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1 **Setting up an outpatient parenteral antimicrobial therapy (OPAT)**

2 **unit in Switzerland: review of the first 18 months of activity**

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12

13 **Abstract**

14 *Objectives*

15 Outpatient parenteral antimicrobial therapy (OPAT) has been recognised as a useful, cost-effective and
16 safe alternative to inpatient treatment, but no formal OPAT unit existed in Switzerland until recently. In
17 December 2013 an OPAT unit was established at Lausanne University Hospital. We review here the
18 experience of this new OPAT unit after 18 months of activity.

19 *Methods*

20 Patient characteristics, clinical activities and outcomes were recorded prospectively. Need and acceptance
21 was evaluated as number of OPAT courses administered and number of patients refusing OPAT. Safety
22 and efficacy were evaluated as: 1) adverse events linked to antimicrobials and catheters, 2) re-admission
23 to hospital, 3) rate of treatment failures and 4) mortality.

24 *Results*

25 Over 18 months, 179 courses of OPAT were administered. Acceptance was high with only 4 patients
26 refusing OPAT. Urinary tract infections with resistant bacteria and musculoskeletal infections were the
27 most common diagnoses. Self-administration of antibiotics using elastomeric pumps became rapidly the
28 most frequently used approach. 16 patients presented with adverse events linked to antimicrobials and
29 catheters. OPAT- related readmissions occurred in 9 patients. The overall cure rate was 94%.

30 *Conclusion*

31 This study shows that OPAT is very well accepted by patients and medical staff, even in a setting which
32 has not used this type of treatment approach until now. Self-administration using elastomeric pumps
33 proved to be particularly useful, safe and efficient. OPAT offers a good alternative to hospitalisation for
34 patients presenting with infections due to resistant bacteria that cannot be treated orally anymore and for
35 difficult to treat infections.

36 **Keywords**

37 OPAT, drug delivery, antibiotic resistance, difficult-to-treat infections

38 **Introduction**

39 Some patients require parenteral antibiotic therapy, but are well enough to return home. Outpatient
40 parenteral antimicrobial therapy (OPAT) was first developed in the USA in the 1970s for patients with
41 cystic fibrosis, before being adopted by many countries [1-4]. It has been recognised as a useful, cost-
42 effective and safe alternative to inpatient treatment. It is now a standard care in several countries and
43 different national guidelines have been established [5-7]. There are various models of care for OPAT and
44 most OPAT centres provide hospital-centred nursing programmes or services based on nurses visiting the
45 patient's home. A few centres have also shown that self-administration of intravenous antibiotic therapy is
46 an effective and safe option for selected patients [8, 4]. Furthermore, use of continuous infusion of
47 antibiotics increases the number of feasible treatments. Continuous infusion by pumps of antibiotics with
48 a time-dependent killing mechanism is a practical option which has been described for treatment of

49 methicillin-susceptible *Staphylococcus aureus* (MSSA) infections and exacerbations of cystic fibrosis
50 [9,10,11]. In Europe, even if many specialists feel that OPAT is required in their country, it is still
51 underdeveloped because of lack of funding, lack of leadership and lack of coordination between hospitals
52 and community care [12].

53 In the last decades, programmes to enhance care delivery on an outpatient basis in order to contain health
54 costs have been developed in Switzerland. Administration of outpatient intravenous antibiotic therapy for
55 patients who require parenteral therapy, but are otherwise fit enough to go home, hasn't been used widely
56 until recently and, to our knowledge, no official OPAT programme has been implemented in our country.
57 In December 2013, an outpatient parenteral antibiotic treatment (OPAT) unit was initiated at Lausanne
58 University Hospital with the goal of offering an alternative treatment programme that is equally effective
59 and as safe as inpatient treatment.

60 The purpose of this study was to review the experience after implementation of a new OPAT unit in the
61 context of the Swiss Health System. Data were prospectively recorded in an OPAT registry in order to
62 evaluate the need and acceptance, as well as the efficacy and security of the programme.

63 **Methods**

64 *The OPAT service*

65 The University Hospital of Lausanne is a 1462-bed teaching hospital providing care in all major
66 specialties. The OPAT service is led by infectious diseases physicians and a team of nurse practitioners.
67 Patients are referred to the OPAT service by the physicians from the inpatient hospital wards, emergency

68 department, outpatient clinics and private hospitals. The Infectious Diseases Society of America (IDSA)
69 guidelines are used as a basis for the organisational aspects of the unit [5, 13]. Antimicrobials are
70 administered via peripheral catheters or peripherally inserted central catheters (PICC lines), the latter
71 being inserted by specialist radiologists. The route of therapy (peripheral catheter vs PICC line) depends
72 on the length of treatment and the type of administration (intermittent vs continuous drug administration),
73 PICC lines being usually used for treatment longer than 7 days and for continuous infusions. Antibiotic
74 administration is ensured using one of three options: 1) an OPAT nurse at the infusion centre (hospital
75 OPAT); 2) at home with a visiting nurse (homecare OPAT); 3) the patient himself or a relative using
76 elastomeric infusers (Easypump, B. Braun, Germany and Autofuser, Teleflex, Germany) (self OPAT).
77 Elastomeric pumps are non-electronic pumps which deliver medication by deflation of an elastomeric
78 membrane. They are prepared by a commercial compounder and are delivered to the infusion centre or
79 directly to the patient's home. In addition to being used for self-administration of intermittent infusions,
80 elastomeric infusers are employed for continuous infusions of all antibiotics showing good stability for at
81 least 24 hours [14, 15].

82 If self OPAT is considered feasible, the patient is provided with training in self-administration of
83 antibiotics prior to discharge. Training takes place at the bedside and requires 1-2 hours of nursing time. If
84 necessary, the patient is seen once or twice more at the OPAT clinic for additional training.

85 Patients needing short courses of antibiotics (less than 4 days) are usually proposed to be treated at the
86 OPAT clinic and those with limited mobility are treated at home by homecare OPAT.

87 Patients are reviewed by a physician and a nurse at least once a week at the OPAT clinic for symptom
88 review, inspection and care of the intravascular device and blood monitoring. Follow-up imaging studies
89 are done if considered necessary.

90 *Data collection*

91 Demographic data, site and nature of infection, antibiotic used, mode of administration, duration of
92 therapy, and outcome of infection were prospectively recorded for all patients treated at the OPAT unit
93 between December 2013 and May 2015 (18 months). Patient readmissions, adverse events related to
94 antibiotics requiring stopping therapy, vascular access complications and death were also recorded. If a
95 patient was, for any reason, re-hospitalized during an OPAT course and then re-enrolled without any
96 change in diagnosis or treatment, he was included as the same OPAT episode and was not regarded as
97 failure.

98 Failure was defined as any evidence of relapse during antibiotic treatment, need for unanticipated surgery
99 to control the infection or recurrence of infection within 90 days of cessation of intravenous antibiotics.

100 The study was approved by the Ethics Committee of Vaud Canton. Patients were informed about the data
101 collection and gave informed consent.

102 **Results**

103 *Patients*

104 Over the study period of 18 months, 237 patients were referred to the OPAT unit. The OPAT unit refused
105 to take care of 73 patients (30%). 20 presented health conditions not suitable for ambulatory care. 16 were
106 living too far away (> 20km). 20 were switched to oral therapy or didn't need antibiotics anymore. 17
107 were refused for other reasons. Only 4 patients refused OPAT.

108 179 courses of OPAT (= OPAT episodes) were administered to 160 patients, resulting in a total of 2533
109 days of patient care (median per patient: 9 days, range 1-78). The majority of patients were male
110 (101/160; 63%) and the median age was 58 years (range 18-92). Over those 179 OPAT episodes, 86
111 patients (48%) had a PICC line, 84 patients (47%) a peripheral catheter and 9 patients (5%) a portacath.
112 The majority of patients (36%) were referred from surgical departments, followed by ambulatory care
113 (33%) and internal medicine (31%).

114 *Diagnosis and microbiology*

115 The infectious diseases diagnoses are summarised in Figure 1. The most common primary diagnoses were
116 urinary tract infections (58 episodes, 32%) and bone and joint infections (40 episodes, 22%).

117 Microbiological data were available for 159 patients (88%). The most frequent microorganisms isolated
118 were *Enterobacteriaceae* (59 cases, 33%). *Escherichia coli* was by far the most common pathogen and
119 was found in 50 episodes (28%). Extended-spectrum β -lactamase (ESBL) producing and

120 fluoroquinolones-resistant *E. coli* were predominant (27/50 and 14/50 respectively). The second most
121 common microorganism was *Staphylococcus aureus*, identified in 21 patients (12%). Methicillin-resistant
122 *S. aureus* was isolated in only 3 patients. *Streptococcus spp* were isolated in 18 patients (10%),
123 *Staphylococcus epidermidis* in 15 patients (8%) and *Pseudomonas aeruginosa* in 9 patients (5%).

124 We took charge of 11 patients more than once for different infectious episodes. 8 patients presented with
125 recurrent urinary tract infection and were colonised with resistant Enterobacteriaceae (fluoroquinolones-
126 resistant *E. coli* or ESBL-producing Enterobacteriaceae) or *P. aeruginosa*. 4 of those patients were solid
127 organ transplant recipients. Those episodes were not related one to another and were not regarded as
128 failure (too much time between episodes, different sites of infection, different types of bacteria).

129 *Antimicrobial therapies*

130 Antimicrobials used are shown in Figure 2. β -Lactams and glycopeptides were the most commonly used
131 antibiotics. The most frequently prescribed agents were ceftriaxone which was used in 64 OPAT episodes
132 for 825 days of treatment (33%), followed by ertapenem in 38 OPAT episodes (469 days of treatment,
133 17%) and flucloxacillin in 19 OPAT episodes (308 days of treatment, 12%). Vancomycin was used in 11
134 OPAT episodes (213 days of treatment, 9%) and teicoplanin in 6 (189 days of treatment, 8%). The
135 hospital OPAT model was used for 82 patients (46%), self-administered OPAT for 55 patients (31%) and
136 the homecare OPAT model for 42 patients (23%). As illustrated in Figure 3, self-administration was the
137 preferred service model (1109 days, median per patient: 9; range 3-66) in terms of treatment-days and a
138 significant increase of this approach was noticed during the 18 months of follow-up with 75% of patients
139 treated this way during the last 6 months. Elastomeric pumps were used for 66 OPAT episodes (37%).

140 Continuous intravenous infusion was used for all antibiotics showing sufficient stability for 24 hours
141 infusion. 42 patients were administered continuous infusions (24%) of flucloxacillin (19 episodes),
142 cefepime (6), piperacillin-tazobactam (6), vancomycin (5), cefazolin (3), amoxicillin (2), and ceftazidime
143 (1).

144 *Adverse events and outcome*

145 Drug-related and line-related adverse events were recorded. 16 of 179 OPAT episodes (9%) had some
146 complication recorded. Drug-related adverse events accounted for the majority of complications and
147 occurred in 10 patients (5.5%): drug rash $n=3$, thrombocytopenia $n=2$, acute hepatitis $n=2$, neutropenia
148 $n=1$, acute renal insufficiency $n=1$, fever $n=1$.

149 Three patients were readmitted to hospital for these drug-related adverse events. There were 6 line-related
150 adverse events (3.5%), all related to PICC lines. Two were PICC line related thrombosis of the upper arm,
151 which were treated by anticoagulation for 6 weeks. Neither of these patients had clinical evidence of
152 pulmonary embolism. Three patients had PICC line infections. One patient presented with two distinct
153 episodes of catheter-related bacteraemia with two different bacteria (*Enterobacter aerogenes* and
154 *Klebsiella pneumonia*). He was readmitted to hospital for change of the PICC line for both episodes. A
155 second patient also presented with bacteraemia and secondary infection of his knee's spacer. He was
156 readmitted for surgery. In both cases, antibiotics were administered at home by a nurse. The last patient
157 was self-administering antibiotics for a *Staphylococcus aureus* bacteraemia. He was asymptomatic, but
158 had control blood cultures which were positive for *Enterobacter cloacae*.

159 We did not observe any episode of *Staphylococcus aureus* PICC line infection or *Clostridium difficile*
160 colitis during treatment or during the 3 months of follow-up after completion of treatment.

161 Re-admission to hospital occurred in 24 OPAT episodes (12%), of which 7 were planned re-admissions
162 and 8 unrelated to OPAT. OPAT-related re-admissions occurred in nine patients (5%) of whom two were
163 self-administering antibiotics. Two patients were readmitted for PICC line infections, one of whom was
164 readmitted twice. Three patients (1.6%) were readmitted because of drug-toxicity. Only three patients
165 (1.6%) were readmitted because of treatment failure during OPAT. No patient died during OPAT.

166 The overall cure rate was 94% with 11 patients presenting as clinical failure. Five patients needed surgical
167 intervention for source control: three for abscess incision and two for removal of osteosynthesis material.
168 Six patients relapsed after treatment completion. All of them had a urinary tract infection and were
169 successfully retreated in an ambulatory setting. Outcomes are summarised in Table 1.

170 **Discussion**

171 There is a continuous pressure on hospital beds in Switzerland and the health authorities encourage a
172 more community-based model of care in order to reduce hospital stay, reduce costs and increase
173 availability of beds. In December 2013, an OPAT service was established at the University Hospital of
174 Lausanne to improve ambulatory care of patients needing intravenous antimicrobials, but whose general
175 condition allows them to go back home. This study shows that there is a real need and a high acceptance
176 for an OPAT structure. During the first 18 months following the implementation of the service, 179
177 patients were treated by OPAT, a number that concords with what has already been described and shows

178 that there is a real demand from the inpatient structure [16-18]. Furthermore, 2533 bed-days of inpatient
179 admission have been avoided, which meets the demands of the hospital and the National Health System.
180 These figures are a strong argument for the development of other OPAT programmes in our country.

181 Musculoskeletal infections predominated in terms of treatment-days administered. This is not surprising
182 considering that prosthetic surgery is increasing in an aging population as in Switzerland, and that
183 prosthetic infections do invariably occur in a small percentage of these cases. It is to be expected that
184 patient need for OPAT will increase in the future. Most of the patients with urinary tract infection treated
185 by our OPAT unit had infections with ESBL producing and fluoroquinolones-resistant gram-negative
186 bacilli. Switzerland is currently facing a strongly increasing burden of infections with resistant gram-
187 negative bacilli, which will in the future increase the need for parenteral treatment [19]. These data
188 suggest that OPAT structures will be increasingly needed for “difficult to treat” - such as prosthetic
189 infections, as well as for new situations like the current epidemic of resistant gram-negative bacillary
190 infection.

191 A characteristic of the OPAT model in Lausanne is its adaptability to a wide range of clinical situations
192 and lengths of treatment. The fact that the OPAT service proposes three different types of administration
193 means that any intravenous antibiotic can be administered in an ambulatory setting. Patients can be taken
194 care of promptly by hospital OPAT if they present with a diagnosis which doesn't need hospitalisation,
195 like urinary tract or skin and soft tissue infections. Collaboration with home care providers has also made
196 it possible to treat patients with limited mobility at home. The home care providers have been particularly
197 flexible in the sense that they can ensure up to 4 antibiotic injections per day. Finally, self-administered

198 OPAT has been shown in our setting to be particularly useful, well accepted and safe. Patients receiving
199 both, long and short antibiotic courses, tend to appreciate the advantages of treatment with elastomeric
200 pumps and demonstrate good abilities for managing those treatments themselves. In addition, the
201 organisation of the hospital discharge is facilitated when self-administration is chosen. Beside the
202 instruction of the technique of self-administration with the pumps, this approach does not require the
203 availability of OPAT nurses or infrastructure, except for the occasional follow-up visits. During the last
204 six months of the study period, an important increase of self-administration was observed and currently
205 75% of patients are treated by self-administered OPAT. This is probably explained by a concordance of
206 different factors, such as development of clear guidelines, more confidence about the use of pumps by the
207 team and high satisfaction of the patients.

208 Self-administration using elastomeric pumps is likely to be interesting from an economic point of view.
209 Elastomeric pumps cost about US\$ 50 per piece and the cost to prepare them is about US\$ 50 per pump
210 excluding the drug cost [20]. One treatment day with an elastomeric pump costs therefore US\$ 100,
211 which is less than the cost of 2 hours of nursing time (US\$ 80 per hour) for a home visit, or the nursing
212 time and the cost of the treatment room to administer the antibiotics at the hospital [21]. This cost
213 difference between self OPAT and nurse-administered OPAT is particularly important if the antibiotics
214 have to be administered several times a day. A complete economic analysis is currently being conducted
215 to clarify this point.

216 Antibiotics being traditionally given in hospital, it was not known how patients and medical staff would
217 accept this new way of treatment. Acceptance was better than expected and only 4 patients refused to be

218 taken care of by the OPAT unit. We noticed however that some habits are difficult to change. For instance,
219 patients are traditionally kept at hospital until the end of fever even if their clinical situation has been
220 stabilised. Many practitioners also don't know that some antibiotics that require multiple doses per day,
221 for example flucloxacillin, can be prescribed by continuous infusion, which facilitates treatment at home.

222 Cure was achieved in 94% of patients, which is in line with the results from other published cohorts. In
223 addition, the re-admission rate of 12% is comparable to what has already been described and only 9 of
224 those were related to OPAT care [2, 18, 22, 23]. These figures are reassuring, considering that a relatively
225 large proportion of the patients have been self-administering their treatment with elastomeric pumps. It
226 can in particular be highlighted that line-related complications were rare and infections were not related to
227 self-administration in three cases out of four.

228 The use of elastomeric infusers for self-administration is well described and antibiotic stability tables
229 have been published [15, 24-26]. Most antibiotic stability data have been produced by manufacturers of
230 elastomeric pumps under standardised laboratory conditions and there can be a concern about drug-
231 stability depending on the infuser temperature under real-life conditions. Preliminary data measuring drug
232 concentrations in the elastomeric pumps and in the plasma of patients (data not shown) seem to be
233 reassuring, but additional such data will be collected in the future at our OPAT unit.

234 **Conclusion**

235 In conclusion, this study demonstrates that there is a real need and acceptance for an OPAT unit even in a
236 setting that has traditionally been favouring hospital-based treatment of patients requiring intravenous

237 antibiotics. The data collected also prove that it is safe and efficient with low levels of failures and
238 complications, even if a large proportion of patients were treated by self-administered OPAT using
239 elastomeric pumps. Considering that infections due to multi-drug resistant bacteria, and difficult-to-treat
240 such as prosthetic infection were the most frequent infections treated by the OPAT unit, and that these
241 types of infection are likely to increase, it is probable that the need for an OPAT unit will even be more
242 important in the future.

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249 **Conflicts of interest:**

250 None to declare

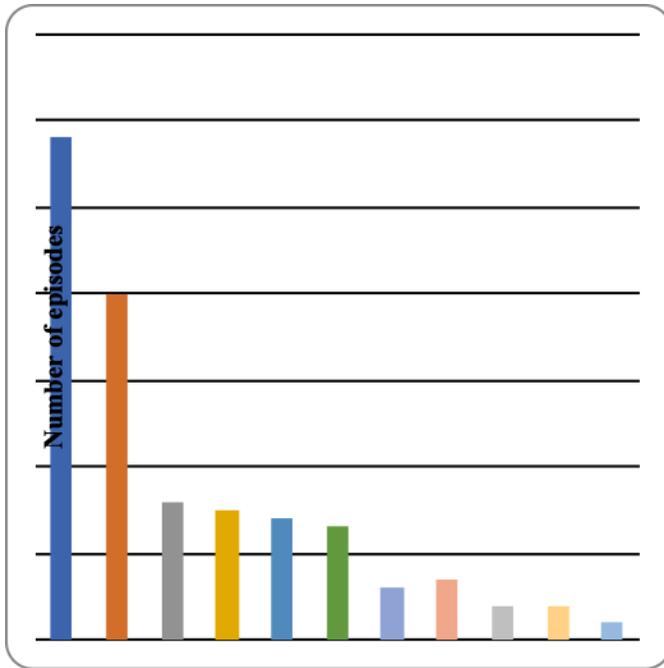
251 **Transparency declarations**

252 None to declare

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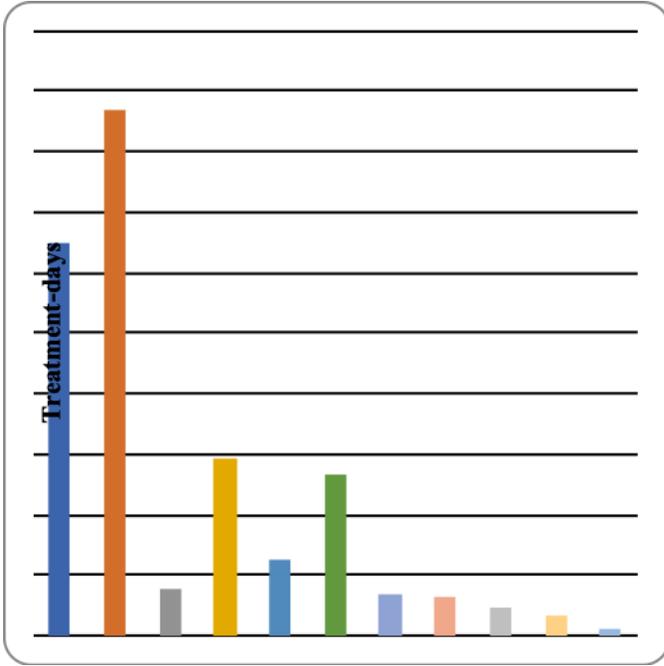
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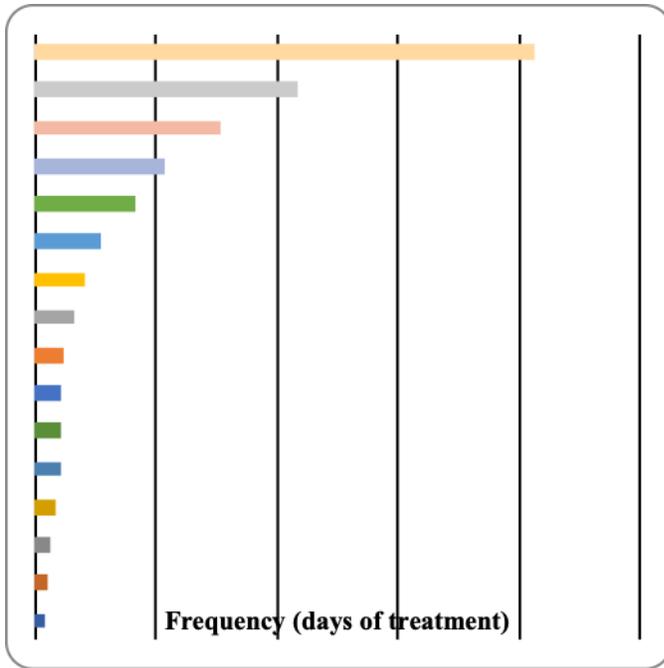
320 **Fig. 1A** Infections treated in terms of number of episodes (total number of episodes n = 179)

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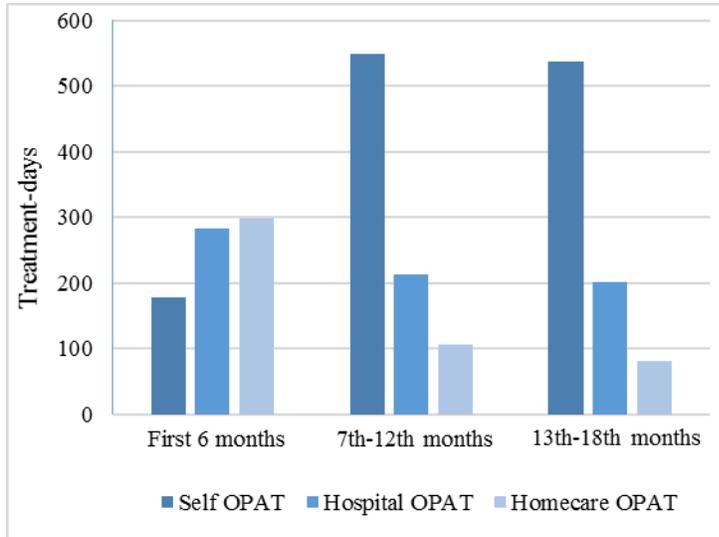
323 **Fig. 1B** Infections treated in terms of treatment-days administrated (n = 2533)



324

325 **Fig. 2** Antimicrobials used

326



327

328 **Fig.3** Evolution over 18 months of the service models used in term of treatment-days (n=2533)

329

| Re-admissions | No (%) of patients | Cumulative risk per 1000 OPAT treatment-days |
|---------------------------------------|--------------------|---|
| Total | 24 (13%) | 9.5 |
| Planned | 7 (4%) | 2.8 |
| Unplanned | 17 (9%) | 6.7 |
| Treatment failure | 3 | |
| Adverse drug reaction | 3 | |
| PICC line infections | 3 | |
| Other medical complications | 8 | |
| <hr/> | | |
| Specific adverse events | No (%) of patients | Cumulative risk per 1000 OPAT treatment-days |
| Total | 16 (9%) | 6.4 |
| Adverse drug reaction | 10 (5.5%) | 4.0 |
| Rash | 3 | |
| Thrombopenia | 2 | |
| Acute hepatitis | 2 | |
| Neutropenia | 1 | |
| Acute renal insufficiency | 1 | |
| Fever | 1 | |
| Line-related adverse events | 6 (3.5%) | 2.4 |
| Line infections | 4 | |
| Line thrombosis | 2 | |
| <hr/> | | |
| Treatment failures | No (%) of patients | Cumulative risk per 1000 OPAT treatment-days |
| Total | 11 (6%) | 4.4 |
| Unplanned surgery | 5 (2.8%) | 2.0 |
| Surgical drainage of an abscess | 3 | |
| Removal of material of osteosynthesis | 2 | |
| Relapse after treatment completion | 6 (3.2%) | 2.4 |

331 **Table 1** Outcomes and adverse events