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Validation of a Classification to Identify Emergency Department Visits suitable for Subacute and Virtual Care Models: A Randomized Single-Blinded Agreement Study Protocol

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ABSTRACT

Introduction

Redirecting appropriate patients from the emergency department (ED) to alternative subacute settings may assist in reducing ED overcrowding whilst delivering equivalent care. The Emergency Department Avoidability Classification (EDAC) was constructed to retrospectively classify ED visits that may have been suitable for safe management in a subacute or virtual clinical setting. The EDAC has established face and content validity but has not been tested against a reference standard as a criterion.

Objectives

Our primary objective is to examine the agreement between the EDAC and ED physician judgements in retrospectively identifying ED visits suitable for subacute care management. Our secondary objective is to assess the validity of ED physicians' judgement as a criterion standard. Our tertiary objective is to examine how the ED physician's perception of a virtual ED care alternative correlates with the EDAC.

Methods and Analysis

A randomized single centre, single-blinded agreement study. We will randomly select 79 ED charts between January 1 and December 31, 2019 from an academic hospital in Hamilton, Canada. Consenting ED physicians will evaluate randomly assigned ED charts for suitability to have been managed appropriately and safely in subacute or virtual model of care. Each chart will be reviewed by two physicians independently. We will use kappa statistics to measure interrater agreement. A repeated measures regression model of physician ratings will provide variance estimates that we will use to assess the intraclass correlation of ED physician ratings and the EDAC.

Ethics and Dissemination

This study protocol has been approved by the Hamilton Integrated Research Ethics Board, reference 2022-14625. Results will be submitted for publication in a peer-reviewed journal. If validated, the EDAC may provide an ED-based classification to identify potentially avoidable ED visits, monitor ED visit trends, and proactively delineate those best suited for subacute or virtual care models.

Keywords

Epidemiology, patient classification, emergency department, community medicine, health services, health quality.

ARTICLE SUMMARY

Strengths and limitations of this study

- To the best of our knowledge, this is the first study to validate an epidemiological classification against physician determinations a reference standard
- Emergency department physicians will be used as a criterion reference in absence of a 'gold standard' for validation, and examined for interrater reliability
- Single-centre study at an academic hospital
- Validation of this classification could permit epidemiologists to accurately identify retrospective emergency departments visits that were more suitable for subacute or virtual care models
- Physicians are not blinded to identifying data within the patient record, which may incorporate some implicit bias

Introduction

Ontario emergency departments (EDs) are challenged with providing timely medical care despite steady increases in utilization and overcrowding.[1–3] ED's are commonly the first point of contact to engage with the healthcare system, independent of need or ability to seek non-emergency alternatives.[4,5] Non-emergent visits constitute the majority of all ED encounters, and play an important role in determining measures of performance and quality of care (i.e. time to physician assessment, patient satisfaction, overall department workload).[3,6–9] In Ontario, ED utilization by patients with non-emergent conditions has doubled population growth (13.4% vs. 6.2%) in the past decade [6,10] With Ontario's continued population growth, the demand for ED healthcare may continue to increase, further challenging departments to manage an already overburdened workloads.[11–13]

The Emergency Department Avoidance Classification (EDAC) was constructed using a multi-stage, multicentered, consensus process of leading emergency and primary physicians in Ontario, Canada.[3,14] The EDAC aims to retrospectively identify ED visits that could have been appropriately managed in a subacute clinical setting.[3,14] This classification addresses gaps of previously developed models by uniquely identifying informative patient features, beyond acuity or diagnostic category alone.[15–17] Specifically, the EDAC (1) identifies patients that could have sought care in a subacute centre, (2) determines which subacute setting could be appropriate (urgent care and/or general practice), (3) has high specificity to avoid including patients that require ED care, and (4) has established face and construct validity through a consensus process.[10] Limitations of the EDAC's utility persist without understanding it's agreement with a reference standard, and constitutes a challenge in the absence of a gold-standard for comparison.[18,19] If the EDAC can be validated against a criterion standard, such as ED physicians evaluations of potentially avoidable emergency visits, the EDAC could be used to support proactive decision-making about health resource allocation.

Our primary objective is to examine agreement between the EDAC and ED physicians in retrospectively identifying ED visits that could have been redirected to subacute primary care. Our secondary objective is to assess the validity of ED physicians as a criterion standard by examining interrater agreement amongst ED physicians. Our tertiary objective is to examine how the ED physician's perception of a virtual ED care alternative correlates with EDAC and ED physicians' perception of primary care redirection.

METHODS/DESIGN

Study Design and Setting

We will conduct a single centre, single-blinded, randomized agreement study. We will recruit ED physicians from a single-centered academic hospital to review randomly selected electronic ED patient charts. Physicians will rate whether the ED visit could have been safely managed in a subacute care setting and/or via a virtual care visit, while blinded to the EDAC classification. ED charts will be identified as potentially avoidable in this study using the inclusion criteria of the EDAC, and agreement between ED physician ratings and the EDAC will be analyzed. This study will commence in September 2022.

RECRUITMENT OF PHYSICIAN RATERS

Physician Eligibility and Recruitment

Inclusion in our study will require ED physicians to meet the following criteria: (1) currently clinically practicing and (2) holding a staff emergency physician position at the academic hospital. Eligible study physicians will be recruited by the study's principal investigators. An information letter and consent form will be provided, and all will be given the opportunity to review and ask questions prior to enrolling. Upon acceptance, each physician will sign and return a study consent form. A participant demographic questionnaire will be distributed to all physicians to report aggregate characteristic information in the final manuscript (i.e., sex, years of practice, primary practice setting, College designation). Participating physicians will receive financial compensation for completing the study's tasks.

EMERGENCY DEPARTMENT CHARTS

Emergency Department Patient Chart Eligibility

Patient charts will be eligible for inclusion in the study if:

(1) all patient fields that specify the EDAC are inputted (patient age, triage Canadian Triage and Acuity Scale (CTAS), physician main intervention, specialist consult completed, ED visit outcome),
(2) patients did not leave against medical advice, and,
(3) the visit occurred between January 1, 2019 and December 31, 2019. This timeframe represents the most recent 12-month period prior to the Covid-19 pandemic when ED utilization changed.[20]

Chart Selection and Randomization

We will provide the academic hospitals Health Information Management Department with the criteria needed to specify an EDAC visit, shown in *Appendix 1*. ED charts meeting the eligibility criteria will be identified as either an ED visit suitable for management in subacute care model when meeting all EDAC criteria, or not suitable when not all EDAC criteria are met. When eligible ED charts have been identified, study relevant data elements of the charts will be extracted by the academic hospital and provided to the study investigators using an encrypted file. Data from ED charts will include the medical report number (MRN), mode of arrival, month and time of visit, sex, main diagnosis, previously attended the ED within 30 days and all criteria of the EDAC (age, triage acuity, specialist consult conducted in the ED, ED visit disposition, main physician intervention).

We will randomly select 150 ED charts using a block design from the list provided by academic hospital for inclusion in the study. An equal number of ED charts (50) for each block of: all EDAC criteria met, all EDAC criteria met except triage acuity (Canadian Triage and Acuity Scale 3; urgent), and not all EDAC criteria met. The block where all EDAC criteria are met except for triage acuity when the CTAS is urgent will be used to assess the plausibility of a middle-level category not recognized in the EDAC. The EDAC was constructed using a conservative and highly specific approach to identify patients retrospectively, however we hypothesize that judging all urgently triaged patients as ineligible for subacute care models may limit the range of the classification to assess ED visits that are likely to be suitable for subacute models.

We will assign all ED charts used in the study a unique study ID number; the study key matching MRN's with their corresponding study ID will be securing stored with only the principal investigator (PI).

STUDY PROCESS

Data Collection and Handling

We will provide all participating physicians with a password protected Excel file containing all assigned ED chart MRN's to evaluate in the academic hospitals electronic ED database using secure electronic communications. Physicians will be requested to review the ED chart and complete a questionnaire within the Excel file related to this specific ED chart. Following completion, the Excel file will be returned to the PI using secure electronic communication.

We will randomly distribute ED charts evenly amongst the participating physicians. Each individual ED chart must be rated in duplicate by independent physicians, and no two physicians can be paired to rate an ED chart more than once in each block.

Outcome Measures

Table 1 shows the data collection questionnaire for the outcome measures. First, physicians will be requested to judge whether an ED visit could have been appropriately and safely managed in a subacute and/or virtual care model. Physicians will be permitted to select multiple care settings, and will be asked to provide a confidence score of each selection. Physicians will be given a 5-point Likert scale to rate their confidence in their decision, ranging from not confident (1) to very confident (5).[21] Descriptions, definitions, staffing, diagnostic imaging and care services (i.e. laboratory, pharmaceutical) will be provided for each centre to align understanding amongst physicians prior to ratings, shown in *Appendix 2*.[3]

Table 1: Ratings questionnaire to be completed by each participating physician at time of blinded ED chart review.

Study Question	Possible Answers	Confidence score*
From a retrospective position, which of the following care settings **could** have appropriately and safely managed this ED visit? *(Select all that apply)*	• Urgent care centre • Family medicine walk-in care centre • Virtual care with an emergency physician • Virtual care with a family physician • Only the emergency department	(1) Not Confident (2) Slightly Confident (3) Moderately Confident (4) Very Confident (5) Extremely Confident
From a retrospective position, which of the following is the **best** care setting to appropriately and safely manage this ED visit? *(One selection only)*	• Urgent care centre • Family medicine walk-in care centre • Virtual care with an emergency physician • Virtual care with a family physician • Only the emergency department	(1) Not Confident (2) Slightly Confident (3) Moderately Confident (4) Very Confident (5) Extremely Confident
Note: ED = emergency department. * A confidence score will be requested for each care setting selection.		

Blinding

Physicians will be blinded to the EDAC criteria and the randomization block. The ED charts format, information or presentation will not be altered in any way for the study. ED charts

will be shown in the format they expect when completing the charts at the time of a patients ED visit.

Data Handling

All Excel questionnaires and related study documents will be stored and only accessible to the PI. After all questionnaires have been completed and returned to the PI, all questionnaires will be combined for analytical purposes. At this time, all MRN's will be removed and replaced with their study ID numbers to minimize any risk of MRN reidentification. All study files returned to the PI will be stored in a locked computer as an encrypted file, only accessible to the PI until deidentification occurs (MRN's substituted with study ID's). Following the completion of the study the MRN cross walk will be permanently deleted.

Study Steps

Figure 1 shows a summary of all study steps to assemble the study data used to compute the analysis.

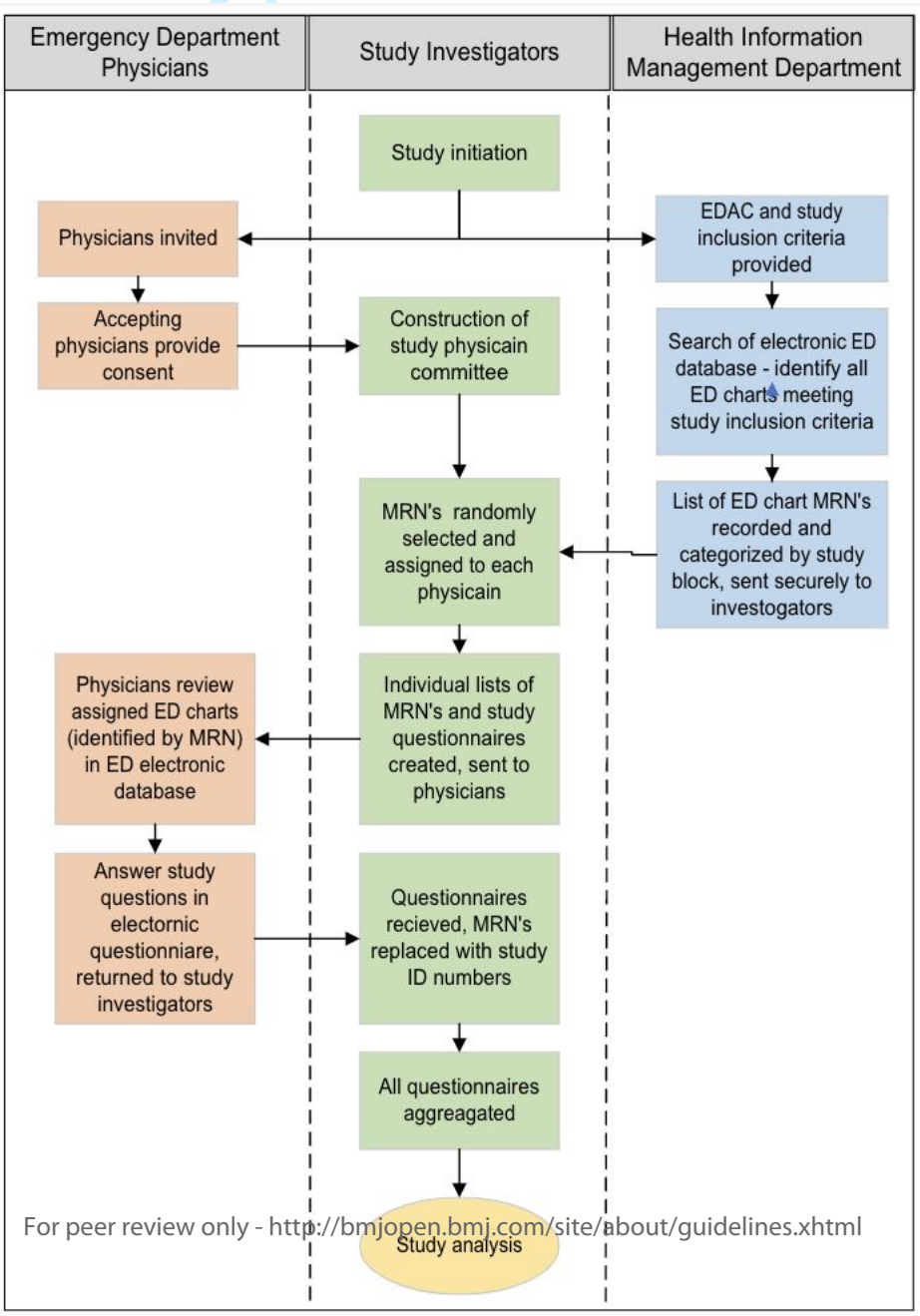

Figure 1: Steps to collect study data from recruited academic hospital physicians.

Sample Size Estimates

We estimate this study will require a minimum of 79 ED charts to be reviewed by two independent physicians to draw meaningful conclusions using a 95% confidence interval, though we aim to complete 100 ED charts to increase our sample size and statistical power.

Based on 80% (± 5%) physician agreement for subacute care suitability and chance agreement estimated at 25%, we expect a Cohen's kappa statistic of 0.8. This kappa constitutes a very high level of agreement to infer study conclusions that are beyond the probability of chance, though a kappa of 0.6-0.8 will be acceptable which indicates substantial agreement.[22] We estimate a minimum sample size of 79 ED charts are required given a minimum acceptable Kappa of 0.6, our anticipated Kappa of 0.8, proportion of the outcome is 0.5 (binary outcome, yes/no of redirection suitability), a 0.05 alpha (two-tailed), using a power of 70%.[23]

We estimate a minimum of 12 physicians should be recruited to participate in this study. Given each physician has an equal chance of being paired with another participant to rate one ED chart, but cannot occur twice, we estimate each physician will rate 13 ED charts. We will encourage participants to complete more ED charts than their minimum, and make every effort to recruit more than 12 participants. We estimate a single ED chart may take two to five minutes to complete, culminating in 25 to 60 minutes of study contributions from each participant.

Statistical Plan

Participant demographic and ED chart descriptive statistics will be reported using general measures of central tendency and frequency.

Physician ratings will be tested as a criterion standard by computing the interrater quadratically-weighted kappa agreement of all ED charts. Criterion will be established if a kappa of 0.6 is achieved on ED charts where the EDAC criteria was met. To examine the agreement of physician ratings with the EDAC, a repeated measures regression model will calculate a variance estimate, which will inform the final computation of an intraclass correlation.

To examine a possible mid-level category outside the inclusion of the EDAC, the ED charts that met all EDAC criteria but were assigned a CTAS 3 will be compared to the EDAC using repeated measures regression model and intraclass correlation analysis, and compared to the first intraclass correlation model.

ED physician perceptions of virtual care ED alternatives will be measured for interrater kappa agreement of all ED charts. A kappa regression will be computed with physician answers and their confidence scores.

Patient and Public Involvement

Potential implications of this study's findings were discussed with Ontario ED clinicians and epidemiologists to gauge their satisfaction with this study's methodology and outcomes. This protocol received input from ED's across Ontario, where frontline ED clinicians were asked focused questions on their perspectives of alternative healthcare centres for patients that require primary care. Additionally, clinicians were asked to speculate on patient's perceptions of alternative healthcare centres and whether they would have been more appropriate than the ED. All input helped to modify the study design.

ETHICS AND DISSEMINATION

Ethics Approval

This study protocol has been approved by the Hamilton Integrated Research Ethics Board (HiREB), review reference 2022-14625-GRA.

Risk to Participating Physicians

No known risks to physicians are anticipated as a result of study participation. Participating physicians will be asked to review and rate ED patient charts, a task that is within their scope of clinical practice. Psychological distress is unlikely, though withdrawal is permitted at any time for any reason (i.e., burden of time). All physicians will be informed of their rights and can terminate their participation without any consequence, with their data withdrawn upon request.

Confidentiality

All participating physicians of this study will have their anonymity maintained by the researchers. All documents will be stored securely and are only assessable by the investigators.

Results Dissemination

The results of this study will be made public through peer-reviewed publication, study registries, conference publications and thesis manuscripts. Communications will be sent to relevant stakeholders with the study's results for distribution in reports and newsletters.

DISCUSSION

Assessing criterion validity for EDAC against an independent standard could establish EDAC as an accurate identifier of retrospective ED visits potentially manageable in non-ED centres.[24] Additionally, with appropriate validation, this algorithm could be used to proactively delineate patients better suited for subacute clinical settings. Leveraging physician determinations as a criterion is an appropriate measure to test experimental validity in this

circumstance, as there are no gold standard classification to establish appropriateness or have not been experimentally validated.[25] Given validation testing tends to perform better on data used to construct a classification or scale, examining EDAC with a panel of physicians who are unaware of the EDAC's components can provide a more unbiased estimate of EDAC's true accuracy and performance.[19,26,27] This also mimics clinical practice, were emergency physicians are not given this information during clinical decision-making. If the performance of EDAC is validated against a criterion standard using complete ED records, this could be a strong indicator the EDAC is reproducible and generalizable to new settings as a criterion to describe avoidable ED visits.[18]

If validated, the EDAC could be established as an authentic benchmark to inform numerous epidemiological fields, including prehospital, paramedicine, emergency, virtual, and primary care. In paramedicine, the EDAC could support prospective research in alternative destination models of care and aim to improve the safety of paramedic clinical judgements regarding transport decision making. In emergency medicine, the EDAC could be used to identify patients' cohorts for further research to understand rationales and healthcare seeking behaviours of patients that sought scarce ED resources when non-ED care alternatives were as appropriate. The EDAC could inform virtual care applications to classify which ED visits may have been avoidable with support of a virtual care visit with a physician, and support virtual care as a model for further research. Epidemiologically, the EDAC could help to provide an ED-based resource to explain ED appropriateness and monitor trends in ED resources over time. Lastly, an output of this study could construct an ordinal scale, instead of a binary classification, which could aid in describing likely avoidable ED visits, but are not recognized in EDAC.

To our knowledge, this is the first study to examine an ED avoidance classification for criterion validity. This research study is methodologically rigorous and sufficiently powered to evaluate the experimental validity of EDAC. This research has the potential to contribute evidence to support new care models of care development that can identify patients that sought ED care, when subacute alternatives were likely more appropriate.

Several outcomes are plausible from this study that are informative of validation of ED physicians as a criterion and the EDAC as a validated classification. If ED physician's perceptions of ED charts are in agreement, ED physicians can be established as an appropriate criterion standard. If a criterion is established and demonstrates agreement with the EDAC, the EDAC can demonstrate criterion validity. In circumstances where ED physician perceptions do not agree on ratings of ED charts, an appropriate criterion standard cannot be created. In absence of establishing a criterion standard but the perceptions are not significantly different from between rater agreement with the EDAC, the EDAC could be determined to be no different than ED physician perspectives, thus cannot be validated.

This study conveys a risk the EDAC may not be validated by an external group of physicians for retrospective epidemiological purposes. However, we contend the high internal validity process used to construct the EDAC has assembled a favourably conservative inclusion criteria that carries the highest potential for validation. We anticipate the EDAC classification to establish criterion validity in this study.

Study Timeline

We expect to conduct this study between September and November 2022, with probable publication by January 2023. The academic hospital's ED physicians will be recruited beginning in September 2022 and may occur throughout the study period. Assignment of ED charts to participants will occur from October to November 2022, with data collection occurring upon completion of each ED chart review. Analyses of results will occur at the conclusion of the study, anticipated for December 2022.

Acknowledgements

Not applicable.

Contributions

RPS, SM and APC led the conceptualization of the study objective and methodology. RPS designed the study, drafted and revised the manuscript. RPS and LEG computed the estimated sample size and statistical plan. All authors made critical revisions to the design, methodology and manuscript, and agreed to be accountable for all aspects of this manuscript.

Competing Interests

The investigators declare that they have no competing interests.

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Appendix 1

Criteria of the Emergency Department Avoidability Classification (EDAC)

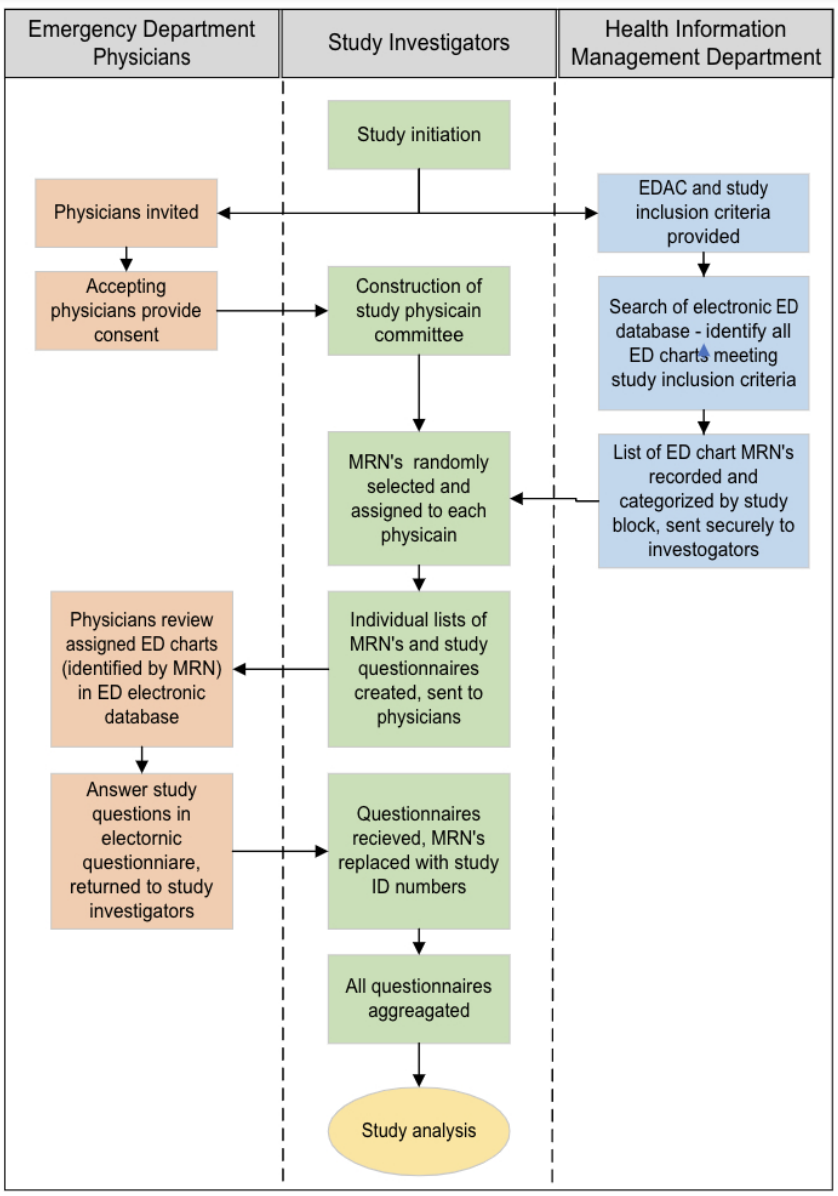
Patient Characteristic	Categorization	EDAC Specification	NACRS Object Name	NACRS Codification
Age	Years	18 to 70	AGE	18 to 70
Triage Acuity	Canadian Triage and Acuity Scale (CTAS)	4 and 5	TRIAGE	4 and 5
Specialist consult performed in the ED	Yes/No	No specialist consult performed in the ED	CONSULTDATE1	*NA* or missing value
ED Visit Disposition	Categorical	Discharged from ED	VISDISP2005	1, 15, 16, 17
Main Physician Intervention	Canadian Classification of Health Interventions (CCI)	Appendix 1[14]: Strum RP, Tavares W, Worster A, Griffith LE, Costa AP. Emergency department interventions that could be conducted in subacute care settings for patients with nonemergent conditions transported by paramedics: a modified	INCODE1	1ET13CAZ9, 1ET13CAGX, 1ET13CANP, 1PM52CATS, 1NQ57CJ, 1VG03JASR, 1TA03JASQ ,1NF53CATS, 1KX53HAFT, 1PM54CATS, 1NF54HATS, 1GZ32CAMY, 1LZ35HHC7, 1NQ35CAZ9, 1GZ35CAR3, 1ZZ35HAC1, 1ZZ35HAK4, 1ZZ35HAN1, 1ZZ35HAP2, 1NP73JH, 1UB73JA, 1YE80LA, 1YA80LA, 1YA80JAFF, 1YA80LAW4, 1YS80LA, 1YT80LA, 1YT80JAFF, 1YC80LA, 1YF80LA,

		Delphi study. *Can Med Assoc Open Access J.* 2022;10(1):E1-E7. doi:10.9778/cmajo.20210148		1YF80JAFF, 1YF80LAW4, 1YW80LA, 1YB80LA, 1YB80JAFF, 1YB80LAW4, 1YU80LA, 1YU80JAFF, 1YU80LAW4, 1YV80LA, 1YV80JAFF, 1YD80LA, 2ZZ02ZZ, 2HZ24JAXJ, 2PM58VE, 2PM58VD, 2GZ58TA, 2NQ70CA, 2ZZ13RA, 3OT30DA, 3OT30LA, 3KG30DC, 3PM30DA, 3RZ30DA, 3RZ30LA, 3PC30DA, 3VZ30DA, 3QG30DA, 3GY30DA, 3JU30DC, 3KR30DA, 3KR30DC, 3KR30DD, 3OT10VA, 3WA10VA, 3SM10VA, 3TM10VA, 3EI10VA, 3VC10VA, 3WG10VA, 3UZ10VA, 3VA10VA, 3TK10VA, 3UL10VA, 3PS10VA, 3VG10VA, 3GT10VA, 3EE10VA, 3ET10VA, 3SQ10VA, 3TV10VA, 3SL10VA, 3SF10VA, 3TA10VA, 3EQ10VA, 3SC10VA, 3SK10VA, 3GY10VA, 3VQ10VA, 3UB10VA, 6AA02CP, 6AA02SK, 6AA02ZZ, 6AA10AD, 6AA10BE, 6AA10CD, 6AA10CT, 6AA10MA, 6AA10ZZ, 6AA30CTAA, 6VA02ZZ, 7SP10ZZ, 8MK70HABK
Note: NACRS = National Ambulatory Care Reporting System				

Appendix 2

Descriptions of healthcare centre staffing and diagnostic resources.

	Emergency Department	Urgent Care Centre	Walk-In Medical Clinic	Virtual Care with ED Physician	Virtual Care with Family Physician
Staffing					
Physician	Yes	Yes	Yes	Yes	Yes
Registered Nurse	Yes	Yes	Possibly	No	No
Medical Radiation Technologist	Yes	Yes	No	No	No
Pharmacist	Yes	Yes	No	No	No
Diagnostic Imaging					
Computer Tomography (CT)	Yes	No	No	No	No
Magnetic Resonance Imaging (MRI)	Yes	No	No	No	No
X-Ray	Yes	Yes	No	No	No
ECG Cardiac Monitoring	Yes	Yes	Yes	No	No
Phlebotomy (Blood Draw)	Yes	Yes	Yes	No	No
Ultrasound	Yes	Yes	No	No	No
Services					
Blood Lab Onsite	Yes	Yes	No	No	No
Pharmaceuticals	Yes	Yes	No	No	No



Steps to collect study data from recruited academic hospital physicians.

123x174mm (144 x 144 DPI)

BMJ Open

Validation of a Classification to Identify Emergency Department Visits suitable for Subacute and Virtual Care Models: A Randomized Single-Blinded Agreement Study Protocol

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Validation of a Classification to Identify Emergency Department Visits suitable for Subacute and Virtual Care Models: A Randomized Single-Blinded Agreement Study Protocol

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ABSTRACT

Introduction

Redirecting suitable patients from the emergency department (ED) to alternative subacute settings may assist in reducing ED overcrowding whilst delivering equivalent care. The Emergency Department Avoidability Classification (EDAC) was constructed to retrospectively classify ED visits that may have been suitable for safe management in a subacute or virtual clinical setting. The EDAC has established face and content validity but has not been tested against a reference standard as a criterion.

Objectives

Our primary objective is to examine the agreement between the EDAC and ED physician judgements in retrospectively identifying ED visits suitable for subacute care management. Our secondary objective is to assess the validity of ED physicians' judgement as a criterion standard. Our tertiary objective is to examine how the ED physician's perception of a virtual ED care alternative correlates with the EDAC.

Methods and Analysis

A randomized single centre, single-blinded agreement study. We will randomly select ED charts between January 1 and December 31, 2019 from an academic hospital in Hamilton, Canada. ED charts will be randomly assigned to participating ED physicians who will evaluate if this ED visit could have been managed appropriately and safely in a subacute and/or virtual model of care. Each chart will be reviewed by two physicians independently. We compute our needed sample size to be 79 charts. We will use kappa statistics to measure interrater agreement. A repeated measures regression model of physician ratings will provide variance estimates that we will use to assess the intraclass correlation of ED physician ratings and the EDAC.

Ethics and Dissemination

This study has been approved by the Hamilton Integrated Research Ethics Board, 2022-14625. If validated, the EDAC may provide an ED-based classification to identify potentially avoidable ED visits, monitor ED visit trends, and proactively delineate those best suited for subacute or virtual care models.

Keywords

Epidemiology, patient classification, emergency department, community medicine, health services, health quality.

ARTICLE SUMMARY

Strengths and limitations of this study

- To the best of our knowledge, this is the first study to validate an epidemiological classification against physician determinations as a reference standard
- Emergency department physicians will be used as a criterion reference in absence of a 'gold standard' for validation, and examined for interrater reliability
- Single-centre study at an academic hospital
- Validation of this classification could permit epidemiologists to accurately identify retrospective emergency departments visits that were more suitable for subacute or virtual care models
- Physicians are not blinded to personal health identifying information within the patient record, which may incorporate some implicit bias

Introduction

Ontario emergency departments (EDs) are challenged with providing timely medical care despite steady increases in utilization and overcrowding.[1–3] ED's are commonly the first point of contact to engage with the healthcare system, independent of need or ability to seek non-emergency alternatives.[4,5] Non-emergent visits constitute the majority of all ED encounters, and play an important role in determining measures of performance and quality of care (i.e. time to physician assessment, patient satisfaction, overall department workload).[3,6–9] In Ontario, ED utilization by patients with non-emergent conditions has doubled population growth (13.4% vs. 6.2%) in the past decade [6,10] With Ontario's continued population growth, the demand for ED healthcare may continue to increase, further challenging departments to manage already overburdened workloads.[11–13] Challenges of ED overcrowding extend beyond Canada; international research reports similar increases in patient volumes and longer admission times.[14–16]

The Emergency Department Avoidance Classification (EDAC) was constructed using a multi-stage, multicentered, consensus process of leading emergency and primary physicians in Ontario, Canada.[3,17] The EDAC aims to retrospectively identify ED visits that could have been appropriately managed in a subacute clinical setting.[3,17] This classification addresses gaps in previously developed models by uniquely identifying informative patient features (beyond acuity or diagnostic category alone), and including criterion validity examination, a core component for generalizability absent from numerous ED classifications.[18–20] Specifically, the EDAC (1) identifies patients that could have sought care in a subacute centre, (2) determines which subacute setting could be appropriate (urgent care and/or general practice), (3) has high specificity to avoid including patients that require ED care, and (4) has established face and construct validity through a consensus process.[10] Limitations of the EDAC's utility persist without understanding its agreement with a reference standard, and constitutes a challenge in the absence of a gold-standard for comparison.[21,22] If the EDAC can be validated against a criterion standard, such as ED physician evaluations of potentially avoidable emergency visits, the EDAC could be used to support proactive decision-making about health resource allocation.

Our primary objective is to examine agreement between the EDAC and ED physicians in retrospectively identifying ED visits that could have been redirected to subacute primary care. Our secondary objective is to assess the validity of ED physicians as a criterion standard by examining interrater agreement amongst ED physicians. Our tertiary objective is to examine how the ED physician's perception of a virtual ED care alternative correlates with EDAC.

METHODS/DESIGN

Study Design and Setting

We will conduct a single centre, single-blinded, randomized agreement study. We will recruit ED physicians from a single academic hospital to review randomly selected electronic ED patient charts. ED charts will be categorized into three study blocks based on the EDAC criteria. Physicians will rate whether the ED visit could have been safely managed in a subacute care setting and/or via a virtual care visit, while blinded to the study block the ED chart belongs. ED charts will be identified as potentially avoidable in this study using the inclusion criteria of the EDAC, and agreement between ED physician ratings and the EDAC will be analyzed. This study will commence in September 2022.

RECRUITMENT OF PHYSICIAN RATERS

Physician Eligibility and Recruitment

Inclusion in our study will require ED physicians to meet the following criteria: (1) currently clinically practicing and (2) holding a staff emergency physician position at the academic hospital. Eligible study physicians will be recruited by the study's principal investigators. An information letter and consent form will be provided, and all will be given the opportunity to review and ask questions prior to enrolling. Upon acceptance, each physician will sign and return a study consent form. A participant demographic questionnaire will be distributed to all physicians to report aggregate characteristic information in the final manuscript (i.e., sex, years of practice, primary practice setting, College designation). We estimate a minimum of 10 physicians should be recruited to participate in this study. Participating physicians will receive financial compensation equivalent to their hourly compensation for completing the study's tasks.

EMERGENCY DEPARTMENT CHARTS

Emergency Department Patient Chart Eligibility

Patient charts will be eligible for inclusion in the study if:

(1) all patient fields that specify the EDAC are inputted (patient age, triage Canadian Triage and Acuity Scale (CTAS), physician main intervention, specialist consult completed, ED visit outcome),
(2) patients did not leave against medical advice, and,
(3) the visit occurred between January 1, 2019 and December 31, 2019. This timeframe represents the most recent 12-month period prior to the Covid-19 pandemic when ED utilization changed.[23]

Chart Selection and Randomization

We will provide the academic hospitals Health Information Management Department with the criteria needed to specify an EDAC visit, shown in *Appendix 1*. When eligible ED charts have been identified, study relevant data elements of the charts will be extracted by the academic hospital and provided to the study investigators using an encrypted file. Data from ED charts will include the medical report number (MRN), mode of arrival, month and time of visit, sex, main diagnosis, previously attended the ED within 30 days and all criteria of the EDAC (age, triage acuity, specialist consult conducted in the ED, ED visit disposition, main physician intervention). Due to personal health identification legislation, only these features of the ED charts can be extracted, not the entire ED chart.

We will group all eligible ED charts into one of three study blocks. Assignment to a study block will be dependent on an ED charts alignment with the EDAC, categorized as: (1) all EDAC criteria met, (2) all EDAC criteria met except with an urgent triage acuity (Canadian Triage and Acuity Scale 3), and (3) not all EDAC criteria met. Block 2 will be used to assess a plausible middle-level of the EDAC, where some ED visits could have been suitable for subacute care models but are not recognized by the EDAC. We hypothesize that classifying all urgently triaged patients as ineligible for subacute care models may limit the range of the classification to assess ED visits that are likely to be suitable for subacute models. Given the EDAC was constructed using a conservative and highly specific approach to identify patients retrospectively,

a middle-level classification concerning EDAC visits but with an urgent acuity is plausible and warrants investigation.

We will randomly select an equal number of ED charts from each block, these will be used as the study charts. We will assign all ED charts used in the study a unique study ID number; the study key matching MRN's with their corresponding study ID will be securely stored with only the principal investigator (PI).

Sample Size Estimates

We estimate this study will require a minimum of 79 ED charts to be reviewed by two independent physicians to draw meaningful conclusions using a 95% confidence interval, though we aim to complete more than this minimum to increase our sample size and statistical power.

Based on 80% (± 5%) physician agreement for subacute care suitability and chance agreement estimated at 25%, we expect a Cohen's kappa statistic of 0.8. This kappa constitutes a very high level of agreement to infer study conclusions that are beyond the probability of chance, though a kappa of 0.6-0.8 will be acceptable which indicates substantial agreement.[24] We estimate a minimum sample size of 79 ED charts are required given a minimum acceptable Kappa of 0.6, our anticipated Kappa of 0.8, proportion of the outcome is 0.5 (binary outcome, yes/no of redirection suitability), a 0.05 alpha (two-tailed), using a power of 70%.[25] We aspire to complete 126 ED chart reviews given feasibility, which would increase our study's power to an optimal 80%.

STUDY PROCESS

Data Collection and Handling

We will provide all participating physicians with a password protected Excel file containing all assigned ED chart MRN's to evaluate in the academic hospital electronic ED database using secure electronic communications. Physicians will be requested to review the ED chart and complete a questionnaire within the Excel file related to this specific ED chart. Following completion, the Excel file will be returned to the PI using secure electronic communication.

We will randomly distribute ED charts evenly amongst the participating physicians. Each individual ED chart must be rated in duplicate by independent physicians, and no two physicians can be paired to rate an ED chart more than once in each block. Given each physician has an equal possibility of being paired with another participant to rate one ED chart, but cannot occur twice, we estimate each physician will rate 13 ED charts. We will encourage physicians to complete more ED charts than their minimum, and make every effort to recruit more than 12 physicians. We estimate a single ED chart may take two to five minutes to complete, culminating in 25 to 60 minutes of study contributions from each participant.

Outcome Measures

Table 1 shows the data collection questionnaire for the outcome measures. First, physicians will be requested to judge whether an ED visit could have been appropriately and safely managed in a subacute and/or virtual care model. Physicians will be permitted to select multiple care settings. Physicians will be given a 5-point Likert scale to rate their confidence in their decision, ranging from not confident (1) to very confident (5).[26] Descriptions, definitions, staffing, diagnostic imaging and care services (i.e. laboratory, pharmaceutical) will be provided for each centre to align understanding amongst physicians prior to ratings. Second, physicians will be requested to judge which of the subacute or virtual care models is the best care centre that could have managed this ED visit. A second 5-point Likert scale will be used to rate the confidence in their selection. All study questions were reviewed independently by three ED physicians (none eligible for study inclusion), no interpretation issues were identified.

Table 1: Study questions to be completed by each physician for each ED chart review.

Study Question	Possible Answers	Confidence score*
From a retrospective position, which of the following care settings **could** have appropriately and safely managed this ED visit? *(Select all that apply)*	• Urgent care centre • Family medicine centre (with their family physician) • Family medicine walk-in care centre • Virtual care with an emergency physician • Virtual care with a family physician • Only the emergency department	(1) Not Confident (2) Slightly Confident (3) Moderately Confident (4) Very Confident (5) Extremely Confident
From a retrospective position, which of the following is the **best** care setting to appropriately and safely manage this ED visit? *(One selection only)*	• Urgent care centre • Family medicine centre (with their family physician) • Family medicine walk-in care centre • Virtual care with an emergency physician • Virtual care with a family physician • Only the emergency department	(1) Not Confident (2) Slightly Confident (3) Moderately Confident (4) Very Confident (5) Extremely Confident
Note: ED = emergency department. * A confidence score will be requested for each care setting selection.		

Blinding

Physicians will be blinded to the knowledge of the EDAC criteria or components, and the study block to which an ED chart belongs. The ED charts format, information and presentation will not be altered in any way for the study. ED charts will be shown in the format the physicians expect when completing the charts at the time of a patient's ED visit.

Data Handling

All Excel questionnaires and related study documents will be stored and only accessible to the PI. After all questionnaires have been completed and returned to the PI, all questionnaires will be combined for analytical purposes. At this time, all MRN's will be removed and replaced with their study ID numbers to minimize any risk of MRN reidentification. All study files returned to the PI will be stored in a locked computer as an encrypted file, only accessible to the PI until deidentification occurs (MRN's substituted with study ID's). Following the completion of the study the MRN cross walk will be permanently deleted.

Study Steps

Figure 1 shows a summary of all study steps to assemble the study data used to compute the analysis.

Figure 1: Steps to collect study data from recruited academic hospital physicians.

Statistical Plan

Participant demographic and ED chart descriptive statistics will be reported using general measures of central tendency and frequency.

Physician ratings will be tested as a criterion standard by computing the interrater quadratically-weighted kappa agreement of all ED charts. Criterion will be established if a kappa of 0.6 is achieved on ED charts where the EDAC criteria were met. To examine the agreement of physician ratings with the EDAC, we will use a repeated measures regression model to calculate a variance estimate. This variance estimate which will inform the final computation of an intraclass correlation of the EDAC in each block.

To examine if a plausible middle-level could be incorporated into the EDAC, physician ratings of the EDAC visits that have an urgent triage acuity (block 2) will be compared to the EDAC (block 1) using repeated measures regression model and intraclass correlation analysis, and compared to the first intraclass correlation model.

ED physician perceptions of virtual care ED alternatives will be measured for interrater kappa agreement of all ED charts. A kappa regression will be computed with physician answers and their confidence scores.

Patient and Public Involvement

Potential implications of this study's findings were discussed with Ontario ED clinicians and epidemiologists to gauge their satisfaction with this study's methodology and outcomes. This protocol received input from ED's across Ontario, where frontline ED clinicians were asked focused questions on their perspectives of alternative healthcare centres for patients that require primary care. Additionally, clinicians were asked to speculate on patient's perceptions of alternative healthcare centres and whether they would have been more appropriate than the ED. All input helped to modify the study design.

ETHICS AND DISSEMINATION

Ethics Approval

This study protocol has been approved by the Hamilton Integrated Research Ethics Board (HiREB), review reference 2022-14625-GRA.

Risk to Participating Physicians

No known risks to physicians are anticipated as a result of study participation. Participating physicians will be asked to review and rate ED patient charts, a task that is within their scope of clinical practice. Psychological distress is unlikely, though withdrawal is permitted at any time for any reason (i.e., burden of time). All physicians will be informed of their rights

and can terminate their participation without any consequence, with their data withdrawn upon request.

Confidentiality

All participating physicians in this study will have their anonymity maintained by the researchers. All documents will be stored securely and are only assessable by the investigators.

Results Dissemination

The results of this study will be made public through peer-reviewed publication, study registries, conference publications and thesis manuscripts. Communications will be sent to relevant stakeholders with the study's results for distribution in reports and newsletters.

DISCUSSION

Assessing criterion validity for the EDAC against an independent standard could establish EDAC as an accurate identifier of retrospective ED visits potentially manageable in non-ED centres.[27] Additionally, with appropriate validation, this algorithm could be used to proactively delineate patients better suited for subacute clinical settings. Leveraging physician determinations as a criterion is an appropriate measure to test experimental validity in this circumstance, as there is no gold standard classification to establish appropriateness or have not been experimentally validated.[28] Given validation testing tends to perform better on data used to construct a classification or scale, examining EDAC with a panel of physicians who are unaware of the EDAC's components can provide a more unbiased estimate of EDAC's true accuracy and performance.[22,29,30] This also mimics clinical practice, were emergency physicians are not given this information during clinical decision-making. If the performance of EDAC is validated against a criterion standard using complete ED records, this could be a strong indicator the EDAC is reproducible and generalizable to new settings as a criterion to describe avoidable ED visits.[21]

If validated, the EDAC could be established as an authentic benchmark to inform numerous epidemiological fields, including prehospital, paramedicine, emergency, virtual, and primary care. In paramedicine, the EDAC could support prospective research in alternative destination models of care and aim to improve the safety of paramedic clinical judgements regarding transport decision-making. In emergency medicine, the EDAC could be used to identify patients' cohorts for further research to understand rationales and healthcare seeking behaviours of patients that sought scarce ED resources when non-ED care alternatives were as appropriate. Additionally, the EDAC could be leveraged to develop a prospective tool for ED triage to direct care resources, and compared to standard practices in future research. The EDAC could inform virtual care applications to classify which ED visits may have been avoidable with support of a virtual care visit with a physician, and support virtual care as a model for further research. Epidemiologically, the EDAC could help to provide an ED-based resource to explain ED appropriateness and monitor trends in ED resources over time. Lastly, an output of this study could construct an ordinal scale of the EDAC, instead of a binary classification, which could aid in describing likely avoidable ED visits that presently not recognized in the EDAC criteria.

To our knowledge, this is the first study to examine an ED avoidance classification for criterion validity. This research study is methodologically rigorous and sufficiently powered to

evaluate the experimental validity of EDAC. This research has the potential to contribute evidence to support new care models of care development that can identify patients that sought ED care, when subacute alternatives were likely more appropriate.

Several outcomes are plausible from this study that are informative of validation of ED physicians as a criterion and the EDAC as a validated classification. If ED physician's perceptions of ED charts are in agreement, ED physicians can be established as an appropriate criterion standard. If a criterion is established and demonstrates agreement with the EDAC, the EDAC can demonstrate criterion validity. In circumstances where ED physician perceptions do not agree on ratings of ED charts, an appropriate criterion standard cannot be created. In absence of establishing a criterion standard but the perceptions are not significantly different from between rater agreement with the EDAC, the EDAC could be determined to be no different than ED physician perspectives, thus cannot be validated.

This study conveys a risk the EDAC may not be validated by an external group of physicians for retrospective epidemiological purposes. However, we contend the high internal validity process used to construct the EDAC has assembled a favourably conservative inclusion criteria that carry the highest potential for validation. We anticipate the EDAC classification to establish criterion validity in this study.

Study Timeline

We expect to conduct this study between September and November 2022, with probable publication by January 2023. The academic hospital's ED physicians will be recruited beginning in September 2022 and may occur throughout the study period. Assignment of ED charts to participants will occur from October to November 2022, with data collection occurring upon completion of each ED chart review. Analyses of results will occur at the conclusion of the study, anticipated for December 2022.

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Not applicable.

Contributions

RPS, SM and APC led the conceptualization of the study objective and methodology. RPS designed the study, drafted and revised the manuscript. RPS and LEG computed the estimated sample size and statistical plan. SM, FIB, AW, LEG, WT, PM, EH, KA, RS and APC made critical revisions to the design, methodology and manuscript, and agreed to be accountable for all aspects of this manuscript.

Competing Interests

The investigators declare that they have no competing interests.

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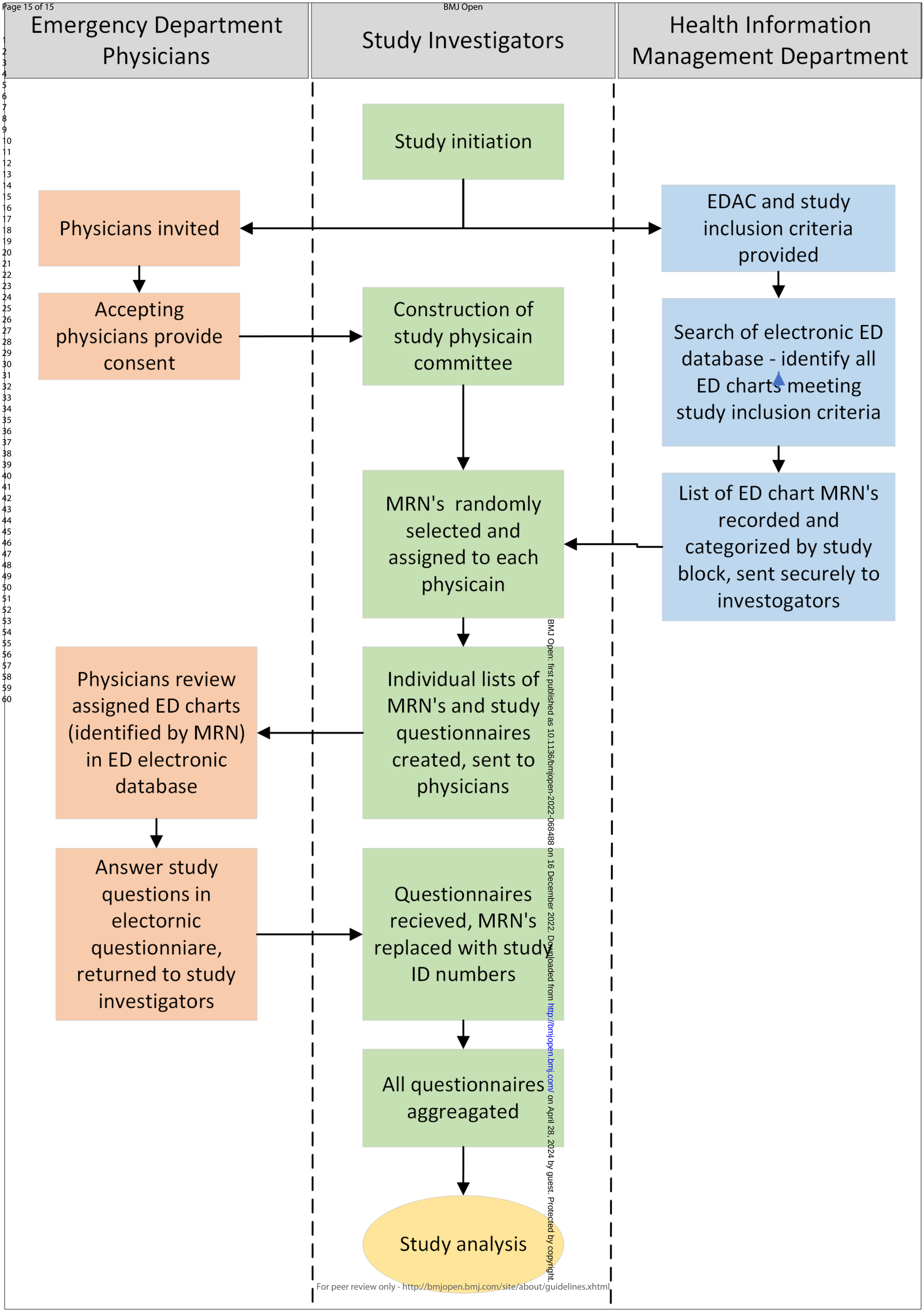

Appendix 1

Criteria of the Emergency Department Avoidability Classification (EDAC).

Patient Characteristic	Categorization	EDAC Specification
Age	Years	18 to 70
Triage Acuity	Canadian Triage and Acuity Scale (CTAS)	4 and 5
Specialist consult performed in the ED	Yes/No	No specialist consult performed in the ED
ED Visit Disposition	Categorical	Discharged from ED
Main Physician Intervention	Canadian Classification of Health Interventions (CCI)	Appendix 1[17]: Strum RP, Tavares W, Worster A, Griffith LE, Costa AP. Emergency department interventions that could be conducted in subacute care settings for patients with nonemergent conditions transported by paramedics: a modified Delphi study. *Can Med Assoc Open Access J.* 2022;10(1):E1-E7. doi:10.9778/cmajo.20210148