How to develop a successful business case for Outpatient Parenteral Antimicrobial Therapy (OPAT) service?


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What was the business case?

Outpatient parenteral antimicrobial therapy (OPAT) service enables patients who are medically fit for discharge from an inpatient setting or do not require hospital admissions to receive intravenous antimicrobial therapy at home or in an outpatient setting. In the United Kingdom (UK), various models of OPAT service have been adopted to suit the level of resources and clinical demand at local health system.

During the early years of OPAT in the UK, many OPAT services were led by the infectious diseases or acute medicines physicians, delivered through an 'infusion centre' model, where patients attend an outpatient setting daily, such as the ambulatory care unit or OPAT infusion unit.[1] As the National Health Service (NHS) and the private industry develop more infrastructure to support homecare therapy nationally, many OPAT centres begin to offer therapy at patient's home or own care setting using the 'visiting nurse' model, where district nurses, hospital based OPAT nurses or private homecare nurses visit the patient to administer antimicrobial therapy daily.[1] In recent years, the 'self-administration' model, where the patient or a carer is trained to administer antimicrobial therapy with regular supervision from the OPAT team, has become increasingly popular to many OPAT centres as an alternative option to a carefully selected cohort of patients.[1] OPAT service model continues to evolve, with community based OPAT services emerging as reported by Nazarko.[2]

Despite the wide adoption and increasing diversity of OPAT service, there is no specific coding strategy or national tariff to fund the service in the UK.[3] Given the fragmented approach in reimbursement mechanism, the funding arrangement of an OPAT service, specifically on the three core aspects: staffing, activities and pharmaceutical formulations, is usually negotiated and agreed between the care providers and the local clinical commissioning groups (CCGs).[3] This scenario necessitates a business case to demonstrate quality improvement and financial efficiencies of an OPAT service to the local CCGs and key decision makers.

An OPAT business case is a document that provides an overview of the proposed service structure and evaluates its benefits and risks to the patients, organisation and commissioners. If utilised effectively, an OPAT business case presents an opportunity for the care provider to design a service model that improves patient care and delivers cost efficiency by repurposing local health resources. One of the key principles that underpins a successful OPAT business case is demonstrating clinical, operational and financial viability of the proposed service structure, meeting specific demand in patient care, organisational goals and public health strategies. A good starting point is to conduct an option appraisal of various OPAT service models available and identify the strengths and weaknesses of each option. This exercise helps to set the scene for the proposed OPAT pathway in the business case.

At United Lincolnshire Hospitals NHS Trust (ULHT), the OPAT initiative began when an opportunity to utilise the East Midlands OPAT homecare contract arose in 2018. Following a stringent option appraisal, a 'visiting nurse' model was proposed in the business case, utilising private homecare nurses to reconstitute and administer intravenous antimicrobial therapy at patient's home or care setting daily. This OPAT model was selected as the proposed service structure in the ULHT OPAT business case because of three important reasons:

- Patient demographics – Lincolnshire has an increasing ageing population and this will result in increasing demand for nursing support on OPAT.
- Healthcare accessibility – ULHT covers a large geographical area at Lincolnshire

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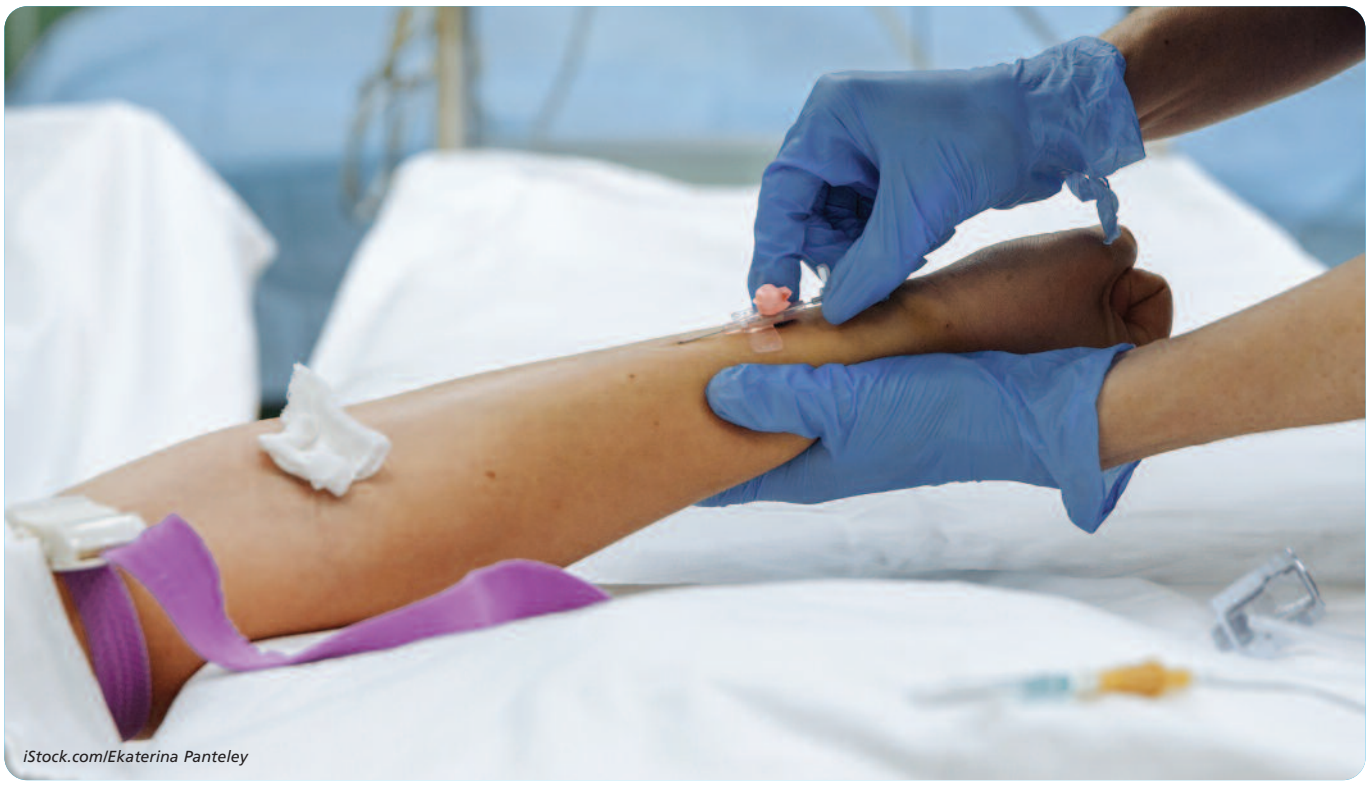

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and therefore a home based therapy will improve patient experience and accessibility to the OPAT service.

- Contracting – Utilising a regional contract offers the advantage of competitive pricing framework and service specifications that will strengthen the business case and will negate the requirement to undertake a full local tender on every aspect of the service, hence improving the celerity to implementation of OPAT.

The business case successfully received support and approval from various stakeholders, including the local CCGs and Trust Board. Utilising winter pressure funding, the ULHT OPAT team initiated a pilot service amongst adult patients within one month and subsequently developed OPAT into a substantive service in the new financial year.

Where was evidence obtained?

An effective OPAT business case should be supported by evidence on the benefits and risks of the service and justification on the resources requested. The benefits, risks and resource allocation outlined in the case should consider a multi-stakeholder perspective and this can be achieved through engaging with key clinical, operational and financial stakeholders throughout the development of the business case. Being resourceful and demonstrating values to key stakeholders underpin the success of an OPAT business case.

Improving patient's care and quality of life is one of the key drivers for implementing an OPAT service. OPAT service has been shown to be a safe and effective pathway change for patients to receive intravenous antimicrobial therapy after being discharged from an inpatient setting, with low rates of complications and re-admissions and high level of patient satisfaction.[4] Whilst clinical benefits delivered by OPAT are often challenging to be captured through qualitative measures, the ULHT OPAT team presented several patient case studies alongside the business case to demonstrate the positive impacts an OPAT service could bring to a patient's care and quality of life.

One of the cases involves a single mother who requires six weeks of intravenous ertapenem for the treatment of infected hidradenitis suppurativa, a rare and chronic skin condition. Having three children under her care, this patient could have benefited from an OPAT service that allows her to be treated at home, thus minimising impact on her caring responsibility for her children.

The benefits of OPAT has been increasingly recognised as playing an important role in antimicrobial stewardship. OPAT has been recommended as one of the five antimicrobial decision options in the Department of Health 'Start Smart-Then Focus' stewardship programme when reviewing antimicrobial therapy after an initial empirical approach.[5] Patients who are referred to OPAT receive input and review from a group of infection specialists on infection management and optimisation of antimicrobial therapy, thus reducing the risk of antimicrobial resistance secondary to ineffective or inappropriate use of antimicrobial. In addition, OPAT reduces the risk of patients acquiring healthcare associated infections by avoiding hospital admission or reducing their length of stay in the hospital.[6]

The ULHT OPAT team presented a case study where an elderly patient developed hospital acquired pneumonia in her third week of hospital stay whilst she remained to complete intravenous antibiotic for

the treatment of severe cellulitis, further extending her hospital stay and increasing her risks of developing secondary infections.

The most commonly known healthcare associated infections, for which mandatory reporting is currently required within the NHS Standard Contract, include those caused by meticillin-resistant *Staphylococcus aureus* (MRSA), meticillin-sensitive *Staphylococcus aureus* (MSSA), *Clostridium difficile* (C difficile) and *Escherichia coli* (E coli).[6] Since the NHS Trusts are being monitored on the incidence of these infections against trajectories, an OPAT business case could be further supported by demonstrating how an OPAT service helps to tackle the infection control challenges faced by the local health and social care system through reducing length of stay and exposure to a healthcare setting.

When assessing financial impact of a proposed OPAT service, it is important to consider the system-wide impact, in terms of costs of running the service and projected savings, and what it means to the Trust and the commissioners. Common OPAT indications, such as skin and soft tissue infections, infective endocarditis and bone and joint infections,[7] were used as worked examples in the case to form the basis of costing analysis and saving projection.

The costs of running an OPAT service varies considerably according to the service structure, team composition, pharmaceutical formulations, governance structure, technology resources and the presence of local or regional contract. Pharmacy homecare and procurement colleagues are valuable contacts to gain access to details about pricing frameworks and regional contracts. When developing the ULHT OPAT business case, the antimicrobial pharmacists, who led the development of the case, calculated the costing of pharmaceutical formulations, ancillaries and private nursing visit fees per patient using the rates agreed with selective private homecare providers in the East Midlands OPAT contract. Where a regional contract for OPAT antimicrobial formulations and activities is absent, the local OPAT team should consider running a local tender to negotiate a viable pricing framework with third party providers. Considerations should also be given to the projected usage of the English NHS Payment-by-Results (PbR) excluded antimicrobials and their reimbursement mechanisms in OPAT service, especially when these therapies are sourced from third party providers in compounded formulations that come in additional costs. Some examples of PbR excluded antimicrobials at the time of writing this article include liposomal amphotericin, caspofungin and anidulafungin.

Staffing resources within the OPAT team form another aspect of OPAT service costs. The British Society of Antimicrobial Chemotherapy (BSAC) good practice recommendations made a recommendation about multi-disciplinary composition of the OPAT team.[8] Abiding to this recommendation, the ULHT OPAT team consists of a lead OPAT physician specialising in acute medicines, lead OPAT surgeon specialising in vascular and colorectal surgeries, clinical microbiologist, OPAT nurses specialising in vascular devices, antimicrobial pharmacists and OPAT administrators. BSAC describes the key evidence gap relates to the appropriate time commitment for OPAT team members based on the service structure.[8] Therefore, the ULHT OPAT team sought advice from other OPAT centres with the 'visiting nurse' pathway to understand the staff-to-patient ratio. Before proposing the OPAT team structure in the business case, communication should take place between team members and their respective business units to ensure protected time for OPAT is achievable following funding approval to meet the projected service demand and governance structure. The OPAT team should also consider leveraging existing staffing resources at the whole health economy level, identifying opportunities to collaborate within the sustainability and transformation partnerships (STP). Once the skill mix and time commitment are agreed between the team members, finance department should be consulted to project the staffing costs in the business case.

Other costing aspects to consider within an OPAT clinical pathway include the resources and logistics required for insertion, removal and management of vascular devices, phlebotomy, drug administration and patient monitoring during OPAT. In addition to direct treatment costs, an OPAT business case should also consider the resources required to collect and manage patient data, activity data and OPAT interventions, using an electronic database or online outcome registry as recommended by BSAC,[1] to allow regular reviews of the service and benchmarking against national guidelines and other OPAT centres.

OPAT has been shown to reduce the number and duration of hospital admissions.[9-12] Commissioners benefit from the lower overall costs because of reduction in excess bed day payments for a hospital stay that would have exceeded the trim point with a given healthcare resource group (HRG) code in the absence of OPAT. Providers benefit from better efficiency in utilising hospital beds

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in addition to improvement in infection prevention and control. To quantify these benefits in the business case, the ULHT OPAT team adopted a three-step approach. The first step is to consult an established OPAT centres with a 'visiting nurse' model and of similar bed numbers to estimate the number of OPAT treatment days per annum for six common OPAT indications (cellulitis, osteomyelitis, infective endocarditis, bronchiectasis, diabetic foot ulcer and prosthetic joint infections). The second step is to consult the coding department to establish the number of hospital admissions for the six indications and their average length of stay in the past financial year. The final step is to estimate the numbers of OPAT patients and bed day savings per annum using pro-rata sampling of the figures obtained from the first and second steps, adjusted to stages of three years to ramp up towards a fully established service.

Once all aspects of costings and savings are understood, the OPAT business case should clearly outline the overall financial impact to the provider and commissioners based on the projected patient number to encourage a transparent approach in agreeing a payment mechanism. Two important principles when agreeing a local contracting approach for an OPAT service are to maintain scalability of the service to benefit more patients as the service expands and to ensure sustainability of the payment mechanism through incentivising both the provider and commissioners.

Some OPAT centres may consider any activities that can be coded to a HRG code to fall within PbR reimbursement, and therefore a separate payment mechanism for these activities are not pursued locally. These activities include undertaking phlebotomy, inserting, removing and managing devices in a hospital setting and running a weekly face-to-face outpatient clinic. Other OPAT centres may consider negotiating an OPAT 'bundle' tariff to cover all the standard OPAT activities or specific tariffs to cover pharmaceutical formulations and nursing visits.

In the absence of a national OPAT reimbursement mechanism, Jones et al.[3] highlights the variable financial impact on the English NHS providers calculated using the PbR payment mechanism, ranging from net loss, cost-neutral to net gain, based on a patient receiving cellulitis treatment via inpatient and different OPAT clinical pathways. Cost-effectiveness analysis of an OPAT service is further skewed by the consistency and quality of coding a patient episode. Providers and commissioners should take a pragmatic approach at the outset of the discussion to agree on metrics for outcome measures at patient and service levels and commit to regular review of the payment mechanism. OPAT team should also identify the ceiling of capacity based on the initial resources requested in the business case and set a threshold to review for additional resources.

Finally, an OPAT business case should outline evidence of how OPAT could benefit the local health and social care system outside the conventional OPAT patient cohorts and demonstrate the benefits in specific metrics. For example, the ULHT OPAT team identified a challenge faced by the organisation, that is high cancellation rate of elective surgeries due to limited availability of hospital beds. If OPAT could deliver the projected bed day saving in the first year, fewer operations will be cancelled and in turn the Trust's performance will improve. To identify local challenges, organisational communications and care quality commission (CQC) reports are good reference points.

Who had to be convinced?

An OPAT business case should consider the collective views of patients and key clinical, financial and operational stakeholders. Communication and engagement with these stakeholders should take place at the outset of writing the business case, outlining clear responsibilities and milestones for each member and jointly as a group.

At ULHT, the antimicrobial pharmacists first sought support from the Chief Pharmacist and homecare team about the proposed service structure. Next, discussion with the private homecare providers was initiated to identify opportunities for collaboration and to understand service specifications. Regular communications were essential to ensure the private providers move in tandem with the Trust's OPAT working group to achieve key milestones within the project and ultimately lead to fruition, i.e. service implementation.

Pharmacy governance and drug and therapeutic committee were involved in assessing the risks and mitigation plans from a pharmaceutical formulation and prescription management perspective to ensure the proposed service structure meets the Trust's medicines management policy, relevant standards and legislations. Additional considerations should be given to product quality assessment when elastomeric devices or compounded formulations are proposed in the service pathway. This can be achieved through completing a stability assessment for each product with the local pharmaceutical quality assurance lead in accordance to the NHS yellow cover documents on stability assessment of aseptically prepared small molecules[13] and pharmaceutical issues concerning OPAT,[14] if a regional quality assurance endorsement is not in place already.

Having the service structure in mind, the antimicrobial pharmacists approached the key members of the proposed OPAT team to discuss time commitment and agree on active participation in building the business case. Each member was tasked to liaise with their respective business units to agree on job planning and backfilling of role. Vascular specialists were approached at early stage of the discussion to ensure the business case clearly highlights the importance of

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managing vascular devices in the OPAT clinical pathway.

Trust infection specialists, including clinical microbiologists and infection prevention and control team, were consulted at the Trust wide antimicrobial stewardship strategy group to assess the impact of OPAT on antimicrobial stewardship. The group agreed that OPAT will offer an alternative clinical pathway for patients who no longer require any interventions in the hospitals and in turn will support the local infection prevention and control initiatives.

The Deputy Director of Urgent Care has been instrumental in embedding the OPAT initiative into the wider Trust's work stream. Keeping OPAT on the Trust's high level agenda is pivotal to initiate the discussion with key decision makers at the earliest opportunity.

One of the rate-limiting steps was to obtain the costing figures and activity data to convince the financial stakeholders. Early engagement with the finance, contracting and coding departments, as well as other OPAT centres, will improve the overall celerity of completing the business case. The Trust's finance department required any costing aspects that were not reimbursed through the PbR payment mechanism, as well as any proposed savings and financial efficiencies to both the commissioners and the Trust, to be clearly outlined in the business case to facilitate discussion on payment and income with the commissioners.

ULHT and the local CCGs adopted a collaborative and transparent approach when discussing the payment mechanism and finance modelling of OPAT service. The Head of Commissioning and Urgent Care Project Manager from the local CCG were supportive of the OPAT initiative and their contribution has been pivotal in appraising different contracting options in the business case.

Once the OPAT team has achieved common understanding with clinical, operational and financial stakeholders, the business case was expedited to the capital, resources and investment group and then to Trust's executive team for final approval.

What arguments "won the day"?

The ULHT OPAT team has taken a system-wide approach in constructing the business case and this approach underpinned the success of the business case. Through demonstrating careful consideration on patient experience, Trust's priorities and commissioners' interest, the proposed service structure was expected to achieve a system-wide improvement that is mutually beneficial at the STP level. OPAT bridges the gap between primary and secondary care. Fostering new care model is especially important at rural areas, where resources are conventionally fragmented and patients have limited access to healthcare setting.

The ULHT OPAT team has the aspiration to maintain agility, plurality and scalability of the service, moving in tandem with advances in pharmaceutical formulations and devices, antibiotic choices, vascular devices, digital technology and model of care. The ability to leverage expertise from private homecare industry to meet organisational goals and the dynamic of the NHS is demonstrated through the diverse composition of the OPAT working group and the multi-perspective content of the business case.

Checklist for success for anybody else considering this?	
Objectives	**Examples on how to achieve this**
Identify **demand** for OPAT and outline the purpose of case	• Undertake audit projects • Present patient case studies • Identify local infection control priorities • Identify local challenges on bed flow management (e.g. Red2Green performance)[15] and operational performance
Identify **key stakeholders** on clinical, financial and operational aspects and form a project team or OPAT working group	• Engage with: - local infectious diseases specialists - leads of service of specialities for which common OPAT indications fall under - local and regional experts on homecare, pharmaceutical formulations and stability - local experts on vascular devices and phlebotomy - local leaders and working groups responsible for management of bed flow - local and regional finance and contracting teams
Undertake **options appraisal** and decide on initial OPAT service model(s)	• Leverage experience from homecare team and other OPAT centres • Engage with private providers to understand service specifications • Engage with a contracting expert to scrutinise service specifications • Identify opportunities within the local STP • Outline the pros and cons of each option • Tailor the service structure to tackle challenges in the local health and social care system
Outline **patient pathway** as per the proposed service model, maintaining quality, safety and efficacy of care on OPAT	• Consider how suitable patients will be identified or referred • Outline inclusion and exclusion criteria • Emphasise role of OPAT MDT when screening suitability from a clinical, social, pharmaceutical and vascular perspective • Governance tools to support training patient/carer • Outline care transition between the referring team and OPAT • Monitoring on OPAT e.g. face-to-face clinics or telemedicine • Identify a clear escalation pathway • Outcome measures and end-of-treatment review
Outline OPAT **team composition**	• Refer to BSAC good practice recommendations[8] • Establish staff-to-patient ratio by consulting established OPAT centres with similar service structure • Outline key responsibilities of each member • Discuss job planning with respective business units and secure time commitment for OPAT
Demonstrate **benefits** of OPAT from a system-wide perspective	• Include patient benefits from clinical and social perspectives • Include impact on antimicrobial stewardship and infection prevention and control • Include impact on bed flow and organisational priorities • Provide forecast bed day savings • Outline benefits to the commissioner in terms of reduction in excess bed days payment and improvement in elective spells
Risk assessment and mitigations	• Assess patient safety risks on OPAT e.g. clinical deterioration, sepsis, drug allergies, blockage and displacement of vascular devices • Assess operational risks e.g. ceiling of capacity, staff absences, access to technology resources • Assess financial risks e.g. costs that are not reimbursed through PbR system, loss of excess bed days income • Assess contractual risks e.g. ease of implementing a contract, requirement to undertake a local tender • Propose risk mitigation plans and governance tools e.g. policies, guidelines, training
Outline **resources** required from the Trust and commissioners	• Consider staff and non-staff resources and their associated costs • Consider resources required for surveillance and audit trail
Summarise overall **financial impact** on the Trust and commissioners	• Identify one-off and recurrent costs • Translate activity impact (e.g. bed day savings) into monetary value • Summarise income impact on the Trust • Summarise expenditure impact on the commissioners
Identify **outcome measures**	• Identify key performance indicators at patient and service levels • Outline forecast efficiencies in terms of patient numbers and bed days • Agree on frequency of budget and service review
Outline **assumptions and key dependencies**	• Identify ceiling of capacity based on initial staffing resources
Set **milestones** in SMART format	• Specify the actions required from key decision makers • Specify the steps to be taken following approval/rejection of the case

Learnings - was there anything, in the light of experience, you might do differently?

Following service implementation, one of the key learning points the ULHT OPAT team has identified is the improvement required in coordinating the discharge process between the referring team, discharge planning team and OPAT, especially for OPAT patients who require social care referral. There were occasions where social care package has not been secured to facilitate timely discharge of OPAT patients and therefore opportunities were lost. Poor coordination also resulted in high transaction costs and suboptimal flow during the transition of care from inpatient to OPAT. Better coordination between the discharge planning team and OPAT team can be fostered through better understanding in processes on both ends and early engagement with a social care representative during the service development phase.

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Declaration of interests

Member of the Editorial Council, *Journal of Pharmacy Management.*

"Keeping OPAT on the Trust's high level agenda is pivotal to initiate the discussion with key decision makers at the earliest opportunity."

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