# An audit to review the podiatry supply of flucloxacillin under Prescription Only Medicines exemption (POM-S) in cases of mild infection within Belfast Health and Social Care Trust

*Ashling McElvanna, John McCarry, Suzanne Doyle, Jill Cundell and Anne McDaid*

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**Key words**

- Diabetic foot ulcer
- Medicines Exemption
- Mild foot infection
- Podiatry
- Prescription only

**Article points**

1. Clinical diagnosis of diabetes foot infections is key to their timely management.
2. Timely supply of antibiotics is key in preventing the rapid progress of infection in the diabetes foot.
3. Podiatrists having access to the supply of flucloxacillin in cases of mild infection, can help improve and resolve infection, reducing hospital admission for diabetes foot infections.

**Authors**

Author details can be found on p2

**Background: The timely treatment of diabetes foot infections is important to prevent the rapid progression of infection, hospital admissions and amputation (Lipsky et al, 2020). Antibiotic therapy is necessary for all diabetes foot infections (NICE, 2019). Podiatrists with HCPC POM-S annotation can supply flucloxacillin 500mg (one four times a day for 7 days) for mild foot infections (Health and Care Professions Council, 2021). Aim: The aim of this audit was to review the issue of 500mg of flucloxacillin and assess patient outcomes within community foot protection teams. Methods: The records of all patients diagnosed with mild infection according to International Working Group on the Diabetic Foot (Lipsky et al, 2020) classification, and issued 500mg of flucloxacillin (one four times a day for 7 days), between 23/8/19–11/09/20, by a podiatrist working in a Community Wellbeing and Treatment Centre within Belfast Health and Social Care Trust were included. All podiatrists were required to adhere to the Safe Operating Procedure for supply of flucloxacillin to patients. Data analysis was performed using Microsoft Excel 2016®. Results: A total of 35 patients were supplied 500mg of flucloxacillin (one four times a day for 7 days) by a community podiatrist during 23/8/19–11/09/20. Twenty one cases of infection completely resolved and four cases of infection improved. Four patients changed antibiotic after microbiological/radiological investigations. Two cases of infection deteriorated with the patient requiring hospital admission, two cases of infection did not improve due to deteriorating ischaemia and two cases of infection remained static. Conclusions: This audit has shown the supply of flucloxacillin 500mg (one four times a day for 7 days) by community podiatrists can improve and resolve mild foot infections. It can also ensure timely access to antibiotics avoiding delays in therapy. Podiatrists with HCPC POM-S annotation should utilise supplying for mild foot infection where appropriate.**

Podiatrists diagnose and treat pathologies of the foot and ankle, including foot infections. Infection has been defined as "an invasion and multiplication of microorganisms in host tissues that induces a host inflammatory response, usually followed by tissue destruction" (Lipsky et al, 2020).

Foot infections can be caused by nail pathologies, such as paronychia and onychocryptosis, which sometimes require antibiotic treatment. In patients with diabetes, foot infections are most commonly caused by foot ulcerations (Uçkay et al, 2015). Diabetes foot infections remain the most common diabetes complication requiring hospital admission and lower-extremity amputation (Lipsky et al, 2020).

The National Institute for Health and Care Excellence (NICE) advise diabetes foot infections require antibiotic treatment following clinical rather than microbiological diagnosis of infection, to prevent delay of antibiotic treatment. Timely prescription of antibiotics for diabetes foot infections

**Table 1. International Working Group on the Diabetic Foot (IWGDF) classification for defining the presence and severity of an infection of the foot in a person with Diabetes (Lipsky et al, 2020).**

| IWGDF Classification of infection | Clinical classification of infection |
|---|---|
| 1 - Uninfected | No systemic or local symptoms or signs of infection |
| Infected | At least two of these features are present:<br>• Local swelling or induration<br>• Erythema >0.5 cm around the wound<br>• Local tenderness or pain<br>• Local increased warmth<br>• Purulent discharge<br>No other cause of skin inflammation (e.g., trauma, gout, Charcot arthropathy, fracture, thrombosis or venous stasis disease) |
| 2 - Mild infection | Infection with no systemic manifestations (see below) involving:<br>• Only skin or subcutaneous tissue (not any deeper tissues), and<br>• Any erythema present does not extend >2 cm around the wound |
| 3 - Moderate infection | Infection with no systemic manifestations, and involving:<br>• Erythema extending ≥2 cm from the wound margin, and/or<br>• Tissue deeper than skin and subcutaneous tissues (e.g., tendon, muscle, joint, bone; see below) |
| 4 - Severe infection | Any foot infection with two or more associated systemic mani-festations (per systemic inflammatory response syndrome [SIRS] criteria):<br>• Temperature >38° C or <36° C<br>• Heart rate >90 bpm<br>• Respiratory rate >20 breaths/min or partial pressure of carbon dioxide <4.3 kPa (32 mmHg)<br>• White blood cell count >12,000/mm$^3$, <4,000/mm$^3$, or >10% immature (band) forms |
| 3(O) or 4(O) – Moderate or severe infection with associated osteomyelitis | Moderate or severe infection that also involves bone (osteomyelitis) |

is key in avoiding the rapid progression of infection, unnecessary hospital admissions and amputation (NICE, 2019). The International Working Group on the Diabetic Foot (IWGDF) clinical classification of infection (*Table 1*) defines the presence and severity of infection and guides treatment (Lipsky et al, 2020).

The first-choice oral antibiotic recommended by NICE for mild foot infection (*Table 1*) in non-penicillin allergic adults is flucloxacillin 500 mg — 1g four times daily for 7 days (NICE, 2019). Flucloxacillin is a penicillin, which is bactericidal and acts by interfering with bacterial cell wall synthesis (NICE, 2021).

Health and Care Professions Council (HCPC) Registered podiatrists with the 'Prescription-Only Medicines, Supply annotation' (POM-S) are authorised to access and supply flucloxacillin 500 mg, for patients who present with bacterial skin and/or soft tissue infections of the foot (HCPC, 2021). From 2019, podiatrists in Belfast Health and Social Care Trust (BHSCT), with HCPC POM-S annotation, are able to supply flucloxacillin 500 mg (one four times a day for 7 days) for mild foot infections, under POM-S exemption.

The aim of this audit was to review the issuing of flucloxacillin 500 mg (one four times a day for

**Authors**

Ashling McElvanna is Advanced Podiatrist; John McCarry is Principal Podiatrist; Suzanne Doyle is Principal Podiatrist; Jill Cundell is Practitioner & Lecturer, Ulster University, Belfast, UK; Anne McDaid is Head of Podiatry; all at Belfast Health and Social Care Trust, Belfast, UK

**Table 1. Podiatry Department of BHSCT's Safe Operating Clinical Procedure for supply of antibiotics to patients.**

| Clinical procedure |
|---|
| 1. Infection (mild) diagnosed In accordance with International Working Group on Diabetic Foot (IWGDF) classification — erythema spreading >0.5 cm but <2 cm from site, plus one or more item(s) listed in the table below (IWGDF, 2015). **NB: as per BHSCT guidelines — this is only to treat mild infection. Moderate or severe infection must be referred to GP or hospital as appropriate** |
| 2. Patient's penicillin allergy status ascertained and checked on the electronic podiatry patient notes (PARIS) and the regional electronic patient care records (NIECR) |
| 3. Patient/wound are reviewed by second podiatrist |
| 4. Agreed decision by both podiatrists to supply flucloxacillin; this will be 500mg qid for 7 days |
| 5. Wound appropriately debrided and cleansed prior to bacterial sampling — sample sent to microbiology |
| 6. Pack labelling checked by both, including patient's name, DOB, Name of drug, dose, frequency of administration and expiry date |
| 7. Supply logged and signed/countersigned by both podiatrists |
| 8. Details of antibiotics supplied recorded in PARIS notes in medication section and SOAP notes (500mg qid for 7 days). |
| 9. Patient given verbal and written instruction on administration of antibiotics. |
| 10. Patient given practitioners name and contact number. |
| 11. GP notified via letter. |
| 12. Follow up arranged with patient 2/3 days and instructions on course of action if further deterioration. Treatment should be reviewed once sensitivities are known. If no bacteria are cultured, the antibacterial (antibiotics) can be continued or stopped on clinical grounds. |
| 13. If infection is not resolving within 7 days, **NO** further supply of flucloxacillin to be made and **discussion with the patients GP must** occur regarding further course of action. All such discussions must be documented. |

7 days) to patients with mild foot infection in podiatry community wound clinics, and to assess patient outcomes.

## Method

All patients diagnosed with mild infection according to IWGDF classification (*Table 1*), and issued 500mg of flucloxacillin, one four times a day for 7 days, between 23/8/19–11/09/20, by a podiatrist working in a Community Wellbeing and Treatment Centre within BHSCT were included in this study. There are six community wellbeing and treatment centres and all were included. All podiatrists were required to adhere to the Safe Operating Procedure for supply of flucloxacillin to patients (*Table 2*).

Each patient supplied 500 mg of flucloxacillin (one four times a day for 7 days) was recorded in the log book at each community wellbeing and treatment centre. The data from the six log books were collated. The electronic records of those patients issued flucloxacillin were then reviewed for the necessary information surrounding each issue of antibiotic including; source of infection, medical history and clinical outcome. Data analysis were performed using Microsoft Excel 2016®. Ethical approval was not required.

## Results

A total of 35 patients were supplied 500 mg of flucloxacillin (one four times a day for 7 days) by a community podiatrist during 23/8/19–11/09/20. All podiatrists adhered to Podiatry BHSCT Safe Operating Procedure for supply of antibiotics to patients (*Table 2*).

An overview of mild infection outcomes following 500mg of flucloxacillin (one four times a day for 7 days) can be seen in *Figure 1*. Twenty one cases of infection completely resolved and four cases of infection improved. Four patients changed antibiotic after microbiology/radiological investigations. Two cases of infection deteriorated and required hospital admission, and two cases of infection did not improve due to deteriorating ischaemia. Two cases of infection remained static.

Data from electronic records of patients issued

flucloxacillin 500mg, one four times a day for 7 days, which can be seen in *Table 2*.

## Discussion

This audit has highlighted the benefits of timely supply of flucloxacillin 500mg, one four times a day for seven days, under POM-S exemption by foot protection team podiatrists, in cases of mild foot infection. The results show 25 cases of mild foot infections completely resolved or improved after the supply of 500 mg of flucloxacillin, one four times a day for 7 days. Two cases of infection deteriorated which required hospital admission and two cases of infection remained static.

Of those patients whose records were audited, 31 had diabetes. NICE guidelines (2019) recommend antibiotics should be started as early as possible to prevent complications in diabetes foot infection. By supplying antibiotics directly to the patient while at clinic, podiatrists can facilitate prompt treatment of diabetes foot infections. Thus, reducing the risk of complications, including hospital admission and lower-extremity amputation.

Thirty-three patients were issued antibiotics for foot ulcerations. Of the total number of foot ulcerations, 13 completely healed, nine were improving and seven remained static or stable. Diabetes wound healing can be delayed by infection, but other factors, such as ischaemia, neuropathy and poor offloading, can also cause delayed healing (Alexiadou and Doupis, 2012). Ten patients had known peripheral arterial disease which may have influenced outcomes. In two cases, the foot condition got worse due to deteriorating ischaemia rather than infection, one of whom underwent a below-knee amputation.

The increase in antibiotic resistance is a major concern across the world and all health and medical professionals have a responsibility to use any antibiotics carefully and appropriately to help preserve their future effectiveness. This is referred to as antibiotic stewardship (NICE 2015). One of the goals of antibiotic stewardship is to prevent misuse and overuse of antibiotics as drivers for the development of antibiotic resistance (WHO, 2021). The data from this audit show all antibiotics were supplied in cases of confirmed infection, which highlights each podiatrist's consideration of

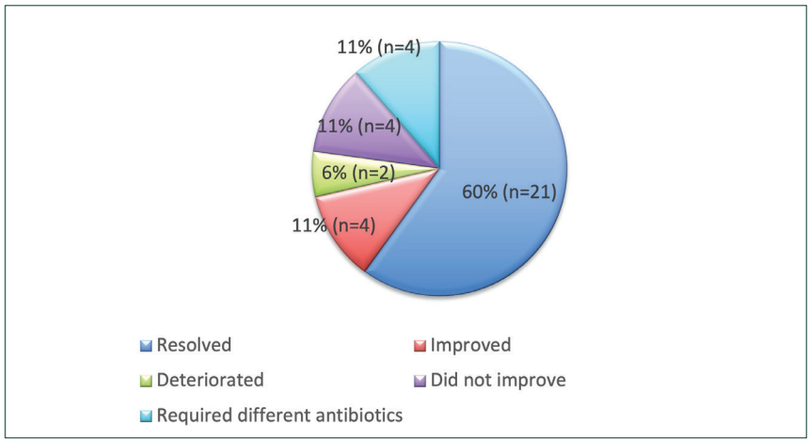


*Figure 1. Outcome for mild diabetes foot infection following treatment with 500mg of flucloxacillin (August 2019-September 2020).*

**Table 2. Information surrounding each issue of flucloxacillin 500mg including; source of infection, medical history and clinical outcome.**

| Outcome | % of patients | Number of patients |
|---|---|---|
| Confirmed infection | 100 | 35 |
| Diagnosis of diabetes | 89 | 31 |
| Diagnosis of peripheral arterial disease and diabetes | 29 | 10 |
| Issued antibiotics for onychocryptosis | 6 | 2 |
| Issued antibiotics for foot ulceration | 94 | 33 |
| Wound completely healed. | 37 | 13 |
| Wound healing or reduced in size. | 26 | 9 |
| Wound remained static or stable. | 20 | 7 |
| Needed surgical drainage or amputation | 17 | 6 |

antibiotic stewardship. In four cases, antibiotics were switched from flucloxacillin 500 mg (one four times a day for 7 days), to another antibiotic following review of wound culture sensitivities. Obtaining would culture sensitivities is in adherence to national guidelines (NICE, 2019) and Podiatry BHSCT Safe Operating Procedure for supply of antibiotics to patients (*Table 2*) and enables antibiotic treatment to be amended as appropriate. This ensures optimal use of antimicrobials to improve patient outcomes.

The results of this audit indicate that POM-S exemptions are a useful tool for the community-based foot protection team podiatrist. Initiation of antibiotic therapy at wound treatment appointments can improve and resolve infection. It can also facilitate timely access to antibiotics in cases of mild infection and avoid delays in therapy. Prior to the utilisation of POM-S exemption by foot protection team, it had been custom and practice for podiatrists to request general practitioners to prescribe antibiotics for patients presenting with a mild infection. This caused delay in therapy and treatment.

Utilisation of non-medical prescribing by other healthcare professionals has been shown to have many benefits, including an increase in the convenience and speed with which patients receive their medication, improvement in continuity of care for patients and improvement in patient safety (Courtenay et al, 2011; Coull et al, 2017). In addition, it enables non-medical prescribers to make more effective use of their knowledge and skills (Coull et al, 2017) and it enables general practitioners and non-medical prescribers to make more efficient use of their time and resources, which has important implications at a time of constraint in the NHS (Courtenay et al, 2011).

Reflecting on the results, podiatrists with HCPC POM-S annotation should utilise supplying for mild infection where appropriate. In addition, podiatrists without HCPC annotation should be encouraged to undertake the required additional training to become POM-S annotated on the HCPC register.

## Limitations

The low number of patients involved limited the size of the data available for analysis.

## Conclusion

Supply of flucloxacillin 500 mg (one four times a day for 7 days) in cases of mild foot infection can improve and resolve infection. Having the option for supplying 500 mg of flucloxacillin (one four times a day for 7 days) facilitates timely access to antibiotic treatment for mild infections in accordance with national guidelines (NICE, 2019). Timely supply of antibiotics can help reduce the risk of lower-extremity amputation and hospital admission in diabetes foot infections. ■


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