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Short Communication

The virtual CF clinic: Implications for sputum microbiology

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ABSTRACT

The COVID19 pandemic has shifted the paradigm of how outpatient clinics are delivered within CF care, resulting in a significant reduction of patient visits to CF centres. One consequence of this has been a reduction in the number of sputa/cough swabs that patients submit for routine analysis. This report examines why it is important to maintain optimal sputum microbiology and explores (i) the microbiological efficiency of postal submission of sputum specimens from the community and (ii) the regulatory conditions that must be met through postal submission of respiratory specimens. Virtual clinics have now been established within CF care and it is incumbent on each speciality within the CF MDT to explore ways to nurture and support their individual contribution to the success of the virtual clinic. Within microbiology, adopting innovative approaches to sputum collection in the community and transportation via postal services will allow for continued microbiological vigilance thereby supporting patient safety.

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In a thoughtful Letter (JCF; published ahead of print; June 2020), Bryan Garcia and colleagues from the Medical University of South Carolina describe their experiences, as precipitated by the COVID 19 pandemic, relating to the delivery of virtual CF care amongst rural CF populations in South Carolina [1]. Previously, Ketchell in a review of telemedicine concluded that telemedicine in CF is the future of CF care [2]. Coupled with these, other innovations including the UK CF Trust's SmartCareCF platform (<https://www.cysticfibrosis.org.uk/the-work-we-do/resources-for-cf-professionals/smartcarecf>) and other CF centres sudden need to deliver virtual consultations and clinical guidance due to the COVID 19 pandemic has reduced the requirement of CF patients to travel as frequently to clinic. Ultimately, it will take some time for the optimal CF virtual care model to emerge, largely aligning with what works best for individual clinics and their specific circumstances, but undoubtedly, such a model will eventually emerge, that will reduce the physical need for patients to attend clinic, as frequently as in the past.

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One aspect of such movement to virtual delivery is how to successfully embrace the virtual, but not lose the important aspects of the physical, namely maintaining our vigilance in detecting early infection and changes in microbiological status of our patients, through optimal microbiology diagnostics. We wish to support and nurture such virtual approaches by giving insight into how to maintain effective microbiology diagnostics through sharing of resources (below) and information that may help integrate effective microbiological diagnostics within any new virtual delivery framework.

Until now, CF patients physically attending clinic would have routine sputum/cough swab microbiology performed on a specimen taken during their visit. The UK CF Trust Consensus care document, recommends that standard microbiological methods to identify infection should be undertaken at each hospital visit (eight weekly or more frequently) and at times of respiratory exacerbation (<https://www.cysticfibrosis.org.uk/the-work-we-do/resources-for-cf-professionals/consensus-documents>). Furthermore, Pressler and colleagues in the EuroCareCF Working Group report recommended that over the course of one year either (i) a minimum of six samples – if sputum – in separate months should be examined or (ii) a minimum of eight samples in separate months should be examined – if other samples (cough swab,

nasopharyngeal aspirate) are used [3]. Increased virtual interaction accompanied with a pro rata reduction in clinic visits thus creates the challenge of physically obtaining sufficient sputa/cough swabs remotely from the patient to fulfil these requirements for optimal sputum microbiological analyses.

Specimen collection and transportation of clinical specimens from patient to laboratory, whether that be from outpatient clinic, the ward or from patients' homes has remained a mundane task, yet the science supporting optimal recovery of pathogens from specimens remains critically important. For a seminal review on specimen collection and transportation, see Wilson [4]. Previously, Pye and colleagues examined the effect of postage of sputum on viable bacterial numbers from bronchiectasis sputa. Quantitative culture was performed immediately on one aliquot and the remaining aliquot was posted by first-class post to arrive the following day. Quantitative culture was performed on the "posted" aliquot, and viable numbers compared to those obtained from the fresh aliquot. Posting was not found to affect the subsequent recovery of the bacterial species present. Posted sputum samples was accurate both in terms of qualitative and quantitative results. These data confirmed that sputum samples can be posted to the microbiology laboratory from patients in the community without affecting qualitative or quantitative results [5].

Transportation of clinical specimens is governed by several regulations and statutes, including those for domestic, as well as international shipping. Such regulations will differ from country to country, therefore it is difficult to specify here any particular legislation and regulations, that would have universal acceptance. However, specific legislation and guidance relating to the requirements of packaging, labelling and shipping of sputum specimens, may be found at:-

- (i) WHO; (https://www.who.int/csr/resources/publications/biosafety/WHO EMC_97_3_EN/en/),
- (ii) International Air Transport Association (IATA); <https://www.iata.org/en/publications/store/infectious-substances-shipping-guidelines/>
- (iii) Federal Aviation Authority (FAA); https://www.faa.gov/hazmat/safecargo/how_to_ship/
- (iv) International Civil Aviation Authority (ICAO) www.icao.int/publications/.../guidance_doc_infectious_substances.pdf
- (v) CDC https://www.cdc.gov/nceh/vsp/cruiselines/OPRP/docs_word/diagnostic_specimen_shipping_detailed.doc

It is therefore important that healthcare professionals check out their local shipping regulations, so that any future postal carriage of patients' sputum complies with all the local regulations in their country and jurisdiction. As such, patients will need detailed guidance from their Centre to ensure that their sputum specimen is shipped securely, safely and complies with local, national and international postal regulations, depending upon its final destination. In order to gain patient buy in to maximise sputum being sent to the laboratory, any mechanism needs to be simple, convenient and cost-neutral for the patient.

Therefore, in order to ensure safe shipping through compliance with local/national/international shipping regulations and consistency of product/service, it may be prudent to prepare "ready shipping packs" and distribute to patients, thus allowing patients to collect, prepare and ship their sputum to their clinical microbiology laboratory, as conveniently as possible.

One innovation in the UK is the SafeBox, which is supplied by the UK postal provider, Royal Mail (<https://www.royalmail.com/sites/royalmail.com/files/2019-10/Royal-Mail-Safebox-Terms-Conditions-June-2019.pdf>), which provides a simple and convenient way for CF patients to mail in their sputum specimens to their CF centre laboratory. It is appreciated that such a product and service may not be available in many countries that would

facilitate convenient, safe and reliable transportation of patients' sputum specimens to the clinical microbiology laboratory supporting their CF centre. However, we believe that the concept and description of the SafeBox may prompt clinicians and other CF healthcare providers into discussions with their state run postal services and private couriers in their countries, to develop such similar products/services, using the SafeBox as the exemplar/template to emulate.

Such shipping innovations may also aid the shipping of sputum internationally, particularly when patients are travelling abroad or are working/living as expatriates in foreign countries.

In practice the virtual clinic decreases the disruption to the patient's everyday life caused by regular face to face clinic appointments and facilitates essential clinical review. The long term success of the virtual clinic depends on safeguards such as a patient centred service, clear procedures on modes of usage, effective CF team support and seamless integration into the CF service. The virtual clinic has the potential to empower people with CF to have greater choice in the way they access CF care and it should support them as they self manage their CF. But this patient empowerment is predicated on a need to ensure virtual clinics do not leave people with CF feeling abandoned to manage their CF care alone in the community. In the delivery of virtual clinics there is a need to recognise the high treatment burden of CF care and any additional stress for people with CF from virtual clinics such as sending sputum samples to their CF centre laboratory should cause the minimal possible disruption to every day life.

Where patients are non-productive, alternative methods of airways microbiology sampling may be warranted, including induced sputum, which would require physical attendance at clinic, based on clinical assessment.

CF sputum/cough swabs should ideally be obtained from patients at clinic and processed microbiologically on the same day as collection. With increased use of virtual interaction and where on site/clinic collection of specimens is not possible, CF patients should remain microbiologically vigilant by providing sputum specimens via postal services, as requested by their healthcare professional. Patients should perform physiotherapy at home prior to mailing a freshly expectorated high quality specimen to their CF microbiology laboratory. There is no strong evidence to suggest that one type of airway clearance physiotherapy is superior to another in terms of sputum yield or outcome measures such as FEV₁, however patient/carer preference has been shown to be an important deciding factor [6]. Airway clearance should be performed with appropriate timing of mucolytics and bronchodilators to achieve optimal results and a treatment regime will have been established for each individual. For those individuals who are non-productive after physiotherapy coaching of carers in the technique of taking cough swabs will be required to ensure the standard of number of samples per year is met.

Virtual clinics have now been established within CF care and it is incumbent on each speciality within the CF MDT to explore ways to nurture and support their individual contribution to the success of the virtual clinic. Within microbiology, adopting innovative approaches to sputum collection in the community and transportation via postal services will allow for continued microbiological vigilance thereby supporting patient safety.

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