(s), identify problems and determine the patient's need for further information and support. The NMS intervention interview schedule will normally be used to guide this assessment.

14. The pharmacist will provide advice and further support and will agree one of the following next steps with the patient:
    a. the patient is adhering to the medicine(s) and no problems have been identified - agree time and location for the follow up (typically between 14 and 21 days after the initial intervention).
    b. problems are identified and it is the clinical judgement of the pharmacist that intervention by the patient's GP is not required – agree the time and location for the follow up (typically between 14 and 21 days after the intervention) and any appropriate remedial steps to be taken by the patient in the meantime. For the current cohort of patients, such steps could include the use of items such as reminder charts but these should not create an extra cost pressure on the NHS.
    c. problems are identified and it is the clinical judgement of the pharmacist that intervention by the patient's GP is required – explain this to the patient, complete the NMS feedback form and refer the matter to the patient's GP practice. At this point the service will have been completed except in the circumstance described in the footnote[4].

15. At this stage the pharmacist may also offer the patient opportunistic advice on healthy living / public health topics in line with the promotion of healthy lifestyles essential service.

Follow up

16. The pharmacist and patient will have a discussion at the agreed time and via the agreed method (again it is expected that this will normally be a face-to-face conversation but alternatively it could take place as a telephone conversation if the patient prefers this). If the discussion does not happen at the agreed time, the pharmacist will make at least one additional attempt to follow up with the patient (i.e. the pharmacist will try to arrange another face-to-face meeting with the patient or will try to have another telephone conversation with the patient). If the pharmacist is unable to contact the patient then the service will have been completed.

17. The pharmacist will assess the patient's adherence to the medicine(s), identify problems and determine the patient's need for further information and support. The NMS follow up interview schedule will normally be used to guide this assessment.

18. The pharmacist will provide advice and further support and agrees one of the following next steps with the patient:
    a. patient adhering to regimen – exit from service. At this point the service will have been completed.
    b. problem identified – pharmacist and patient agree solution. At this point the service will have been completed.
    c. problem identified – referral to the GP practice for review. At this point the service will have been completed.

19. At this stage the pharmacist may also offer the patient opportunistic advice on healthy living / public health topics in line with the promotion of healthy lifestyles essential service.

20. The patient will not normally be eligible for a Medicines Use Review (MUR) within six months of completing the service, unless in the reasonable opinion of the pharmacist the patient would benefit from an MUR during that period. For example, a patient with multiple long-term conditions may be prescribed a new medicine for one condition and be supported in using this medicine by the NMS, but may benefit from the wider advice and support

[4] If the NMS episode covers multiple medicines and not all medicines prompt the need for referral to the GP practice, steps a or b will be undertaken for the medicines that do not require referral to the GP practice.

provided in an MUR in relation to medicines they use for another condition. Patients on high-risk drugs or patients who experience a "trigger event" which would highlight the need for an MUR may also benefit.

Pharmacy records

Pharmacy records for the service will be maintained to support the delivery of the service and audit. Pharmacy contractors will need to maintain records of the following for each patient who receives the NMS:

a. date and method of entry to service
    a. patient referred from GP practice
    b. patient identified in the pharmacy

b. patient demographic details
    a. name
    b. address
    c. gender
    d. date of birth
    e. NHS number (where available)
    f. ethnicity

c. registered GP practice

d. condition(s) / therapy area(s) of new medicine
    - asthma and COPD
    - diabetes (Type 2)
    - antiplatelet / anticoagulant therapy
    - hypertension

e. name of new medicine(s)

f. date and method of intervention and date and method of follow up
    a. face to face in the pharmacy
    b. telephone

g. healthy living advice provided at each stage of the service (i.e. *recruitment*, *intervention* and *follow up*). This data may be collated using the following standard descriptors:
    a. diet and nutrition
    b. smoking
    c. physical activity
    d. alcohol
    e. sexual health
    f. weight management

h. where appropriate, reason why a patient does not take part in the *intervention* phase of the service:
    a. prescriber has stopped new medicine
    b. patient has withdrawn consent for information sharing
    c. patient has withdrawn consent to receive the service
    d. patient could not be contacted
    e. other

i. matters identified during the discussion with the patient at the *intervention*. This data should be captured using the following standard descriptors:
    a. patient reports using the medicine as prescribed
    b. patient reports not using the medicine as prescribed
        i. patient has not started using the medicine

ii. prescriber has stopped new medicine
iii. patient is not using the medicine in line with the directions of the prescriber
iv. patient reports missing a dose in the past 7 days

c. patient reports need for more information about the medicine (information needs will be addressed by the pharmacist and this will be captured in the data set out below)
d. patient reports side effects
e. patient reports negative feelings about the medicine (the pharmacist should provide further details about this using a free text box)
f. patient reports uncertainty on whether the medicine is working
g. patient reports concern about remembering to take the medicine
h. patient reports difficulty using the medicine due to its pharmaceutical form / formulation
i. other - free text option

If the NMS relates to more than one medicine for an individual patient, this data should be captured for each medicine.

j. outcome of the discussion with the patient at the *intervention*. This data should be captured using the following standard descriptors:
    a. action taken / to be taken by pharmacist:
        i. information provided – interactions with other medicines
        ii. information provided – why am I using the medicine / what is it for
        iii. information provided – how to use the medicine
        iv. information provided – correct dose of the medicine
        v. information provided – effects of the medicine on the body / how it works
        vi. information provided – why should I take the medicine
        vii. information provided – timing of the dose
        viii. information provided – interpretation of side effect information
        ix. advice provided – reminder strategies to support use of medicine
        x. advice provided – change to timing of doses to support adherence
        xi. advice provided – how to manage or minimise side effects
        xii. Yellow Card report submitted to MHRA
        xiii. reminder chart / MAR chart provided
        xiv. referral – patient's issues raised with the new medicine need to be considered by the prescriber. The reason(s) for the referral should be captured using the following standard descriptors:
            1. drug interaction(s)
            2. potential side effect(s) / adverse drug reaction preventing use of medicine
            3. patient reports not using medicine any more
            4. patient reports never having started using medicine
            5. patient reports difficulty using the medicine
                a. issue with device
                b. issue with formulation
            6. patient reports lack of efficacy
            7. patient reports problem with dosage regimen
            8. patient reports unresolved concern about the use of the medicine
            9. other – free text option
        xv. other action – free text option
    b. action for patient to take:
        i. carry on using medicine as prescribed
        ii. use medicine as agreed during the *intervention*
        iii. submit Yellow Card report to MHRA
        iv. other action – free text option

If the NMS relates to more than one medicine for an individual patient, this data should be captured for each medicine.

k. where appropriate, reason why a patient does not take part in the *follow up* phase of the service:
    a. prescriber has stopped new medicine
    b. patient has withdrawn consent for information sharing
    c. patient has withdrawn consent to receive the service
    d. patient could not be contacted
    e. other

l. matters identified during the discussion with the patient at the *follow up*. This data should be captured using the following standard descriptors:
    a. patient reports using the medicine as prescribed
    b. patient reports not using the medicine as prescribed
        i. patient has not started using the medicine
        ii. prescriber has stopped new medicine
        iii. patient is not using the medicine in line with the directions of the prescriber
        iv. patient reports missing a dose in the past 7 days
    c. patient reports need for more information about the medicine (information needs will be addressed by the pharmacist and this will be captured in the data set out below)
    d. patient reports side effects
    e. patient reports negative feelings about the medicine (the pharmacist should provide further details about this using a free text box)
    f. patient reports uncertainty on whether the medicine is working
    g. patient reports concern about remembering to take the medicine
    h. patient reports difficulty using the medicine due to its pharmaceutical form / formulation
    i. other - free text option

If the NMS relates to more than one medicine for an individual patient, this data should be captured for each medicine.

m. outcome of the discussion with the patient at the *follow up*. This data should be captured using the following standard descriptors:
    a. action taken / to be taken by pharmacist:
        i. information provided – interactions with other medicines
        ii. information provided – why am I using the medicine / what is it for
        iii. information provided – how to use the medicine
        iv. information provided – correct dose of the medicine
        v. information provided – effects of the medicine on the body / how it works
        vi. information provided – why should I take the medicine
        vii. information provided – timing of the dose
        viii. information provided – interpretation of side effect information
        ix. advice provided – reminder strategies to support use of medicine
        x. advice provided – change to timing of doses to support adherence
        xi. advice provided – how to manage or minimise side effects
        xii. Yellow Card report submitted to MHRA
        xiii. reminder chart / MAR chart provided
        xiv. referral – patient's issues raised with the new medicine need to be considered by the prescriber. The reason(s) for the referral should be captured using the following standard descriptors:
            1. drug interaction(s)
            2. potential side effect(s) / adverse drug reaction preventing use of medicine
            3. patient reports not using medicine any more
            4. patient reports never having started using medicine
            5. patient reports difficulty using the medicine
                a. issue with device
                b. issue with formulation
            6. patient reports lack of efficacy

7. patient reports problem with dosage regimen
8. patient reports unresolved concern about the use of the medicine
9. other – free text option

xv. other action – free text option

b. action for patient to take:
   i. carry on using medicine as prescribed
   ii. use medicine as agreed during the *follow up*
   iii. submit Yellow Card report to MHRA
   iv. other action – free text option

If the NMS relates to more than one medicine for an individual patient, this data should be captured for each medicine.

New Medicine Service – requirements for reporting to PCTs

Each participating pharmacy must complete the reporting template (a standard spreadsheet) by collating the necessary data from pharmacy records for the NMS conducted in that quarter and ensuring that it is available to be requested after the end of 10 working days from the last day of that quarter (last day of June, September, December and March). Completed templates must be provided to the PCT or successor organisation on request (which may be an ongoing request).

The following data will be requested on the spreadsheet:

a. pharmacy ODS code
b. pharmacy name
c. pharmacy address (1st line)
d. outcome of discussion with patient at the patient engagement stage:
   i. number of patients declined the offer of the service
   ii. number of patients recruited
e. outcome of the discussion with the patient at the intervention stage (using the standard list of descriptors below):
   i. number of patients who did not attend / non contactable / withdrew consent
   ii. number of patients whose prescriber has stopped the medicine
   iii. number of completed interventions
   iv. number of patients to whom information was provided
   v. number of patients to whom advice was provided
   vi. number of Yellow Card reports submitted to MHRA
   vii. number of reminder charts / MAR charts provided to patients
   viii. number of patients referred to GP
f. outcome of the discussion with the patient at the follow up stage (using the standard list of descriptors below):
   i. number of patients who did not attend / non contactable / withdrew consent
   ii. number of patients whose prescriber has stopped the medicine
   iii. number of patients adherent
   iv. number of patients non adherent
   v. number of patients to whom information was provided
   vi. number of patients to whom advice was provided
   vii. number of Yellow Card reports submitted to MHRA
   viii. number of reminder charts / MAR charts provided to patients
   ix. number of patients referred to GP
g. number of patients in each condition / therapy group (using the standard list of descriptors below):
   i. asthma and COPD
   ii. antiplatelet / anticoagulant therapy
   iii. hypertension
   iv. type 2 diabetes
h. number of completed NMS claimed for
i. number of patients provided with healthy lifestyle advice at each of the following stages of the service:
   i. patient engagement

ii. intervention
iii. follow up