

Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.

Remote Device Interrogation Kiosks (ReDInK) - Pharmacy Kiosk Remote Testing of Pacemakers and Implantable Cardioverter-Defibrillators for Rural Victorians. A Novel Strategy to Tackle COVID-19



Joshua Wong, MBBS*, Anthony Longhitano, MD, Jessica Yao, MD, Pavithra Jayadeva, MBBS, Kim Arendshorst, BBiomedSc, Leeanne Grigg, MBBS, FRACP, Gareth Wynn, MD, MRCP, FRACP, Irene Stevenson, MBBS, FRACP

Royal Melbourne Hospital, Melbourne, Vic, Australia

Received 22 November 2020; accepted 31 December 2020; online published-ahead-of-print 28 January 2021

Background	In the era of COVID-19, travel restrictions and social distancing measures have changed the landscape for device interrogations of pacemakers and defibrillators for rural Victorians. Previously, device checks were performed infrequently in large volume, face-to-face rural clinics by visiting cardiologists and technicians. Access to remote areas and social distancing restrictions have made these clinics unfeasible to operate. The Cardiac Society of Australia and New Zealand (CSANZ) and Heart Rhythm Society (HRS) COVID-19 consensus statements have suggested the utilisation of remote monitoring to minimise the potential spread of COVID-19 infections between clinicians and high-risk patients. A novel solution to this challenge was the implementation of a remote device interrogation (RI) service located in two kiosks at two rural pharmacies. This service was termed Remote Device Interrogation Kiosks (ReDInK).
Aim	This cross-sectional observational study aimed to describe the set-up process, safety and efficacy of RI and customer satisfaction of the ReDInK program.
Methods	Two-hundred-and-ninety-two (292) rurally located patients with implantable cardiac devices were iden- tified via the cardiology department database. Of these, 101 (44%) were enrolled into the ReDInK program across two rurally located pharmacies between April and July 2020. RI was performed and download outcomes were reviewed. A customer satisfaction survey assessed attitudes towards the program and explored options of ongoing service application.

*Corresponding author at: Royal Melbourne Hospital, 300 Grattan Street, Parkville, Vic, 3050, Australia; Email: joshua.wong@mh.org.au © 2021 Australian and New Zealand Society of Cardiac and Thoracic Surgeons (ANZSCTS) and the Cardiac Society of Australia and New Zealand (CSANZ). Published by Elsevier B.V. All rights reserved.

Results	Of 101 patients enrolled into ReDInK, 96 (95%) resulted in satisfactory device checks. Four (4) individuals failed-to-attend and one individual experienced technical download issues. Of the 96 satisfactory device checks, three required in-person follow-up for reasons including battery replacement, lead repositioning and in-person programming. No adverse events were reported. A satisfaction telephone survey was conducted with 81 (83%) participants enrolled in ReDInK. Seventy-one (71) individuals (88%) of those surveyed expressed satisfaction and 73 (90%) labelled the process as efficiently conducted. Sixty-nine (69) (85%) participants felt reassured that this service was established during the pandemic. However 47 (58%) participants reported they would still feel comfortable to undergo in-person reviews despite social distancing recommendations.
Conclusions	With the COVID-19 pandemic posing restrictions to social distancing and reducing unnecessary in-person interaction, the ReDInK program emerges as an efficacious and safe solution for patients in rural Victoria. The program's widely positive reception and successful conduction in rural Victoria invites further opportunity for a wider application of similar programs, expanding its role to metropolitan areas.
Keywords	COVID-19 • Coronavirus • Device interrogation • Pacemaker • Implantable cardiac defibrillator • Remote interrogation • Remote monitoring • Rural • Remote

Introduction

The COVID-19 pandemic has had an unprecedented effect on health care systems worldwide, with particular challenges in the management of patients with cardiac implantable electronic cevices (CIEDs). In-person CIED clinics present inherent risks with COVID-19, as transmission is predominantly via droplet spread through close personal contact. The clinical severity of infection with the Severe acute respiratory syndrome (SARS)-2 virus varies widely, with the greatest morbidity and mortality risk in older patients who have pre-existing co-morbidities [1]. The CIED patient population is largely in this vulnerable cohort. Regular device interrogation is critical for detecting complications such as device malfunction, battery-end-oflife, as well as new onset of arrhythmias such as atrial fibrillation (AF). We explored and implemented a successful remote, low personal contact device interrogation service to minimise the risk of acquisition and transmission of COVID-19.

There has been a rapid re-evaluation of routine CIED testing worldwide as well as in Australia. Major international societies, including the Cardiac Society of Australia and New Zealand (CSANZ), have published emergent guidelines suggesting rapid shifts towards the utilisation of home monitoring as a means to ensure appropriate continuity of care whilst simultaneously reducing transmission rates of COVID-19 infection amongst high-risk patients and clinicians [2–4].

Home CIED monitoring can be a safe and cost effective adjunct to routine in-person clinic assessment [5]. Home monitoring includes remote interrogation (RI) with or without the inclusion of remote monitoring (RM). RI is the routine scheduling of 3-12 monthly remote device interrogations, similar to an in-person device checkup [4]. RM is the automatic transmission of 'alerts' when pre-specified abnormal criteria (ie arrythmias/battery depletion) are met. Currently in Australia, the majority of both public and private patients lack access to home monitors.

Challenges in a rural setting are often magnified owing to resource access, allocation and local expertise with evolving technology. Arnold et al. reports that amongst regional Victorians, only 25% of patients have access to home monitoring [2]. Standard practice for patients is to travel to a metropolitan centre for follow-up or attend large volume clinics often run by specialist cardiac electrophysiologists and physiologists, who travel relatively infrequently from metropolitan hospitals. With the current COVID-19 pandemic travel restrictions and social distancing regulations, operating these clinics, especially at a pre-COVID capacity, has become unfeasible [2]. These vulnerable patients have also been discouraged from travelling to metropolitan centres to access cardiologist review [2,6,7].

Several CIED companies now have manual device interrogation monitors (Medtronic CareLink Express and Abbott Merlin on Demand) compatible with most of their devices with ability to perform RI. These generic monitors, which are able to perform a 'one-touch' RI, are neither patient nor device specific as opposed to home monitors, which are exclusive to a single device and patient. Ahmed et al. describes the use of RI in CIEDs within the emergency department setting where their use has expedited device interrogation and interpretation [8]. Remote interrogation is also validated as a safe and effective alternative to in-clinic follow-up in the home monitoring setting [9].

To overcome the challenges of continued safe CIED follow-up in rural and regional Victoria during the COVID-19 pandemic, we implemented a RI service using Carelink express (Medtronic, Dublin, Ireland) and Merlin on Demand (Abbott, Chicago, IL, USA) interrogation monitors, placed at regional Victorian pharmacies. This service was termed 'Remote Device Interrogation Kiosks' (ReDInK). This novel application of generic RI monitors for routine scheduled

remote CIED interrogation has not previously been described.

We describe the patient and clinician experience of ReD-InK whilst also addressing how ReDInK can further expand to incorporate other rural as well as metropolitan areas, especially in the context of this pandemic.

Methods

Study Population

This single centre cross-sectional observational study was conducted at the Royal Melbourne Hospital (RMH), a tertiary hospital in Melbourne, Australia. Patients due for scheduled CIED follow-up at the RMH Shepparton and Albury clinics for the period from April to July 2020 during COVID-19 restrictions were included. Those without home monitors and with compatible devices were offered a remote device interrogation kiosk (ReDInK) check at a local pharmacy. Patient data including device information and underlying cardiac history were extracted from clinical records within the electronic hospital medical record system.

Pharmacy Set-Up

A partnership was formed between the RMH CIED service and two regional local pharmacies, one in Shepparton and one in Albury. The RI modules (Carelink Express- Medtronic and Merlin-on Demand-Abbott) were positioned in designated health screening areas where other pharmacy led interventions such as blood pressure, blood glucose level and weight monitoring are performed. The respective CIED company representatives installed the RI modules and provided training to pharmacy staff on the download procedure.

Patients were scheduled half-hourly to hourly and were required to present either a paper or text message to pharmacy staff, specifying patient details, time of appointment and brand of device.

Remote Interrogation Testing Procedure

Pharmacy staff direct patients to the relevant monitor and supervise them with the ReDInK download. The process of RI includes the patient holding the testing 'wand' over their CIED, on the surface of their clothing. The testing module then confirms the download is successful. The process takes 10 minutes to conduct. The ReDInK remote communicators are diagnosis only, thus unable to perform device reprogramming. Pharmacy staff are required to sanitise equipment between patients as per infection control recommendations.

Data is transmitted from the patient's CIED via telemetry to either the Carelink (Medtronic) or the Merlin-on-Demand (Abbott) remote monitoring module and subsequently via the internet to a secure email of the RMH cardiology CIED team. Checks are reviewed by the RMH cardiology team which includes an electrophysiologist and cardiac physiologist. Patients are then either informed of their satisfactory device check and scheduled for their next appointment (usually 3, 6, or 12 months) or contacted to organise an inperson review for required programming changes. The patient's general practitioner and relevant physicians are sent correspondence regarding the outcome of the ReDInK CIED check.

This process is summarised in Figure 1.

Satisfaction Survey

All patients enrolled into the ReDInK program were contacted for a telephone survey. This included a questionnaire regarding patient satisfaction, efficiency, attitudes towards social distancing measures and future applications of the service.

Results

Patient Characteristics (Table 1)

The RMH cardiology department had 292 patients scheduled for in-person CIED follow-up in the regional Shepparton and Albury clinics during the period April to July 2020. Onehundred-and-ninety-one (191) of these patients did not participate in the ReDInK program. Sixty-four (64) had access to home remote monitoring; 64 had older/incompatible devices; 21 had device follow-up elsewhere; 32 had followup after the designated timeframe; and 10 declined participation. The remaining 101 (44%) patients were enrolled into the ReDInK program. Median age was 76 years and 69% were male. Of the 96 devices interrogated, 87 were pacemakers and nine were implantable cardioverter defibrillators (ICD). Medtronic devices made up 68 of the cohort with Abbott Medical (previously St Jude Medical) the remaining 28. Common comorbidities included congestive cardiac failure, diabetes and chronic pulmonary disease.

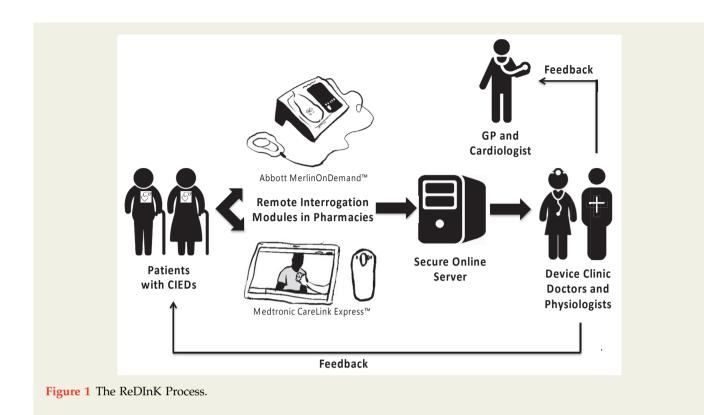
Device Interrogation Results (Table 1)

Of the 101 patients enrolled into ReDInK, 96 (95%) patients achieved a successful initial RI download from the pharmacy, four (4%) cancelled their appointments or failed to attend and two (2%) experienced errors with downloading data, although one patient on follow-up had a successful download.

Of all successful RI downloads, three patients required inperson review for generator replacement, lead repositioning and reprogramming respectively. Three (3) patients required medication changes, which were organised through their local general practitioner.

Satisfaction Survey

Eighty-one (81) (83%) of the total ReDInK patients completed a telephone survey. Of those who participated in the survey, 71 (88%) patients were satisfied with the new RI service performed at the pharmacy kiosks with 73 (90%) patients describing the process as efficient. A further 69 (85%) patients reported feeling reassured that this service had been established in response to the COVID-19 pandemic.



A total of 10 (12%) of the 81 patients who completed the survey were dissatisfied with the absence of face-to-face contact with an experienced clinician during their device check. As previously mentioned, two patients encountered technical issues, which resulted in a repeat interrogation attempt. Other issues identified in the survey included absence of immediate feedback as well as a perceived lack of confidence in the accuracy of results without a formal medical review.

Sixty (60) patients (74%) were satisfied with device interrogation results being directed to their general practitioner. Of those surveyed, 50 (62.5%) were content to continue RI pharmacy kiosk downloads post the COVID-19 pandemic. Over half, 47 (58%) would have been comfortable to continue to congregate in large groups for their device checks (as performed prior to the pandemic).

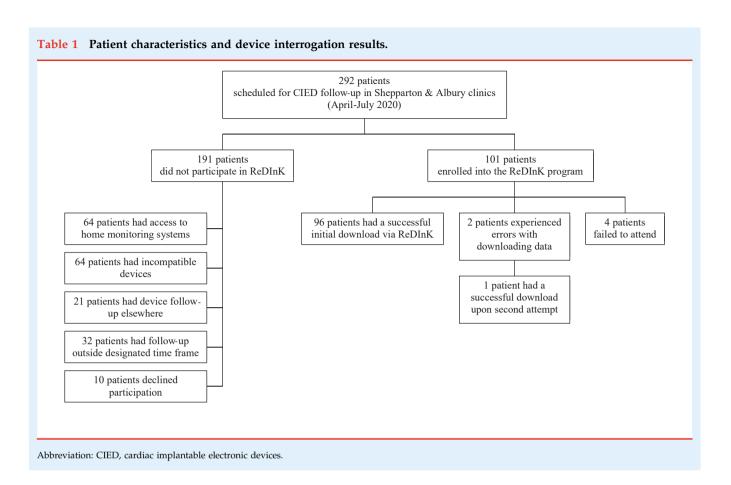
Discussion

Our study describes the novel use of ReDInK in two pharmacies within the regional and rural Victoria setting and found it an effective method of providing safe, scheduled CIED follow-up during the COVID-19 era. ReDInK allowed effective interrogation in 95% of eligible CIEDs with no adverse events.

Although home monitoring has been recommended by both international and local cardiology societies as desirable during the COVID-19 pandemic, implementation, particularly in legacy CIED patients, is not straightforward. Challenges include changes to workflow as well as the substantial financial cost of purchasing home monitors. With home monitoring, education of all involved personnel, in particular, patients, about their responsibilities and expectations is crucial. This however requires specific expertise and is time consuming. *In essence, to pivot safely and rapidly to remote home monitoring is simply not feasible for many hospital departments, CIED service providers and patients.*

As a COVID-19 safe alternative, the ReDInK program has proven to be efficient and acceptable to most patients. Almost all data that are obtained in a usual in-person device checkup, including identification of arrhythmias, measures of lead integrity and battery status can also be obtained through RI.

There are, however, limitations of RI data collection, often more prevalent in older devices. These include the absence of threshold results (if automatic thresholds testing is not possible or activated), difficulties identifying the underlying rhythm, and an inability to perform manoeuvres checking for lead noise. ReDInK is less suitable for certain devices due to programming methods, as well as particular types of patients. Examples include conduction system pacing and conventional cardiac resynchronisation therapy, which require a greater direct input with more complex, nuanced programming and often symptom driven changes. Reviews with these devices often warrant clinical assessment through the use of history taking, clinical examination and electrocardiograph (ECG) monitoring. Another limitation of ReD-InK, universal to both RI and RM, is an inability to implement any device programming changes.



As per our satisfaction survey, patients overall reported a high degree of satisfaction with the pharmacy driven RI download process, noting it to be a straightforward and efficient process with two-thirds happy to continue with the ReDInK clinic post the COVID-19 pandemic. A third of patients cited the opportunity to ask questions, the ability to garner immediate feedback on device performance and the human interaction with a cardiologist, as reasons they preferred the previous system.

Interestingly, more than half of the patients would have been comfortable to continue attending the large crowded pre-COVID-19 clinics, perhaps reflecting the low level of COVID-19 infection in regional Victoria as well as a disconnect between perceived and actual vulnerabilities in this population. Emerging literature continues to show patients with established cardiac disease and associated comorbidities are a high risk demographic for morbidity and mortality associated with COVID-19 infection [1], this cohort is typical of those attending regional CIED clinics.

As the pandemic progresses and COVID-19 case numbers reduce, travel restrictions will eventually begin to ease. The new "COVID normal" including social distancing, mask wearing and reducing exposure to vulnerable populations, will seemingly become a new way of life for the foreseeable future.

At this stage we plan to continue the ReDInK program, supplemented by in-person follow-up at regular intervals, unless issues are identified from the pharmacy RI. We are proposing an in-person review every 18–24 months for pacemakers and 12-monthly for defibrillators and cardiac resynchronisation devices. This will provide the opportunity for pacing threshold testing in those devices without automatic capture algorithms, to adjust programmed parameters and provide the patient the opportunity to ask questions.

The partnership with community pharmacies did not include direct funding for the use of ReDInK. However, the expected increase in foot-traffic would likely contribute positively to the business model of the establishment. Community pharmacies have also been enhancing their engagement with consumers by providing accessible and convenient health care services. This so called "**point-of-care**" testing includes providing blood pressure monitoring, flu vaccination and blood glucose monitoring [10]. Expansion of the "point of care" model with CIED testing has further enhanced patients' overall health care whilst also promoting collaboration between multi-disciplinary health professionals.

Limitations – Patient/Doctor Relationship

Remote interrogation has clear benefits from a safety and effectiveness perspective, however a compromise of the doctor-patient relationship arises. In-person device interrogation provides an opportunity for patients to receive immediate feedback of their device performance and also ask direct questions, not possible through ReDInK. A lack of immediate feedback may be further magnified as a formal inperson CIED follow-up is only scheduled in the context of abnormal findings. However, it should be noted that all general practitioners (GPs) and caring cardiologists do receive correspondence regarding their patient's ReDInK presentation.

To address this communication issue, there are now plans for both patients and their caring doctors to receive feedback on device interrogation. The value of feedback is further highlighted in the satisfaction survey results, which indicate that three-quarters of individuals want direct feedback of device performance, regardless of outcome.

Future of Remote Interrogation

The main challenges encountered through implementation of ReDInK were logistical in nature. Such issues are addressed with an increase in administrative support to improve coordination and scheduling between patients, pharmacists and the CIED team at the primary hospital centre. Minimal infrastructure is required for set-up (remote modules, pharmacy space and download analysis area in cardiology department).

Our data encourages application on a wider scale. This could be achieved through involvement of multiple community pharmacies across the state. Enrolled patients would be linked to a particular registered cardiology department or provider. Device interrogation modules could then be programmed to automatically transmit the RI data to the cardiology service to which each patient belongs. Expansion of the service would require a dedicated team of logistics staff providing clerical and administrative services, enabling linkage of pacing teams across the state.

Conclusion

The COVID-19 pandemic has required health care systems worldwide to re-evaluate their modus operandi. The close personal proximity of busy in-person CIED clinics, coupled with a highly vulnerable older population, increases both the risk of COVID-19 infection and its potentially devastating consequences. The ReDInK program is a novel and feasible alternative to remote home monitoring, addressing the risks of ongoing deferral of CIED checks during the COVID-19 pandemic whilst maintaining both patient and health care worker safety. We are currently implementing an extension of this service to the metropolitan Melbourne setting.

Financial Support

No external financial support was required for this project.

References

- Liu Y, Mao B, Liang S, Yang J-W, Lu H-W, Chai Y-H, et al. Association between age and clinical characteristics and outcomes of COVID-19. Eur Respir J. 2020;55(5).
- [2] Arnold RH, Tideman PA, Devlin GP, Carroll GE, Elder A, Lowe H, et al. Rural and remote cardiology during the covid-19 pandemic: Cardiac Society of Australia and New Zealand (CSANZ) Consensus Statement. Heart Lung Circ. 2020;29(7):e88–93.
- [3] Kumar S, Haqqani H, Wynn G, Pathak RK, Lipton J, Mahajan R, et al. Position statement on the management of cardiac electrophysiology and cardiac implantable electronic devices in Australia during the COVID-19 pandemic: a living document. Heart Lung Circ. 2020;29(6):e57–68.
- [4] Slotwiner D, Varma N, Akar JG, Annas G, Beardsall M, Fogel RI, et al. HRS expert consensus statement on remote interrogation and monitoring for cardiovascular implantable electronic devices. Heart Rhythm. 2015;12(7):e69–100.
- [5] Varma N, Marrouche NF, Aguinaga L, Albert CM, Arbelo E, Choi JI, et al. HRS/EHRA/APHRS/LAHRS/ACC/AHA worldwide practice update for telehealth and arrhythmia monitoring during and after a pandemic. Heart Rhythm. 2020;17(9):e255–68.
- [6] Hajduk AM, Gurwitz JH, Tabada G, Masoudi FA, Magid DJ, Greenlee RT, et al. Influence of multimorbidity on burden and appropriateness of implantable cardioverter-defibrillator therapies. J Am Geriatr Soc. 2019;67(7):1370–8.
- [7] Uslan DZ, Tleyjeh IM, Baddour LM, Friedman PA, Jenkins SM, St Sauver JL, et al. Temporal trends in permanent pacemaker implantation: a population-based study. Am Heart J. 2008;155(5):896–903.
- [8] Ahmed I, Patel AS, Balgaard TJ, Rosenfeld LE. Technician supported remote interrogation of CIEDs: initial use in US emergency departments and perioperative areas. Pacing Clin Electrophysiol. 2016;39(3):275–81.
- [9] Chen J, Wilkoff BL, Choucair W, Chen TJ, Crossley GH, Johnson WB, et al. Design of the Pacemaker REmote Follow-up Evaluation and Review (PREFER) trial to assess the clinical value of the remote pacemaker interrogation in the management of pacemaker patients. Trials. 2008;9:18.
- [10] Buss VH, Shield A, Kosari S, Naunton M. The impact of clinical services provided by community pharmacies on the Australian healthcare system: a review of the literature. J Pharm Policy Pract. 2018;11(1):22.