Supply of nicotine replacement therapy (NRT) to pregnant women who smoke

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Summary

Reducing barriers to accessing evidenced-based stop smoking aids for pregnant women who smoke increases the chance of these aids being used properly, making it more likely that service users will be able to stop smoking.

The Medicines and Healthcare products Regulatory Agency (MHRA) has issued a clarification on directly supplying nicotine replacement therapy (NRT): "**Supply of these products by non-medically qualified staff is permitted in medicines legislation**. This is subject to the products being pre-packed and supplied from lockable premises."

This means that whilst **staff who are not clinically registered can provide a direct supply of NRT**, unfortunately **they can't do it in people's homes**.

The Office for Health Improvement and Disparities (OHID) previously issued guidance on this subject, principally that **NRT should be stored in a lockable cupboard and that there must be good local governance**, including protocols, a Standard Operating Procedure, stock control and monitoring. More details are in the section below: *Good clinical practice for supplying nicotine replacement therapy (NRT) to pregnant women who smoke.*

Background

Stopping smoking in pregnancy is the single most important modifiable change a woman can make for a healthy pregnancy, and to give their child the best start in life by being in a smokefree home.[1] To increase the chances of quitting successfully, easy access to NRT is vital – this is part of individualised care to treat their tobacco dependence. High quality and effective smoking cessation support involves easy access to NRT and reducing barriers to quitting.[2,3]

The employment of Tobacco Dependence Advisers (TDAs) as part of the NHS Long Term Plan has resulted in a significant increase in non-clinically registered stop smoking practitioners.

Best practice

The MHRA clarification in full states that:

> **"Over the Counter/General Sales List (GSL) medicines can be supplied from a wider range of premises (including online) without the need for a licence. They are suitable for sale and normal use without supervision or advice from a pharmacist or doctor.**
>
> **Supply of these products by non-medically qualified staff is permitted in medicines legislation.**
>
> **To comply with the legislation you will need to supply the medicines from premises that can be closed to exclude the public (i.e. lockable). The medicines must be in its original packaging with patient information and being supplied to the end user (patient). Medicines need to have a UK Product Licence and Marketing Authorisation."**

The statement from the MHRA provides reassuring clarification on the legislation concerning direct supply of NRT. They state that **NRT is an over the counter (OTC)/General Sales List (GSL) medicine and therefore non-medically trained staff can supply treatment from a wide range of premises (including online)** without the need for a licence, or supervision and advice from a pharmacist, doctor, registered nurse, or midwife.

To comply with legislation and medicines management, **services will need to supply NRT from premises that can be closed to exclude the public. Services should supply NRT in its original packaging (i.e. not split and including the patient information insert)**, and can supply to patients directly.

The NCSCT has produced a stop smoking aids quick reference guide[4] and has an online course focusing on the behavioural support associated with effective use of stop smoking aids.[5]

We suggest that services work in partnership with their local pharmacy/maternity pharmacy leads, sharing this national directive from the MHRA, to develop a Standard Operating Procedure to demonstrate compliance, outline responsibilities and put procedures in place to maintain effective medicines management.

Please note: if a pregnant woman chooses to quit smoking using a nicotine vape, providing behavioural support is important to achieve success. More information and resources around vaping can be found on the Action on Smoking and Health (ASH) website .[6]

Conclusion

It is essential that compliance with the law surrounding direct supply of stop smoking aids is operationalised alongside the aim to provide pregnant women who smoke with timely access to effective stop smoking aids and evidence-based support.

References

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4. Stop smoking aids quick reference guide
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5. Stop smoking aids online training module
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Good clinical practice for supplying nicotine replacement therapy (NRT) to pregnant women who smoke

Midwives

- The Medicines and Healthcare products Regulatory Agency (MHRA) advises that Midwives may store, supply/distribute NRT from any location including during home visits.
- Midwives are free to issue direct supply of NRT at home as registered healthcare professionals.
- The Midwives Exemption List is not relevant here as it relates to Prescription Only Medicines.

Maternity Support Workers (MSWs) and Tobacco Dependence Advisers (TDAs)

- MSWs and TDAs are not regulated professions and are restricted to supplying NRT from clinical premises.
- MSWs and TDAs may store and supply/distribute NRT from any clinic location in a venue that can be closed to the public

Health Visitors

- Health Visitors trained in smoking cessation can deliver effective stop smoking interventions to pregnant women and families during home visits. Health Visitors and members of the team who are registered healthcare professionals can undertake direct supply of NRT in the patient's home.

Nursing Associates

- A qualified Nursing Associate can supply NRT, if it falls within their scope of practice, after completing the necessary training and competency assessments within their trust. This is because supply of NRT falls within the routes of medication administration they are authorised for, such as oral and subcutaneous administration.

Midwives, MSWs, TDAs, Health Visitors and Nursing Associates must operate within their employer's clinical governance policies and procedures.

Considerations for effective medicines management

Producing a Standard Operating Procedure (SOP) will provide governance and equip staff who issue NRT guidance and local procedures. The SOP should include purpose, scope, staff responsibilities, staff authorised to issue NRT, competences and training required. It should also include medicine management requirements for documentation, record keeping, stock control and safe storage. Your SOP should be agreed, ratified and signed by clinical governance and pharmacy teams, and shared with all relevant personnel.

- Ordering of NRT should be via locally agreed pharmacy protocols e.g. using an online system or drugs ordering book.
- On receipt of NRT, products should be checked as accurate by two members of staff and stock control documented as received and signed.
- NRT should be stored in a dedicated locked cupboard in a dry place, and in a room not accessible to members of public.
- Stock removed should be recorded, to provide an inventory of stock movement.
- Temperature control using a room thermometer should be recorded weekly.
- Transport of NRT to, for example, family/community hubs should be made in lockable bags.
- To avoid wastage of products, expiry dates should be monitored. Stock stored with shortest expiry dates should be used first and ordering of products should reflect current stock levels.
- NRT should not be left overnight in cars and, ideally, when transported should be out of view.
- For recall of any defective NRT products, the following information should be collected electronically:
  - Type and brand of NRT
  - Route of administration
  - Number of boxes/treatments issued
  - Strength
  - Batch number
  - Expiry date

Direct supply

Community hubs are where stop smoking interventions are delivered from a healthcare venue in the community, easily accessible for pregnant women to attend for their stop smoking support and where NRT could be supplied in line with the regulations.

Community hubs are often used collaboratively by a number of organisations but with a single host organisation managing the premises. The MHRA have advised that operating out of a community hub would be in compliance with the law, even if the MSW or TDA's direct employer was not the host organisation. Governance and accountability arrangements (for example, policies on how products are stored, accessed and issued) between the organisations sharing the hub must be robust, meet local and national requirements for direct supply of medication and be signed off by relevant departments within the organisations.

Alternatives to direct supply

Where MSWs, Healthcare Assistants (HCAs) and TDAs are trained to deliver stop smoking interventions, services may consider alternative options for ensuring access to NRT:

- **Voucher schemes**: involve the patient being provided with a form (electronic, email or hard copy) to take to a pharmacy participating in the scheme where the NRT will be dispensed. Regular 'vouchers' are provided to ensure sufficient supply.

  Regular checks should be made to ensure that pharmacies continue to participate in the system. Pharmacies usually require payment.

- **Postal system**: is where chosen NRT products are mailed to the home address of patients. Systems should be in place to ensure regular review and posting of additional supply as required. Products should be stored in a lockable cupboard in the stop smoking/maternity service premises.

  The possibility for delivery delays (e.g. bank holidays and weekends) and lost packages (e.g. when delivering to complex buildings with multiple occupancy) are potential drawbacks to this system.

- **Primary care prescription**: use local electronic systems to request prescriptions for NRT for patients receiving support from a stop smoking practitioner; including repeat prescriptions to ensure ongoing and adequate supply of NRT. Local ICBs and GP practices can be engaged to establish the system.

  Consideration should be given to the fact that GPs often require 48 hours or more to issue repeat prescriptions.

Further information

Increasingly, MSWs deliver public health interventions including tobacco dependence services. Some sites may already have MSWs directly supplying NRT at home and this is in breach of the law. The role of the MSW has been developed and mapped to a competency framework, which includes a description of their role in public health.

Nursing and Midwifery Council (NMC) registrants must "operate within the law" and this includes the full breadth of drugs and medicines legislation.

Regulation 221 of the Human Medicines Regulations 2012 (1) applies, which is that:

A person may not … supply… a GSL medicine other than at a registered pharmacy unless: the place where the medicine is … supplied… consists of premises that the person is the occupier and the person can close to exclude the public; and the product was made up for sale in its immediate and outer packaging elsewhere, and that packaging hasn't been opened since being made up.

Under Regulation 223, registered midwives have a blanket exemption to sell or supply all GSL and Pharmacy only (P) medicines, and some Prescription Only Medicines (POMs) in their course of their professional practice, so they can supply GSL and P medicines from wherever they happen to be. There is no similar exemption for MSWs.