

Title Page

Title: The provision of prescription only medicines for use on United Kingdom based overseas expeditions

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Abstract: Expedition teams without accompanying medical professionals traveling overseas from the United Kingdom frequently carry medical kits containing Prescription Only Medicines (POMs). Access to safe, basic POMs whilst on expedition is important, as the quality and availability of medicines in-country may not be acceptable and delay in treatment may be hazardous.

At present there is no published guidance relating to drug acquisition and administration in these situations. In the UK, a number of different practices are currently in use, with uncertainty and medico-legal concerns currently hampering safe and efficient provision of POMs on overseas expeditions.

A guideline is proposed for the management of prescription only medications in an expedition setting.

Key Words: Expedition medical kits, First-aid kits, wilderness first-aid, Prescription-only medicines

Introduction

Expedition parties, for example school trips, charity challenges, adventure races, explorers or journalists, traveling abroad from the United Kingdom (UK) frequently carry medical kits containing prescription only medicines (POMs). Access to safe, basic POMs whilst on expedition is important, as the quality and availability of medicines in-country may not be acceptable and delay in treatment may be hazardous.

Expeditions without accompanying medical professionals rely on non-medics administering POMs, and at present there is no published guidance relating to drug acquisition and administration in these situations, despite previously documented concerns (1). A number of different practices are currently in use, with uncertainty and medico-legal apprehension currently hampering safe and efficient provision of POMs on overseas expeditions.

A guideline is proposed for the management of prescription only medications for UK expeditions unaccompanied by a trained medical professional. This paper has been compiled by four authors with extensive expedition experience, and who provide medical support, training and medication to expeditions leaving the UK. It is hoped that by clarifying the clinical and legal position within United Kingdom practice, this guidance will be useful for those who practice expedition and wilderness medicine, whilst encouraging international colleagues to review local protocols.

Medical kits for remote travel

Expedition members accept their activities come with risk of injury and illness, potentially far from healthcare. The range of medical problems is well documented and there are a number of handbooks providing guidance on expedition medicine(2)(3). Access to a range of medicines is an essential requirement of any expeditionary activity and not all groups have an accompanying medically qualified expedition medical officer.

Obtaining medications prior to departure is a necessity, as the quality and availability of medications available overseas is variable (4). Most groups will plan to carry a small range of POMs; mainly antibiotics, analgesics and anti-emetics.

Expedition types vary greatly, affecting both the level of medical support and the manner in which medicines are obtained. Expedition companies/charities (referred to as commercial expeditions) often employ the services of a medical advisor (MA) – a medical professional with expedition experience and knowledge. Smaller, individually organised (non-commercial) expeditions will typically source their own medical kits and healthcare advice. Clause 6.7 of the British Safety Standard 8848(5) highlights specifically the responsibilities of expedition providers in relation to the provision of suitable first-aid and medical kits, and medical training and support.

Guidelines Development

The Royal Geographical Society Expedition Medical Advisory Committee (RGS-MAC)(6) was established in 1996, with a remit to provide medical advice and support to overseas expeditions. Since its creation, the RGS-MAC has been involved in research publications relating to health and safety in remote and wilderness environments, culminating in the development of two of the UK's most significant expedition health and safety publications (2)(5).

Guidelines were developed from a position paper produced and subsequently discussed at a meeting of the Royal Geographical Society Medical Advisory Committee. These set out what the authors believe should be adopted as best practice. To summarise in a 'statement of need':

“In the absence of an appropriately qualified expedition medical officer, the authors wish to develop a mechanism that legally permits non-medically qualified individuals, in an emergency situation, to carry a small number of prescription only medicines, supplied in the UK prior to departure, for the treatment of illness or injury for the benefit of expedition team members.”

Provision of Prescription Only Medicines and UK Law

Obtaining and carrying POMs in the UK is governed by the Human Medicines Regulations 2012(7) (amended 2014, replacing the Medicines Act 1968(8)). Legislation is interpreted and enforced by the Medicines and Healthcare products Regulatory Agency (MHRA).

Furthermore, the MHRA produces guidelines intended to make practices safer still, though there is a precedent for the MHRA agreeing not to enforce such guidelines in particular circumstances. The

MHRA has identified alternative practices for certain groups whose roles and environment require them to work outside existing legislation. For example, British Army Combat Medical Technicians required to carry and use medications overseas.

Those involved in prescribing are bound by professional codes of practice. The General Medical Council (GMC), the Nursing and Midwifery Council (NMC) and the Royal Pharmaceutical Society (RPS) have issued standards and frameworks for prescribers (9-12) which are applicable to expedition medicine and prescribing for expeditions.

Unlike legislation that may only apply within the UK, professional bodies may take a view and make judgement on the activities of practitioners wherever in the world they work.

Current Practice

Supply

Provision of POMs in the UK for overseas expeditions, are covered by private prescriptions, as the activity falls outside provisions of the UK National Health Service. Medicines can be supplied to an expedition in one of four ways:

Expeditions with no medical professional in attendance:

1. To an individual on the expedition either under a patient group direction (PGD)(13) or via a private prescription. This is normally undertaken by a registered GP, or Care Quality Commission registered clinic or General Pharmaceutical Society registered pharmacy. Anecdotal evidence would suggest that even though the medicines are prescribed to one individual, when out of the UK they are used as 'group medicines' and given to un-named expedition members as and when medical needs arise. This is in effect, treating a patient with someone else's medicines.
2. To an expedition leader via an expedition company's medical advisor (MA) who uses their own stock. Such stock is obtained via a pharmaceutical wholesaler in original and unlabelled packs. A pharmacy with a wholesaler dealer's licence may supply medicines to a medical practitioner for their own stock. This stock will require careful repacking and clear labelling to make it suitable for its intended purpose. Before departure, the MA supplies medicines to a

named individual on the expedition - normally the expedition leader (EL). **This individual is carrying the medicine ‘on behalf of’ the company MA.** In the absence of a trained medical professional (the ideal scenario) ELs often have a dual role, acting as both medics and leaders. Where authority is delegated (preferably through a written and signed agreement), direction on safe storage and proper use of medicines should be provided by the MA, who remains ultimately responsible. **The approach of supplying from own stock for group use is the most contentious in the view of the MHRA and warrants further discussion.**

3. Medicines and medical care are sourced in country, by the individual patient or the medical officer.

Expeditions with a Medical Officer:

4. If a Medical Officer with prescribing privileges accompanies the expedition, they may dispense medications as required. This model is directly analogous to a GP who carries medicines in the doctor’s bag for emergency use.

All four options seek to balance UK law for the safe prescribing and supply of medicines, against the need to treat individuals abroad in situations where access to safe and adequate healthcare may be either unavailable or sub-optimal in quality.

Carrying medicines across international borders

‘Carrying medicines across international borders is usually restricted to those for personal use, usually no more than one month’s supply, with extra restrictions applied to narcotics and psychotropics. Larger quantities may officially need an import licence (14). Whether a medical kit falls into the category requiring such a licence depends on the country in question, though it would always be good practice for a larger kit to be accompanied by a letter of authorisation from the prescribing clinician, along with a statement highlighting that any medicines are for the sole use of the expedition members and are not the subject of any commercial transaction. In practice, smaller quantities of appropriately packaged and labelled medicines would not normally create problems.

Step-by-step guidelines for the provision of POMs to groups on expedition without an accompanying medical officer

In the absence of a medical officer, many expeditions currently utilise method 1 or 2 above, or a variation thereof. The authors suggest the following guidelines in an attempt to bring the use of POMs on overseas expeditions within a legal framework.

Option One – Individual Medical Kits

1. In liaison with the expedition company, the MA draws up a list of recommended medications for a given expedition.
2. Using the MA's recommendations, a prescription is provided to participants by their GP or another prescriber with expertise in expedition medicine (see point 3).
3. The prescriber must:
 - a. Check the recommended drug list is suitable for patient
 - b. Provide clear written directions about how and why to take each POM, including possible side effects and reasons to stop treatment (some of this information may be present in the drug patient information leaflet (PIL))
 - c. Provide advice about any follow up required following use of POM (e.g. blood tests, review consultation, etc.)
 - d. Provide accurate written storage guidance for the medications
 - e. Provide specific advice regarding medicine import and export restrictions
 - f. Provide a covering letter for the participant to carry – this may be helpful in explaining to authorities why the POMs are being transported

The individual is issued their personal medication from a pharmacist. As the medication is being prescribed for conditions which would arise while travelling outside the United Kingdom, the GP should issue a private prescription. However, GPs may not be willing to issue prescriptions for conditions or situations that fall outside their normal area of expertise.

Option Two – Group medical kit

If an MA is personally supplying a team kit for use by all members, they must:

1. Order supplies directly from a pharmacy (including online pharmacies) with a wholesaler's licence, for delivery to the expedition organisation and ensure they are safely stored
 - a. Supervise appropriate packaging and labelling of the medications
 - b. Provide written instructions on the use of the medicines in each medical kit
 - c. Ensure adequate training of EL regarding the use of the medical kit
 - d. Provide further advice on follow-up, storage and transportation (see paragraphs 3c to e, above)
 - e. Undertake adequate medical screening of all individuals on the expedition (see paragraph 3a, above).
 - f. Highlight any medicines that may be contraindicated for certain members of the team, identifying these medications to the EL and the individual
 - g. Provide instruction on how medicines are selected, checked and issued
2. Make all team members aware of the MA's guidance regarding self-treatment and supply to third parties
3. Arrange for the team medical kit to be carried overseas by the EL. The POMs remain the property of the MA alone and only those screened by the MA may make use of the medications, according to company guidelines
4. In the event that a POM is needed, authorisation for their use should be confirmed in one of three ways. In order of preference:
 - a. Seek telemedical advice from an appropriate UK doctor. Recommendations for telephone consultations are already available from the GMC(10). This may be the MA, the patient's own GP (if they are willing) or a medical advisor at a medical assistance or insurance company. They confirm clinical details and provide advice on treatment. Ideally, the prescriber would advise, since they may be in a position to refer to the participant's medical information. The availability of satellite communication greatly facilitates obtaining medical advice. Some medical assistance

companies can set up ‘conference calls’, which include the patient, the expedition leader, an assistance company medic, and expedition organisers.

- b. Depending upon the qualification and training of the clinician, taking local advice maybe be an option. Whilst often having considerable experience of country-specific medical problems, anecdotal evidence would suggest in-country physicians can also be risk averse when dealing with UK groups, particularly adolescents. Furthermore, there is a risk of unfamiliar and unnecessary drugs being prescribed. However, as previously highlighted the manufacturing quality of local medicines, or risk of counterfeit drugs is a global issue for modern healthcare(4).
- c. In an emergency and in the absence of professional healthcare advice, the EL may either
 - i. Resort to simple first-aid measures or
 - ii. Adhere to previously written instructions for the management of illness on the expedition. Instructions for treatment should be made as clear as possible, tailored to the level of medical training provided. Patient information leaflets (PILs) may also be useful. Non-medics using this option should adhere to the POM administration flow chart (figure i) which can be used each time a medication is dispensed.
 - iii. The EL selects the medication from the kit and confirms the name and dose with another adult and the patient. The patient is deemed to be supplied by the MA according to their instructions, not by the person carrying the medical kit.
5. Accurate records are kept by the EL, including the history, examination, advice received, management recommended and medications used.
6. On return to UK, the MA should consider whether any medical follow up is required for anyone treated on expedition.
7. Any medication that has been dispensed on expedition must be recorded on a patient’s individual record card. On return to the home country, medical records must be stored securely

by the expedition medical officer. It may be advisable in some circumstances for information to be shared with the patient's family doctor or specialist.

8. POMs which are undamaged, have not been exposed to extremes of temperature and remain in date may be retained for future trips. Other medication (including those medications purchased overseas) should be given to a pharmacist for disposal, either in the host country or on return home.
9. Liability in the event of mishap on expedition remains unclear.
 - a. If the medical officer has issued instructions that a supplied medicine is only to be used under medical supervision and the expedition member does not follow that instruction, then the prescriber is unlikely to carry liability (to the author's knowledge, yet to be tested in law).
 - b. If a local practitioner makes an error then it would of course be their responsibility
 - c. In the case where a medicine is prescribed by for an individual and is taken by that individual and something goes wrong that good prescribing practice would have prevented, then, under UK law, the prescriber is responsible.
 - d. The most significant (and potentially most likely) event surrounds an adverse drug reaction following the administration of POMs by an EL without prior medical consultation (perhaps as a result of restricted communication or emergency situation). In this situation there is *potential* for the prescriber to be saddled with contributory liability. However, this, to the authors' knowledge, has yet to be tested in the expedition setting.

The authors propose the following further work:

1. Discussion of the proposed guideline with the MHRA
2. Invite feedback and comment from the wider expedition community
3. Encourage dialogue with medical professional indemnity companies to promote understanding and support for the guidelines
4. Seek medico-legal clarification, particularly around the areas of liability

5. The solutions suggested are relevant to UK based expeditions. The current situation in countries other than the UK is not clear and requires further research involving clinicians familiar with local medical law. This could involve organisations such as Union International Alpiniste Association (UIAA) Medical Commission.

Conclusions

Expedition teams travelling abroad frequently carry medical kits containing prescription only medicines (POMs), as the quality and availability of medicines in-country may not be acceptable and delay in treatment hazardous. Expeditions without accompanying medical professionals rely on non-medics administering POMs and at present there is no published guidance relating to drug acquisition and administration in these situations.

These guidelines suggest a workable protocol for the management of POMs in an expedition environment. In many areas, it exceeds the individual codes of practice of the professional groups involved, but by necessity, some aspects of the protocol fall outside normal practice of medicines management.

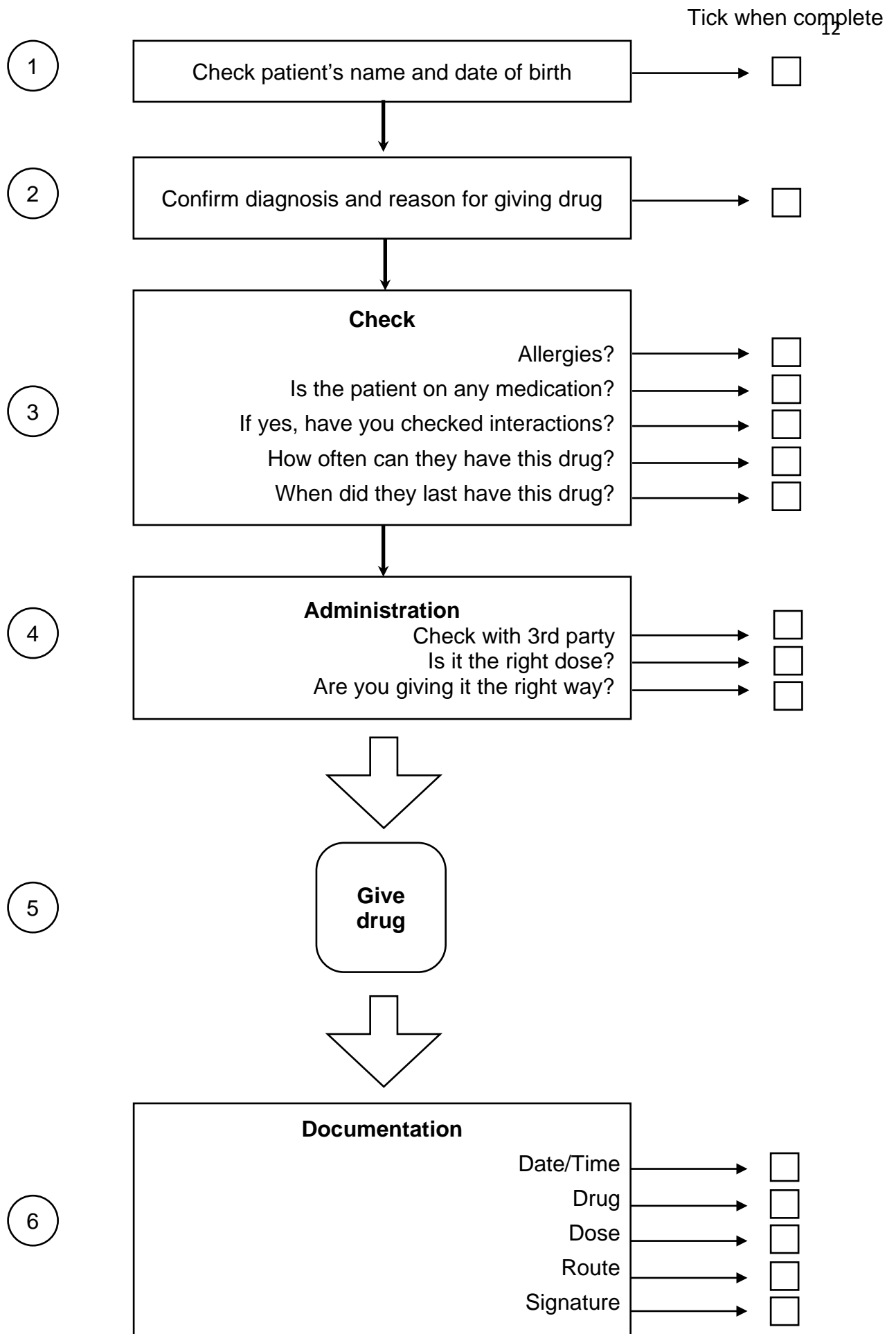


Figure 1. Drug administration checklist for the safe administration of medicines by non-medically trained individuals.

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