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# Driving Change: A Partnership Study Protocol Using Shared Emergency Department Data to Reduce Alcohol-related Harm

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# Driving Change: A Partnership Study Protocol Using Shared Emergency Department Data to Reduce Alcohol-related Harm

## ***Abstract (249/250)***

**Background:** Sharing anonymised emergency department (ED) data with community agencies to reduce alcohol related injury and assaults has been found effective in the United Kingdom. This protocol document outlines the design of an Australian multi-site trial using shared, anonymised ED data to reduce alcohol-related harm.

**Design and Method:** Nine hospitals will participate in a 36-month stepped-wedge cluster randomised trial. After a nine month baseline period, EDs will be randomized in five groups, clustered on geographic proximity, to commence the intervention at three-monthly intervals. “Last-drinks” data regarding alcohol use in the preceding 12 hours, typical alcohol consumption amount, and location of alcohol purchase and consumption, are to be prospectively collected by ED triage nurses and clinicians at all nine EDs as a part of standard clinical process. Brief information flyers will be delivered to all ED patients who self-report risky alcohol consumption. Public Health Interventions to be conducted are: 1) information sharing with venues (via letter), and 2) with police and other community agencies, and 3) the option for public release of ‘Top 5’ venue lists.

**Outcomes:** Primary outcomes will be (a) the number and proportion of ED attendances among patients reporting recent alcohol use, and (b) the number and proportion of ED attendances during high alcohol hours (Friday and Saturday nights, 8pm-6am) assigned an injury diagnosis. Process measures will assess logistical and feasibility concerns, and clinical

impacts of implementing this systems-change model in an Australian context. An economic cost-benefit analysis will evaluate the economic impact, or return on investment.

***Keywords:***

emergency department, alcohol, violence, assault, injury, public health intervention

This study protocol outlines the design of a multi-site trial evaluating the impact of sharing emergency department (ED) data on alcohol-related harm within the Australian context. The World Health Organization promotes the distribution and usage of ED data as a major component in public health approaches to prevent injuries.<sup>1, 2</sup> An emerging trend is the use of ED recorded data on assaults and alcohol-related injuries as a tool for targeting police and other regulatory community level interventions (for e.g. "TASC" - Tackling Alcohol-related Street Crime).<sup>3</sup> The method of anonymised ED data sharing to reduce injury, violence, and assaults has been frequently referred to as the 'Cardiff model'. In a systematic review of evidence for the model,<sup>4</sup> seven of eight included studies were conducted in United Kingdom (UK) EDs. All studies that attempted to measure intervention effectiveness reported substantial reductions of assaults and ED attendances post-intervention, with the exception of one, which reported no change.<sup>5-12</sup> In Cardiff, UK, police-recorded assault rates fell from seven to five a month per 100,000 population compared with an increase from five to eight in comparison cities.<sup>8</sup> Over a 6-year post data-sharing period in Wirral, UK, ED attendances for intentional injuries decreased by 35.6% and alcohol-related assault attendances decreased by 30.3%.<sup>5</sup> Economic evaluations estimate that the cumulative social benefit is £82 GBP for each pound spent on the programme, with a Cost-Benefit Ratio of 14.8 for the health service and 19.1 for the criminal justice system.<sup>13</sup>

Intervention trials of the Cardiff data-sharing model have yet to be implemented in Australia. The public health interventions in this study are based on sharing of anonymised data collected through "last drinks" questions asked of all ED patients in participating hospitals. A pilot project conducted in a single hospital in regional Australia demonstrated the feasibility of collecting these data, which indicate sources and locations of alcohol-related harm.<sup>14</sup> During this six month pilot trial, 10.8% of injury patients reported consuming alcohol in the 12 hours prior to injury. During high-alcohol-hours (HAH; 20:00 Friday to 06:00

Saturday and 20:00 Saturday to 06:00 Sunday), alcohol-related injuries accounted for 36.1% of all ED injury presentations. In total, 41.7% of alcohol-related attendances during HAH were among patients who reported consuming last drinks at identifiable hotels, bars, nightclubs or restaurants, or identifiable public areas/events. Approximately two thirds (60.2%) of attendances with alcohol-related presentations had purchased their alcohol at packaged liquor outlets. The pilot demonstrated the feasibility of implementing sustainable “last-drinks” data collection methods in the ED with minimal cost to the hospital, very high acceptance and cooperation rate amongst triage staff, and no impact to the quality of patient care.<sup>14</sup>

Based on the success of the pilot study, we are undertaking an Australian multi-site stepped-wedge randomised clustered trial evaluating the impact of sharing anonymised ED data on alcohol-related harm. This protocol paper outlines the design of the trial, which has been funded by the National Health and Medical Research Council (NHMRC) Partnership Project scheme and St Vincent’s Hospitals Australia with additional self-funding support provided by The Canberra Hospital, ACT Health.

## ***Method***

### ***Interventions***

Three public health data sharing interventions are based on the approaches previously trialled and reported in the UK by Shepherd et al.<sup>4</sup> Similar avenues exist in Australia for public health interventions around alcohol as exist in the UK, such as dissemination of intelligence through state and city level police and liquor licensing bodies, and established systems of liquor accords and violent venues registers. Data can be also be used to inform and strengthen

opposition to liquor expansions and developments, and provides an important additional source of information for licensing regulators.

### ***Public Health Interventions***

All sites will engage in intervention methods (i) and (ii), with the option to opt out of intervention (iii) at the discretion of local partner investigators.

*(i) quarterly letter to licensed venues outlining how many ED presentations were among individuals who had been drinking in their venue prior to attendance*

In this intervention, the research team generate customised letters for the top five venues reported at each ED, outlining the number of attendances related to their business, anonymised details of the cases including prognoses and, where appropriate, anonymised photos of injuries. Letters will be delivered via the Australasian College of Emergency Medicine (ACEM) to registered licensees.

*(ii) anonymised quarterly data sharing with local authorities*

In intervention *ii*, de-identified, aggregated data is prepared and shared with local police, licensing authorities and local government, identifying the top five venues reported in the relevant ED and providing an aggregated summary of alcohol-related attendances to the ED.

*(iii) quarterly public reports ranking the top five venues reported in the ED and giving anonymous case studies of the associated short and long term harms with excessive alcohol consumption*

Intervention *iii* will publicly report aggregated data every three months for each of the selected hospitals via press release from ACEM, about the source of alcohol for patients with alcohol-related presentations and the number of cases of 'last drinks' attendances for each local venue. Research support staff employed at each hospital will work with clinical staff to generate brief anonymised case studies to accompany data releases. Press releases will be publicly available for download via the ACEM website, will be distributed to local and state media outlets per site, and publicized via ACEM social media channels such as Twitter. ACEM Public Affairs staff will monitor media coverage and estimated audience demographics and exposure for each release for the duration of the project.

### ***Patient brief information pamphlet***

During project development, clinical partners highlighted the service-delivery importance of including an immediate, patient-focused information handout in response to the information obtained through the data collection model. In an effort to proactively reduce drain on resources, many EDs utilise the presentation of alcohol-related injury and harm as an opportunity to motivate reduction in the patients' alcohol consumption and subsequent risk behaviours.<sup>15</sup>

There are mixed findings from reviews, trials and meta-analyses assessing the effectiveness of brief ED-based interventions at reducing risky alcohol consumption and harms, with conclusions varying according to the type and outcome measures. One systematic review reported no impact of single session intervention upon alcohol consumption,<sup>16</sup> and an alternate meta-analysis also concluded that brief interventions based in the ED had no significant effect upon consumption but had a small effect in reduced self-reported incidence of injury at patient follow-up.<sup>17</sup> As such, the inclusion of a clinical information handout in the current model meets a clinical obligation and strikes the best balance of evidence, cost, and clinical demand, but is not expected to result in significant changes in the outcome measures.

Double-sided A4 information handouts will be provided to all attendances who self-report risky alcohol consumption above the NHMRC guideline of two standard drinks on any day,<sup>18</sup> and will be delivered during control and intervention phases of the project. Handouts contain structured advice for reducing alcohol consumption, Australian population drinking norms, and referral information for local services, in a format adapted from the Simple Structured Advice Intervention tool.<sup>15</sup>

## ***Design***

A stepped-wedge design will be used, with the duration of the trial being 36 months (Figure 1). The stepped-wedge cluster randomised trial is a form of cross-over design with unidirectional cross-over (from control to intervention). In the application of this design, the public health intervention will be introduced in a staggered roll-out where the sequence of clusters (i.e. emergency departments) and time-period is randomly allocated at the start of the trial.<sup>19-21</sup> All clusters sequentially cross-over into an intervention-delivery phase in a randomly selected order, until all EDs are delivering the intervention (Figure 1). The stepped wedge design was deemed most appropriate because the intervention model has demonstrable effectiveness in previous international trials, and the design makes the best use of the number of participating emergency departments. A stepped wedge design is ideal for scenarios where a body of evidence for the intervention exists, yet a controlled trial evaluation is still required.<sup>22</sup> In this study, the model strikes a balance between the researcher's need for a randomised trial to demonstrate evidence of effectiveness, and the pragmatic and clinical requirements of service partners who are responsible for providing evidence based practice.

Randomisation of the clusters was conducted using a random number sequence by a biostatistician not involved in the project. Clusters were determined according to geographic

location, with EDs located closely to each other grouped within the same cluster to minimize the risk of contamination of effect between clusters.

Outcomes are measured in each ED at every time period, hence measurement of outcomes takes place at each step in the wedge; each ED provides data points in the control and intervention conditions allowing each ED to act as its own control.<sup>23</sup> .

INSERT FIGURE 1 HERE.

### ***Setting and Participants:***

The nine EDs that have committed to participate are located in Melbourne, Sydney, Canberra, and two are located in regional centres Geelong and Warrnambool, both in Victoria. In the 2013/14 financial year participating EDs had a combined total of 490,000 attendances.

### ***Patient Inclusion and Exclusion criteria:***

Inclusion criteria are all attendances by patients aged  $\geq 18$  years, and being sufficiently alert and oriented to respond to study items either at triage or follow-up. Exclusion criteria are patients aged  $< 18$ , those suffering from a severe or life-threatening injury or illness, a serious mental health problem, being too intoxicated to respond to clinician questions, or being excluded at the discretion of the administering clinician. As such, in addition to *Yes* and *No*, clinicians have the following response categories available for question one of the data collection model: *Non-Communicative*: Patient is unconscious, too intoxicated or impaired to respond; *Refused*: Patient refuses to answer the question; *Unknown*: Patient is confused, or offers an unintelligible response; *Ethical*: Clinician perceives a cultural or interpersonal issue, or other clinical judgement, that makes the questions inappropriate; *NESP*: patient is of non-English speaking background.

### ***Data Collection Model***

The key principle of the last-drinks intervention model is that information is collected systematically and mandatorily, and that this information is used as intelligence guiding public health level interventions. All patients presenting to the ED who meet inclusion criteria are screened for alcohol intake. Every ED will implement systematic data collection and respond with a brief information pamphlet for every patient who screens positive for hazardous alcohol use. Implementation at each site requires modification of existing ED information systems to create a mandatory and reliable system that will have minimal impact to established clinical process (see Figure 2).

Study data (Figure 2) are prospectively collected by ED triage nurses, clerks, and clinicians at all nine EDs as a part of standard clinical process continuously throughout the data collection period of 36 months. During the 36-month data collection period, research staff employed by the participating hospitals will extract and de-identify the last drinks data. These de-identified data will be provided to the research team for analysis and preparation of intervention materials. Starting at nine months and subsequently at each three-month interval, clusters of EDs will commence delivering the public health intervention according to the randomisation schedule.

INSERT FIGURE 2 HERE

### ***Measures:***

#### *Outcome measures:*

Primary outcomes will be (a) both the absolute number and proportion of presentations (per total number of presentations within inclusion criteria) in which the patient reports alcohol use via the proposed data collection system, and (b) both the number and proportion of presentations (per total number of presentations within inclusion criteria) assigned an

injury diagnosis that also occurred during 'high alcohol hours' (HAH; 20:00 Friday to 06:00 Saturday and 20:00 Saturday to 06:00 Sunday, recorded at time of triage). This data coding method has been employed in a number of previous studies.<sup>24-26</sup>

*Process measures:*

Previous research by Boyle et al.<sup>12</sup> found that staff acceptance of the data collection model was high when combined with feedback of project results. Process measures will monitor the logistical and feasibility concerns, barriers, challenges, and clinical impacts of implementing the intervention model in an Australian context. A sample of 80 clinical staff at participating EDs will be sought for anonymous, self-completed staff experience surveys at 1, 6, 12, 24, and 36-month intervals following the commencement of data collection. Staff surveys will address estimated completion time, experience of negative feedback or negative patient reactions, reasons for avoiding or skipping study items, and perceptions of the value of the model overall. Further data will be collected regarding added time to clinical interactions and administration process. Staff feedback will be provided to all ED site managers via bi-monthly newsletters to be distributed to ED staff.

*Economic evaluation:*

The economic evaluation will use tools of economic appraisal to estimate the return on investment associated with the intervention.<sup>27</sup> The analysis requires the development of a logic pathway to describe the aims of a research project, the activities undertaken and the subsequent research outcomes. The logic pathway will use the available evidence to estimate the likelihood that the research outcomes will be adopted by the end-user (i.e., clinicians, policy makers, police). Program costs including labour and non-labour costs will be monitored and collected throughout the intervention period. A comparison of the economic benefits (observed changes in the primary outcomes (a) number of presentations (per total

number of presentations within inclusion criteria) in which the patient reports alcohol use via the proposed data collection system, and (b) both the number of presentations (per total number of presentations within inclusion criteria) assigned an injury diagnosis that also occurred during 'high alcohol hours' (HAH; 20:00 Friday to 06:00 Saturday and 20:00 Saturday to 06:00 Sunday), with the economic costs of the program, provides an indication of the return on investment, or the cost-benefit of the program. Sensitivity analysis will be conducted to test the robustness of results where parameter uncertainty may exist.

***Analysis Plan and Power Calculations:***

Based on previous data the expected proportion of presentations that are alcohol related is 11% and the proportion during high-alcohol hours is 36%. A six month pilot trial of the data collection returned a data compliance rate of 100%, including 3.1% of patients who were recorded as declining a response or non-responsive.<sup>14</sup> Power and sample size calculations were undertaken using Stata's "*steppedwedge*" program.<sup>28</sup> Each ED is expected from previous data to contribute an average of 26,000 total attendances over a six month period of the study (total of 36 months). Using an average cluster size of 26,000 and an Intra-class Correlation of 0.05, with 80% power and a 5% level of significance, a sample size of 1,404,000 total attendances would be large enough to detect a difference between intervention and control proportions of alcohol-related attendances of 0.3% (i.e. 11% - 10.7%). This would allow for a relative risk reduction for alcohol-related injuries of 3% (11% - 10.7% / 11%) to be detected.

Generalised linear mixed models will be used to model all outcome measures. These models will have a fixed effect for time to adjust for any temporal variation in the outcome and an indicator variable to estimate the effect of the intervention. The models will also include random effects for the variation between clusters and the variation between time

within a cluster. These will account for the repeated measures on clusters over the duration of the study with the potential for seasonal effects.

## **Conclusions**

The current approach to monitoring the burden associated with alcohol and other drug use in Australian EDs is flawed. There is no systematic method of screening and monitoring the alcohol (or drug)-related harm for patients attending the ED, nor is there any method of identifying the sources of these harms in the community. The proposed study will provide an evaluation of an innovative approach to reducing alcohol-related harm in Australia.

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The authors would like to thank Emergency Department clinicians and administrative staff at all participating hospitals who have agreed to support this project.

***Conflicts of Interest***

Peter Miller has acted as a paid expert witness in legal proceedings on behalf of a licensed venue and a security firm.

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|           | T <sub>0</sub> | T <sub>1</sub> | T <sub>2</sub> | T <sub>3</sub> | T <sub>4</sub> | T <sub>5</sub> | T <sub>6</sub> | T <sub>7</sub> | T <sub>8</sub> | T <sub>9</sub> | T <sub>10</sub> | T <sub>10</sub> |
|-----------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|----------------|-----------------|-----------------|
| Cluster   | 3m             | 6m             | 9m             | 12m            | 15m            | 18m            | 21m            | 24m            | 27m            | 30m            | 33m             | 36m             |
| A (2 EDs) | 0              | 0              | 0              | 0              | 1              | 1              | 1              | 1              | 1              | 1              | 1               | 1               |
| B (3 EDs) | 0              | 0              | 0              | 0              | 0              | 1              | 1              | 1              | 1              | 1              | 1               | 1               |
| C (1 ED)  | 0              | 0              | 0              | 0              | 0              | 0              | 1              | 1              | 1              | 1              | 1               | 1               |
| D (1 ED)  | 0              | 0              | 0              | 0              | 0              | 0              | 0              | 1              | 1              | 1              | 1               | 1               |
| E (2 EDs) | 0              | 0              | 0              | 0              | 0              | 0              | 0              | 0              | 1              | 1              | 1               | 1               |

**Figure 1 - Stepped wedge cluster randomised trial design for nine emergency departments (ED) grouped into five geographic clusters**

0 = control; 1 = intervention active (all sites perform intervention (i) and (ii), and can opt-in to (iii))  
 Un-shaded (1) areas are the periods in which intervention is active. Grey shaded (0) area represents the control period where baseline data are collected. Geographic clustering: (a) Southwest Victoria, 2 EDs; (b) Eastern Suburban Melbourne, 3 EDs; (c) Central Melbourne, 1 ED; (d) Central Sydney, 1ED; and (e) Canberra, 2 EDs.

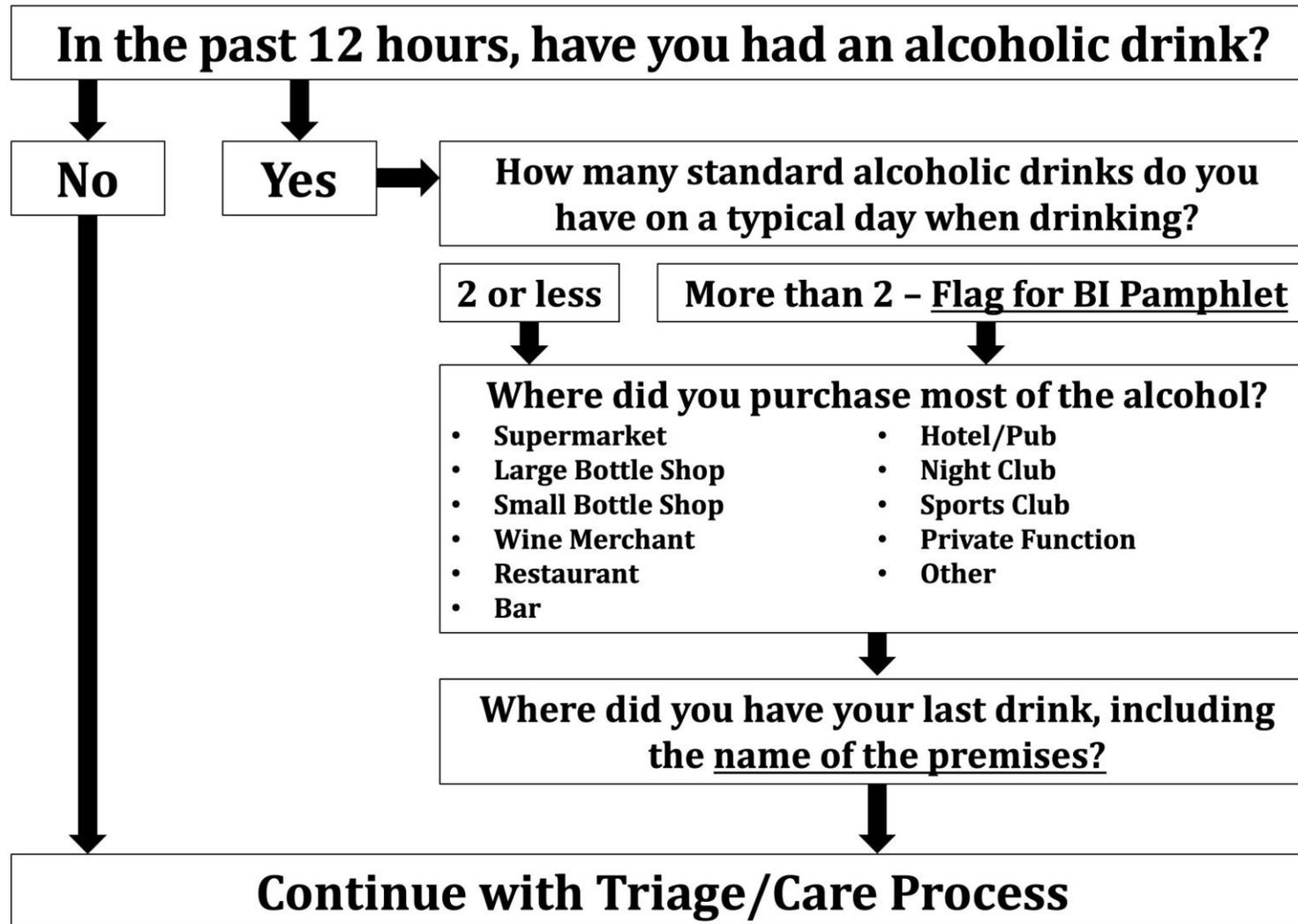


Figure 2 – Mandatory data collection model