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

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Abstract

Aim

Outpatient parenteral antimicrobial therapy (OPAT) is an option in patients who require parenteral antimicrobial administration and are clinically well enough for hospital discharge. This is an update of the Irish National OPAT guidelines which were last reviewed in 2011.

Methods

The guideline was devised through a collaborative process with the national OPAT Working Group and a review of the literature. It is intended for clinicians who prescribe any intravenous (IV) antimicrobials outside of the inpatient setting in the Republic of Ireland.

Results

Patient care while on OPAT should be provided by a designated OPAT service, with clear managerial and clinical governance lines of responsibility. It should be conducted using a team approach with a clinical lead on each site either as an infection specialist, or a general medical physician with infection specialist input and an OPAT nurse. An antimicrobial pharmacist is also desirable. Several factors must be considered when assessing patient's suitability for OPAT including exclusion criteria, infection-specific factors, and patient specific factors such as physical, social and logistic criteria.

Conclusion

This updated guideline advocates a more individualised OPAT approach, with the recognition that specific antimicrobials and/or specific delivery models may be more appropriate for certain patient groups. Full guidelines are available through www.opat.ie.

Introduction

Outpatient parenteral antimicrobial therapy (OPAT) is a treatment option in patients who require parenteral antimicrobial administration, and are clinically well enough not to require inpatient hospital care[1]. OPAT has consistently been shown to be safe, while decreasing healthcare cost, and maximising patient benefit[1, 2].

Increasingly, OPAT is successfully used to safely treat more complex and serious infections[2-4]. However, despite successes, complications, some serious, may occur, highlighting the need for well-developed protocols and policies for patient selection and follow-up within the context of a formal OPAT service[5].

In 2011, the Infectious Diseases Society of Ireland (IDSI) advocated successfully to the Health Service Executive (HSE) for the establishment of the National OPAT Programme. Since then, a considerable volume of new literature has been published[6, 7]. These publications have informed this update of the Irish National OPAT guidelines.

Methods

This guideline was devised through a collaborative process with the national OPAT Working Group. This group is led by the National Clinical Lead for OPAT and is comprised of Infectious Diseases (ID) Physicians and Clinical Microbiologists engaged in OPAT provision, an OPAT nurse, and the Programme Manager, who is the administrative lead for OPAT within the HSE. The literature review was conducted by E.S, 437 articles were initially identified during a PubMed search for the keyword "OPAT". Of those, 110 articles were deemed relevant, accessed, and read. Overall, 70 articles were included. The evidence appraisal was reviewed by E.M. This guideline is intended for clinicians who intend on prescribing any intravenous (IV) antimicrobials outside of the inpatient setting in the Republic of Ireland (ROI).

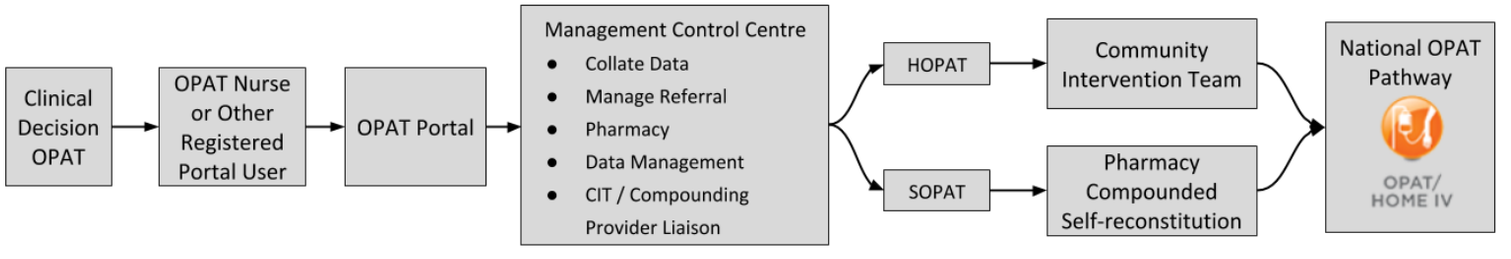
Results

The headings chosen are comparable to previously proposed OPAT "care bundles" which identify the key considerations when planning an OPAT program[8].

OPAT governance

In non-inpatient settings, IV antimicrobials should be delivered within a formal OPAT service with clear governance pathways delineated to ensure patient safety. In the ROI, this service is provided for public patients by the HSE through the National OPAT programme *(Figure 1)*. While other OPAT providers are available and utilise alternative referral pathways, it is expected that all providers will follow these guidelines.

Figure 1. Referral pathway for public patients



OPAT team

OPAT should be conducted using a team approach, with clear managerial and clinical governance lines of responsibility. The team leader should be a consultant infection specialist (ID Physician or Clinical Microbiologist). In hospitals without an ID service, a local clinical lead for OPAT should be identified; a general medical physician with an interest and experience in the provision

of OPAT. In this context, it is recognised that care is provided by the discharging consultant with ongoing infection specialist input from clinical microbiology.

This clinical responsibility is important in ensuring a high-quality service with clear accountability[9]. The OPAT nurse plays a central role, with responsibility for patient assessment, education, consent, training, and monitoring. An antimicrobial pharmacist is desirable for assessing drug interactions, potential adverse events, and monitoring. The OPAT team are responsible for the selection of vascular access, antimicrobial agent, duration of therapy, and coordinating medical evaluations during the entirety of the OPAT course[7]. Each member of the OPAT team is responsible for their own personal continuing professional development.

Management plan

For each patient, the OPAT plan should be agreed between the OPAT and referring team. Clinical responsibility for patients may be shared between the two teams e.g. between discharging consultant and infection specialist or assumed by an infectious diseases service alone. The plan should include choice, dose and frequency of antimicrobial agent, anticipated duration of therapy, along with any requirement for interval imaging[10]. There should be communication between the OPAT team, the referring clinician, the patient's general practitioner and community nursing services (as appropriate).

Data collection

Local data on all referrals to the OPAT service, and OPAT outcomes should be recorded prospectively in a local database which can then contribute to the national database. Audit of individual processes should be undertaken regularly and an annual service review to ensure compliance with national recommendations is advised.

Patient assessment and selection

Studies demonstrate that when infection specialists are consulted for consideration of OPAT, recommendations often include a change in antimicrobial plan or note that OPAT is unnecessary[11]. Possibility of an antimicrobial oral switch should be considered for every patient at time of assessment[6]. All patients must be evaluated by a competent member of the OPAT team, which may be the OPAT nurse, prior to OPAT initiation[6, 7].

Self- OPAT versus Health care professional -OPAT

S-OPAT refers to administration of IV antimicrobials by the patient, or caregiver. H-OPAT refers to administration of IV antimicrobials by a healthcare worker. S-OPAT is preferred and should be considered for all patients, with H-OPAT reserved for those in whom S-OPAT is not appropriate. Most OPAT happens at home, but other settings e.g., day ward or dialysis unit, may be appropriate.

Infection-specific factors

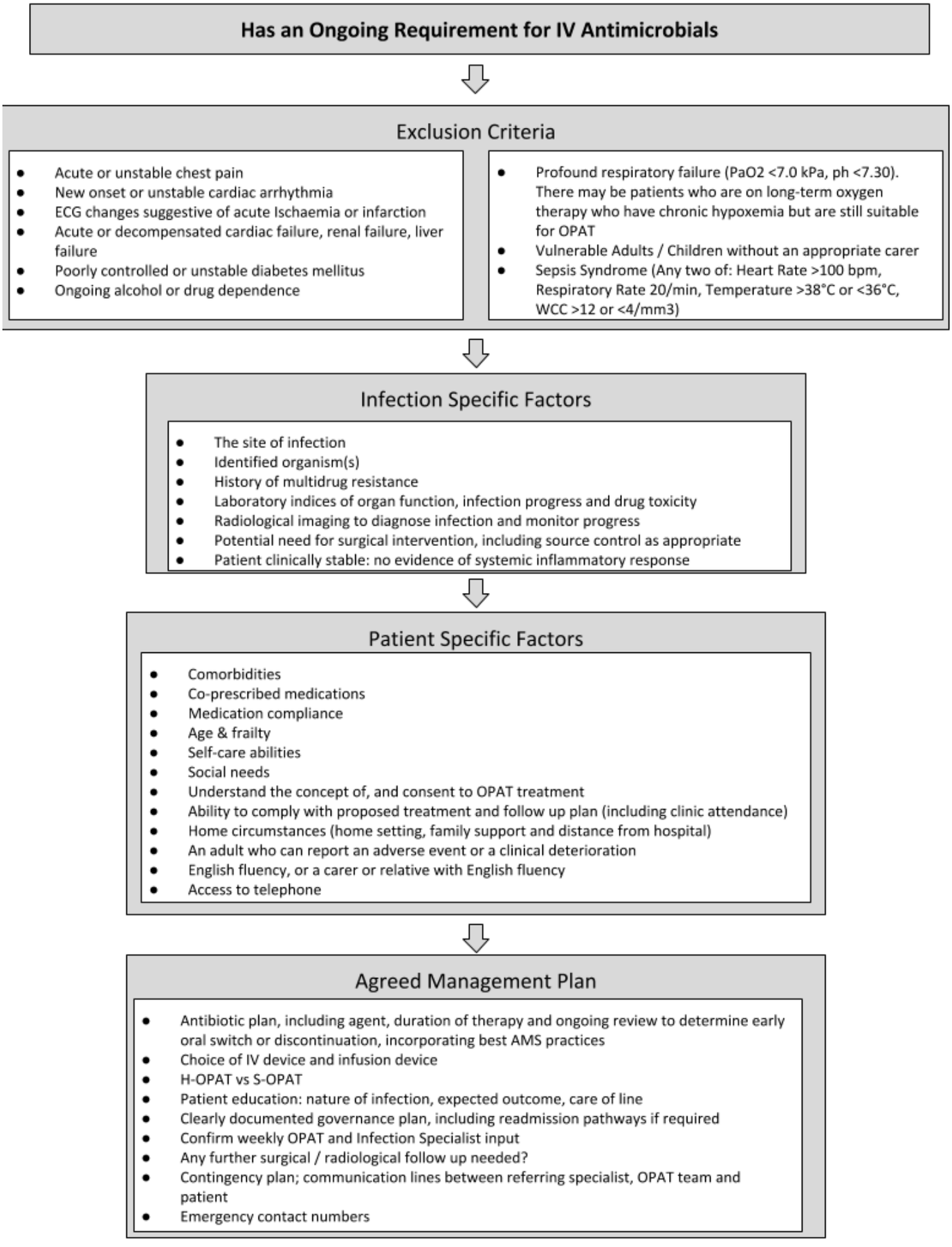
The site of infection, the causative organism(s) and previous microbiology should be considered, with source control achieved and any required surgical intervention performed. The need for interval imaging (e.g., radiology, echocardiography) must be clarified and incorporated into the treatment plan[12].

Patient specific factors

Physical, social and logistic criteria must be considered. The patient must be clinically stable and deemed suitable for discharge on OPAT by a senior clinician, with consideration of inclusion and exclusion criteria *(See figure 2)* for each case. Patients and/or carers must be informed about the nature of OPAT and provide consent[6]. For S-OPAT, either with a compounded agent or one requiring reconstitution, at least one adult should be present who can reliably learn and perform sterile infusion technique and communicate any adverse events with the team[4, 7, 13]. All patients considered at risk of venous thrombosis should be considered

for prophylaxis during OPAT[6]. 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[14].

Figure 2. Inclusion / Exclusion criteria and other factors for consideration



Patient education

Competencies to be covered will be contingent on the S-OPAT versus H-OPAT model; 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[15]. Patient information leaflets[16], and standardised teaching should be used to support patient education[13, 17]. Both the nurse and patient/carer must be satisfied that each aspect has been discussed, demonstrated, and practised to ensure competency before sign off, and this should be documented[6].

Antimicrobial selection

OPAT is one of the five key antimicrobial stewardship (AMS) decisions in the Department of Health's antimicrobial stewardship program 'Start Smart — then Focus'[18]. 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. OPAT team member representation on local AMS committees is desirable, so that OPAT can be a standing item on the committee meeting agenda[6]. Antimicrobials requiring specific monitoring should only be prescribed when the suitable support is available. Appropriate selection and prescription of antimicrobials during OPAT must be in accordance with the referring hospital's antimicrobial guidelines and incorporate the HSE's national policy on restricted antimicrobial agents[13, 19, 20]. The oral route should always be used in preference to the IV route, where there is equivalent bioavailability or efficacy, unless there are other precluding factors. Recent studies have been published on the use of complex oral antimicrobial regimens for treatment of bone and joint infections[21]. Irrespective of the route of administration, ambulatory management of such infections is complex and requires 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'[22]. The first dose of a new antimicrobial should be administered in a supervised setting. Reconstitution and administration of antimicrobials should comply with HSE guidelines, and all administered doses documented on a medication card.

Vascular access

Short peripheral venous catheters are recommended when OPAT is expected to be seven days or less, while a midline or peripherally inserted central catheter (PICC) should be utilised for longer courses[23]. Other patient factors, such as existing vascular access devices (e.g. portacath) or future potential need for vascular access (e.g. dialysis patients) should be considered and decisions individualised.

Infusion devices

IV antimicrobials can be administered via continuous infusion or as a bolus in the outpatient setting; a variety of different delivery systems are available. Choice of device and mode of delivery is dependent on local resources, training and availability of compounding services, and the compatibility and stability of the antimicrobial agent[9].

Safety on discharge & Care transition

Each public patient accepted for OPAT should be entered into the national OPAT registry portal. All patients must have their initial outpatient appointment made prior to hospital discharge; this must be within a week of discharge. The patient should receive written notification of the appointment, along with contact details of the OPAT team should adverse events arise[10].

Follow up, monitoring, discontinuation of therapy and management of readmission

Monitoring whilst on OPAT mandates that the patient have access to weekly outpatient review[4]. OPAT patients whose weekly laboratory values are not available to clinicians have a higher risk (2.53 fold) of readmission than those whose results are monitored weekly[1, 24]. Blood tests should be determined by the antimicrobial agent utilised, and some may require more frequent monitoring[6, 7]. The OPAT team is responsible for monitoring clinical response, tolerability of antimicrobials and coordinating weekly clinic review. If a treatment plan needs revisiting, there should be a mechanism in place for urgent multidisciplinary discussion, review of emergent clinical problems or readmission, as necessary. Regular review of local OPAT

outcomes, including readmission rates (Irish national target < 5%) and reasons for readmission must be recorded. The discontinuation of OPAT should be a clinical decision, based upon the patient's clinical and laboratory response to therapy, and must involve an infection specialist.

Paediatric considerations

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. As with caring for adults on OPAT, AMS approaches and oversight is imperative in paediatric OPAT (pOPAT)[25]. In discharging children with pOPAT similar factors should be considered as outlined for adults above. Consultation with paediatric ID services is recommended to ensure the safe and efficacious discharge of children with pOPAT.

Outcome measurement

Data on OPAT referrals should be recorded prospectively to evaluate service workload, inform AMS opportunities and identify areas for service improvement. Data should include patient demographics, antimicrobial agent(s) used, duration of treatment, method of OPAT used, type of vascular access and infusion device, bed days saved and all adverse events[6]. Patient-specific aims of therapy outlined in *Figure 3.* should be established in the original management plan and recorded upon completion of IV therapy. Although standardisation of OPAT outcomes are lacking, we have chosen the recent "Updated good practice recommendations for OPAT in adults and children in the UK" outcome proposals[6] *(figure 4).*

Figure 3. Treatment Aims

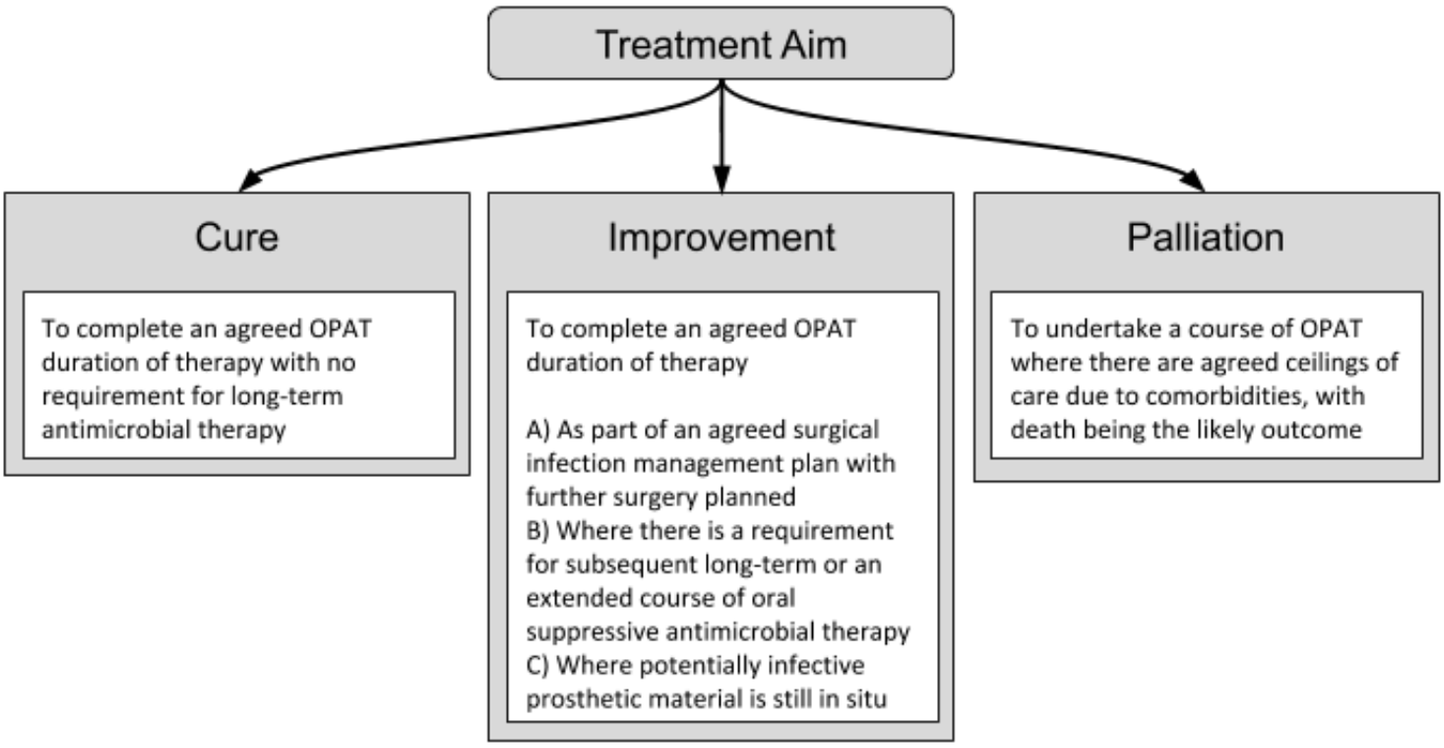
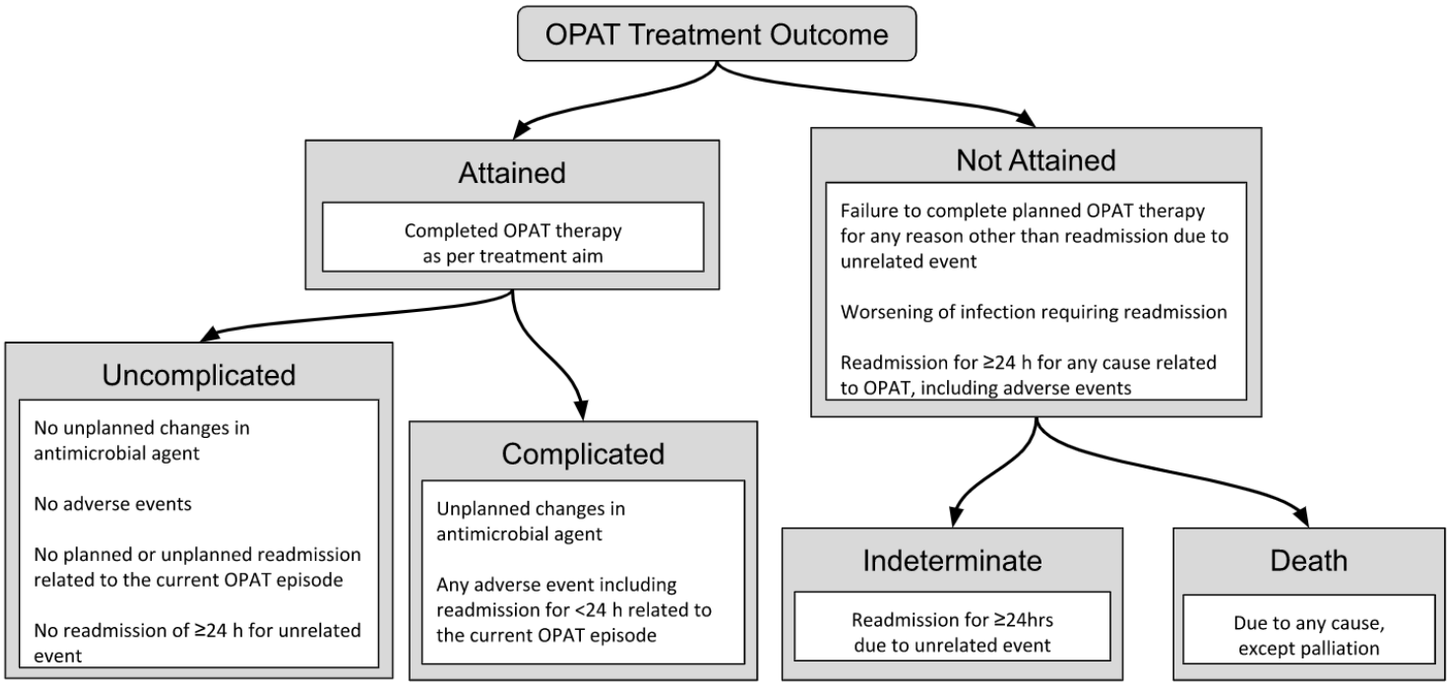


Figure 4. OPAT Treatment Outcomes



Discussion

The number of patients treated through the National OPAT programme continues to increase as the programme expands nationally. These guidelines should inform the safe and efficacious care of patients discharged with OPAT in Ireland and allow further expansion of OPAT services in a structured, safe, and robust fashion. It is not intended to replace clinical judgement in the management of individual patients. Evidence gaps remain within the OPAT literature; prospective research predictive measures on the likelihood of success of a patients OPAT episode, particularly in paediatrics, would be beneficial. More data on antimicrobial stability in infusion devices and the use and monitoring of new antimicrobials, such as the long-acting semi-synthetic glycopeptides is required[6].

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