**RESEARCH PROTOCOL**

***Full Title:* Virtual ED: The Role of Telehealth in reducing ED attendances.**

# INTRODUCTION

In January 2022, the Alfred, Monash and Peninsula Health Networks set up their own “Virtual EDs” with the primary aim of reducing the number of presentations to our Emergency Departments, through pre-hospital telehealth consultations for patients’ with low acuity presentations. We propose a cohort study of the initial patients who have utilized this service in the hope that the results may add to work done by those previously, and contribute to the refinement of this exciting and increasingly utilized tool in delivery of Emergency Care.

# BACKGROUND

 The recent elevation of Victoria’s COVID-19 response to a state

wide code brown on January 18th, 2022, has prompted many healthcare systems to implement and evaluate strategies to reduce the burden on scarce ambulance and hospital resources. With COVID-19 cases in Victoria peaking at over 50,000 in early January and COVID-19 related hospitalizations reaching record highs of over 1200, it was recognised that our current system could struggle to meet the inevitable demand being placed on it. Compounding this demand is the significant staff shortages faced by many irreplaceable services due to the staff being positive on covid19 testing themselves or being forced to quarantine as close contacts. Thus, there is an urgent need to reduce avoidable emergency department presentations. The use of a ‘Virtual ED’ may allow ambulance services to confidently assess patients as being able to remain at home with ongoing healthcare needs of these patients to be met in the community.

 The Virtual ED was instigated at the Alfred, Peninsula and Monash Health Networks and will run for the foreseeable future, as standard care for patients seeking emergency care and planned by Ambulance Victoria to be transported to one of the relevant Emergency Departments. The model the virtual ED is as follows: paramedics will attend patients who call an ambulance, where they will make a decision regarding the patient’s eligibility to participate in the virtual ED program. If the patient is eligible to participate, the ambulance will call the virtual ED consultant between 12pm-10pm. They are initially seen by a ward clerk to record patient demographics and be given an MRN. They are then seen by the virtual ED clinician who will make a plan regarding patient’s initial management and disposition. A decision will then be made as to whether to treat remotely, or determine an alternative disposition (e.g. outpatient care, teams), or determine that they need to be seen in the ED. The project will involve local clinicians who are familiar with their respective local health system and resources available within Alfred Health and are rostered on to participate as the virtual ED consultant that day. If the patient is diverted from physically attending the ED, then a care coordinator will attempt to call the patient at 24 hours to follow-up with them regarding their status and outcomes.

# AIM OF STUDY / RESEARCH QUESTIONS

* To determine the proportion of patients that participate in a virtual ED consultation who are able to be safely diverted from needing to be physically transported to attend the Emergency Department, and
* To compare the characteristics of patients for whom a virtual ED consult resulted in not physically attending an ED with patients who, following a virtual ED consult, physically attended an ED.

# STUDY DESIGN

Retrospective and Prospective cohort study. From the date of Ethics approval, data will be collected prospectively until the 27/01/2023. Data from patients who have been seen in the Virtual ED between the 27/01/2022 and the date of Ethics approval will have the same data retrospectively collected.

**STUDY SETTING/LOCATION**

1. **Sites**

The Study will take place in Emergency Department across 6 Hospitals: the Alfred Hospital (Alfred Health), Sandringham Hospital (Alfred Health), Monash Medical Centre (Monash Health), Dandenong Hospital (Monash Health), Casey Hospital (Monash Health), Frankston Hospital (Peninsula Health), Rosebud Hospital (Peninsula Health).

# ELIGIBILITY CRITERIA

Inclusion criteria:

* Patient referred to Virtual ED by Ambulance Victoria

Exclusion criteria:

* Nil

# STUDY OUTCOMES

***Primary Outcomes***

* Proportion of virtual ED consults that were able to be diverted from requiring ambulance transport to The Emergency Department for in-person ED attendance.

***Secondary Outcomes***

* Secondary outcomes include: duration of time taken for virtual ED consult, COVID-19 status of virtual ED patient attendances, ED disposition destination for patients who physically attended the ED.
1. **Methods of data collection**
* Identifiable data will be collected to enable analysis at individual sites. Data will be extracted from the Electronic Medical Record and will then be coded and then stored in a secure password-protected hard drive secure servers with each individual Hospital network. Data will be retrieved through a combination of automatic upload onto a secure Redcap data base and through manual chart review, combined with physical entry into the same Redcap databases. Reports containing only contain non-identifiable and summary data will be produced and sent to the principal investigator for collation.
1. **Access to Existing Data**

**N/A**

1. **Data Linkage Management**

Data will be collected at each individual site from individual medical records. Data linking for individual patient encounters will not be required.

1. **Safety considerations**

This research will involve reviewing medical records that are used as part of the routine care for patients using this service. There will be no direct routine intervention on the part of the researchers and are unlikely to be any safety considerations. In the rare circumstance, that the research reviewing the medical records is of the opinion that unsafe practice has been executed by a treating clinician, the advice would be intervene in whatever capacity to protect patient safety.

1. **Data monitoring**

There will be no direct intervention with regards to research in this study. Whilst

monitoring will take place to ensure appropriate research conduct is taking place with regards to protecting patient confidentiality, no formal ongoing monitoring will take place with regards to the performance of the Virtual ED service (which is being conducted as routine care). Each individual Health Network will perform their own quality to audit process to the performance of the service, which will take place separate to research activities.

1. **Protocol Deviations**

Not applicable. There will be nil intervention on the part of the researchers in this project.

1. **Unexpected or Serious Adverse Events**

One potential adverse event that has the potential to occur due to research

 activities would be a confidentiality breach. The principal investigator will use continuous vigilance to identify and report adverse events of this nature within 72 hours of identification of the event to all approving HRECs and relevant Research Governance Officers.

# DATA ANALYSIS

1. **Selection of subjects**

All patients presenting to the Virtual Emergency Departments from inception of the service until the 27th January 2023 will be included in this study.

1. **Statistical methods**

Internal comparison within the cohort will be used to determine the relative risk of re-presentation the Physical Emergency Department following Virtual Emergency Department when comparing various demographic factors (eg. Age, location, presenting complaint etc.). Appropriate statistical methods will be used to facilitate comparison regarding the relative risks of each variable on the re-presentation rate.

1. **De-identification**

Data extracted from patients medical records will be coded and then stored in a secure password-protected hard drive at each site. Patient will not be readily identifiable from the data extracted for this study. Only the principal investigators at each site, and Dr. Lisa Brichko (Alfred Health), will have access to documentation required to enable re-identification of individuals from the study code. This documentation held by each principal investigator will be restricted to only patients that have presented to their respective Health Networks.

# DATA HANDLING AND RECORD KEEPING

1. **Data Collection and Management Responsibilities**

Data collection will be the responsibility of the research staff of name researchers under the supervision of their respective Principal Site Investigator in their affiliated Health Network. The Principal Site Investigators will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

Raw Data will be collected from medical records at each individual Health Network. Data will be de-identified and processed and then sent to project Principal Investigator in a de-identified summary form.

All individual patient data will be stored in secure password-protected hard drives in each of the Health Networks.

The project Principal investigator will have overall responsibility with regards to the overall interpretation and analysis of data, as well as write up of study findings.

1. **Study Records Retention**

Data will be held for period of 7 years, after which point it will be deleted from all servers.

# PUBLICATION & INTELLECTUAL PROPERTY

1. **Dissemination of results to participants**

It is our aim that findings from this study will be published in a peer-reviewed journal. Patients who have had care through the Virtual ED will not be directly contacted with the results of this study.

# ETHICAL CONSIDERATIONS

1. **Indemnity & Compensation for Injury**

Not applicable. There is no intervention on the part of the researchers in this study.

1. **Vulnerable populations**

Vulnerable populations will be part of this study as they will seek care through the Virtual ED. Obtaining informed consent from these individuals is non applicable as a waiver of consent is sought.

1. **Waiver of Consent**

A waiver of consent is sought for the project. Justification, with reference to Section 2.3 of the National Statement is based on the following:

a) Involvement in the research carries no more than low risk (see paragraphs 2.1.6 and 2.1.7, page 18) to participants

*The research involves minimal risk to subjects and participants will be treated according to best current practice. The research does not involve therapeutic intervention or other clinical or diagnostic interventions.*

b) The benefits from the research justify any risks of harm associated with not seeking consent

*The possible benefits of this study – assessing the results and feasibility of the ongoing quality improvement project, to therefore inform and guide possible improvements to standard patient care – justify the risk associated with seeking consent in potentially distressing and traumatic circumstances*

c) It is impracticable to obtain consent (for example, due to the quantity, age or accessibility of records)

*It may be impracticable to gain consent in many cases due to the potentially distressing, traumatic and time-sensitive nature inherent in many emergency medicine consultations*

d) There is no known or likely reason for thinking that participants would not have consented if they had been asked

 *There is no identifiable reason as to why participants would not have consented if they had been asked, given quality of care is not changing throughout this project*

e) There is sufficient protection of their privacy

*Privacy will be protected through the use of a secure storage system, as well as aggregating results to avoid the possibility of identification of individual patients*

f) There is an adequate plan to protect the confidentiality of data

*Data confidentiality will be assured as per section C3 of this proposal.*

g) In case the results have significance for the participants’ welfare there is, where practicable, a plan for making information arising from the research available to them (for example, via a disease-specific website or regional news media)

*All data will be derived from individual patient records and therefore each patient is entitled access to this information.*

h) The possibility of commercial exploitation of derivatives of the data or tissue will not deprive the participants of any financial benefits to which they would be entitled

 *There is no risk of commercial exploitation of participant data*

i) The waiver is not prohibited by State, federal, or international law.

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1. **Confidentiality**

Data will be extracted from patient electronic medical records at each individual Health Network. The desired data will be extracted from the Heath records and stored in a de-identified form with a study id on secure servers managed by the individual Health networks.

De-identified summary data will be sent from the Monash and Peninsula Health networks to the project Principal researchers for collation and analysis periodically.

The Principal site investigators at each Health network will hold documentation which will enable re-identification of study data for the purposes of reviewing for error or seek clarification regarding a presentation. Access to this documentation will not be made available to others involved in the study.

1. **Ethical Review**

Overall ethical approval will be sought from the following HRECs:

* Alfred Health Human Research Ethics Committee

Site specific assessment approval will be sought from the following HRECs:

* Monash Health Human Research Ethics Committee
* Peninsula Health Human Research Ethics Committee

# OUTCOMES AND SIGNIFICANCE

Our study will provide a preliminary insight into the utility of the Virtual ED as a mechanism to attempt to divert physical presentations from the Emergency Departments covering Melbourne’s Southeast to more appropriate avenues of care. These results will provide the basis on which to amend the service moving forward and make decisions regarding the feasibility of this initiative. Eventual publication of results will inform other health services in their design of their own Virtual services.

# REFERENCES

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