

CME Infectious diseases

Edited by **Dr Gavin Barlow**, consultant physician and honorary senior lecturer, Department of Infection and Tropical Medicine, Hull and East Yorkshire Hospitals NHS Trust, UK; **Dr Hiten Thaker**, consultant physician, honorary senior lecturer and clinical lead for the Department of Infection, Hull and East Yorkshire Hospitals NHS Trust, UK

Outpatient parenteral antimicrobial therapy (OPAT) and the general physician

DA Barr, specialist registrar; **RA Seaton**, consultant physician

Brownlee Centre for Infectious diseases, Gartnavel General Hospital, Glasgow, UK

Introduction

Outpatient parenteral antimicrobial therapy (OPAT) refers to outpatient or community-based management of an infection via the administration of an intravenous (IV) antimicrobial without an overnight hospital stay. Patients may be managed without admission or may transition to OPAT following hospitalisation. By minimising hospital stay, OPAT is increasingly recognised as a cost-efficient and acceptable management strategy for a variety of selected patients requiring either short- or medium- to long-term parenteral therapy in the UK (Table 1).^{1–5} This short article outlines good practice recommendations and highlights OPAT management of infections commonly encountered by physicians with acute medical duties.

How does OPAT normally work in the UK?

The precise structure and function of OPAT differ between services and are adaptable to local requirements. It is recommended that the core OPAT team includes a consultant

clinician, a medically qualified infection specialist (for example an internal medicine specialist and a clinical microbiologist, or an infectious diseases physician holding both roles), a clinical pharmacist with antimicrobial interest and an OPAT nurse specialist with intravascular access expertise. Delivery of antimicrobials may occur in an OPAT clinic area (which will require patient transport to and from the clinic) or in the home (with the patient or carer trained to administer IV treatment or with visits from OPAT staff or community nurses). Increasingly, some aspects of OPAT (such as the management of cellulitis) are delivered in the context of an acute-medicine-led 'hospital at home' service, which may encompass other lower-risk acute medical conditions, such as selected venous thrombo-embolism, chronic obstructive pulmonary disease (COPD) exacerbation and chronic cardiac failure. Selection of patients with infection who are suitable for ambulatory care is essential. Substantive considerations include infection severity, patient mobility, stability of comorbidity and the need for ancillary management and understanding of care.

Good clinical practice recommendations for OPAT

OPAT guidelines have been produced in a number of countries and updated good clinical practice (GCP) recommendations were published for the UK in 2012, covering five key components of OPAT services (Table 2).⁶

Specific conditions pertinent to medical specialties and acute medicine

Skin and soft tissue infections

Cellulitis and erysipelas alone account for about 70,000 admissions to hospital in England annually.⁷ A large point prevalence survey of inpatient antibiotic use in Scotland found that 10% of hospitalised patients were receiving IV antibiotics, one in six of whom were being treated for skin and soft tissue infection (SSTI).⁸ Randomised control trial (RCT) data suggest about one-third of patients with an SSTI requiring IV antimicrobial therapy could be managed as outpatients, with equivalent clinical outcomes and higher patient satisfaction.⁹

Complicated and drug-resistant SSTI cases can also potentially be treated through OPAT. This has been facilitated in recent years by novel broad-spectrum antimicrobial agents with expedient pharmacokinetic properties allowing once daily dosing. In a phase III RCT establishing ertapenem for complicated SSTI treatment, 40% of patients were managed in whole or in part as outpatients.¹⁰ Similarly, in a retrospective

Key points

Outpatient parenteral antimicrobial therapy (OPAT) is an increasingly utilised, safe and effective model of care in the UK, endorsed by the Department of Health as a key antimicrobial prescribing decision within an antimicrobial stewardship programme

National and international guidelines and clinical governance standards have been published to support quality assurance in OPAT services

Several models of OPAT organisation and delivery are in use with adaptability to local circumstances

Skin and soft tissue, and bone and joint infections account for a large proportion of OPAT episodes, but a wide variety of infections including endocarditis can be treated in OPAT safely and effectively

Novel antimicrobials with long half-life are useful in OPAT and can allow convenient management of drug resistant microbes

KEY WORDS: Cellulitis, endocarditis, bone and joint infection, antimicrobial stewardship, hospital at home

Table 1. Characteristics of recently published UK OPAT service cohorts.

Cohort	Number of OPAT episodes	Example conditions treated (% OPAT episodes)	Antibiotics used (% OPAT episodes)	IV access device*	Site of delivery
Glasgow ¹	2,638	SSTI (52.7)	Ceftriaxone (58.8)	Butterfly needle (50.1)	C-OPAT (76.6)
		BJI (24.5)	Teicoplanin (26.4)	Short peripheral device (27.7)	S-OPAT (18.7)
		Endocarditis (3.1)	Daptomycin (2.0)	Midline (23.6)	OPAT nurse H-OPAT (3.9)
		Meningitis (2.3)	Ertapenem (1.8)	PICC (1.3)	Primary care nurse H-OPAT (0.1)
		UTI (1.7)	Flucloxacillin (1.1)	Tunnelled central line (5.3)	
Oxford ⁴	2,059	BJI (73.3)	Ceftriaxone (43.0)	PICC (65.6)	H-OPAT (76.0)
		SSTI (5.6)	Teicoplanin (36.8)	Tunnelled central line (31.4)	S-OPAT (24.0)
		Bacteraemia (5.7)	Meropenem (6.2)	Midline (1.6)	
		Endovascular (3.5)	Vancomycin (5.9)	Non-tunnelled central line (1.1)	
			Ertapenem (1.6)		
Sheffield ²	334	SSTI (59)	Ceftriaxone (80.5)	Peripheral cannula (77.0)	Predominantly C-OPAT and S-OPAT
		CNSI (10)	Vancomycin (3.6)	PICC (14.7)	
		Endovascular (7)	Amphotericin B (3.3)	Tunnelled central line (7.5)	
		Intra-abdominal (5)	Teicoplanin (3.0)		
		BJI (4)	Ertapenem (3.0)		
London ³	303	SSTI (36.6)	N/A	N/A	Primary care nurse H-OPAT (77.2)
		BJI (32.3)			C-OPAT (18.5)
		RTI (10.2)			Private company H-OPAT (2.3)
		Endovascular (5.9)			S-OPAT (2.0)
		UTI (5.9)			

BJI = bone and joint infection; CNSI = central nervous system infection; C-OPAT = OPAT delivery in OPAT clinic/infusion centre; H-OPAT = delivery of OPAT in patient's home by OPAT nurses, primary care nurses or private companies; IV = intravenous; N/A = not applicable; OPAT = outpatient parenteral antimicrobial therapy; PICC = peripherally inserted central catheter; S-OPAT = OPAT delivery by self (patient or carer) in patient's home; SSTI = skin and soft tissue infection; RTI = respiratory tract infection; UTI = urinary tract infection.

*Some percentages have been calculated from published absolute numerators/denominators or graph charts and therefore may be approximate. Proportions that do not total 100% are due to using more than one device in a single OPAT patient episode.

analysis of data from the Cubicin® outcomes registry, 276 of 435 (63%) patients treated for SSTI with daptomycin received OPAT, with a 95.5% success rate in those with complicated SSTI.¹¹

UK OPAT services now have extensive experience of SSTI management and are responsible for a number of service innovations. Based on population pharmacokinetic modelling of patients treated through OPAT, teicoplanin dosing guidelines have been developed which provide effective and convenient individualised three-times-weekly regimens, which are useful for selected SSTIs treated in OPAT.¹² Specialist nurse-led outpatient management of SSTIs, including parenteral antimicrobial prescribing under a 'patient group direction' (PGD) protocol, may be associated with shorter duration of therapy for moderately severe cellulitis.¹³

Even with careful patient selection based on severity classification, failures of OPAT

in SSTI are seen. In a cohort of 963 OPAT-treated SSTI cases in Glasgow, progression of infection occurred in 2.8% of patients. 6% required admission to hospital from OPAT and significant adverse events (predominantly drug reactions) were observed in 7.1%.¹⁴ This emphasises the need for accessible and well-defined pathways for prompt review and escalation of care for OPAT services managing SSTIs.

Infective endocarditis

While OPAT is being used to avoid hospital admission for SSTI, it is also of use in supporting early discharge of patients with conditions requiring more prolonged parenteral antimicrobial therapy. This use is well exemplified by the increasing practice of completing endocarditis treatment through OPAT following initial inpatient stabilisation. In contrast to SSTI, no RCT

data exist for OPAT management of endocarditis. International OPAT guidelines for endocarditis recommend stringent patient selection criteria. Contraindications to outpatient therapy include the presence of a prosthetic valve, persistently positive blood cultures, congestive cardiac failure, vegetations greater than 10 mm in length, recurrent embolic events, conduction abnormalities and *Staphylococcus aureus* aetiology.¹⁵ It is, however, clear from more recent cohort reports that OPAT services are successfully treating *S aureus* and prosthetic valve endocarditis,^{16–18} and recent European Society of Cardiology recommendations do not explicitly preclude this practice (Table 3).¹⁹ It remains standard practice to initially manage endocarditis with a minimum inpatient stay of 2 weeks prior to OPAT, with the possible exception of clinically stable patients with 'oral' streptococcal infection. Careful follow up

during OPAT and consideration of adverse drug reactions, disease progression and complications is essential.

Bone and joint infection

The general physician will encounter bone and joint infections most commonly in the context of diabetic foot or vertebral osteomyelitis/discitis and native joint septic arthritis. Typically, such infections require a combined surgical and medical management approach, including prolonged antibiotic therapy with a significant proportion of IV therapy. The majority of such infections may be managed for a proportion of their therapy via OPAT, although the elderly, those with resistant organisms or diabetic foot disease have a greater chance of a complicated OPAT course (disease complications, drug reactions or readmission), and therefore should be carefully selected and monitored.²⁰

Other infections

A multitude of other infections may be amenable to OPAT therapy, including bacterial meningitis (following initial inpatient management), drug resistant mycobacterial infection, complex Lyme infection²¹ and some imported parasitic infections.²² In particular, Gram-negative infections and extended spectrum beta-lactamase (ESBL) infections are increasingly managed via OPAT.¹ These are usually in the context of a urinary tract infection (UTI)²³ that is not amenable to oral therapy and reflect epidemiological change in the hospital population.

Complications of OPAT

Parenteral treatment outside an inpatient environment potentially exposes patients to a different risk profile. As with any model of healthcare delivery, complications can be anticipated and ameliorated.²⁴ It is recommended that OPAT services systematically record adverse outcomes for quality assurance purposes.⁶ Many (but not all) OPAT models make use of indwelling intravascular access devices (Table 1). These are associated with line infections (at a rate of 0–3 per 1,000 OPAT patient days in published cohorts), while other line events, such as thrombosis and mechanical and chemical phlebitis, occur at higher rates

(0.5–5 per 100 OPAT patient days).^{3,25–27} This underlines the need for specialist nursing involvement with intravascular device expertise in OPAT. Rates of health-care associated infection (HAI) are lower than in hospitalised patients. For example, *Clostridium difficile*-associated disease (CDAD) is rare in OPAT patients, with rates of less than 0.5% per OPAT patient episode in UK cohorts reporting on CDAD.^{1–4} Overall rates of unplanned

readmission from OPAT range from 6% to 12%.^{1–4} Appropriate and well supported self-administration of OPAT by patients or carers at home has not been associated with increased rates of complications.^{4,25}

Antimicrobial stewardship and OPAT

Antimicrobial stewardship is a locally based programme to ensure safe, effective and

Table 2. Summary of good clinical practice recommendations for OPAT in UK.⁶

Component of OPAT service	Description
OPAT team and service structure	<ul style="list-style-type: none"> Explicit delineation of clinical responsibility including an identifiable medically qualified lead clinician, minimum OPAT MDT participation, agreement of plan with referring clinician and adequate formal communication, eg with primary care
Patient selection	<ul style="list-style-type: none"> OPAT team competency to agree infection specific inclusion and exclusion criteria documented for each patient
Antimicrobial management and drug delivery	<ul style="list-style-type: none"> Treatment plan is the responsibility of OPAT infection specialist following discussion with referring clinician with assessment and oversight from clinical pharmacist and local antimicrobial stewardship program OPAT team competency and responsibility for selection, insertion and care of drug delivery device in concordance with RCN standards (including patient/carer training if applicable) All administered doses of IV antimicrobial prescribed and documented, with initial doses given in a supervised setting
Monitoring of the patient during OPAT	<ul style="list-style-type: none"> OPAT team responsibility for monitoring clinical response, including weekly 'virtual ward round', minimum weekly blood monitoring and regular formal review of patients on OPAT for >7 days Explicit adequate pathways for urgent review and 24 hour access to advice/review/admission for OPAT patients
Outcome monitoring and clinical governance	<ul style="list-style-type: none"> Prospective data collection and audit of standardised outcome measures for all patients treated through OPAT

MDT = Multidisciplinary Team; OPAT = outpatient parenteral antimicrobial therapy; RCN = Royal College of Nursing; IV = intravenous.

Table 3. European Society of Cardiology recommendations on suitability of patients for OPAT treatment of endocarditis 2009.¹⁹

Phase of treatment	Guidelines for use of OPAT
Critical phase (weeks 0–2)	<ul style="list-style-type: none"> Complications occur during this phase Preferred inpatient treatment during this phase Consider OPAT if patient has oral streptococci, patient is stable and/or there are no complications
Continuation phase (beyond week 2)	<ul style="list-style-type: none"> Consider OPAT if medically stable. Do not consider OPAT if patient has or has had heart failure, concerning echocardiographic features, neurological signs or renal impairment
Essential for OPAT	<ul style="list-style-type: none"> Educate patient and staff Regular post discharge evaluation (nurses 1/day, physician 1–2/week) Prefer physician directed program, not home infusion model

OPAT = outpatient parenteral antimicrobial therapy.

prudent use of antimicrobials in order to optimise outcome and minimise unintended consequences such as CDAD, methicillin-resistant *Staphylococcus aureus* (MRSA) infection and drug-related toxicity. Following the decision to prescribe an antimicrobial, OPAT has been identified as one of the five key prescribing decisions by the Department of Health in England,²⁸ highlighting the importance of early identification of patients who could be safely and effectively managed in a non-hospital setting. Within the OPAT programme, antimicrobial stewardship principles are similarly important, minimising unnecessarily prolonged IV therapy, promoting early switching from IV to oral treatment and, whenever possible, simplification of antimicrobials to the narrowest spectrum possible.⁶ It is therefore essential that every patient undergoing OPAT has an antibiotic plan and that the plan is reviewed regularly and adapted as circumstances evolve. The development of a patient group direction in skin and soft tissue infection, giving clinical nurse specialists the facility to implement a timely IV-to-oral switch without the need for medical review, has been associated with progressive reductions in the duration of IV therapy.^{13,14} While IV therapy is regarded as a standard of care in the management of many deep-seated infections, the relative efficacy of IV vs oral antibiotic therapy in bone and joint infections is unknown. An Oxford-initiated UK multicentre randomised study of IV vs oral treatment is currently underway and may better define the role of OPAT in this important patient group.

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Address for correspondence:
Dr RA Seaton, Brownlee Centre for Infectious Diseases, Gartnavel General Hospital, 1053 Great Western Road, Glasgow G12 0YN.
Email: andrew.seaton@ggc.scot.nhs.uk

Antibiotic stewardship

Kieran Hand, consultant pharmacist for anti-infectives and post-doctoral clinical academic fellow

University Hospital Southampton NHS Foundation Trust

Introduction

Sir Frank MacFarlane Burnet, winner of the Nobel Prize for Medicine in 1960, wrote of the decline of infectious diseases in 1962: 'One can think of the middle of the twentieth century as the end of one of the most important social revolutions in history, the virtual elimination of the infectious diseases'.¹ Any clinician who has cared for a patient with severe sepsis due to a multi-drug resistant (MDR) *Klebsiella pneumoniae* will recognise the significance of this misconception. Bacteraemias due to MDR bacteria are estimated to have caused more than 8,000 deaths and excess costs of €62 million in Europe in 2007, and prevailing trends indicate that infections caused by MDR Gram-negative bacteria are rapidly increasing, including in the UK.²

Drug resistance is an inevitable consequence of the evolution of microorganisms under antibiotic selection pressure. This phenomenon mandates a perpetual quest to discover new agents that can circumvent emerging resistance mechanisms. Drug discovery and development are expensive, and factors unique to antibiotics, such as relatively short treatment courses, have diverted investment to more profitable areas, leaving an increasingly unmet clinical need.³ Although resistance is inevitable, the pace and extent of propagation of resistant organisms is governed by human behaviour – most importantly antibiotic consumption by humans and animals, as well as hygiene, sanitation and infection control. The profound consequences of antibiotic resistance for individual patients and society create an ethical imperative to protect public health by all available means, including antibiotic stewardship.

Stewardship is as an ethic that embodies responsible planning and management of finite resources. The term antibiotic stewardship has been adopted widely to

encompass initiatives that promote the responsible use of antibiotics, with the goal of preserving their future effectiveness and safeguarding public health.^{4–7} The physician may perceive the concept of stewardship as patronising or insulting and a threat to clinical freedom; nonetheless, physicians in the USA have recently called for mandatory implementation of antibiotic stewardship backed by legislation.⁸ This article sets out the case for antibiotic stewardship and describes commonly used stewardship strategies and the evidence supporting their effectiveness.

Misuse of antibiotics

Antibiotic misuse (Table 1) is common in the UK and throughout the world. In 2009, family doctors in Britain prescribed 50% and 25% more antibiotics per head of population than their contemporaries in the Netherlands and Sweden, respectively.⁹ A cross-sectional study of 8,057 general practices (GPs) in England revealed that antibiotic prescribing volumes varied fivefold between practices at the extremes of the study sample and twofold between practices on the 10th and 90th percentiles.¹⁰ Only one-sixth of this variability could be explained by patient characteristics. A recent study of more than 1.5 million patient visits to GPs in the UK that resulted in a diagnosis of acute respiratory infection reported that the number needed to treat for antibiotics to prevent one admission to hospital due to pneumonia was 12,255.¹¹ Sixty-five per cent of patient visits resulted in a prescription, with prescribing rates varying from 3% to 95% by practice.

At any one time in hospitals in the UK, about one-third of inpatients are prescribed an antibiotic, with the main drivers being respiratory, urinary and skin and soft-tissue infections. Rates of antibiotic misuse in hospitals have remained unchanged at about 50%.^{12,13} Overprescribing of broad-spectrum antibiotics is frequent, with such 'defensive prescribing' attributed to the precedence of treatment success in current patients at the expense of loss of effectiveness due to resistance in the future.¹⁴

Antibiotic prescribing and resistance

The relationship between antibiotic prescribing in the community and resistance is