Irish National Guidelines on the Provision of Outpatient Parenteral Antimicrobial Therapy (OPAT).

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1. Introduction:

Outpatient parenteral antibiotic therapy (OPAT) is a treatment option in patients who require parenteral antibiotic administration, and are clinically well enough not to require inpatient hospital care keller¹. OPAT was first developed in 1970s for the treatment of cystic fibrosis exacerbations and has since become an established, safe, and cost effective treatment modality ². It enables the early discharge, or admission avoidance, of patients with clinically-responding infections whilst maintaining safe, structured care, with ongoing specialist medical, nursing, and pharmacy input³. Studies have consistently highlighted the benefits of OPAT for the treatment of infections that require prolonged antimicrobial therapy, without increasing patient complications ^{1, 4-6}. Financial benefits are both direct and indirect. Significant cost savings can be achieved for the hospital; up to 30-40%⁷. For patients, OPAT can potentially allow earlier return to work or school, and the intangible benefits of being at home ^{1, 7, 8}.

While traditionally OPAT was utilised to treat less severe or less complex infections, recent studies demonstrate that the OPAT healthcare model can also be safely be used to treat infections of greater complexity and severity (i.e. infective endocarditis ^{5, 9, 10} and patients with fungal infections¹¹). Despite these successes, treatment failures resulting in mortality have occurred, highlighting the need for well-developed protocols and policies for patient selection and follow-up within the context of a formal OPAT service ¹².

In 2011, the Infectious Diseases Society of Ireland (IDSI) developed national OPAT guidelines and advocated successfully to the HSE for the establishment of a national OPAT programme. At that time, a survey of Irish general physicians reported that 74% had discharged patients on intravenous (IV) antimicrobials, 47% did not have a designated OPAT service available ¹³. Over the past seven years, a considerable volume of new OPAT literature and guidelines have been published and there are now formal OPAT referrals occurring across all hospital groups. Recent guidelines, are in general, shifting from rigid patient selection criteria to a more individualised approach, with the recognition that specific antimicrobials and/or specific delivery models may be more appropriate for certain patient groups ^{3, 14}. The latest publications have informed this update of the Irish National OPAT guidelines.

The guideline was devised through the collaborative process with the national OPAT Working Group. This group is led by the National Clinical Lead for OPAT and Community Intervention Teams (CIT) and is comprised of Infectious Diseases Physicians and Clinical Microbiologists engaged in OPAT provision, an OPAT nurse, and the Programme Manager who is the administrative lead for OPAT within the Health Service Executive (HSE). The headings chosen are comparable to that of proposed OPAT "care bundles" which identifies several components that require attention when planning an OPAT program a set of practices that together should improve clinical outcomes ¹⁵.

Literature review

A total of 437 articles were identified during a Pubmed search "OPAT". Of those, 110 articles were accessed and read, with 70 articles referred to.

Using this guideline

This guideline is intended for clinicians who intend on prescribing any parenteral or IV antimicrobials outside of the inpatient setting in Republic of Ireland. The guideline is not intended to replace clinical judgement in the management of individual patients.

2. OPAT governance

In non-inpatient settings, IV antimicrobials should be delivered within a formal OPAT service with clear pathways for early discharge or admission avoidance, in order to ensure patient safety. In the Republic of Ireland this service is provided for public patients by the HSE through the National OPAT programme, with some private health insurers also providing OPAT to patients. The referral pathway for public patients to the HSE national OPAT programme is outlined in *Figure 1*. Private providers may have alternative referral pathways, however, would be expected to conform with guidelines as outlined in this document.

Figure 1 Referral pathway for public patients



2.1 OPAT team:

OPAT should be conducted using a team approach with clear managerial and clinical governance lines of responsibility. The team leader should be an infection specialist (Infectious Diseases Physician or Clinical Microbiologist) who has allocated time for OPAT in their job plan. In the case of a hospital without an Infectious Diseases service a local clinical lead for OPAT should be identified; this can be a general medical physician with an interest and experience in the provision of OPAT. This general physician should be supported by a clinical microbiology service. This clinical responsibility is important in ensuring a high-quality service with clear accountability¹⁶. The OPAT nurse plays a central role, with responsibility for assessment of patient suitability, patient education and consent, training, and monitoring. An antimicrobial pharmacist is also desirable by assessing the potential drug–drug and drug–host interactions, antibiotic compliance, potential adverse events and monitoring needs, and how these are best addressed in an out-of-hospital setting. Ideally the OPAT team are responsible for the selection of vascular access, antimicrobial agent, duration of therapy, and medical evaluations during the entirety of the OPAT course ^{14, 17}, however it is recognised that in centres

without an infectious diseases physician the care is shared with the discharging physician or surgeon with ongoing infection specialist input from a clinical microbiology service. Each member of the OPAT team is responsible for personal continuing professional development relating to best clinical practice.

2.2 Management plan:

The OPAT management plan for each patient should be agreed between the OPAT team and the referring team. Clinical responsibility for patients may be shared between the two teams e.g. in sites where there is no infectious diseases physician the clinical governance remains with the prescribing physician, with antimicrobial choice and duration guided by a clinical microbiology service. In contrast in sites where there is an infectious diseases physician these clinicians assume the full clinical governance of the patient. The plan should include choice and dose of antimicrobial agent, frequency of administration, anticipated duration of IV therapy, potential for and timing of oral antimicrobial switch if clinically appropriate, along with any requirement for interval imaging, taking into account flexibility based upon clinical response ¹⁸. The follow-up care of patients has been shown to be compromised in up to 25% of patients following hospital discharge, due to the lack of availability of a discharge summary ¹⁹. As such, there should be communication between the OPAT team, the referring clinician, the patient's general practitioner and the CIT (where appropriate). As a minimum, this should include notification of acceptance onto the OPAT programme, notification of completion of therapy and notification of further management plan post-OPAT. The written communication should be available and accessible to all relevant members of the clinical team, including out of hours. A mechanism should be in place for urgent discussion and review of emergent clinical problems during therapy according to clinical need. This must be conveyed to the patient both verbally and in writing³. There must be a written referral pathway within each hospital participating in OPAT, with a clear readmission pathway outlined.

2.3 Data collection:

Local data on all referrals to the OPAT service, OPAT discharges and outcomes should be recorded prospectively for production of periodic local activity and outcome reports, service planning, delivery and improvement and to inform quality assurance. A local database with an outcomes registry can facilitate this process and contribute to the national database ²⁰. A large proportion of the OPAT team workload is fielding the referrals and inclusion of this data informs on local activity, resource requirements and outcome reporting. Data on every patient referred for OPAT, including those to private health insurers, and those who do not proceed to OPAT should be retained locally. Risk assessment and audit of individual processes (particularly new processes) should be undertaken as part of the local clinical governance programme. An annual review of the service to ensure compliance with national recommendations is advised.

3. Patient assessment and selection

Although the benefits of OPAT are evident for reasons outlined above, it is associated with some risk including but not limited to: a patients failure to adhere to care, unexpected changes in the patient's clinical condition, adverse drug reactions, or IV access events ¹. It is thus critical that careful patient assessment occurs with consideration of inclusion and exclusion criteria *(See figure 2)* for each individual case to decrease risk and sustain good outcomes.

3.1 Who should do the patient assessment for suitability of OPAT?

Studies demonstrate that when infection specialists are consulted for consideration of OPAT, recommendations often include a change in antimicrobial agent, route, format, dosage, or duration or note that OPAT is unnecessary ²¹. Possibility of IV to oral switch of antimicrobials should be considered for every patient at time of assessment, as inappropriate antibiotic usage and unnecessary costs may be prevented while still leading to successful clinical outcomes ²². Additionally, the involvement of infection specialists decreases OPAT readmissions and Emergency Department (ED) attendances during the first 30 days after index events ^{21, 23, 24}. Every decision to discharge a patient with OPAT must have the timely involvement of an infection specialist or be in accordance with clearly defined local pathways endorsed by an infection specialist. All patients must be evaluated by a competent member of the OPAT team prior to OPAT initiation ^{3, 14}. Traditionally a doctor made this assessment; however, it is recognised that in an experienced OPAT team, competency in patient assessment can also be available from non-medical members, for example an OPAT nurse ³.

3.2 Factors for consideration: See figure 2.

3.2a Self OPAT versus Health professional OPAT

S-OPAT refers to administration of IV antimicrobials by the patient, relative, or caregiver. Selfadministration of IV antimicrobial therapy, in selected patients under the supervision of a specialist team, is a safe and feasible strategy ^{23, 24}. H-OPAT refers to administration of IV antimicrobials by a healthcare professional. Most OPAT happens at home, but a designated infusion clinic or return to a day service e.g., day ward or dialysis unit might be utilised also in selected cases. In general, S-OPAT is preferred and should be considered for all patients, H-OPAT should be reserved for those in whom S-OPAT is not appropriate.

3.2b Infection-specific factors such as the site of infection, the causative organism(s) previous microbiology should be considered. Additionally, the availability of oral antibiotic options should be considered for every patient. Ensure source control has been achieved and that any required surgical intervention is performed. The need for interval imaging (e.g., radiology, echocardiography), and, the ultimate duration of treatment should be clarified and incorporated into the patient treatment plan²⁵⁻²⁷.

3.2c Patient specific factors need to incorporate physical, social and logistic criteria. Firstly, the patient must be clinically stable and deemed suitable for discharge on OPAT by a senior clinician. Co-morbidities, co-prescribed medications, self-care abilities, social needs and overall home circumstances (including home setting, family support, distance from hospital, and ability to be contacted) must be established. Although older and frail patients may have greater risks of adverse events and treatment failure, studies demonstrate that OPAT is safe and effective option when patients are appropriately selected and monitored ^{28, 29}.

OPAT can also be effective in patients who inject drugs (PWID) and the homeless, but loss to follow-up is a significant barrier ³⁰. Decisions should be made on a case-by-case basis provided there is careful patient selection, good patient engagement, and sufficient resources allocated for patient management ^{14, 31, 32}. Identification of recent or ongoing IVDU should be considered as a contraindication to OPAT ³³.

Patients and carers must be fully informed about the nature of OPAT and provide consent ³. For S-OPAT, where the antimicrobial can be a compounded agent or require reconstitution, at least one adult should be present who can reliably learn and perform sterile infusion technique and communicate and adverse event or a clinical deterioration with the treatment team ^{3, 14, 15, 17, 25}.

3.2d Venous thromboembolism (VTE) risk

All patients who have been assessed as being at risk of venous thrombosis as inpatients should be considered for further prophylaxis during OPAT if assessed as having ongoing risk³.

Figure 2 Inclusion / Exclusion criteria and other factors for consideration

Has an Ongoing Requirement for IV Antimicrobials J **Exclusion Criteria** Profound respiratory failure (PaO2 <7.0 kPa, ph <7.30). There Acute or unstable chest pain New onset or unstable cardiac arrhythmia may be patients who are on long-term oxygen therapy who have chronic hypoxemia but are still suitable for OPAT ECG changes suggestive of acute Ischaemia or infarction Vulnerable Adults / Children without an appropriate carer Acute or decompensated cardiac failure, renal failure, liver Sepsis Syndrome (Any two of: Heart Rate >100 bpm, failure Respiratory Rate 20/min, Temperature >38°C or <36°C, WCC Poorly controlled or unstable diabetes mellitus Ongoing alcohol or drug dependence >12 or <4/mm3) Q Infection Specific Factors The site of infection Identified organism(s) History of multidrug resistance Laboratory indices of organ function, infection progress and drug toxicity ٠ • Radiological imaging to diagnose infection and monitor progress Potential need for surgical intervention, including source control as appropriate Patient clinically stable: no evidence of systemic inflammatory response

Patient Specific Factors

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- Comorbidities
- Co-prescribed medications
- Medication compliance
- Age & frailty

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- . Self-care abilities .
 - Social needs
- Understand the concept of, and consent to OPAT treatment
- Ability to comply with proposed treatment and follow up plan (including clinic . attendance)
- Home circumstances (home setting, family support and distance from hospital) An adult who can report an adverse event or a clinical deterioration
- English fluency, or a carer or relative with English fluency
- Access to telephone

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Agreed Management Plan

- Antibiotic plan, including agent, duration of therapy and ongoing review to
- determine early oral switch or discontinuation, incorporating best AMS practices Choice of IV device and infusion device
- H-OPAT vs S-OPAT .
- Patient education: nature of infection, expected outcome, care of line
- Clearly documented governance plan, including readmission pathways if . required
- Confirm weekly OPAT and Infection Specialist input
- Any further surgical / radiological follow up needed?
- Contingency plan; communication lines between referring specialist, OPAT team and patient
- Emergency contact numbers

4. Patient Education

The evidence base is particularly lacking in the areas of patient education ¹⁵. OPAT, particularly S-OPAT, requires patients and/or caregivers to undertake many new tasks. Similar to hospital settings, understanding and mitigating potential safety hazards in OPAT is important. Competencies to be covered will be contingent on the S-OPAT versus H-OPAT model, but education on IV line care, troubleshooting on-therapy, monitoring, and provision of contact numbers for OPAT team and infusion nurses is imperative for all patients ⁸. Patient information leaflets ³⁴, standardised teaching with teachback and use of cognitive aids should be used by the OPAT team to support patient education ^{17, 25, 35}. Both the OPAT nurse and patient/carer must be satisfied that each area has been discussed, demonstrated, and practiced to ensure competency before sign off and this should be documented ³.

5. Antimicrobial selection

5.1 Antimicrobial stewardship:

OPAT has been highlighted as one of the five key antimicrobial stewardship decisions in the Department of Health's antimicrobial stewardship program 'Start Smart — then Focus ³⁶. Choosing the most effective, safe and narrow-spectrum agent for a specific indication is regarded as a primary aim for individual patient care in an effective antimicrobial stewardship (AMS) programme. Awareness of evolving antimicrobial resistance and specific local resistance data through the AMS programme is vital to guide empiric antimicrobial prescribing in OPAT and wherever possible, every effort made to obtain clinical specimens, so that empiric treatment may be individualised upon review of relevant recent microbiology results, which may facilitate de-escalation to narrower spectrum agents.

It is highly desirable for a member of the OPAT team to be represented on the local AMS committee or equivalent, and for OPAT to be included as a standing item on the committee meeting agenda ^{26, 37}. Although convenience of dosing to optimise early hospital discharge or admission often occurs, OPAT should mirror, when possible, that of the local AMS programme in order to maximize opportunities for identification and selection of suitable patients and to optimize appropriate management by considering antimicrobial spectrum, penetration and target to minimize unintended consequences of antimicrobial therapy³. Antimicrobials requiring specific monitoring e.g. Therapeutic drug monitoring (TDM) should only be prescribed when the appropriate support is in place.

Other considerations should include allergies, side effect profile, drug-drug interactions, requirement for therapeutic drug monitoring, cost, mode of delivery and potential for orally bioavailable antimicrobial alternatives. The anticipated duration of antimicrobial therapy and criteria for stopping or switching to oral treatment should be determined upon initiation of treatment and reviewed regularly throughout the patient's treatment course ^{1, 26}.

5.2 Restricted antimicrobials:

Appropriate selection and prescription of antimicrobials during OPAT must be in accordance with referring hospitals antimicrobial guidelines and incorporate the HSE's National Policy of Restricted Antimicrobial agents, notably with regards restriction to carbapenems ^{17, 38, 39}. Oral antimicrobial therapy should always be used in preference to IV therapy where there is equivalent efficacy unless there are other relevant factors, e.g. toxicity, lack of oral route, allergies or drug–drug interactions. Certain agents (co-trimoxazole, clindamycin, clarithromycin, erythromycin, fluoroquinolones, rifampicin, doxycycline, metronidazole, linezolid, and triazole antifungals) are not available through the OPAT programme, except in exceptional circumstances and on discussion with the National Clinical Lead for OPAT and CIT programmes.

5.3 Oral antimicrobials "Complex outpatient antimicrobial therapy— 'COpAT'":

Recent studies have been published on the use of complex oral antibiotic regimens for treatment of bone and joint infections⁴⁰. Irrespective of route of antibiotic administration, ambulatory management of such infections are not straightforward and require a well-organized management approach as exemplified within existing OPAT services. OPAT should remain an important part of a comprehensive bone and joint infection service: complex outpatient antimicrobial therapy—'COpAT' ⁴¹. This has been supported in recent BSAC guidelines where ongoing involvement and oversight of the OPAT team is recommended to advise on appropriate follow-up for toxicity, compliance and outcome monitoring for those patients deemed suitable for complex oral antibiotic regimens, as well as the monitoring of infection suppression where cure is not the intent ³.

5.4 Antimicrobial administration:

The first dose of a new antimicrobial should be administered in a supervised setting. This may be the patient's own home if the antimicrobial is administered by a person competent and equipped to identify and manage anaphylaxis³. All administered doses of IV antimicrobials should be documented on a medication card or equivalent, including doses administered out of hospital. Reconstitution and administration of antimicrobials should comply with published hospital guidelines, e.g. Hospital pharmacy guidelinesⁱ or agreed guidelines between individual institutions and external compounding facilities where utilised. Appendix A outlines the antimicrobials currently available for use on the OPAT programme. New antimicrobials may become available depending on clinical need following discussion at the OPAT working group.

6. Vascular access

Appropriate selection of vascular access is key to the success of OPAT and will depend on the characteristics of the drug infusion, number of doses daily, duration of treatment and the characteristics of the patient. A large prospective cohort of OPAT patients demonstrated that adverse events related to the vascular catheter exceeded those related to the antimicrobial agent chosen for OPAT ²⁵. Vascular access complications occur in ~9% of patients treated with OPAT at home. Most of these are catheter occlusions, whereby there is an inability to infuse the IV antibiotic because of lack of flow. Catheter thrombosis and line infection each occur in <1% of OPAT courses at home ⁴². It is not necessary to remove a vascular access device if CA-VTE develops during OPAT, as long as the catheter remains well positioned and arm pain and swelling decrease with anticoagulation ¹⁴.

The OPAT team, in collaboration with referring team, is responsible for the choice of vascular access for each patient ³. Insertion and care of the intravascular access device must comply with published RCN standards, and with local and national infection prevention and control guidance. the duration of IV catheter use should be minimised by regular and efficient AMS throughout the course of OPAT ²⁵. The removal of IV catheters can be performed in the hospital clinic or in the community setting (e.g. by a CIT service) however, this removal must be documented and communicated to all members of the team caring for the patient.

Short Peripheral Venous Catheters (PVS) are recommended when OPAT is expected to be seven days or less ⁴³. There is insufficient evidence on OPAT outcomes with respect to outcomes to advice use Peripherally Inserted Central Cannula (PICCs) over Midline Catheters (MC's) ⁴⁴, however in general Midline catheters should be considered for IV courses between 7 days and up to 4 weeks, and PICCs for longer courses. Other factors, such as existing vascular access devices (e.g. portacath) or future potential need for vascular access (e.g. CKD or dialysis patients) should be considered when choosing the appropriate vascular access device and decisions individualised based on patient circumstances.

7. Infusion devices

IV antimicrobials can be administered via continuous infusion or as a bolus in the outpatient setting and a variety of different delivery systems are available. Choice of device and mode of delivery is dependent on local resources, training and familiarity, as well as availability of compounding services and the compatibility and stability of the antimicrobial agent ¹⁶. The use of elastomeric infusers for self-administration is becoming increasingly popular, due to their numerous advantages over electronic pumps. They are low in weight and size, easy to use, interfere less with sleep, preserve patient mobility/ and promote patient autonomy with no maintenance costs ⁴⁵. The biggest advantage of infusion devices is the increased availability of antimicrobials to the OPAT programme which are ordinarily dosed three or four times daily. This has a considerable impact on reducing cost and

improving efficiency, while also improving AMS ^{17, 46-48}. As more data on antimicrobial stability is published, an increase in antimicrobial selection is anticipated. When elastomeric devices are used, the influence of temperature on stability and infusion rate needs to be explained to patients⁴⁸

8. Safety on discharge

8.1 Portal:

Each public patient accepted for OPAT should be entered into the national OPAT registry portal. <u>www.opat.ie</u>.

8.2 Care transition:

To achieve optimal OPAT care, all professionals involved should provide appropriate OPAT care at all stages of the care pathway; ranging from the organizational phase of OPAT, through the initiation and continuation phase at home, to discontinuation ¹⁸. Successful care transition from hospital to home or an alternative healthcare facility is important for patients' well-being, as well as to limit the potential for readmission. Aside from 30-day readmission rates in published series of OPAT patients which are between 6% and 20% ^{8, 23, 49}, data on care transitions in OPAT patients is limited¹⁵. One study demonstrated that using a transition-of-care OPAT bundle with a comprehensive Multi-Disciplinary Team significantly decreases 30-day hospital readmissions from 26.1% to 13.0% ⁵⁰.

9. Follow up, monitoring, discontinuation of therapy and management of readmissions

Patients receiving OPAT are at risk for complications such as those from IV access, medications, and the infection being treated ³⁵. Unplanned readmission, treatment failure and adverse effects of antimicrobial treatment are potential risks of OPAT that require close patient monitoring ³. It is for those reasons that regular clinic-based review of OPAT patients is required and should take place at a minimum of once weekly while OPAT continues. In certain selected cases, less regular review might be appropriate (e.g. low risk patient, geographically remote from clinic) but only in exceptional circumstances, and after careful consultation with the infection specialist; regular blood monitoring and oversight are still required. Studies suggest that Adverse drug reactions (ADRs) occur in 15% to 45% of patients receiving OPAT ⁵¹⁻⁵⁵with 3% to 10% of patients needing to discontinue therapy prematurely. Other negative outcomes of ADRs include hospital readmissions, ED visits, increased morbidity and mortality. These findings underscore the importance of judiciously prescribing OPAT agents, ensuring appropriate dosage of medication, educating patients about ADRs with careful monitoring ⁵⁶.

9.1 Weekly follow up & Monitoring:

Patients whose weekly laboratory values are not available to clinicians have a higher risk (2.53 fold) of readmission than those whose laboratory results are monitored weekly ^{1, 52, 57}. Monitoring whilst on OPAT mandates that the patient have access to weekly outpatient review ¹¹. Blood tests should include full blood count, renal and liver function, C-reactive protein (CRP) (as appropriate) and therapeutic drug monitoring depending on the chosen agent (e.g., vancomycin) and for the duration of its administration. Other tests may be required for specific indications or therapies ^{3, 14}.

In addition to blood investigations, the OPAT team is responsible for monitoring clinical response and tolerability to antimicrobial management and clinic review. Ready access to the input of an infection specialist or a physician experienced in OPAT / familiar with OPAT guidelines must be available for OPAT patients who remain under the care of their admitting clinician while on OPAT, as opposed to those cared for by an infectious disease's physician. Assessment should include review of treatment response to ascertain need for additional specialist input (e.g. surgical intervention, podiatry etc), extension of treatment duration, and suitability for oral switch or cessation of antimicrobials. This enables early detection of adverse events such as those associated with intravascular catheters or side effects or toxicity of administered agent(s) and monitoring of significant co-morbidity ^{11, 58}. If the treatment plan needs to be revisited or discontinued there should be a mechanism in place for urgent discussion and review of emergent clinical problems during therapy in consultation with the referring specialist in rationale from the infection specialist involved forwarded to the National Clinical Lead. There should be a clear pathway for 24-hour immediate access to advice/review/admission for OPAT patients and this should be communicated to the patient both verbally and in writing.

Some patients with skin and soft tissue infection may require more frequent review to optimize speed of IV to oral switch. See Appendix B. Cellulitis pathway

9.2 Readmissions:

Studies show that 5% of patients on OPAT have an ED visit within 30 days of initiation of OPAT ⁵⁹. OPAT hospital re-admission rates for patients vary in the literature, as there is no standard definition of re-admission rate (e.g. re-admission time frame such as 'end of therapy' or '30-day follow-up') and often difficult to make distinctions between 'infection-related' or 'all-cause' readmissions due to specific patient characteristics, including advanced age, co-morbidities and prior hospitalizations in past 12 months ^{1, 53}. Studies recommend the development of evidence-based interventions to prevent OPAT readmissions using appropriate risk stratification to ensure that efforts target the highest-risk patients^{3, 53}. Regular review of local OPAT outcomes, including readmission rates (Irish national target < 5%) and reasons for readmission should be integral to governance of any local programme.

9.3 Discontinuation of OPAT:

The discontinuation of OPAT should be a clinical decision, based upon the patient's clinical and laboratory response to therapy, and must involve the input of an infection specialist to decide whether a switch to oral antimicrobials or cessation of antimicrobial therapy is feasible. Upon completion of IV antimicrobials, OPAT team must arrange timely removal of IV access and arrange follow-up for further monitoring as appropriate.

10. Paediatric considerations

10.1 Patient selection:

Similarly, to adults, more prospective research is required to enable us to predict more accurately which paediatric patients are most likely to have a successful, or unsuccessful, outcome of their OPAT episode.

10.2 Antimicrobial Selection:

A retrospective case series of 707 children managed between 2008 and 2015 describes a 13.5% readmission rate due to antimicrobial side effects ⁶⁰. Particularly high rates of ADRs have also been described with piperacillin/tazobactam (fever, transaminitis, neutropenia and rising inflammatory markers). In a cohort of 106 children, 80% had 3 or more ADR and 26% of children required readmission. Adverse events occurred after a minimum of 14 days of treatment in 93% of cases ⁶¹. More recent UK and Australian pOPAT cohorts describe much lower incidences of readmissions due to drug side effects occurred in only 0%–2.3% ^{62, 63}.

As with caring for adults on OPAT AMS approaches and oversight is imperative in pOPAT with an increase in evidence that its absence results in higher rates of bug/drug mismatches, drug-dosing errors and readmissions, and less rigorous laboratory monitoring of drug side effects ⁶⁴. Duration of IV antimicrobials are also reduced through earlier cessation of antimicrobials or prompt IV-to-oral switching ^{65, 66}.

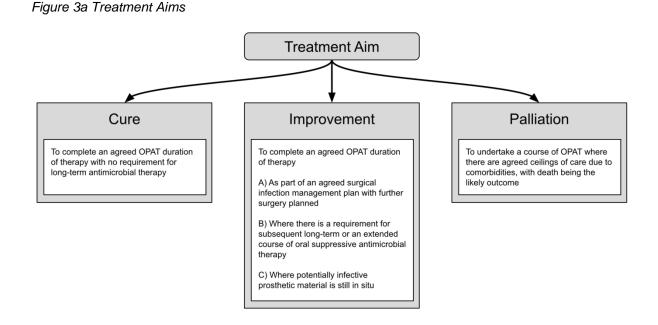
10.3 Intra venous access:

Paediatric OPAT (pOPAT) studies have described an 8%–15% complication rate for PICC lines use with infections being responsible for less than 25% adverse events ^{60, 62, 67}.

11.Outcome measurement

In accordance with clinical governance requirements, data on OPAT referrals should be recorded prospectively to evaluate service workload, inform AMS opportunities and identify areas for service improvement and quality assurance.

Data should include patient demographics, antimicrobial agent(s) used, duration of treatment, stratified so that both inpatient and OPAT treatment durations can be evaluated, method of OPAT used, type of vascular access and infusion device, bed days saved and all events (ADRs, vascular access complications, readmissions within 30 days of discharge and healthcare-associated infections, e.g. *Clostridioides difficile* infection and catheter-related blood stream infection, along with data on causative pathogens ³. Patient-specific aims of therapy outlined in *Figure 4a* should be established in the original management plan (i.e. cure, improve or palliation) and should be recorded upon completion of IV therapy.



Although there is a lack of standardization and clarity about which outcomes are measured and how they should be determined, we have chosen to utilise the recent "Updated good practice recommendations for OPAT in adults and children in the UK" outcome proposals ³ *figure* 4b. The OPAT portal will be updated accordingly to include these new data points. Although a local database with an outcomes registry can facilitate the process, ultimately all data must be uploaded to the OPAT portal to ensure there is robust national data against which centres can be benchmarked.

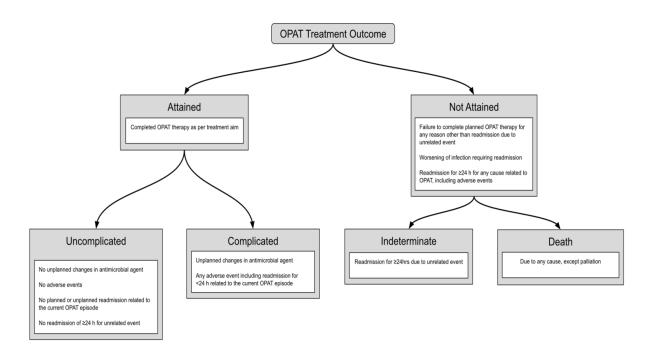


Figure 4b OPAT Treatment Outcomes

12. Patient experience

Patient satisfaction surveys, monitoring and trending of patient complaints, and general feedback help inform service and adaptions required. Each hospital should consider periodic patient satisfaction surveys and record collected data. Open disclosure of complications, such as medication safety incidents (e.g., prescribing, dispensing administration etc.) and their full investigation must be performed in accordance with HSE policy⁶⁸.

13. Conclusion:

The expansion of OPAT worldwide in recent years has been driven by several factors including a drive for more cost-effective use of resources, reduced risks of healthcare acquired infection, alignment with the philosophy of patient driven care, an aim to achieve high levels of patient acceptability and satisfaction ⁴. OPAT programmes increase the availability of hospital beds by reducing or avoiding hospital stays and by releasing beds occupied by patients with multidrug-resistant infections ⁶⁹. In 2017, 4 years after the launch of the Irish National OPAT Programme 100,000 bed days were saved cumulatively, and this continues to increase as the programme expands nationally. When the key components of an OPAT programme are in place, such as appropriate patient selection with monitoring and antimicrobial stewardship considerations as described in this guideline, the optimisation of resources and reduction in cost still results in the delivery of high-quality health care without compromising clinical outcome ^{15, 70}.

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Appendices:

Appendix A: Antimicrobials currently available on OPAT Appendix A: Antimicrobials currently available on OPAT

Antimicrobial	Recommended Monitoring	Specific Considerations
Cefazolin	Weekly FBC, LFT, U&E.	
Ceftazidime	Weekly FBC, LFT, U&E.	
Ceftriaxone	Weekly FBC, LFT, U&E.	
Flucloxacillin	Weekly FBC, LFT, U&E.	Hepatitis
Benzylpenicillin	Weekly FBC, LFT, U&E.	Hypersensitivity
Piperacillin- tazobactam	Weekly FBC, LFT, U&E.	
Ertapenem	Weekly FBC, LFT, U&E.	
Meropenem	Weekly FBC, LFT, U&E.	
Aztreonam	Weekly FBC, LFT, U&E.	
Vancomycin	Weekly FBC, U&E, TDM	"Red Man Syndrome" with rapid infusion, neutropenia, leucopenia
Teicoplanin	Weekly FBC, U&E, TDM	Fever, anaemia, thrombocytopenia
Daptomycin	Weekly FBC, LFT, U&E. CPK at least weekly.	Myositis, GI side effects, pneumonitis
Tigecycline	Weekly FBC, LFT, U&E.	Nausea/ vomiting
Gentamicin	Twice weekly U&E. Weekly FBC, LFT. TDM at minimum of weekly but determined by prior levels	Nephrotoxicity and vestibular toxicity
Clindamycin	Weekly FBC, LFT, U&E.	Consider switch to oral
Ciprofloxacin	Weekly FBC, U&E, LFT	Tendonitis/tendon rupture; peripheral neuropathy Consider switch to oral
Linezolid	Weekly FBC, LFT	Pancytopenia, peripheral and optic neuropathy Consider switch to oral
Trimethoprim- Sulfamethoxazole	Weekly FBC, LFT, U&E.	Rash, marrow suppression Consider switch to oral
Amphotericin B (liposomal)	Twice weekly U&E Weekly: FBC, LFT, Mg	Nephrotoxicity, Low K, Mg
Caspofungin	Weekly FBC, LFT, U&E	Hyponatraemia early in course reported

Acyclovir	Twice weekly FBC, U&E, Mg	Nephrotoxicity
Ganciclovir	Twice weekly FBC, U&E	Pancytopenia, nephrotoxicity

Appendix B. Cellulitis Pathway

https://portal.opat.ie/Dox/Cellulitis%20Pathway.pdf