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# Managing a National Intrathecal Pump Service During the COVID-19 Pandemic

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## ABSTRACT

**Objective:** The healthcare and social disruption caused by the COVID-19 pandemic could pose significant risk to patients with intrathecal pump (ITP) who may miss refill or replacement appointments. In some cases, this could be life-threatening. We designed and piloted a novel refill protocol to assess its efficacy and safety.

**Materials and Methods:** Screening of our ITP database for patients most at risk of harm was conducted. These patients were risk-assessed for COVID-19 infection and were enrolled in a protocol to optimize the safety and efficiency of their pump replacement or refill.

**Results:** Of note, 31 of 51 database patients were deemed to be high risk of ITP failure during the pandemic. Thirty patients were successfully refilled with only one patient refusing to leave their house for refill. There were no significant adverse outcomes.

**Conclusion:** Our protocol offers a safe and efficient pathway for ITP management during a pandemic.

**Keywords:** Coronavirus, intrathecal pump, pandemic

**Conflict of Interest:** None of the authors have a conflict of interest to declare.

## INTRODUCTION

Intrathecal pump (ITP) therapy is an effective treatment in controlling intractable cancer-related pain and in reducing spasticity in patients with neurological disorders (1,2). It requires initial screening of patients to determine suitability, followed by a surgical procedure to implant an intrathecal catheter connected to a subcutaneous pump. Successful ITP therapy usually continues for the rest of the patients' life and requires continuous input from specialist services to maintain effective therapy. In particular, pumps are refilled via a transcutaneous needle at regular intervals (three to six months). The most commonly used drugs in the pump are preservative-free baclofen or morphine. Also, ITPs have a life-span of several years and require surgical replacement toward the end of their battery life.

Pump failure or a delayed pump refill can result in a serious withdrawal syndrome. In the case of baclofen, this may be life-threatening with complications like rhabdomyolysis, seizure, coma, and death (3). Patients with ITP are normally managed in specialized centers with regular patient follow-up and tracking to mitigate these risks. The current 2019 novel coronavirus disease (COVID-19) pandemic has presented a number of unique challenges to patients with ITP and their clinical teams:

1. Patients with ITPs have an advanced neurological disease (e.g., multiple sclerosis), a neurodevelopmental disorder (e.g., cerebral palsy), or metastatic cancer with associated immunosuppression. These patients are more likely to have a poor outcome if they contract COVID-19 (4). In Ireland, these patients have been advised to "cocoon" themselves in their

homes/residential care settings and to only leave for essential reasons (e.g., urgent medical care).

2. These patients may regularly have fevers due to respiratory or urinary tract infections and may have cognitive or communication deficits. This means screening them for COVID-19 is often difficult and unreliable.
3. The COVID-19 pandemic has created unprecedented healthcare and social disruption. Most healthcare activity, except for urgent care, has ceased following "lockdown" of societies. ITP replacements and refills have been designated as urgent procedures (5). However, routine services like public transport, medication delivery to pharmacies, and outpatient clinic administration are disrupted.
4. Medical and nursing teams that care for these patients with ITP may be under pressure to re-deploy to intensive care or other environments to care for patients with COVID-19.

Our team manages a national intrathecal pump service for Ireland. The challenges above were considered early in the pandemic and a mitigation strategy was put in place to limit the risk to our patients. The Neuromodulation Society UK and Ireland

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(NSUKI) issued guidance on managing patients with ITP during the pandemic on the April 5, 2020 (6). However, there is no published record of effective ITP management strategies during the pandemic. We expect the following protocol and record will be useful for ITP teams.

## MATERIALS AND METHODS

Analysis and publication of this data was approved by our institutional ethics committee. A review of our patient database was performed to identify high-risk patients. These were patients that required refill of their ITP or pump replacement in the next three month. Patients living in more remote locations were prioritized.

### Patient Screening

Telephone consultations were performed by JOB and MD with either the patient or their carer. A structured telephone interview was conducted, and a questionnaire was completed (Supplementary Document 1). Patients were advised that their appointment was being expedited due to the risk of lockdown disruption, clinic closures, and the increasing risk of them being infected with the virus later in the pandemic. The patient was advised that the clinic appointment would be different to their usual experience with a more rapid transition through the clinic. They were advised that there would be minimal interaction with the two clinicians (medical/nursing) in the room, who would be dressed in full personal protective equipment (PPE).

The patients were screened for possible COVID-19 by enquiring about fever, new shortness of breath, new cough, returning from an affected area in last 14 days, close contact with confirmed or suspected case in last 14 days, carer returned from affected area in last 14 days, carer contact with confirmed or suspected case in last 14 days. A positive response to any of the above questions prompted a discussion with our local Infectious Disease (ID) team to advise on the appropriate course of action.

If patients refused or were unable to attend the clinic for refill, alternative solutions were explored with an outreach team (AKP, JOB, and MD). If there was unacceptable risk to the outreach team or the patient, an alternative treatment pathway was considered.

### Refill Procedure

Two outpatient clinic rooms were used for the refills. There was a preparation room (PR) and a refill room (RR). Two clinicians (a Refiller and a Programmer) worked as a team to perform the refills. In the PR, a pump refill kit was opened and an aseptic technique was used to prepare for the refill and draw up the required medication with concentration and volume checked against patient records. The refill kit was arranged into layers on a sterile sheet to form a "refill bundle" as follows: (from top to bottom) ChlorPrep 3 mL clear applicator; spare sterile gloves for Refiller; sterile drape with hole for pump access; transparent sterile ultrasound probe cover (for pump communicator); pump refill template; access needle—filter—empty 10 mL syringe (all connected, with aspiration line clamped); 20 mL syringe(s) full with refill drug; wound dressing. The above is the sequence in which the items were required and layering aimed to reduce the time spent in the RR with the patient and therefore reducing the risk of infection transmission to the patient or the clinicians.

The clinicians donned full PPE as per local guidance in the PR (7). The Refiller double gloved with sterile gloves. The Programmer carried the sterile refill kit with the layered items, a drape to protect the patients clothing, a second pair of sterile gloves for the Refiller, the programmer, and the communicator. The Programmer opened and closed all the doors for the Refiller who remained sterile. The Programmer maintained a safe distance (1-2 meters) from the patient and carer at all times. The Refiller helped the carer to position the patient and exposed the pump site. They then removed the contaminated gloves and replaced with fresh gloves from the refill pack. After sterilizing, the skin with the ChlorPrep applicator, the Refiller received the pump communicator into the sterile ultrasound cover from the Programmer. This was placed over the pump site and the Programmer interrogated the pump, confirmed the drug concentration and volume required for the refill, the expected remaining volume, updated the pump with the refill volume, and noted the next refill date. The Refiller then dropped the communicator back to the Programmer out of the sterile cover and proceeded with the sterile refill procedure. Once the dressing was applied and the patient readjusted in their wheelchair, they were invited to leave the room by the Programmer who opened and closed the door. The Refiller disposed of all the clinical waste in the relevant bins in the RR. Doffing of the PPE as per local guidelines took place in the RR and the PR with the Programmer taking responsibility for carrying the programmer and communicator and opening/closing the doors.

There were one-hour gaps between patient appointments to allow time for each refill, room cleaning, and room air exchanges in between patients.

## RESULTS

A total of 51 patients were screened. Thirty-one patients were identified as possible at risk patients requiring urgent refill. All patients had Medtronic Synchromed II pumps in situ. Patients were located throughout Ireland with over more than located in the greater Dublin area. Table 1 shows the demographics and diagnoses of these patients.

All patients were contacted for telephone consultation. Three patients were deferred due to adequate pump reserves to continue infusion beyond the three month time frame. Over the subsequent three weeks, 20 patients attended the outpatient clinic independently with their carer, four patients attended by ambulance inter-hospital transfer, two patients required remote refill by

**Table 1** Refill Patient Data: Values for Age, Time to Next Refill, and Dose Are Represented As Mean (Range). Time to Next Refill is (Date of Planned Refill) – (Date of Actual Refill).

Age (years)		41 (18-76)
Male:female (n)		16:15
Time to next refill (days)		38 (5-95)
Diagnosis	Multiple Sclerosis (n)	10
	Cerebral Palsy (n)	16
	Cancer-related pain (n)	2
	Other (n)	3
Dose	Baclofen (µg/day)	319 (50-550)
	Morphine (mg/day)	5 (5-5)

our outreach team in other clinical locations, one patient had a pump replacement and refill, and one patient refused to leave their house and were converted to oral baclofen. All patients who attended our clinic were in wheelchairs and were accompanied by a carer. Almost all patients were refilled in their wheelchairs, apart from two who presented on an ambulance trolley.

A 76-year-old woman with motor neuron disease required an intrathecal pump replacement as well as a refill. She was on the waiting list for admission to the hospital for replacement and the Elective Replacement Indicator (ERI) on the pump showed a requirement for pump replacement within two weeks. The patient was counseled on the risk of surgery in the early stages of a pandemic. We proceeded with day case surgery to replace the pump and closed the surgical wound with dissolvable sutures to avoid the need for clinic return. The patient was monitored remotely by telephone and had an uneventful post-operative recovery.

One patient, resident in a care home facility, had a positive COVID-19 screening during their phone interview, with new onset cough and fever, and was subsequently admitted to their local hospital for three days intravenous antibiotic treatment. Our ID team advised COVID-19 testing which was negative, and we proceeded with their refill one week later by ambulance transfer.

One patient living remotely was unable to secure private transport to our institution. We agreed that public transportation posed too high a risk to him. Our outreach team (APK and JOB) traveled to his local primary care center to facilitate the refill. This involved a 220 km round trip for the team. One patient with metastatic cancer-related pain was in a hospice and too unwell to leave, so our outreach team (JOB and MD) performed the refill in the hospice. The same refill procedure as described above was followed during the outreach visits.

Another patient deemed the risk of leaving her home too high and refused to attend for refill. She was a 71-year-old woman with multiple sclerosis and recently diagnosed lung cancer. She was receiving intrathecal baclofen at a low dose of 50 µg per day. We felt the overall risk to the outreach team and the patient was too high to perform a refill in the patients' home due to inadequate sterility and donning/doffing facilities. We counseled the patient on the risk of discontinuing her ITP treatment, and we put in place a transition plan to oral baclofen.

Two mild adverse events occurred during the period with no lasting harm. A carer felt unwell with pre-syncope symptoms at the end of the refill procedure but recovered after sitting and resting. The communicator battery failed during another refill requiring a member of the team outside the room to hand in a new programmer/communicator set to the Programmer.

## DISCUSSION

The COVID-19 pandemic has presented unprecedented challenges to our healthcare system. New, innovative practices have been employed to deliver urgent medical care to our patients in the safest possible environment for both clinicians and patients. Recent publications document new oncology treatment protocols to mitigate the pandemic associated risks in this patient cohort (8,9). However, we believe this is the first publication to document the management of patients with ITP during a pandemic.

Early and fast intervention was vital in successfully refilling all our consenting patients. The first case of COVID-19 was diagnosed in Ireland on the 29th February, and the situation escalated to an

ultimate "lockdown" of the Irish population on the 27th March. We started screening patients on the 3rd March, and our refills started on the 5th March and completed by the 31st March. The refill date for patients was brought forward by an average of 38 days. A delay in this process could have resulted in some patients being COVID-19 positive by the time they were due for refill, with a potentially difficult decision on how to proceed. Also, at this stage, these high-risk patients should be "cocooning" with the rate of infection at its peak. In addition, our staff availability has been reduced with some of the team members now enrolled on intensive care rosters with limited time to commit to ITP management.

Recommendation 12e in the NSUKI guidelines recommends avoiding oral substitution of baclofen due to the high risk of withdrawal complications and 12f proposes home refills (6). This is at odds with our management of the patient who refused to attend for refill. In theory, home refills are a good option; but in practice, during a serious pandemic, we feel the risk to clinical team members, the patient, and other residents is too high. The refill is being performed in a foreign environment with no clinical waste disposal mechanisms, no designated areas for donning/doffing, and no clinical backup. The question of what happens if the patient refuses to attend hospital but then requires urgent admission due to a complication (e.g., pocket refill) also needs to be addressed.

Protecting the clinician during this pandemic is very important (10) and probably merits greater emphasis in the NSUKI guidelines. ITP teams are often small groups of clinicians with limited or no backup in the wider hospital community. If team members become ill, there is a serious threat to the care of patients. Our protocol advocates two team members in the room and all preparation complete before entering the room, thus reducing contact time to a minimum. Guidelines recommend less than 15 min contact with individuals to limit your risk of infection (11). However, 15 min is an arbitrary cut-off, and the key message is to reduce exposure time to a minimum. In addition, our protocol recommends that the Refiller and Patient engage in clinical contact, whereas the Programmer acts as a buddy, supporting the Refiller at a distance, whereas remaining "clean." The Programmer also isolates the Refiller from making contact with, and contaminating, the external environment until they are fully "doffed."

The patients who presented on an ambulance trolley were easier to refill, and there was a greater distance between the Refiller and the patients face. Refilling a wheelchair patient brings the Refiller and patient closer together. However, it would be more challenging to hoist the wheelchair patients onto a trolley. Equally, we considered the need for the carers to be in the room. Technically, it would be safer to limit the number of people in the room; but, the carers presence is useful in positioning the patient for refill and in helping to manage anxiety. We made the decision to keep all patients in the mobility vehicle they arrived in and we allowed carers to be present during refill.

An additional measure that we did not include in our protocol is a patient surgical face mask. Some of our patients and carers did present with facemasks; but, we did not insist on it. The literature is equivocal on the use of masks by patients to protect other contacts (12,13).

This report is limited due to the fact that it is observational and has a small sample size. Without a control group, we can only speculate that the planning and protocols that we put in place resulted in better patient outcomes.

## CONCLUSION

ITP therapy is an effective treatment of spasticity and pain in patient groups that are particularly vulnerable to COVID-19. Our protocol resulted in the safe and efficient refilling and replacement of pumps in all consenting patients with ITP attending our service.

## Authorship Statement

Anil K. Patel, Mairead Dowling, Andrew Purcell, Joanne O'Brien, and David Moore designed the protocol and conducted the study, including data collection, and data analysis. Anil K. Patel, Mairead Dowling, Joanne O'Brien, and David Moore prepared the manuscript draft. Anil K. Patel, Mairead Dowling, Andrew Purcell, Joanne O'Brien, and David Moore reviewed the final manuscript for publication. No funding was provided for the study. Anil K. Patel, Mairead Dowling, Andrew Purcell, Joanne O'Brien, and David Moore had complete access to the study data. We would like to thank our administrative colleagues and pharmacy department for facilitating this project.

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## COMMENTS

This is good article on the practical conduct of IT drug delivery service. This explores the pros and cons on management during the COVID-19 situation. The principles could be utilized to suit the service according to their geographic location and local policies.

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This is a helpful framework for similar ITP services to model. The challenge for many private, and some smaller hospital practices, will be the availability of the full PPE equipment used here, but appropriate adjustments are advisable.

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