An outpatient parenteral antibiotic therapy (OPAT) map to identify risks associated with an OPAT service

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Objectives: Administering parenteral antibiotics outside the confines of a ward setting is becoming an attractive way of treating infections in the UK. However, as well as having many advantages, an outpatient parenteral antibiotic therapy (OPAT) service potentially introduces new risks to staff and patients involved. In the United States, healthcare organizations are now prospectively analysing processes to try and prevent errors occurring using the Healthcare Failure Mode Effect Analysis (HFMEA™) tool. The objectives of this study were to map out and agree the OPAT process and sub-processes and to identify potential OPAT system failures using steps 1–3 of the HFMEA™ tool, so that the resulting OPAT map can be used to design an OPAT service where risk is minimized.

Methods: The study was undertaken using a consensus development panel to which the HFMEA™ process was applied. Key stakeholders in the local OPAT process were invited to join the HFMEA™ team with the aim of describing and agreeing (defined as 100% participant agreement) an OPAT map, its sub-processes and potential OPAT system failures.

Results: The HFMEA™ team identified 6 processes, 67 sub-processes and 217 possible failures over the course of four meetings. Key areas identified in the OPAT map concerned identifying and checking patient suitability for an OPAT service, involvement of a multidisciplinary team and robust communication channels.

Conclusions: An OPAT map was developed, which may serve as a practical model for other organizations setting up a similar service.

Keywords: antibiotic stewardship, antimicrobials, risk management

Introduction

Administering parenteral antibiotics to patients in an outpatient setting is not new. Outpatient parenteral antibiotic therapy (OPAT) was first described in 1974 for the management of pediatric patients with cystic fibrosis.1 Since its introduction, OPAT has widely been proven to improve the quality of life for patients for whom administration of intravenous (iv) antibiotics is their primary reason for occupying a hospital bed and has the added benefit of reducing associated inpatient costs.2–5 Although these reductions in inpatient costs have been shown in countries where healthcare systems are different to that of the UK, there is no reason to assume that they would not be seen in the UK. This, together with recent advances in drug delivery via peripherally inserted central catheter (PICC) lines and anti-infectives with longer half-lives, has meant that OPAT is an attractive treatment option for specific patient populations.6

In the UK, patient acceptance and clinical experience with OPAT are increasing, particularly in the management of skin and soft tissue infections, osteomyelitis and endocarditis.7–11 In 1998, an OPAT working party published guidance on how a UK OPAT service could be delivered.12 The suggestions made in this guidance were later supported in the practical OPAT guidelines by the Infectious Diseases Society of America in 2004.13

In November 2006, Hammersmith Hospitals NHS Trust (HHINT), at that time a 1000 bed teaching trust in west London,
approved a business case for the development of an OPAT service, run by the infectious diseases (ID) team. The principal aim of the service was to provide a clinic-based service offering short-term outpatient therapy for patients with cellulitis and prolonged therapy for patients with osteomyelitis and endocarditis. The service was set up with a specialist nurse responsible for the day-to-day running and acting as a single point of contact for referrals and patient follow-up. An infectious diseases physician provided medical input when necessary and would review all patients requiring long-term therapy before they were accepted onto the service and at intervals thereafter. In addition, the service benefited from the advice of a pharmacist, who would review patients, antibiotic dosing and monitoring with respect to along with interpreting drug levels. Patients could be referred to the service Monday to Friday, 9 am to 4.30 pm. Prior to the development of a formal OPAT service, selected patients had been discharged with iv antibiotics, with a range of different arrangements made for individual patients. One of the drivers for establishing a formal OPAT service was that problems had arisen with the old ad hoc system, including PICC lines not being removed, wrong medication being supplied or wrong advice being given in 4 of 35 patients who had been sent home on iv antibiotics over a 2 year period (April 2004–April 2006). This suggested that the ad hoc arrangements were not risk-free.

Within healthcare, most of the lessons learnt from an adverse event are typically learnt after the event has occurred. The examination of adverse events is usually by means of a root cause analysis, which investigates the event to determine root causes or contributing factors that led to the event, and then identifies corrective actions and formulates outcome measures. The National Patient Safety Agency supports this method of analysis in the UK.14

In the USA, the Joint Commission (formally known as Joint Commission on Accreditation of Healthcare Organizations) is leading a concept to prospectively analyse healthcare processes to try and prevent errors occurring.15–17 The technique, called failure mode effect analysis (FMEA), has been used by the engineering community to focus on the processes that are involved in manufacturing products and to identify failure modes and their causes.15,16

The US Veterans Administration National Centre for Patients Safety has developed the FMEA concept further by combining ideas from its own root causes analysis programme and the US Food and Drug Administration’s Hazard Analysis and Critical Control Point tool.17 The resulting model is called the Healthcare Failure Mode Effect Analysis (HFMEA™) tool.17,18 HFMEA™ uses interdisciplinary teams, process map diagrams, failure modes (i.e. ways in which something could go wrong), failure mode cause identification, a hazard-scoring matrix and a decision tree algorithm to identify vulnerabilities in a system. As part of the process, solutions are suggested, developed and actioned for the key vulnerabilities identified in a system.17 Examples of where HFMEA™ has been applied within a healthcare setting include reviewing practices for medication administration in paediatric oncology, improving the safety of iv drug administration and reducing risks associated with blood transfusions.19–23 Currently, the HFMEA™ tool is being promoted by the American Society for Healthcare Risk Management in US hospitals.24

When the OPAT service received formal approval at HHNT, a care pathway was mapped out for how the service should be delivered. This pathway was based on a review of the literature available and experiences of an individual ID physician and ID pharmacist of how an OPAT service could be run. These experiences may not have identified all the potential vulnerabilities within the pathway, and with four problems having occurred previously, the question arose as to whether HFMEA™ could be applied to the development of the HHNT OPAT service to examine potential failures in the proposed system and to design a future system to minimize risk. The aim of this paper is to describe the development of the OPAT map through steps 1–3 of the HFMEA™ process and suggest how it might be used by other centres considering developing an OPAT service.

Objectives
(i) To map out and agree the OPAT process and sub-processes.
(ii) To identify potential OPAT system failures.

Methods
Overview
The HFMEA™ process through which the OPAT map was developed is outlined in Figure S1 [available as Supplementary data at JAC Online (http://jac.oxfordjournals.org/)]. Ethics approval for this study was granted by the local Research Ethics Committee (December 2006 Co-Rec Reference: 06/Q0411/169). Key stakeholders were invited to take part in the process as part of service development.

Composition and role of the HFMEA™ team
The role of the HFMEA™ team was to discuss and gain consensus (defined as 100% participant agreement) on the OPAT process map and then to identify potential system failures as described in the HFMEA™ procedure.

Key stakeholders in the local OPAT process were invited to join the HFMEA™ team following full written explanation as to what the study entailed. The participants invited were as follows:

- Two ID consultants
- A clinical pharmacist
- A specialist vascular access nurse
- A district nurse
- A hospital risk manager
- A patient representative

Those who agreed to attend were asked to give informed consent.

A team leader (M. G.), who was not part of the HFMEA™ team, explained the HFMEA™ process and facilitated the discussions. An independent observer (J. P. P.) attended all meetings to ensure participants’ views were accurately recorded.

HFMEA™ procedure
The HFMEA™ procedure used to examine potential failures in the proposed OPAT system was taken from the HFMEA™ guidelines.

Step 1 (identification of the topic) and step 2 (selection of the HFMEA™ group) had already been defined. Step 3 consisted of a series of meetings. These were structured as follows:
(i) The HFMEA™ team was asked to discuss and map out the anticipated OPAT processes, from start to finish, based on their experience. Each process was consecutively numbered as a step. Following this, the group was then asked to discuss and identify all the sub-processes associated with each process that they thought occurred. Again, these steps were consecutively lettered. For example:

Sub-processes to this process might be:

1(a) Patient referred direct from Accident and Emergency or
1(b) Patient referred from a ward setting

A consensus view of the OPAT process and sub-processes was required before proceeding with the HFMEA™. Where there were differing views about a particular process or sub-process, the team leader identified a common theme or presented a pragmatic viewpoint to facilitate discussion and progression. At the end of the meeting, team members were asked to observe the processes and sub-processes in practice before the next meeting to verify their existence and suggest any amendments as appropriate.

(ii) At the next meeting, the HFMEA™ team reviewed the process and sub-process maps to verify that they were correct following their observations in practice. If any team member wished to amend, add or remove a process or sub-process, this was discussed with the group and the change was only accepted if all team members agreed.

(iii) Following the mapping process, the next step involved identifying and exploring any potential failure modes that could be associated with each sub-process step. These failure modes were documented and a consensus view reached that they did exist. Again, team members were asked to go back to the practice environment and verify their existence.

(iv) At the next meeting, any suggestions that the HFMEA™ team members had regarding the failure modes were discussed and agreed as appropriate. The team was then invited to review each failure mode and identify one or more causes.

During step 4 of HFMEA™, the failure mode causes identified undergo a hazard analysis process. This involves the team giving each of the failure causes identified a severity and probability score based on pre-set criteria. This then results in a hazard score. A hazard score of 8 or higher is considered high enough to require analysis of the failure in greater detail using a HFMEA Decision Tree™. The tree examines failures on the basis of:

- Criticality (i.e. is the failure critical enough that it would result in an adverse event or is there a single point in the process that if it failed would be critical?)
- Absence of effective control measures (i.e. what control measures are already in place to prevent the failure?)
- Lack of detectability (i.e. is the failure obvious or visible enough that it could be detected before an adverse event occurred?)

Finally, in identifying why the failures occur (via the decision tree), steps are sought to resolve the causes of these failure modes. These include outcome measures and deciding who is best placed to action these so that the recommendations from the HFMEA™ process could be made to the OPAT system to ensure risk is minimized. Stages 4 and 5 of this process were not completed for the purposes of this study.

Meetings

Meetings were scheduled at ~2 week intervals with the next planned meeting date confirmed at the end of each meeting. Meetings would not go ahead if more than two members were absent. During each meeting, comments and suggestions were recorded by the team leader and observer independently. These were discussed following the conclusion of each meeting to ensure these were correct and accurate. Team members were then fed back a written review of the outcomes from the last meeting 2 days later.

Results

Overview

All the participants who were identified as key stakeholders agreed to attend. In total, it took four meetings to map out and agree upon the OPAT map with its associated failures; these were held between 21 February and 18 April 2007. Each meeting lasted ~2 h and the majority were attended by six out of the seven HFMEATM team members. The district nurse was unable to attend any meetings, although full details of each meeting were sent to the district nurse (along with other members of the HFMEA™ team). The district nurse reviewed this information with other district nurses in their team and their comments were discussed at the beginning of each meeting, with any appropriate changes made before progressing further.

Meeting 1

Present: team leader, two consultants, pharmacist, vascular access nurse, hospital risk manager and patient representative.

A discussion took place from team members’ experiences of providing an OPAT service, and by the end of meeting 1, seven processes were agreed by the HFMEA™ team (Figure 1).

From the mapped-out OPAT process, the members started to discuss and identify the sub-processes associated with these. By the end of the first meeting, the first four processes had been mapped out. Team members identified and agreed upon:

- 8 sub-processes associated with process 1 (patient satisfies basic criteria for OPAT)
- 6 sub-processes associated with process 2 (discussion with patient regarding potential OPAT)

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**Figure 1.** OPAT process map following meeting 1.
• 10 sub-processes associated with process 3 (patient assessment by OPAT team)
• 10 sub-processes associated with process 4 (patient accepted onto OPAT)

Meeting 2
Present: team leader, two consultants, pharmacist, vascular access nurse, hospital risk manager and patient representative.

At the start of the second meeting, comments and suggestions from the first meeting were discussed. A number of changes were suggested and agreed upon as illustrated in Table S1 [available as Supplementary data at JAC Online (http://jac.oxfordjournals.org/)]. No changes were suggested by the district nurse.

Figure S2 [available as Supplementary data at JAC Online (http://jac.oxfordjournals.org/)] represents the refined OPAT process map following meeting 2. Following these changes, the remaining sub-processes (5 and 6) were subsequently discussed and mapped out. Due to the complexity of the fifth sub-process ‘Ongoing treatment’, it was suggested and agreed that this sub-process should be further divided into three separate sub-processes. These were:

• Sub-process 5 Ongoing Treatment (daily administration of iv antibiotics by OPAT nurse and/or District Nurse)
• Sub-process 5.1 Ongoing Treatment (weekly medical review)
• Sub-process 5.2 Ongoing Treatment (follow-up of outstanding patient issues by OPAT nurse, e.g. blood results and drug levels)

Meeting 3
Present: team leader, two consultants, pharmacist, risk manager and patient representative.

No changes were introduced by any of the HFMEATM members to the processes or sub-processes identified in the previous two meetings.

The group was then asked to revisit subsequent sub-processes to identify any failures that could be associated within each. Initially, the group had difficulty trying to establish a definition of a failure. To avoid not identifying a failure, the team leader accepted a failure as anything the team members thought could possibly go wrong with a particular aspect of the sub-process. Figure 2 illustrates an example of failures identified for sub-process 3 at meeting 3.

By the end of the meeting, three sub-processes had been examined and failures listed. The number of failures identified for each sub-process was as follows:

• 12 failures for sub-process 1 (patient satisfies basic criteria for OPAT)
• 20 failures for sub-process 2 (discussion with patient regarding potential OPAT)
• 31 failures for sub-process 3 (patient assessment by OPAT team)

Meeting 4
Present: team leader, two consultants, pharmacist, vascular access nurse and patient representative.

No changes were suggested from the district nurse following meeting 3. The remaining failures were identified for sub-processes 4–6. The failures identified for each sub-process were as follows:

• 31 failures for sub-process 4 (patient accepted onto OPAT and treatment initiated)
• 24 failures for sub-process 5 (ongoing treatment—daily)
• 35 failures for sub-process 5.1 (ongoing treatment—weekly)
• 24 failures for sub-process 5.2 (ongoing treatment—follow-up of outstanding patient issues by OPAT nurse)
• 36 failures for sub-process 6 (intravenous therapy under OPAT concluded)

Process and sub-process consultation following meeting 4
Participants were circulated the overall process, sub-process and failure modes that had been agreed over the preceding four meetings via email. Each participant was asked to ensure that they agreed with the findings and were given 10 days to make any alterations.

Four main suggestions were made by the team members as shown in Table 1 and were agreed by other team members (through e-mail).

Figure 3 outlines the final OPAT map that was agreed.

Total number of sub-processes and failures identified

After the four meetings and the consultation period, the HFMEATM members had discussed and agreed on the following:

• 6 main processes for OPAT pathway
• 67 sub-processes within the 6 main processes
• 217 failure modes identified from the 67 sub-processes

Full details of the final overall sub-processes and failure modes are shown in Figure S3 [available as Supplementary data at JAC Online (http://jac.oxfordjournals.org/)].

Discussion

On face value, setting up and delivering an OPAT service might appear to be relatively simple and risk-free. However, as part of this study, it took four meetings (~8 h in total) to map out and agree upon the full OPAT process along with the associated potential failures, suggesting that this is not the case.

Over the four meetings, the team managed to identify 6 overall processes from which 67 sub-processes followed. From these 67 sub-processes, 217 failures were then identified that could have potentially led to patient harm or errors occurring. Interestingly, each sub-process identified a similar number of failures (between 20 and 35) with the exception of sub-process 1 where only 12 failures were identified. The lower number of failures for sub-process 1 may not be unexpected as this process dealt with the patient meeting basic criteria for OPAT, compared with the other more complex processes later on in the pathway.

The total failure figure confirms the complexity of an OPAT
service and the detail is useful in helping to identify gaps in a proposed OPAT service that may not have been previously thought of. It is believed that this is the first time a full OPAT service has been mapped out, and although there may be subtle differences in the way other organizations deliver OPAT, it may serve as a useful template for others planning to set up an OPAT service or for those wishing to review their current service.

Some of the areas identified, which were not previously in the original HHNT OPAT model, were:

(i) Discussing fully with the patient and relatives the idea of receiving outpatient antibiotics through OPAT
(ii) The responsibility of the OPAT nurse in liaising with a full range of practitioners regarding the practicalities of OPAT both prior to and during the patient’s outpatient therapy
(iii) The variety of external factors (patient transport, clinic attendance and mobility issues) that could present as problems to an OPAT patient

<table>
<thead>
<tr>
<th>Table 1. Suggestions following the consultation period</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Suggested amendment or addition</strong></td>
</tr>
<tr>
<td>Change the process title in OPAT process 1 to ‘Patient considered for OPAT’</td>
</tr>
<tr>
<td>Addition of failure modes to 4L</td>
</tr>
<tr>
<td>Extra failures under 5C and 5.2C, which focused on communication problems</td>
</tr>
<tr>
<td>Inclusion of extra failures in 5A and 5.1A</td>
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</tbody>
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Figure 2. An example of failures identified at meeting 3 for sub-process 3.
The identification of 67 sub-processes in this study supports previous work that has tried to describe the wider issues that need to be considered when setting up an OPAT service. Both Nathwani and Conlon\textsuperscript{12} and Tice et al.\textsuperscript{13} suggested that clinical and non-clinical issues concerning healthcare professionals and the patient must be addressed when setting up and/or delivering an OPAT service; examples include:\textsuperscript{12}

\begin{itemize}
  \item Appropriate selection of suitable patients
  \item Suitable home environment
  \item Appropriate drug selection, delivery and monitoring
  \item Adequate and thorough discharge planning
  \item Follow-up and support measures
  \item Effective communication methods between relevant healthcare professionals
  \item Patient record keeping
\end{itemize}

What was reassuring was that all the above factors independently came out and were discussed during the course of the four meetings in the present study.

Interestingly, of the final six OPAT processes (Figure 3), half of these (processes 1, 2 and 3) were about identifying and checking the suitability of the patient for the OPAT service; clearly the team felt that time invested here was time well spent. In addition, 31 of the 60 failures (52\%) in these processes (1–3) surrounded process 3 ‘Patient assessment by OPAT team’, illustrating that this stage in the process requires careful consideration by the specialist (ID or microbiology) teams.\textsuperscript{25–27}

One process that caused a lot of debate in the meetings was process 5 ‘ongoing treatment’. The group found the need to split this process into three further processes, in recognition of the different methods in which OPAT could be delivered and monitored. Although the daily administration of antibiotics was either via the OPAT nurse or district nurses, there was also the weekly monitoring of OPAT patients in the OPAT medical review clinic. Furthermore, the HFMEA\textsuperscript{TM} team recognized that the OPAT nurse would need to follow up outstanding patient issues (for example, blood results, drug levels and booking scans) to ensure optimal patient monitoring. The resulting three separate processes highlighted that ‘ongoing treatment’ was not as simple as first thought in terms of a single process and that out of all the steps involved, this process had the greatest potential for something to go wrong.

Nearly all of the processes included failures that were linked with communication either between (i) the patient and the OPAT service, (ii) the OPAT service and other internal/external departments and (iii) OPAT team members themselves, indicating that robust communication systems need to be in place to ensure communication is effective. For example, communication was highlighted by the team as an area of concern especially surrounding process 4 (treatment initiation) and process 5 (ongoing therapy) as there were numerous multidisciplinary factors and variables that needed arranging. Of all the failures identified in the OPAT map, 123 (57\%) were focused around communication issues.

The number of detailed sub-processes and failures identified in this study endorses how important the HFMEA\textsuperscript{TM} team’s composition was. This study also included the viewpoint from a patient. The patient recruited was able to bring practical experiences to the development of the map from having previously had chemotherapy together with treatment for multiple infections following surgery. The patient representative discussed and challenged medical issues raised, despite not being medically trained. This approach ensured that the patient’s view and experience was represented at all times and allowed a patient-centred approach to the design of a potential OPAT service.

**Limitations**

The lack of the district nurse in the face-to-face HFMEA\textsuperscript{TM} team meetings could be seen as one of the main limitations. Although the district nurse did review the outcomes of each meeting and suggest changes as appropriate, this was undertaken in isolation from the rest of the group. This might have prevented the district nurse interacting with the HFMEA\textsuperscript{TM} team and therefore made it difficult for them to defend or suggest points that may have been critical to patient care in the primary-care setting. Furthermore, the absence of a district nurse at these meetings meant that the group was mainly composed of secondary-care health professionals, which could have resulted in not all the sub-processes or potential errors associated with community nursing being identified. To date, most HFMEA\textsuperscript{TM} studies\textsuperscript{19–23} have been conducted in the USA, where some of the hospital’s management team assisted the relevant department team members in attending meetings. However, this was not possible for the present study.

A further potential limitation may have been that the team leader was an ID pharmacist and would have his own views on the OPAT service. However, the additional presence of an independent observer ensured that participants’ views were accurately recorded and were not biased.

**Conclusions**

We used key stakeholders in a local OPAT process to help map out an OPAT process. In doing so, 6 overall processes were mapped out with 217 failures identified that potentially could have caused harm or errors to patients. With OPAT being an attractive option for treating certain types of infections in the UK, careful local planning needs to occur, particularly around lines of communication, when considering the setting up of an OPAT service. The OPAT map developed in this study may serve as a practical model for other organizations considering the setting up of a similar service.
OPAT map to identify risks associated with an OPAT service

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Transparency declarations

None to declare.

Supplementary data

Figures S1, S2 and S3, and Table S1 are available as Supplementary data at JAC Online (http://jac.oxfordjournals.org/).

References