MUSKOKA ALGONQUIN HEALTHCARE	**Policy/Procedure:** Operating procedure: Oral Penicillin Challenge
Manual: Administration	**Number:** 1
Section: Risk Management	**Effective Date: October 1, 2022**
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Purpose
To outline the procedure for the Direct Oral Penicillin Challenge (DOC) Clinic

Scope
The procedure applies to the Direct Oral Penicillin challenge located in the Surgical clinic Huntsville District Memorial Hospital.

Procedure

1. **Patient referral**

Patients will be referred to the DOC through their primary care provider, healthcare professionals, or through self-referral.
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2. **Patient Screening**

Patients who are identified or self-identify as allergic to penicillin may be eligible to voluntarily participate in a direct oral penicillin challenge (DOC) that may later demonstrate through the DOC that these patients are not truly allergic to penicillin and can safely take these medications. To be eligible for participation in the DOC, patients must be labelled as allergic to penicillin and found to be a low-risk candidate following clinic screening.
Patients will be booked for a screening interview, which will take place in the NOSM portion of Building on the HDMH property at 100 Frank Miller Drive.

We will use similar inclusion and exclusion criteria that has been proven safe for the DOC study (3–8).

Using the data acquisition sheet, a DOC clinic physician will complete the screening to ensure patients are eligible, and verify each of the criteria below are confirmed:

1. No penicillin reaction in past 10 years
2. Never hospitalized with a reaction to penicillin
3. No evidence of a Severe Cutaneous Adverse Reaction (SCAR)
4. No evidence of Drug Related Eosinophilia and Systemic Symptoms (DRESS)
5. No history of Asthma
6. Cannot recall nature of reaction or history of isolated non-allergic symptoms (eg.GI upset only) or pruritus only without rash or simple macular papular rash as a child with Amoxicillin
7. Only a family history of reaction
8. No history of IgE mediated hypersensitivity reaction or angioedema

Exclusion Criteria:

- Pregnancy

- Active asthma or any other illness that will increase the participants' risk
- Do not meet the low-risk screening criteria
- Individuals who report an immune-mediated reaction to cephalosporin
- Currently taking Beta Blockers, ACE inhibitors, antihistamines, or steroids at a dose greater than prednisone 10mg per day or equivalent
- If study physicians deem them not to be in stable health
- Glasgow coma scale <15

3. Protocol

Patients who meet the above criteria and are deemed healthy and able to participate by the study physicians (Dr. Jennifer Macmillan – general surgery, Dr. Malcolm Wilson – Internist, Dr. David Johnstone – Internist, Dr. David McLinden – Family Physician) will be scheduled an appointment in the clinic to complete the DOC.

Clinics will be scheduled for one morning or afternoon per month, with availability to expand the options as required. Clinics will take place in the Day Surgery outpatient clinic space on a date confirmed without conflicting bookings.
Patients will be booked for two hours, during which they will be observed with a physician: patient ratio of 1:1.

When patients arrive at HDMH on the day of their clinic, they will register at Patient Registration then proceed to the surgical clinic area (located directly beside the Emergency Department).

Once participants give their consent, the Resident Physician or the Study Investigator will conduct a detailed patient history to confirm that the participant's health is stable and they meet the low-risk criteria. This includes if a family member also reacts to penicillin and what the reaction is (itchy rash, swelling in the face, difficulty breathing, etc.). The physician will determine if the patient qualifies to take part in the DOC study. This information is collected in questions 1-19 on the data acquisition sheet.

If they qualify, participants will drink a low dose of Amoxicillin (25mg - the amount given to children). They will wait in the clinic for 60 minutes under medical supervision. If they do not have an allergic reaction, they will be given a second dose of Amoxicillin (250mg - the amount given to adults). Participants will wait in the clinic for an additional 60 minutes under medical supervision.

The physician will provide no further medication in the DOC if the participant shows signs of an allergic reaction (rash, itching, hives, swelling in the lips or throat, etc.). The physician will treat their reaction as required. The DOC clinic is properly equipped (oxygen, emergency first aid kit, antihistamine, epinephrine, cortisone, and prednisone) and the physician has access to medication used to treat minor and severe allergic reactions. The clinic is also close to the Emergency Department, which can be accessed if emergency care is required. Participants will be under medical supervision when they are in the clinic. Participants will be asked to tell the physician immediately if they feel anything out of the ordinary after taking Amoxicillin.

If the patient has no negative side effects, participants will be discharged home. Before they leave, participants will be asked to complete a brief survey about their DOC experience (Participant Feedback Survey). This survey will take approximately 5 minutes and can be completed in the last 15

minutes of their medical supervision. Someone from the medical team will contact them at 7 days and at 28 days by telephone to inquire, “if the participant has had any type of delayed allergic reaction such as rash, aches and pains (arthritis symptoms)”. If the answer is yes, participants will be asked if they were required to take medication, cream, or seek treatment.

Any adverse events that occur will be recorded and maintained with the clinic records.

In the absence of any reaction patients will have their penicillin allergy removed from their EMR and from their patient file (with their primary care provider).

4. Data Collection and Management

Consent forms will be collected in person while respecting COVID-19 guidelines currently in practice at Muskoka Algonquin Healthcare. There will be no more than 4 people in the clinic at once. We expect to have between 60 to 100 participants in the study.

Data Acquisition sheets will be collected digitally and immediately saved according to the participant’s research ID onto the MAHC server in a file created specifically for this study. The research file has limited access and each sub file has additional security, ensuring only those with specified permission can access each unique file.

Additionally, Muskoka Algonquin Healthcare ensures that each computer user/staff member has a unique login and password. This password is required to be changed on a regular basis and must be entered before accessing the Muskoka Algonquin Healthcare servers. This project has its own shared folder, on the hospital server, and only those members of the research team and their logins will be able to access the research documents. On top of this, Muskoka Algonquin Healthcare servers have firewalls and anti-viral software to protect all patient electronic medical records. The research data will be stored on the same servers as the entire hospitals’ patient electronic medical records. The network is also segmented in virtual LANs and backed up off site.

Sample size
This is a feasibility study, so we performed no formal sample size calculations. However, we expect 60-100 patients during the study period.

5. Benefits to Participants

Benefits to patient participating in the study is the team will facilitate documentation of their penicillin allergy status with their health care team, thereby improving patient access to the most appropriate treatment in the future if needed.

Works Cited

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