Good practice recommendations for outpatient parenteral antimicrobial therapy (OPAT) in adults in the UK: a consensus statement

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These good practice recommendations for outpatient parenteral antimicrobial therapy (OPAT) are an update to a previous consensus statement on OPAT in the UK published in 1998. They are based on previous national and international guidelines, but have been further developed through an extensive consultation process, and are underpinned by evidence from published literature on OPAT. They provide pragmatic guidance on the development and delivery of OPAT services, looking at all aspects of service design, care delivery, outcome monitoring and quality assurance, with the aim of ensuring that OPAT services provide high-quality, low-risk care, whatever the healthcare setting. They will provide a useful resource for teams developing new services, as well as a practical set of quality indicators for existing services.

Keywords: home infusion therapy, guidelines, intravenous antibiotics, community

Introduction

Outpatient parenteral antimicrobial therapy (OPAT) is a method for delivering intravenous antimicrobials in the community or outpatient setting, as an alternative to inpatient care. It is useful for patients who require parenteral therapy for moderate to severe infections but are otherwise well enough to initiate or continue therapy without an overnight stay in hospital. OPAT has been used in many countries for over 30 years and a wealth of evidence has accumulated supporting its clinical justification and cost-effectiveness.

In the UK, until recently OPAT was limited to a small number of specialist centres and led by enthusiastic individuals,1–5 but in the past few years it has started to expand, with increasing recognition of its significant benefits to local healthcare services and patients. Expansion of the traditional UK OPAT model of infectious-diseases-led services has occurred, with new service developments based within clinical microbiology, acute medicine and primary care. The benefits of OPAT include admission avoidance and reduced length of stay in hospital, with resulting increases in inpatient capacity, significant cost savings compared with inpatient care,5,6,7 reduction in risk of healthcare-associated infection and improved patient choice and satisfaction. All these benefits underpin the philosophy and direction of the UK healthcare-quality strategy, with the emphasis on patient-centred and ambulatory care. However, by its very nature OPAT involves less patient supervision than inpatient care, and therefore carries potentially increased risks.8,9 Where services are established with careful attention to risk assessment and management, these risks are minimized. Several countries have developed national guidelines (standards of care) to guide new service development and as a benchmark for clinical monitoring and quality assurance.10–12

In the UK, a consensus statement published in 1998 gave recommendations on the selection of appropriate infections and suitable patients for OPAT, and detailed priorities for OPAT service development.13 A key recommendation within this document was that OPAT should provide treatment at least equivalent to inpatient treatment. However, its very nature OPAT involves less patient supervision than inpatient care, and therefore carries potentially increased risks.8,9 Where services are established with careful attention to risk assessment and management, these risks are minimized. Several countries have developed national guidelines (standards of care) to guide new service development and as a benchmark for clinical monitoring and quality assurance.10–12

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assured. The aim was to develop consistent, usable, UK-wide, good practice recommendations. This document is the result of this process.

The development of these good practice recommendations (GPRs) was a joint initiative by the BSAC and the British Infection Association (BIA), and forms part of a wider national OPAT project led by the BSAC. The details of this project (which included the development of a generic business case toolkit, a repository of useful OPAT resource and experience through the development of a learning and sharing e-community, and an outcomes database for local use and potential national registry) is available at www.e-opat.com.

**Methods**

A working group was established comprising individuals with experience of setting up and running OPAT in different healthcare settings, patient groups and the commercial sector (see Acknowledgements). The group was co-chaired by two infectious diseases consultants (A. L. N. C. and R. A. S.), both of whom run large OPAT services. An initial set of recommendations was formulated in March 2010, based on previous guidelines,10–13 UK clinician experience and local practice.

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The initial recommendations were then reviewed in detail and revised at a meeting of the working group in May 2010, and subsequently by telephone and email communication. The revised recommendations were presented at the BSAC OPAT European Summit in March 2011; further revisions were made as a result of discussions during the meeting and following an electronic survey of participants in the conference. There were a total of nine revisions to the recommendations.

A comprehensive literature review was undertaken to inform and support the recommendations and to ensure that the GPRs represented a broad view of best practice. The literature search included English language publications since the last UK consensus statement.10–13 UK clinician experience and local practice.

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Once references had been divided into the appropriate groups, full-text articles were obtained and reviewed by members of the working group to extract information to support or refute the GPRs. General and Guideline papers were reviewed, together with literature relating to specific key areas. Antimicrobial papers were also reviewed for key area 3 (Figure 1). Papers of relevance to multiple key areas were cross-referenced. Where evidence on a particular recommendation was lacking in the literature this was noted, but as most reviewed references described non-interventional, observational studies or case series, the levels of evidence have not been included in this review.

The draft GPRs developed by the working group, together with supporting evidence from the literature, underwent a formal consultation process with a wide range of stakeholders, and were revised in light of the comments received.

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**Figure 1.** Flow diagram illustrating process of the literature search.

**Figure 2.** Five key areas reflecting the different components of an OPAT service.

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GPRs

For the purpose of these GPRs, ‘OPAT service’ is defined as a clinical team that supervises parenteral antimicrobial therapy in a non-inpatient setting, i.e. where parenteral antimicrobials are administered without an overnight stay in hospital. OPAT services therefore encompass a range of different service models. It is anticipated that these GPRs can be applied to any model of OPAT, including differing models which may co-exist within one healthcare organization. The GPRs have been divided into five key areas, reflecting the different components of an OPAT service (Figure 2). Each of these will be considered in turn, together with the supporting evidence from the literature review.

OPAT team and service structure

Key points are listed in Figure 3. In addition to the General and Guideline papers, 22 references relating to key area 1 were considered. There was general agreement that OPAT should be conducted using a team approach, with the team led by a clinician/infection specialist with experience in OPAT. There was consensus on the point that an infection specialist should be involved in the service; in some services described in the literature the infection specialist also acted as lead clinician with direct contact with patients, while in others infection input was provided by a medically qualified microbiologist. One paper examined a group of patients who were reviewed by an infectious diseases consultant after they had been referred for OPAT. In 89% of patients there was a change in antibiotic management, including immediate intravenous to oral switch in 39%. This was associated with excellent clinical outcome and significant cost saving, and thus supports the involvement of specialist infection doctors in OPAT. The key role of the OPAT specialist nurse was also stressed, and also the importance of community nurse involvement in the team where they are involved in administering therapy. An important principle of OPAT is that pharmaceutical care should be equivalent to that expected for hospitalized patients. This is supported by the literature where the clinical pharmacist was identified as a key member of the OPAT team. In addition, the OPAT team requires administrative and secretarial support, either through a dedicated OPAT support team or through the structures already present within the organization. All papers stressed the importance of excellent communication between team members, and also with referring clinicians and other relevant health professionals.

Clinical responsibility is extremely important in ensuring a high quality service with clear accountability. The GPRs state that clinical responsibility should be shared between the referring clinician and the OPAT clinician, unless otherwise agreed. This recognizes the complementary clinical skills and perspectives of

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<th>Figure 3. OPAT team and service structure.</th>
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1.1 The OPAT team should have clear managerial and clinical governance lines of responsibility.

1.2 The OPAT team should have an identifiable medically qualified lead clinician who has identified time for OPAT in their job plan.

1.3 The OPAT multidisciplinary team should include, as a minimum, a medically qualified clinician (e.g. an infectious diseases physician, internal medicine specialist or a surgeon with an infection interest), a medically qualified infection specialist (infectious diseases physician or clinical microbiologist), a specialist nurse with expertise in parenteral drug administration and intravascular access device selection and placement, and a clinical antimicrobial pharmacist.

1.4 A management plan (including use of standardized treatment regimens or specific patient group directions) should be agreed between the OPAT team and the referring team for each patient and this should be documented.

1.5 Clinical responsibility for patients receiving OPAT is shared between the referring clinician and the OPAT clinician unless otherwise agreed.

1.6 There should be communication between the OPAT team, the patient’s general practitioner, the community team (when appropriate) and the referring clinician. As a minimum this should include notification of acceptance onto the OPAT programme, notification of completion of therapy and notification of further follow-up/management plan post-OPAT.

1.7 The written communication should be clear, multi-disciplinary (e.g. an integrated care pathway) and available and accessible to all relevant members of the clinical team at all times including out of hours.
system-based clinicians and infection specialists. Variable practice is described in the literature, with the OPAT clinician assuming responsibility in some situations, whilst in others the referring clinician retains responsibility, often where the infection specialist in the OPAT team is a microbiologist. Clearly different models may be applicable in different settings, even within the same OPAT service. However, what is important from all the studies, and agreed by the working group, is that there is: (a) a named physician taking overall clinical responsibility for all aspects of each patient’s care, as there would be for an inpatient with an equivalent condition; (b) a clear and documented management plan for each patient agreed with the referring team; and (c) a clear management structure for the OPAT team within the organization in which it is based. In this regard OPAT fits well into antimicrobial stewardship programmes, and is thus well placed to ensure prudent and cost-effective use of antimicrobials.

Patient selection
In addition to the General and Guideline papers, 31 references were considered for this key area. There was considerable support for the recommendations concerning the use of inclusion and exclusion criteria (Figure 4). Some are infection-specific, e.g. for cellulitis, community-acquired pneumonia or endocarditis, while other criteria relate to severity of infection. There was general agreement that a doctor should make this assessment; however, it is acknowledged that in an experienced OPAT team, competency in patient assessment may also be available from non-medical members. All papers stressed the importance of patient-specific criteria, e.g. ability to understand OPAT, suitable home environment for intravenous antimicrobial administration or ability to attend daily for therapy, manual dexterity for self-administration and access to a telephone. Support from family or carers is extremely important, particularly for elderly patients or those with multiple co-morbidities. A safe home environment for visiting healthcare professionals is essential. A team approach to patient selection is important, the OPAT specialist nurse being a key individual in assessing patient criteria for acceptance for OPAT.

All previous guidelines stressed the importance of patient involvement in developing a treatment plan and the need to obtain informed consent, although the need for documentation of consent was mentioned by only a few. It is logical to assume that implicit consent is adequate (for OPAT), as is the case for most other forms of clinical care. If consent is required, it therefore follows that OPAT should always be offered as an alternative to inpatient care and that patients should be able to choose between these options. The importance of providing clear written information designed for patients was generally agreed.

The final recommendation in this key area relates to the need to undertake risk assessment for venous thromboembolism in patients undergoing OPAT following an inpatient stay. Such patients will have already undergone a risk assessment during their hospitalization, and it is therefore logical to consider this risk further as they transfer to OPAT. It is possible that OPAT patients have an increased risk of thromboembolism compared with patients receiving oral antimicrobial therapy in the community (who themselves are at increased risk compared with background population levels), but the magnitude of risk is unknown and thromboprophylaxis in this setting is not supported by any published data. Therefore, the group is currently not making a recommendation for the use of venous thromboprophylaxis in patients who are managed via OPAT without prior hospital admission.

Antimicrobial management and drug delivery
In addition to the General and Guideline papers identified through the literature review, 52 references were reviewed for this key area. Other relevant guidelines were also reviewed, e.g. the American Society of Health-System Pharmacists (ASHP) guidelines on the pharmacist’s role in home care, and current UK Royal College of Nursing (RCN) recommendations. These documents and the papers allocated to this key area from the literature review provide support for most of the recommendations made in this document. Specific issues not covered included, firstly, the question of who writes prescriptions—this was an area that was

Figure 4. Patient selection.
felt to be important by the working group, hence its inclusion. Secondly, the frequency of pharmacological review was not stated clearly in any of the reviewed literature, although the ASHP guidelines recommend that personnel involved in the care of the patient meet regularly. Thirdly, although a number of publications explored the issue of training patients to self-administer therapy, few specifically mentioned development of a formal protocol for documentation of this competency. This was felt to be important by the working group.

Of the recommendations for this key area (Figure 5), one states that choice of antimicrobial is the responsibility of the infection specialist, in conjunction with the referring clinician. One difficult issue is the potential conflict between the choice of the most effective and narrow-spectrum agent, and the need for convenience in dosing and administration. One of the previous guidelines states that ‘antibiotic selection should be based on appropriate prescribing principles rather than purely dosing convenience’. Therefore, antimicrobial use should be subjected to close review by the local antimicrobial stewardship programme. No guidance regarding choice of specific antimicrobial agent has been given in these GPRs, but this is an important consideration for individual OPAT services and clinicians.

Previously published guidance has recommended that the first dose of a new antimicrobial should be administered in a supervised setting, to minimize the risk associated with the development of a serious drug allergy including anaphylaxis. However, the term ‘supervised setting’ has not been clearly defined, and in view of the increasing development of OPAT services based wholly in community settings, the guideline development group felt that this could include the patient’s own home, as long as the healthcare worker administering the dose is trained and equipped to manage anaphylaxis.

Figure 5. Antimicrobial management and drug delivery.
Monitoring of the patient during OPAT

OPAT is inherently associated with increased risk compared with treating in the inpatient setting, since patients are under less close clinical observation.8,9,53 Thus the working group felt that it was very important to produce clear recommendations on how to monitor patients’ progress during therapy, and on developing pathways for rapid access to clinical care if problems arise.12,13 Overall, at least 25% of patients receiving OPAT will develop adverse reactions, which range from mild antibiotic-associated diarrhoea to life-threatening line infections,53–56 and it is important that physicians and nurses managing OPAT patients are familiar with potential complications so that these can be detected early. Up to 10% of patients on OPAT will discontinue their therapy early because of adverse events,12 most of which relate to either the antibiotic or the line.53,57–59 Progression of infection on therapy is an unusual cause of discontinuation of OPAT, although it is more frequent in patients with endocarditis.60 Rates of readmission for any reason from OPAT range from 4%–12%, emphasizing the need for a formal readmission pathway.4,53,54,56 In addition, one study demonstrated that there is a significant need for unplanned access to advice or review, with 6% of patients requesting urgent telephone advice, and a further 6% requesting unscheduled home visits.54 Complications appear to increase with the duration of OPAT, particularly changes to blood parameters,12,53 and thus the proposal that stable patients on prolonged antimicrobial courses could be monitored less frequently may not be appropriate.

The first statement for this key area (Figure 6) relates to clinical reviews of patients receiving OPAT for cellulitis and other soft tissue infections. The working group felt that daily review was appropriate to allow rapid switch from intravenous to oral therapy as soon as clinically indicated. There are a number of publications describing this practice,4,18,29 and none advocates less frequent reviews. The GPRs deliberately mention daily review by the OPAT team, since this may be performed by an experienced OPAT nurse rather than a doctor where the former has the appropriate expertise.18 Some OPAT practitioners advocate the prescription of a standard minimum duration of intravenous antibiotic therapy for skin and soft tissue infections. The working group felt this approach was not supported by published experience or by the principles of good antimicrobial practice within local stewardship programmes, particularly as in these circumstances patients are required to be seen by a trained healthcare professional on a daily basis to receive intravenous antibiotics.

For patients on prolonged antimicrobial courses for other types of infection, the GPRs state that there should be regular clinical reviews, the frequency of which should be decided locally. Other published guidelines also recommend regular reviews.10,12,13 Although a number of papers described weekly (or more frequent) reviews in the short term and twice-monthly reviews for stable patients,60,61 it was felt, during the working group discussions and the subsequent consultation process, that the decision about the precise frequency of reviews should be left to individual teams. The type and frequency of blood test monitoring for different OPAT antimicrobial agents is described in detail in the Infectious Diseases Society of America (IDSA) guidelines,12 and most papers

| 4.1 Patients with superficial skin and soft tissue infection should be reviewed daily by the OPAT team to optimize speed of intravenous to oral switch. |
| 4.2 There should be a weekly multidisciplinary meeting/virtual ward round to discuss progress (including safety monitoring and outcome) of patients receiving OPAT. |
| 4.3 Patients receiving in excess of 1 week of antimicrobial therapy should be regularly reviewed by the OPAT specialist nurse and physician, in addition to discussion at the weekly multi-disciplinary team meeting. The frequency and type of review should be agreed locally. |
| 4.4 Patients should have blood tests performed at least weekly if OPAT <1 month or at least twice monthly if OPAT >1 month. Blood tests should include full blood count, renal and liver function, C-reactive protein (CRP) and therapeutic drug monitoring where appropriate. Other tests may be required for specific indications or therapies. |
| 4.5 The OPAT team is responsible for monitoring clinical response to antimicrobial management and blood investigations, and for reviewing the treatment plan, in conjunction/consultation with the referring specialist as necessary. |
| 4.6 There should be a mechanism in place for urgent discussion and review of emergent clinical problems during therapy according to clinical need. There should be a clear pathway for 24 h immediate access to advice/review/admission for OPAT patients agreed with the referring clinician, and this should be communicated to the patient both verbally and in writing. |

Figure 6. Monitoring of the patient during OPAT.
describe weekly (or more frequent) monitoring, as indicated by the clinical scenario or choice of antimicrobial.\(^4,35,53,60,62,63\) In addition to routine haematological and biochemical monitoring, other specific tests may be required, e.g. creatine kinase in patients on daptomycin;\(^64\) other forms of monitoring may also be appropriate, e.g. vestibular function in patients on long-term aminoglycoside therapy.\(^55,60,65\) In addition to clinical review and ongoing monitoring, the GPRs state that patients should be discussed weekly at a multidisciplinary meeting; this statement is also included in other guidelines and descriptive studies.\(^10,25,53,54\) The adoption of a regular team meeting with discussion of patients currently receiving OPAT (the so-called ‘virtual ward round’) would facilitate the collation of data for outcome monitoring and clinical governance purposes. Time and available resources will dictate the depth of discussion of each patient, and allowances should be made for services where high-volume, short-term therapy predominates, e.g. in OPAT services treating predominantly skin and soft tissue infections, such as those based within an emergency department.

### Outcome monitoring and clinical governance

In addition to the General and Guideline papers, 33 references were considered for this section of the recommendations. The key recommendations are shown in Figure 7. All previous guidelines note the importance of prospective monitoring of outcome data, and this is most easily achieved by a dedicated OPAT database held locally.\(^4,52,59,66\) National/international collections of data would also be helpful to allow comparison between units,\(^67–69\) and the development of a UK database is ongoing through the BSAC OPAT project, as noted earlier. As with inpatient care, it is critical that OPAT services have a robust clinical governance structure and are subjected to the same rigour of inspection and risk assessment.\(^69,70\) This requires central co-ordination of the service(s), whatever the service model; this is more readily achieved with a service run by a single team through a central ‘hub’ than with a more diffuse model of care based wholly in the community, but central co-ordination is equally important for both models.

In monitoring treatment outcome it is recommended, as a minimum, that clinical outcome of the OPAT episode and the response of the infection to the antimicrobial therapy is recorded at the end of intravenous therapy. OPAT outcome should also take into account adverse events, need for change in antimicrobial therapy and readmission. Many studies report the use of simple outcome measures, e.g. ‘cure’, ‘improvement’, ‘readmission’ or ‘no change’, with additional monitoring of adverse events, in particular vascular access complications.\(^3,4,28,71\) The IDSA guidelines\(^12\) describe a more complex series of outcome parameters, specifically:

1. Clinical status (improved, clinical failure or no change)
2. Bacterial infection status (culture negative, persistent pathogen or new pathogen)
3. Programme outcome (treatment completed as planned, or reason for non-completion)
4. Antibiotic use (course completed as planned, or reason for non-completion)
5. Vascular access complications
6. Additional outcome measures (return to work, survival status or performance against physician expectations)

However, although these are useful in the context of a formal review of a service, they are less applicable on a day-to-day basis, and others have suggested more practical outcome measures, e.g. OPAT success or OPAT failure (including admission following initiation of OPAT, any adverse event and progression of infection).\(^72\) It would be useful to develop standard outcomes to facilitate monitoring of the performance of a service over

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**5.1** Data on OPAT patients should be recorded prospectively for service evaluation and quality assurance including audit. A local database would facilitate this process. This information should be shared with all relevant stakeholders, including referring clinicians and general practitioners and may contribute to a national registry.

**5.2** Standard outcome criteria should be used on completion of intravenous therapy. Specifically, data on adverse drug reactions, vascular access complications, *Clostridium difficile*-associated diarrhoea and *Staphylococcus aureus* bacteraemia should be recorded.

**5.3** Risk assessment and audit of individual processes (particularly new processes) should be undertaken as part of the local clinical governance programme.

**5.4.** Regular surveys of patient experience should be undertaken in key patient groups (e.g. short-term treated groups such as those with soft tissue infection and longer-term treatment groups such as those with bone and joint infection).

**5.5** Each member of the OPAT team is responsible for personal continuing professional development relating to best clinical practice.

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**Figure 7.** Outcome monitoring and clinical governance.
time, and to make comparisons between different services; this is a key objective of the BSAC OPAT project as part of the ongoing development of a standardized database. Furthermore it would be useful to standardize the timing of outcome assessments: in most OPAT series, outcomes were measured on completion of intravenous therapy, and longer (potentially more useful) follow-up data were less frequently recorded.

OPAT provides the opportunity to deliver much more patient-centred care than in the traditional inpatient setting, and the importance of patients’ involvement in their care has been stressed repeatedly. These GPRs incorporate a statement relating to the need to monitor patients’ views of the service that they are receiving, to ensure that it remains truly patient-focused. Surveys of patients have been reported by many, and are universally positive. However, the data on objective patient outcome, such as quality of life and return to work, or on subjective outcomes relating to the patient experience are more limited, and this is an area where further work is needed.

The final statement in this section refers to the requirement for each OPAT team member to maintain and update their knowledge to ensure best clinical practice. There are established general guidelines on this point for doctors, nurses and pharmacists. However, currently there is no formal training programme or qualification/accreditation relating to OPAT, and this would be a useful development in the future.

Conclusions

Central to the current healthcare reforms is the provision of high quality, patient-centred, cost-effective care that is easily accessible. In infection management, OPAT offers a highly clinically efficient, cost-effective and safe alternative to inpatient care where parenteral therapy is deemed necessary. Whilst it has been regarded as a standard of care in North America, where the main driver has been financial, only recently have we seen a considerable expansion of services in the UK, which we anticipate will continue to increase. Again, the primary driver in the UK has been economic, but there is also a desire by infection specialists to increase patient choice by providing alternative models of care where appropriate. The potential economic impact of these services and the supporting evidence are communicated in a separate document by a sub-group of the BSAC OPAT Steering group.

Our clinical service recommendations were developed to provide a basis on which this ongoing expansion can continue, to ensure that all OPAT services provide an equivalent quality of care, to maximize patient benefits and to minimize clinical risk. They will serve as a useful resource for groups setting up new services, as well as a set of quality indicators against which existing services can measure their performance. We hope that these recommendations are not only of value to UK healthcare teams, but constitute a sufficiently generic resource to encourage adoption and adaption within European and other healthcare systems.

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