POSITION STATEMENT ON THE MANAGEMENT OF CARDIAC ELECTROPHYSIOLOGY AND CARDIAC IMPLANTABLE ELECTRONIC DEVICES IN AUSTRALIA DURING THE COVID-19 PANDEMIC: A LIVING DOCUMENT from the Heart Rhythm Council COVID-19 Pandemic working group, Cardiac Society of Australia and New Zealand.

Version 3, 11th June 2020

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The recommendations of this document are current as of June 11, 2020 and will be reviewed again, as necessary.

UPDATES IN VERSION 3

- Recognition that the pandemic may wax and wane and recommendations need to be tailored for various phases of the pandemic, in line with Federal Government recommendations.
- Categorising electrophysiology (EP), cardiac implantable electronic devices (CIED) service delivery and delivery of ambulatory services into triage categories 1-4.
- Providing recommendations for EP, CIED, and ambulatory services during various phases of the pandemic namely, lockdown, 25%, 50%, and 75% return to capacity.

EXECUTIVE SUMMARY

The COVID-19 pandemic poses a significant stress on health resources in Australia. The Heart Rhythm Council of the Cardiac Society of Australia and New Zealand aims to provide a framework for efficient resource utilisation balanced with competing risks of appropriately treating patients with cardiac arrhythmias. This document provides practical recommendations for the electrophysiology (EP) and Cardiac Implantable Electronic Devices (CIED) services in Australia. The document will be updated regularly as new evidence and knowledge is gained with time.

Goals

1. Ensure that critical resources are used efficiently namely staff, personal protection equipment (PPE).
2. Provide guidance for the appropriate use of EP and CIED services during various phases of the pandemic, in line with Federal Government directives.
3. Minimise adverse patient outcomes during the pandemic period where resources are limited.
4. Minimise exposure of patients and health care workers.

Key Considerations

1. Mandatory training of staff on use of PPE.
2. Tailoring of the current document to local demand for EP and CIED services, local outbreak patterns, local hospital recommendations, hospital PPE supply chain, and hospital contingency plans and/or crisis capacity status.
3. Encourage patient specific risk assessment and sound clinical judgment, weighing the risk vs. benefits of delaying intervention versus risk of patient and staff infection with COVID-19, and use of precious PPE resources.
4. Realignment of the delivery of EP, CIED and ambulatory monitoring services to align with the relevant phase of the pandemic, and in line with Federal Government recommendations on the delivery of health care during each phase.
5. Division of physician and allied health into separate teams, with minimal in-person interaction between team members, as needed, during various phases of the pandemic.
6. Where feasible, segregation of labs and equipment for use in patients with suspected or confirmed COVID-19.
7. Individual patient screening for COVID-19 exposure risk as per local hospital recommendations, and appropriate use of PPE.
8. Recommendations for category 1-4 elective EP and CIED cases, to be adapted to the Federal Government's response to the pandemic. Furthermore provide guidance for delivery of EP, CIED and ambulatory monitoring services during the lockdown phase of the pandemic, and with 25%, 50%, 75% and 100% return to capacity.

INTRODUCTION

On December 19, an outbreak of the severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) marked the beginning of a pandemic that has had a major impact on health care systems around the world. SARS-Cov-2 also known as COVID-19 causes a pneumonic respiratory illness, with the potential for severe cardiovascular damage. Its high infectivity rate has led to rapid escalation of affected cases around the world. It demonstrates a higher mortality rate amongst patients with pre-existing illness, in particular, those with cardiovascular disease. This has prompted a rapid evaluation of routine cardiac electrophysiology (EP) and Cardiac Implantable Electronic Devices (CIED) services within Australia. Major international societies (Heart Rhythm Society, British Heart Rhythm Society), have emergently released guidelines as live documents for the provision of such services.[1]

In response to this pandemic, the Cardiac Society of Australia and New Zealand (CSANZ) Board has summoned the Heart Rhythm Council to rapidly produce a live document to provide guidance to its members for the practice of EP and CIED services in Australia. This live document takes into account published grey papers from international societies, and advice from key opinion leaders within Australia and overseas, with frequent updates to adapt to the evolving pandemic and its impact on the Australian health system. The guidelines provide a framework for implementing services during the pandemic. It is noted that the practice of EP and CIED management in Australia is varied amongst public and private hospitals, regional and remote areas, and in outreach clinics. **The application of these recommendations will therefore need to be tailored to local models of service delivery.**

In response to the CSANZ board request, the Chair of the Heart Rhythm Council has summoned the formation of the **Heart Rhythm Council COVID-19 Pandemic working group**. The group will be formed by the authors listed in this document whose responsibility will be to contribute to the original source document and provide frequent updates in six domains (authors working on each domain listed at end of the document):

1. Implementing a Framework for altered services.
2. Monitoring and follow up of patients with CIED.
3. Ambulatory monitoring.
4. EP and CIED procedural considerations.
5. Arrhythmic implications of COVID-19.
6. EP and CIED implications for children and adults with congenital heart disease.

As the pandemic may wax and wane, as may local and Federal Government restrictions for delivery of health care services, **the recommendations of this document are now divided into different phases namely: (i) lockdown phase; (ii) return to 25% elective capacity; (ii) 50% elective capacity; and (iii) 75% capacity.**

DOMAIN 1: IMPLEMENTING A FRAMEWORK FOR ALTERED SERVICES

The COVID-19 pandemic requires rapid re-evaluation of EP and CIED services, as outlined below.

1. We recommend mandatory training of all staff involved in EP and CIED services in proper donning and doffing of PPE.
2. We recommend general screening of all patients scheduled to undergo an intervention or in-person interaction with staff delivering EP and CIED services. We recommend adherence to local hospital protocols for such screening methods. Patients could be divided into low, intermediate and high risk patients as per the CSANZ consensus guidelines for invasive cardiology services (https://www.csanz.edu.au/wp-content/uploads/2020/03/CSANZ_CONSENSUS_GUIDELINES_FOR_INVASIVE_CARDIOLOGY_SERVICES_DELIVERY_DURING_COVID_PANDEMIC_29-March_2020.pdf).
    a) Each network, hospital or local health district has developed such screening tools, and should be followed.
    b) "Low exposure risk" patients could be brought to the catheter laboratory with staff observing appropriate PPE during procedure performance (may be routine care in this case) and cleaning procedures applied as per usual practice.
    c) "High exposure risk" patients should have EP and CIED procedures deferred until complete resolution of their illness, unless there is a compelling indication that an urgent procedure would alter their short-term prognosis.
    d) When patients are in the unknown category, for example, non-English speaking patients and there is an urgent clinical need, it is appropriate to treat as "high exposure risk" of COVID-19.

2. During the ***lockdown phase and 25%-75% return to capacity***, we recommend the following:
    a) All physicians involved with the delivery of EP, CIED and ambulatory monitoring services hold a forum within their network, hospital, practice, or local health district to discuss and tailor these guidelines to their local models of service delivery, with frequent visitation of updates. Tele-conferencing is recommended to avoid cross infection of the leadership group.
    b) We recommend nomination of a group leader within the network who will coordinate and implement the action plan and an assistant lead who should monitor national and global trends closely, and adapt, where feasible, to local and national recommendations.
    c) We recommend nomination of a triaging lead physician (1 EP, 1 CIED program) who works with a triage nurse or allied health staff member to review clinical need and urgency of elective procedures.
    d) Each of the networks should work closely with their hospital or network's established COVID-19 Taskforce group ideally comprising of one or more of: cardiology department heads, EP leads, CIED program heads, infectious disease specialists, population health physicians, emergency department physicians, intensive care physicians, nurses and allied health staff, industry partners and hospital administration to formulate a plan for ongoing management of EP and CIED procedures and clinics, using these guidelines as a reference. The group should meet at weekly intervals to ensure maintenance of appropriateness criteria, urgency and alignment of practices with the local outbreak response phase.

e) We suggest that physicians consider telephone or teleconference to reduce in-person interaction of vulnerable patients and/or vulnerable physicians.
f) When in person visits are scheduled, social distancing guidelines promoted by the local state and Federal government and each local health district should be followed.
g) Electronic medical records of arrhythmia patients will need to be available in a format to be shared rapidly with ED physicians, intensive care physicians, general practitioners, and the rural medical workforce.

Setup of allied health staff

The EP and CIED programs are extensively supported by allied health staff. The following are recommendations that apply only during the **lockdown phase.**

1. We suggest that allied health staff responsible for EP and CIED services could be divided into "lab based" vs "clinical based" teams using a rotational roster, whereby teams are not in physical contact with each other. These teams should be kept separate at all times, either via rostered location or rostered times with:
    a) Clinical based teams performing, where feasible, duties from a site remote to areas exposed to direct patient contact.
    b) Lab based teams performing duties that involve direct patient contact.
    c) Teams should be designed to best conserve skill and leadership, and have sufficient competence to perform in-person and remote CIED interrogations, independently of the other teams, in the event that there is a necessity to isolate one team.
2. Potential tasks/activities for a clinical based team(s) could include:

    a) To support scheduled outpatient CIED clinics via teleconferencing, if feasible. These clinics will provide continuing patient education and support. It further aims to avoid unnecessary hospitalisations and in-person visits, thereby reducing the burden on the hospital system and reducing infection risk for patients and staff. Patients with remote monitoring should have downloads scheduled to synchronise with their originally scheduled face to face appointment. Ideally, these remote clinics will occur in a location distant to areas exposed to direct patient contact. Where feasible, additional support from information technology services should be provided with special 'virtual private network' (VPN) access to allow staff access to patient e-records and clinical databases to ensure optimal patient care.
    b) We recommend regular rostering in remote monitoring as much as practically feasible to address CIED alerts in a timely manner. Alerts should be triaged and addressed via patient telecommunication with the aim to avoid in office visits to hospitals, clinics and practices. We strongly discourage in-person device interrogations, which should only be performed in discussion with the cardiac electrophysiology team, if it has the capacity to change the patients' management.
    c) In addition to remote monitoring, we would encourage the "clinical based" team to work on quality improvement projects during the reduced elective case workload period. This could include tasks such as designing and improving departmental protocols, competency assessments and development of educational resources. This will have a positive long-term impact on patient care after re-establishment of normal routines as the pandemic subsides. Furthermore, we recommend the continuation of all local educational

programs to promote departmental skillset diversity across the allied health team. This is particularly pertinent in the event that a significant proportion of staff become infected or require prolonged isolation.

3. The lab based team(s) would be responsible for running and supporting EP, CIED inpatient procedures and elective procedures. One or more nominated members could be designated as "clean" members who should not perform any duties with COVID-19 positive or COVID-19 pending patients. This will allow preservation of staff to provide case coverage, if other members are affected.

Practical considerations for lab maintenance

The following recommendations apply **during the lockdown phase and during 25% return to capacity**.

1. Where feasible, a single lab should be designated as a COVID-19 lab.
2. Where feasible, the following recommendations could be applied to the EP/CIED implant lab:
    a) Move all unnecessary EP equipment and cables out of the lab and into a designated storage area/on a trolley which can be accessed, if needed for a procedure. Remove all unnecessary items out of the control room such as spare cables, folders, storage discs, papers, posters etc.
    b) Created individual ECG dot packets to be taken in per case.
    c) Cleaning of main contact areas in the control room on a regular basis and/or between patients when necessary including but not limited to keyboards, mouse, phone, screens, door handles, light switches etc., using cleaning solutions known to be active against COVID-19, as per local hospital protocol.

DOMAIN 2: MONITORING AND FOLLOW UP OF PATIENTS WITH CIED

Management of patients requiring follow up for device therapy during the COVID-19 pandemic needs to address a number of specific challenges. Namely:

a) Frequent presence of high-risk comorbid conditions including advanced age.
b) Direct physical contact required for in-person device checks.
c) High risk of significant adverse impact of delayed or missed review appointments in selected patients.

d) Appreciation of important variations in practice of device clinics in rural and remote cardiology where access to EP and CIED clinics is limited, or with limited access to remote monitoring, or with minimal COVID-19 outbreak.

SARS-CoV-2/ COVID-19 is predominantly droplet spread, via close personal contact or contact with contaminated surfaces. At a minimum, CIED centres should follow local infection control protocols. Practices operating out of private consulting rooms should consider adopting the guidelines of a local public hospital.

Widespread restrictions imposed at both Federal and State level in Autumn 2020 resulted in a dramatic fall in transmission rates. Consequently, it has become clear that

- **Best practice through the pandemic is unlikely to be a static entity.**
    - **Over the course of the pandemic, there may be several occasions when infection control measures need to be tightened or relaxed.**
- **Geographical variations in disease prevalence and transmission rates have already been seen and are likely to persist.**
    - **Accordingly, geographical variation in infection control precautions may be appropriate and should not be considered to be a deviation from best practice.**

These guidelines have, therefore, been adapted to try to provide guidance that can be used, as appropriate, throughout the pandemic, to best protect healthcare workers and patients, both from COVID-19 and the potential risks associated with healthcare avoidance. It is recommended that the following recommendations are considered to be a step-wise hierarchy where each stage is in addition to the previous in terms of level of infection control.

Basic infection control strategies, appropriate throughout the pandemic and, possibly, beyond.

1. We suggest that remote monitoring be utilised as much as practically feasible, to avoid in office visits to hospitals, clinics and practices. For patients who are not currently enrolled in remote monitoring, new enrolment should be considered. Patients undergoing new device implantation, wherever possible, be provided with remote monitoring devices.
2. When clinical evaluation is required, without a strong expectation of concomitant device reprogramming, we recommend that the treating physician replace routine office visits with a remote consult (video calling or telephone follow-up). Several billing codes have

been released by the Federal Government to help facilitate this arrangement. http://www.mbsonline.gov.au

3. When in-person review is required, we recommend centers arrange appointments in a way that allows maintenance of social distancing and avoids the risk of patients congregating together. These may include, but are not limited to, spacing appointments out over longer than usual time periods, asking patients to wait outside/ in their car until called for their appointment or using "drive through" clinic arrangements. This includes centers where remote monitoring is not feasible, or the practice involves care of patients in remote or rural cardiology.
4. Centres performing in-person CIED checks should evaluate which staff are required for this purpose, balancing the need to provide high quality care against potential risks of infection. Where CIED company representatives are involved in these checks they should abide by the same infection control requirements as other clinical staff at the centre. This includes centers where remote monitoring is not feasible, or the practice involves care of patients in remote or rural cardiology.
5. CIED programmers used for in-person checks should be cleaned with disinfectants approved by hospital protocols to have activity against COVID-19 before and after each interrogation and at the beginning and the end of the day.
6. When possible, when performing in-person checks, consider asking the patient to self-apply the interrogation wand over their device to minimise close contact.
7. Whenever possible, inpatients who are enrolled in home monitoring schemes, who require device interrogation during their hospital stays should be encouraged to have their monitors brought into hospital and used for this purpose.
8. In centres where remote monitoring and telehealth is not feasible, or practical in delivering adequate health care, or the practice involves care of patients in remote or rural cardiology, face to face meetings clinic could continue but with social distancing in place, and the aforementioned principles in 4-7 be followed.

25-75% return to capacity

Increased infection control strategies; risk of COVID-19 infection in a healthcare setting is considered to be neither negligible nor high.

1. The decision about whether in-person CIED testing is appropriate should be individualised for each patient, balancing the potential increased risk of infection due to attendance for CIED check against the potential morbidity risk of sub-optimal device management.
2. When deciding whether to perform in-person testing, clinicians should take into account both *CIED-specific risks* (e.g. expectation of need for reprogramming, unstable lead parameters, recent or history of tachyarrhythmia therapy) and *non-CIED-specific risks* (eg. advanced age, significant comorbidity, patients of Aboriginal or Torres Strait Island origin who may be at increased risk of mortality if they develop COVID-19).
3. Staff involved in in-person CIED checks should be minimised during this period, to reduce potential risk of exposure to COVID-19. In addition, face-to-face interaction should be completed in as short a time as possible and, wherever possible, in less than 15 minutes.

4. When in-person device checks are required, we encourage the use of wireless communication technology by CIED allied staff to maintain a safe distance (>1.5 metres). In addition, we encourage limitation of the number of people present during the device check (i.e. only patient, clinician and CIED allied health staff). To minimise the duration of contact for a device check, device data can be downloaded, saved and reviewed away from direct contact with the patient.
5. For patients in whom in-hospital or ambulatory in-person interrogation cannot be avoided, we recommend screening for symptoms or history of exposure to COVID-19 and utilising PPE as per the local hospital protocol.
6. We recommend that Emergency Departments should have access to on-demand device monitoring systems (e.g. Medtronic Carelink Express and Abbott Merlin on Demand) and that these are used, whenever possible.
7. For CIED implantation, we recommend that the number of personnel during an implant should be kept to the minimum required for a safe procedure. Rotation of staff during a procedure is discouraged.

<u>Lockdown phase</u>

Maximal infection control strategies; to be considered when hospital attendance is considered to confer a high risk of infection and/ or when community transmission is prevalent, or when managing patients known to be suffering with COVID-19.

1. We recommend deferring routine in-hospital and in-person device interrogations in stable patients, with chronic indications for device therapy, and sufficient battery longevity (>9 months).
2. We recommend that centres consider limiting in-person CIED checks to the following circumstances
    a) *When the information cannot be practically obtained using the patient's remote monitor / On-Demand system* ***and***
        i. An ICD shock is reported by the patient, to determine whether appropriate and to guide therapy.
        ii. The patient presents with unexplained presyncope or syncope which is suspicious of CIED malfunction or arrhythmic cause.
        iii. The patient presents with an audible or vibratory alert on their ICD.
        iv. The patient presents with symptoms suggestive of device malfunction with a newly implanted CIED prior to their first check.
        v. When battery longevity assessment cannot be delayed for 3-6 months due to the device approaching elective replacement indicator (ERI), particularly in pacemaker dependent patients or those with previous appropriate defibrillator therapies
        vi. When follow up is required to monitor the progress of a device or lead under advisory or known fault
        vii. When a patient requires radiation oncology treatment with a medium to high risk to impact the CIED, as the local protocol dictates.
        viii. Assessment for detection of AF in a stroke patient.

or

b) *When re-programming is required for;*
   i. A clinically actionable abnormality / need for reprogramming noted on remote monitoring or recorded on ECG and it is deemed clinically inappropriate to delay action for 3-6 months.
   ii. Patients who require CIED reprogramming for urgent magnetic resonance imaging (MRI) where a CT scan cannot be used as an alternative to obtain the necessary information and where automatic reprogramming functions are unavailable.
   iii. Defibrillator deactivation in the event of End-of-Life management, when securing a clinical magnet to the skin over the ICD is not possible
   iv. CIED and EP procedures

or

c) *Perioperative reprogramming*[2,3] *limited to:*
   i. Surgery within 15 cm radius of the CIED (generator) where a magnet cannot be applied
   ii. Procedures above the iliac crest, and where patient positioning would prevent easy securing of a magnet if required (in pacing dependent patients, those with significant baseline bradycardia or to deactivate anti-tachycardia therapies in Implantable Cardioverter Defibrillators (ICDs)
   iii. Pacing dependent ICD patients for procedures above the iliac crest.
   iv. Following surgery if there is ECG evidence of unexpected device malfunction whilst the patient is monitored (A routine CIED check following surgery is not required)..

3. For patients with COVID-19, wherever possible, in-person device interrogation should be delayed until the patient is deemed no longer infectious by the appropriate treating team, according to local or national protocols.
4. If device interrogation cannot be delayed or avoided, we recommend that each department should quarantine a single set of programmers for in-person evaluation of patients suspected or known to have COVID-19. These programmers should be stored in a separate area. Consider covering the programmer interrogation wand with a transesophageal probe cover, sterile wand sleeve or simply a disposable plastic bag, to prevent it from touching the patient and the surrounding area
5. In the event of end-of-life management of a patient with terminal disease with or due to COVID-19 and an ICD in situ, consider asking the treating team to secure a clinical magnet to the skin over the ICD where possible, rather than using the programmer. ICD deactivation cannot be performed remotely.

DOMAIN 3: AMBULATORY MONITORING

As previously noted, as the pandemic waxes and wanes, there may be several occasions when infection control measures need to be tightened or relaxed. The practice at a state and regional level may be influenced by the geographical variations in disease prevalence and transmission rates. We advise the decision on restoration of ambulatory testing be based on clinical triage category of the request and the phase of the pandemic.

Triage Categorisation for ambulatory testing
Category 1: Ambulatory testing will result in change of management likely to prevent hospital admission within 1-3 months.
Category 2: Ambulatory monitoring will result in change of management of patient.
Category 3/4: Ambulatory monitoring is indicated based on guidelines and clinical judgement.

Level of ambulatory testing recommendation during each phase of the pandemic
The following triage categories for ambulatory testing are recommended during each phase of the pandemic.
Lockdown phase: Category 1 requests deferred for 1-3 months if possible (see below for possible alternatives). All other categories deferred.
25% care resumption: Category 1 performed (no deferral).
50% care resumption: Category 1, 2 performed.
75-100% care resumption: Category 1-4 performed.

As the services are restored from 25-75%, social distancing should be maintained in the outpatient waiting room by limiting the number of patients and maintaining a sufficient gap between the bookings.

During the lockdown phase, we advise avoiding the routine use of ambulatory Holter monitors or exercise stress tests (which involve direct patient interaction), for the screening, surveillance, ongoing management and/or follow up of patients with suspected or confirmed cardiac arrhythmias.

1. All inpatient and outpatient Holter requests should be triaged by either an electrophysiologist or a cardiologist, and necessary information should be sought from the referral team or GP to ensure patients are triaged appropriately.
2. Ambulatory monitoring should be delayed for 1-3 months, or until such time the pandemic has passed unless the ambulatory ECG monitoring is expected to pick up a finding that may result in a change of management or prevent ED presentation.
3. In low risk patients (e.g. those with undiagnosed, infrequent palpitations and a structurally normal heart), smartphone or smartwatch acquired ECGs (medical grade quality) may be considered (e.g. AliveCor Kardia). Although small studies and anecdotal reports suggest that these may be useful, large scale randomised controlled data is lacking. The use of heart rate monitors (e.g. Fitbit, Garmin watch) are unlikely to be useful in this setting and hence discouraged.
4. In the rare instance that ambulatory Holter monitoring and/or stress testing is the ONLY option for investigation of a patient, social distancing rules are to be followed. Equipment must undergo a thorough clean before and after each use using hospital approved disinfectants that are active against COVID-19. For handling those Holters, department/practices should have a working policy. While Holter monitors can be shipped and returned through the post, but issues related to damage and loss should be considered.

DOMAIN 4: ELECTROPHYSIOLOGY AND CIED PROCEDURAL CONSIDERATIONS

As noted in Domain 1, the practice of EP and CIED in Australia is variable amongst local health districts, and in regional and remote areas. These guidelines are not mandated, but intend to provide a framework for rationalising outpatient procedures. We encourage that members use these recommendations and tailor them **to local demands for EP and CIED services, models of service delivery, local outbreak patterns, local hospital recommendations, PPE supply chain, and contingency and/or crisis capacity status for each hospital.** Individualised risk assessment for each patient and sound clinical judgment is encouraged, weighing the risk/benefits of delaying intervention versus risk of patient and staff infection with COVID-19, and use of precious PPE resources.

It is plausible that the pandemic will increase or decrease in severity of outbreak, making it difficult to provide static recommendations. As previously noted, **over the course of the pandemic, there may be several occasions when infection control measures need to be tightened or relaxed. Importantly, there will be geographical variations in disease prevalence and transmission rates which will influence practice at a state and regional level.**

On 23rd April 2020, the Federal Government released a statement from the Australian Health Protection Principal Committee (AHPPC) about the restoration of elective surgery (https://www.health.gov.au/news/australian-health-protection-principal-committee-ahppc-statement-on-restoration-of-elective-surgery). The guiding principles in this document for the restoration of elective surgery from April 27, 2020 were:

a. 1 in 4 (25%) of elective surgery to be restarted
b. Health services and their clinicians to be responsible for selection of patients for these lists based on clinical urgency, PPE use, ICU capacity and consistent with the principles in that published document;
c. Those procedures be focused on those normally categorised in the public hospital system as category 1, category 2 and some category 3 procedures.
d. Prioritization of procedures representing low risk, high value care as determined by specialist societies.

In line with state and Federal Government restrictions for delivery of health care services, the recommendations of Domain 4 will now address:

(a) categorisation of elective procedures as category 1-4 and
(b) which categories of procedures are recommended during (i) lockdown phase; (ii) return to 25% elective capacity; (ii) 50% elective capacity; (iii) 75% capacity; (iv) 100% capacity.

The aforementioned guiding principle are now used to provide recommendations in this document. The recommendations in this document are intended to apply to outpatient procedures. Inpatients procedures required to facilitate discharge and/or to avoid emergency department/hospital readmissions should be performed as quickly as possible, if they are deemed urgent.

The definition of what constitutes an elective/non-urgent case is based on a patient-specific risk assessment. The rationale for delaying elective/non-urgent case procedures should be discussed with the patient and documented in the medical record. Discussion amongst local peers is recommended in borderline cases, in the current pandemic era. Where possible, same day discharges, are encouraged. Factors not directly relating to the individual patient, such as PPE/other equipment or allied health staff availability and the ability of the hospital to manage

non COVID-19 patients at a particular point in time may also affect the decision-making process of whether to proceed to an elective procedure.

In line with major societal recommendations, especially those from the Heart Rhythm Society COVID-19 Task Force,[1] expert opinion and direct communication with key opinion leaders around the world, the expert writing committee agreed the **following could be considered as Category 1 procedures:**

1. Pacemaker insertion for those with asystolic pauses or advanced AV block.
2. Lead revision for lead malfunction in a pacemaker dependent patient or defibrillator patient receiving inappropriate therapy.
3. Defibrillator implants for the secondary prevention of sudden death (and associated electrophysiology study, if needed, for clarification).
4. Pacemaker generator replacement for pacing dependent patients who are at elective replacement indicator (ERI) or at device end of life (EOL).
5. Defibrillator generator replacements in those with previous appropriate defibrillator therapies who are at EOL.
6. Catheter ablation of supraventricular arrhythmias causing hemodynamic deterioration, syncope, and/or heart failure that is uncontrolled by antiarrhythmic drugs, rate control, and/or cardioversion, and/or anti-failure medications or if the arrhythmia results in repeated emergency department visits and/or hospitalisations.
7. Catheter ablation for Wolff-Parkinson-White syndrome associated with cardiac arrest or pre-excited AF associated with R-R intervals shorter than 250msecs.
8. Catheter ablation for medically-refractory, ventricular arrhythmia storm
9. Transvenous lead extraction on a case-by-case basis

The following are considered as Category 2 procedures:

1. Catheter ablation of atrial and supraventricular arrhythmias in highly symptomatic patients who have failed, or are intolerant to drug therapy
2. Ablation of arrhythmias thought to be contributing to cardiomyopathy.
3. VT ablation for medically refractory, recurrent ventricular tachycardia.
4. Primary prevention defibrillator implants
5. CIED generator replacement for ERI battery status
6. Cardiac resynchronization therapy (de-novo or upgrades).
7. catheter ablation of highly symptomatic premature ventricular complex (PVC) ablation, who have failed, or are intolerant to drug therapy.
8. Left atrial appendage closure

The following are considered Category 3 procedures:

1. EP testing to evaluate stable tachyarrhythmias or bradycardia.
2. Implantable loop recorder implants.
3. Tilt-table testing.
4. Drug challenges (flecainide, adrenaline)

Outpatient elective procedures recommended according to the extent of restoration of activity

1. Lockdown phase: we would consider outpatient elective activity to be restricted to be Category 1 only.

2. At restoration of 25% capacity, we would consider all Category 1 procedures, and procedures labelled 1-4 in Category 2 to be recommended.

3. At restoration of 50% capacity, we would consider all Category 1 procedures, and procedures labelled 1-6 in Category 2 to be recommended.

4. At restoration of 75% capacity, we would consider all Category 1 procedures, and all Category 2 procedures to be recommended.

5. At full 100% restoration of capacity, we would consider all Category 1-3 procedures to go ahead to be recommended.

DOMAIN 5: ARRHYTHMIC IMPLICATIONS OF COVID-19

The intention of this domain is to provide an updated information source on the arrhythmic implications of COVID-19.

Summary

Palpitations and chest tightness are uncommon but recognised presenting symptoms of SARS-CoV-2 (COVID-19) infection. Increasing age and the presence of multiple medical comorbidities are associated with more severe infection and increased mortality. Many of these patients will suffer from arrhythmias. In at least one series arrhythmias were reported in 16.7% of hospitalised patients and were more common in those patients managed in the intensive care unit. Myocardial injury with raised troponin levels may be identified in hospitalised patients and is a marker of increased mortality. Atrial and or ventricular arrhythmias may be due to exacerbation of pre-existing arrhythmias with underlying cardiovascular disease in the setting of acute respiratory infection, or due primarily to myocarditis, hypoxaemia, inflammation, inotropes, and/or side effects of specific anti-viral therapies (commonly QT prolongation). Details on arrhythmias unique to SARS-CoV-2 infection are lacking. Heart rhythm specialists may be asked to assist in the management of arrhythmias or in the monitoring of empirical drug therapy regimens.

Arrhythmias in COVID-19 patients

Whilst the most common presenting clinical symptoms of SARS-CoV-2 infection are fever, cough and respiratory symptoms, some patients in China first presented with palpitations and chest tightness.[4] The reports of arrhythmias with SARS-CoV-2 infection are limited but arrhythmias do appear to occur commonly in hospitalised patients. Whilst most patients have a mild infection 10-20% may develop severe infection and a proportion of these will require management in an intensive care unit.[5]

In Influenza infection, cardiovascular complications include myocarditis, acute myocardial infarction (plaque rupture secondary to viral inflammation) and exacerbation of heart failure. Previous coronavirus infections have also been associated with cardiovascular complications. The risk of adverse outcomes and the severity of adverse outcomes are increased by pre-existing cardiovascular disease. SARS has previously been associated with hypotension, tachycardia, bradycardia, atrial and ventricular arrhythmias.[6] ECG changes and a troponin rise may indicate myocarditis. Myocarditis may recover with supportive therapy and arrhythmias may be transient.

With SARS-CoV-2 older age and the presence of underlying medical conditions appears to increase complications and mortality.[7] The Italian experience shows that of all deaths, only 1.2% occurred in patients with no co-morbidities and 48.6% of deceased patients had three or more co-morbidities (COVID-19 Surveillance group). This may relate to reduced immunity and it has been noted that the SARS-CoV-2 virus binds to alveolar and myocardial cells via the ACE2 receptor.[8] Myocardial injury with troponin rise may be seen in up to 17% of hospitalised patients[9] and is a risk factor for mortality. The mechanisms of cardiac injury include myocarditis, hypoxaemia, and cytokine storm. Myocarditis may be associated with ECG changes and arrhythmias but detailed observations on arrhythmias specific to SARS-CoV-2 are limited.

The large series published from the Wuhan infection epicentre in China by Wang and colleagues shows illustrative data of the severity of SARS-CoV-2.[10] In this series, the complications included acute cardiac injury 7.2%, shock 8.7%, arrhythmias 16.7% and overall 26% of hospitalised patients required ICU care. Details on specific arrhythmias were not provided but were more common in ICU than non-ICU patients. Other smaller studies have demonstrated similar observations with the development of cardiomyopathy in 1/3rd of patients admitted to ICU.[5]

A separate single-centre retrospective analysis also from Wuhan demonstrates correlation between underlying cardiovascular disease (CVD) and myocardial injury with increased mortality and malignant arrhythmias. One third of the patients (35.3%) had previous CVD, and 52 (27.8%) patients experienced an acute myocardial injury. Troponin T (TnT) elevation likely represents myocardial injury from either myocarditis, infarction with plaque rupture or diffuse ischaemia from hypoxia. Mortality among patients with CVD and elevated TnT levels was 69.44% (25 of 36), compared to 7.62% (8 of 105) among patients without CVD and acute myocardial injury. Patients with CVD were more prone to TnT elevation (54.5% vs 13.2%), and patients with elevated TnT had more frequent malignant arrhythmias. The overall incidence of ventricular tachycardia (VT) or ventricular fibrillation (VF) in this cohort of sick patients with frequent underlying CVD (and a total mortality of 23%) was 5.9%. VT/VF was much more likely in the group with elevated TnT (17.3% vs 1.5%). Events of asystole were not described.[11] These preliminary reports suggest greater incidence of malignant arrhythmias among COVID-19 patients compared to SARS (2003).

Potential drug therapies for SARS-CoV-2 may exacerbate cardiac arrhythmias. Hydroxychloroquine has been touted as a possible agent which might reduce the severity of or prevent infection.[12] Hydroxychloroquine (Plaquenil) is a chloroquine derivative and like all the related drugs in this group may cause QRS widening and QT prolongation. However, it is safer to use than chloroquine. Cases of torsades de pointes secondary to this drug are published. The half-life of the drug is very long, and the risk is related to either over dosage acutely or high dose long term usage. Hydroxychloroquine is being used in combination with the antimicrobial azithromycin in clinical trials and shown to reduce viral load.[13] This drug has anti-inflammatory effects. This antibiotic may cause Long QT and Torsade de Pointes. Case reports exist for potentiation of long QT in patients with hypokalaemia and co-administration of other QT prolonging drugs eg chloroquine.[14]

A recent article from Mayo clinic suggested that the risk of drug-induced Torsade de Points (DI-TdP) and/or sudden cardiac death (DI-SCD) can be mitigated with some precautions. Baseline ECG and individual patient assessment for addition risk factors for QTc prolongation is indicated. Congenital (or inherent tendency for drug induced QTc prolongation), modifiable or non-modifiable QTc risk factors ought to be taken into consideration. Taking into consideration COVID-19's pandemic nature, the small proportion of patients at risk of DI-TdP/DI-SCD represents a significant number of individuals who may experience a life-threatening adverse effect, if these medications are accepted for post-exposure prescription.[15] Rigorous investigation of modifiable risk factors for QTc prolongation and consecutive ECG is mandatory is such patients.

No doubt other therapies are being assessed and include Interferon-alpha and the specific anti-viral Remdesivir.[10] The cardiovascular side effects of the latter are currently unknown.

DOMAIN 6: EP AND CIED IMPLICATIONS FOR CHILDREN AND ADULTS WITH CONGENITAL HEART DISEASE

COVID-19 Infection in children

Children in general tend to have less severe disease than adults and seem to present much less to hospital. Of 72,314 cases reported by the Chinese Centre for Disease Control, less than 1% were under 10 years of age, 60% were male. Of 171 confirmed cases collected in one study, 3 required ICU and there was one death at aged 10 months. Median age of infected children was 6.7 years. Two thirds had some evidence of pneumonia and 16% were asymptomatic.[16] In a series from 10 hospitals from the Hubai province published March 24, only 25 confirmed paediatric cases were identified.[17] Abdominal symptoms, are not uncommon.[18] There was no proven vertical transmission to the foetus among nine pregnant women with COVID 19, but symptomatic newborns as young as day 2 have been reported, some with typical features of respiratory distress syndrome (RDS) on chest X Ray, but with favourable outcome so far.[18] Similar numbers are reported from Italy and the US. Data from the Netherlands supports the fact that children play also just a minor role in the spread of COVID 19 (https://www.rivm.nl/en/novel-coronavirus-covid-19/children-and-covid-19).

Although tachycardia was documented in 40%, no immediate cardiac effects have been described in children as of March 26 2020, aside from an elevated troponin in one 55-day old infant.[19] However, there is no systematic review is available and myocarditis has been reported in young adults with severe RDS.

There is though growing evidence from countries with a high incidence of COVID cases like Italy, England and the US, that children are at risk to have a post – covid syndrome with a clinical picture similar to Kawasaki disease - called paediatric inflammatory multisystem syndrome temporally associated with SARS-CoV-2 (PIMS-TS) which can cause myocarditis and coronary stenosis.

In an article published in *Lancet*, the authors report a strong temporal association between the KD outbreak and SARS-CoV-2 epidemic in Bergamo. The findings support the hypothesis that the immune response to SARS-CoV-2 precipitates KD in susceptible patients. The authors maintain that the disease remains rare, estimating incidence of Kawasaki disease at 1 in 1000 children exposed to SARS-CoV-2.[20]

Post-operative, and adults with congenital heart disease

Data are not available on outcomes of COVID-19 in this group. Known risk factors in adults will apply such as older age, hypertension and diabetes.[9] Intuitively *we would expect those with reduce ventricular function, pulmonary hypertension and Fontan circulation, to tolerate to pulmonary manifestations of disease less well*. One of the deceased patients in the above study had congenital heart disease.

Patients with Channelopathies

Before starting a treatment in COVID-19 affected patients with QT prolonging or experimental drugs, an individual risk vs benefit analysis should be performed and an electrophysiologist should be involved. Adrenaline in CPVT should be avoided even in resuscitation.

Implications of the pandemic to immediate management of arrhythmia in children and adults with CHD (congenital heart disease).

The implications are generally the same as for adult non-CHD patients, and we endorse the above carefully considered statements presented by this council. The biggest burden of this pandemic will be on the adult population, but we have many shared resources, and

interdisciplinary collaboration in this instance may largely be for the paediatric services to make space for the huge onslaught of very sick adult patients.

We also have a responsibility to provide ongoing paediatric cardiac services, since there is no back-up if all become sick. There is a single small team for a whole State, so there is a priority to protect the whole medical and surgical team so that vulnerable yet treatable infants in particular don't die as a consequence of lack of a service at all. Minimising exposure of this team to COVID-19 is thus a major imperative.

As NZ and Australia have been very successful to avoid any widespread outbreak so far and a long period of looming viral outbreak is likely, we support an approach of gradual recommencement of semi-elective procedures and outpatient appointments. The government recently announced that all paediatric elective procedures may now proceed, but for the above reasons, we should proceed with caution in expanding services. It is important to keep a balance between protecting resources, avoiding the spread of the virus and collateral damage by delaying semi-elective procedures and outpatient appointments. This will need constant re-balancing over the next months and a tailored approach depending on the conditions of the hospital/clinic load and the possibilities of social distancing. Due to the fact, that children are less likely to be affected and less likely to transfer COVID-19, the threshold for re-starting procedures might be slightly lower than for adults, on the other hand children are mostly accompanied by their parents when attending the hospital.

We summarise our position below, in essence, this is the same as for older/non-CHD patients, with some minor additions.

<u>Recommendations for EP/ablation in children</u>

During the lockdown phase of the Pandemic

Only category 1 patients including but not limited to the following

a) Cardiac arrest in association with pre-excited AF;
b) Arrhythmia causing need for extra-corporeal membrane oxygenation and unresponsive to medical management;
c) Incessant arrhythmia with severe ventricular dysfunction and failed medical management (where the balance of risks favors ablation rather than protracted inpatient medical management (e.g. tachymyopathy due to atrial tachycardia, permanent junctional reciprocating tachycardia, or ventricular tachycardia).

During 25-75% return to capacity:

a) All category 1 patients
b) Consideration for ablation of all category 2 and 3 patients should be given though assessment of risk of the patient's disease versus risk of COVID 19 based on degree of community spread should be balanced prior to procedure.

<u>Recommendation of pacing/defibrillation in children</u>

During the lockdown phase of the Pandemic

a) Congenital complete heart block– newborn with heart rate less than 55bpm, or at all ages with syncope;
b) Syncope due to slow heart rate /intermittent AV block;
c) Post-operative complete heart block;
d) Pacemaker dependent and pacemaker at EOL;

e) Secondary prevention defibrillator implant;
f) Replacement of defibrillator device at EOL for high risk patients.
g) Removal of infected devices
h) Insertion of loop recorder in known channelopathy/cardiomyopathy only

During 25-75% return to capacity:

a) Primary prevention defibrillator implant
b) Replacement of defibrillator device at EOL for all patients
c) Insertion of loop recorder for unclear Syncope
d) Placement of pacemaker for bradycardia with patient meeting category 1 or 2a HRS/PACES indications
e) All other paediatric patients, where a further delay might have a negative outcome or poses additional strain on the health system

Recommendations for EP/ablation in adult congenital heart disease patients

During the lockdown phase

These are the same as for the general adult population with the possible addition of
a) Cardiac arrest secondary to atrial flutter in RV dependent circulation;
b) VT Storm, particularly in Tetralogy/Rastelli subgroup.

During 25-75% return to capacity:

a) See general adult population
b) EPS and ablation prior to planned cardiac surgery

Outpatient consults

For all patients telehealth should be considered as an option to decrease exposure in the hospital, though for a number of patients examination, electrocardiography, echocardiography or other tests might be needed.

As it is expected that COVID-19 will be around for a significant period of time, the risks vs benefits have to be considered not only for the short term, though also for the longer term.

During the lockdown phase of the pandemic

New patients

New patients should at first be offered virtual/telehealth outpatients review. Note that often a good enough ECG can be obtained from the GP or referring hospital, and AliveCor can be ordered on-line.

Those who may need to be seen in person during lock-down **after** the virtual consult, are those where:
a) the history leads to an impression that *a life-threatening condition seems likely (eg CPVT/LQTS/HCM);*

b) truly arrhythmic sounding syncope, syncope with palpitations, exercise triggered syncope, particularly if there is a malignant family history;
c) syncope with newly diagnosed WPW (not with documented pre-excited AF) diagnosed on ECG by a paediatric colleague can usually be initially managed with an antiarrhythmic such as flecainide/Sotalol remotely or at referring hospital and review when the pandemic shut-downs have finished.

Some of these new patients can be dealt with remotely except that they need ECG, echocardiography and an exercise test. These tests, if they cannot wait, can sometimes be done by another colleague/allied health and not necessarily reviewed face to face by an EP. Medications can usually be started remotely. An exercise test can potentially be deferred by banning exercise in the meantime.

Follow up patients

As per the adult follow up guidelines, each week's clinic list should be reviewed, and patients should be deferred when safe to do so. Those who do need to be seen *should first have telehealth review* and seen *only where treatment cannot safely be optimised remotely.* Some cases may require echocardiography, *but this does not necessarily require the consultant to see the patient during that visit.*

Cases where telehealth +/- in person review should occur include:

a) known cardiac inherited disease with syncope;
b) known congenital heart disease with syncope (e.g. post Rastelli, TOF)
c) Patients requiring pacemaker/ICD follow up, as per adult guidelines. It is generally safe to delay or skip one planned pacemaker or ICD check in patients with or without remote monitoring if they are not pacemaker dependent and had stable battery and lead measurements in the last checks.

During 25-75% return to activity

New patients with a high likelihood to develop more severe symptoms and needing examination / ECG/ Holter / Echocardiography may be seen in an outpatient clinic with reduced throughput, enabling social distancing, minimised waiting periods and maintenance of hygiene of machinery.

All other patients including follow-up patients if they cannot be categorised as safe to be deferred for at least half a year or their condition makes them available for telehealth review.

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