

Running Head: EDVIPE

**Protocol: Effectiveness and Cost-Effectiveness of a Clinical Violence Prevention Team
Based in the Emergency Department**

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Abstract

Introduction

Hospital-based violence intervention programmes, based in Emergency Departments (EDs), have been proposed as a public health response to address the underlying reasons why patients attending with assault-related injuries are exposed to violence. It is believed that addressing underlying vulnerabilities will reduce the likelihood of subsequent violence and attendance to ED generally. Despite worldwide interest in HVIPs there has been no rigorous evaluation of this approach to violence.

Methods and Analysis

A controlled longitudinal natural experiment. Analysis of primary outcome data is on an Intention to Treat basis, with secondary analyses considering a per-protocol analysis. Intervention engagement is defined as a patient agreeing to engage with the VPT, and a patient's or responsible guardian's signature is required on the VPT patient referral form to that effect. (i) The intervention is expected to reduce the recurrence of unscheduled ED attendance, the primary outcome, analysed using recurrent event analysis. (ii) Our second hypothesis is that the implementation of the intervention improves ARA ascertainment. The expectation is an increase in the proportion of injuries identified as an ARA in intervention sites, analysed using interrupted time series analysis. (iii) To determine whether the VPT represents value for money. From the perspective of the NHS, with all NHS costs considered in the base case and health outcomes measured in quality-adjusted life-years. Other health care outcomes measures will also be considered.

Comparator group

Control patients will be those attending a Welsh ED with an assault-related injury and propensity score matched to case patients. They are eligible if they are normally resident in Wales, aged 11 years and older and attended non-intervention Type I ED with an assault-related injury.

Discussion

This is a whole-population, definitive study on the effectiveness and cost effectiveness of two hospital-based violence prevention teams. The expectation that the results of which will be of interest across the United Kingdom and worldwide, and results will be dissemination through the academic literature.

Key words: Emergency Department, Assault, Violence, Injury, Prevention, Treatment

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Title

Protocol: The Effectiveness and Cost-Effectiveness of a Clinical Violence Prevention Team Based in the Emergency Department

Introduction

There is a strong case for hospital-based violence intervention programmes (HVIPs) based in Emergency Departments (EDs) (1-3). HVIPs have recently emerged as a public health response to violent victimisation (3, 4), but despite interest in HVIPs there has been no rigorous evaluation of this public health approach to violence in the United Kingdom (UK). The overarching aim of the proposed work is an effectiveness and cost-effectiveness study of an ED based Violence Prevention Team (VPT). The VPT provides a HVIP with two main functions: the identification and support of patients attending ED with assault-related injury and a broader pedagogical role that increases awareness of these patients' needs in the ED.

Despite uncertainty over effectiveness in a UK context, HVIPs have been widely implemented. For example, the Scottish Violence Reduction Unit has placed Navigators (www.mav.scot/navigator) in EDs, volunteers who connect with assault-related attendances (ARAs) who are typically 25 years of age and younger (5). There is a lack of evidence for ED referral of children involved in violence (6), domestic violence (7, 8) and there is a paucity of robust studies considering referrals for young men involved in violence, the most dominant population in respect of ARA (9), with even fewer studies of victims of sexual violence (10) attending ED.

The need for HVIPs is aligned to broader UK Government initiatives, which aim to promote a whole system multi-agency (WSMA) (11) approach to violence. The 1998 Crime and Disorder Act requires the police, local government, and the National Health Service (NHS) to collaborate on joint crime reduction strategies and this includes data sharing to inform targeted responses. Violence is further prioritised by the UK Government in its Serious Violence Strategy (12) and the UK government has allocated funds for the formation of Violence Reduction Units (VRUs) in England and Violence Prevention Units (VPUs) in Wales, across 18 Police and Crime Commissioner jurisdictions, with the explicit purpose of promoting the WSMA approach (13). These motivations are further aligned with a move towards active population health management, digitally enabled whole-person care and evidence-based treatment pathways outlined in the NHS future plan (14). Integrated Care Systems in NHS England will be expected include violence prevention and reduction standards, which are to be incorporated into the 2021/22 NHS Standard Contract, and there are expectations that hubs will form violence prevention teams like the police VRUs. Furthermore, a public sector duty on partnerships encouraging the prioritisation of serious violence is now before the UK parliament as a part of the Police, Crime, Sentencing and Courts Bill. This legislation includes a serious violence duty placing a statutory obligation on organisations to collaborate, communicate, and act.

EDs work with patients attending with violence-related injuries and engage in broader violence reduction initiatives. Clinical staff typically receive training in adult and paediatric safeguarding, and many EDs have provision to identify and refer children and victims of domestic and sexual violence. However, methods of ascertainment and referral vary considerably and formal relationships with the police and other partners can often lack consistency with multiagency approaches not capturing the entirety of patients' journeys. The need for a public health approach involving the ED is therefore evident. It is particularly notable as, in 2019, there were 175,764 assault-related attendances (ARAs) to EDs in England and Wales (15) and, despite the pandemic, 119,111 ARAs in 2020 (16). Knife crime, and therefore serious trauma, has risen by 71% from 2014 to 2018 (17). Because up to 75% of ARAs are unknown to the police (18-20), EDs hold exclusive data on assault characteristics, and patient

vulnerability and are therefore well situated to play a significant role in the identification of violence, to investigate the circumstances of violence, and to challenge any underlying vulnerability exposing patients to violence.

The overarching aim of the proposed work is a robust effectiveness and cost-effectiveness evaluation of ED-based VPTs. VPTs represent a formal collaboration between police and healthcare, and embody the WSMA approach to violence prevention, in as far as ARAs are screened and referred according to underlying need. This is the first formal evaluation of an ED based HVIP in the UK and will address significant gaps in our understanding of their effectiveness and thereby facilitate future aspirations for evidenced-based referral pathways (14, 21) and a WSMA approach to violence prevention in the UK.

Theoretical Framework

The theoretical motivation for a WSMA approach is that there are many individual factors that, in combination, determine an individual's exposure to violence and therefore ARA. Epidemiologically, these can be usefully described by shared circumstances that in turn signpost opportunities to mitigate exposure, but the responsibility for mitigation can fall across organisations, including healthcare and criminal justice. These include the consumption of alcohol and other psychoactive substances; stressors, such as provocation, goal obstruction and social rejection (22-25); sexual exploitation and homelessness (3, 26). Violence tends to be more prevalent in younger, socially disadvantaged groups (27-33), with male, socio-economically deprived individuals being more likely to endure violence and experience assault-related injury. These characteristics further extend to stable personality features (34), including mental health status (35). This complex interplay of factors that promote violence, and therefore ARA, highlight the need for a WSMA approach to violence. For example, an environment might become synonymous with violence through a process of homophily (36), whereby individuals with shared pursuits who are at risk of violence gather, and includes street drinkers and late night drinking environments. Mitigation might include challenging reasons for frequenting such an environment, including alcohol and substance misuse counselling. Some environments might involve those who use violence to advance their interests, such as acquisitive crime, sexual assault, or sexual exploitation. In which case criminal justice or safeguarding processes to deter violence might be involved, along with support to victims. Chaotic or otherwise disadvantaged households in which domestic violence or harm to children arises might best be approached from a multi-agency process such as the Multi-Agency Risk Assessment Committee and formal investigation (Section 47, Children Act 1989). ED is central to this as it is the only agency receiving those who have sustained a serious injury, including those who are motivated to bypass other agencies or whose assailant is motivated to ensure their victim bypasses other agencies.

Treatment for ARA in ED addresses symptoms that may not necessarily characterise the underlying reasons for violence, and staff do not always have the resources or time available to address any underlying vulnerability. However, without addressing those vulnerabilities, the risk of repeat unscheduled ED attendance remains, including violence recidivism. For these reasons, services like VPTs that work within a WSMA approach to better understand reasons for ARA are required. Moreover, and for those who are most vulnerable, ED may be the only realistic opportunity for patients to enter a system of care. As such, ARA is a sentinel event.

Intervention

ARA, and resulting emergency healthcare utilisation, is symptomatic of chronic vulnerabilities, including alcohol and illicit substance abuse. Police-funded ED-based violence prevention initiatives can support and refer patients to services able to address these vulnerabilities, thus reducing the

likelihood of repeat unscheduled ED attendance and violence recidivism. Since October 2019, a VPT, a collaboration between the police and NHS, has been operational in the Cardiff ED; a second VPT will start in Swansea in late 2021. Comprising a nurse and an advocate, VPTs work with the clinical team, who may be reluctant to explore reasons for injuries with patients, to identify and refer patients according to need.

Aims and Objectives

The overarching aim is to determine whether HVIPs are effective and cost-effective from the perspective of NHS EDs.

Objective 1. To assess whether patient involvement with a VPT reduces the likelihood of unscheduled ED re-attendance. We consider case and control patients' ED unscheduled reattendance for a minimum of 12 months following the initial ARA.

Objective 2. To determine whether the presence of the VPT improves ascertainment of ARAs in ED attendances. Across EDs in Wales, we will consider the change in identified ED attendances across intervention implementation in case and control hospitals.

Objective 3. To derive the costs of the VPT and compare those to the benefits of the intervention, and understand whether the VPT represents value for money from a NHS perspective. The cost-effectiveness analyses will mirror the first objectives timeline. If an effect is observed, then models will estimate the savings over a ten-year period and for a national roll-out.

Population and Data

This is a whole-population evaluation, including all residents of Wales, UK.

Inclusion and exclusion criteria

All residents of Wales, United Kingdom are eligible for inclusion. There are no exclusion criteria.

Data

Data is housed in the Secure Anonymised Information Linkage (SAIL) databank (37).

The EDDS, PEDW and Cause of Death data contain sufficient detail to disambiguate healthcare utilisation (e.g., ED attendance, arrival by ambulance, days of admission into hospital, etc.) from the nature of injuries requiring ED attendance (e.g., injury). Patient Group Code (assault, accident, etc.) is a mandatory field in the EDDS, as well as location (home, not home) (44), nature of injury (e.g., injury, poisoning) and location (e.g., head, left arm, etc.). These data are collected as part of usual patient history and is applicable to all case and control patients. There may be patients whose attendance is coded as an injury rather than an assault. The difference, if any, between control and intervention sites with regards ascertainment is primarily structural, due to clinical resource limitations, and it is informative. For ED attendances not admitted to hospital, the EDDS contains diagnostic codes in positions one to six and are defined (e.g., 01a – Laceration, 01b – Contusion, 01c – Abrasion). For ED attendances resulting in admission, ICD10 codes, within a person super-spell (up to 14 locations), are recorded in PEDW at admission, discharge and transfer between specialities (e.g., S00-S99, T00-T65).

Ethics

The approval to access and analyse data housed in the SAIL databank (37), an ISO 27001 certified and UK Statistics Authority accredited secure data environment, was granted by the SAIL independent Information Governance Review Panel (IGRP) (Ref: 1421). The IGRP comprises representatives from various organisations and sectors including the British Medical Association, Welsh Government, Public Health Wales, National Research Ethics Service, Digital Health and Care Wales, Swansea Bay University Health Board, and members of the public. All routinely collected anonymised data held in SAIL are exempt from consent due to the anonymised nature of the databank (Section 251, Control of Patient Information, 2006 National Health Service Act). At no time will identifiable data be available to the research team. ED staff will curate data pertaining to patients exposure to the intervention, which will be passed to NWIS where it will be anonymised and a project specific linkage field (ALF and RALF) added. These data will be passed to SAIL for linkage.

Methods and Analysis

Design and theoretical/conceptual framework

A controlled longitudinal natural experiment.

There is a complex interplay of factors that promote violence, and therefore ARA, highlighting the need for a WSMA approach to violence. There are aspects of support that can be provided by healthcare, and criminal justice will also play a significant role, particularly in challenging offenders. The fact that violence is also associated with socio-economic status highlights the need to consider the circumstances of individuals in respect of intervention effectiveness. While there is a large literature on the causes and consequences of violence, there has been no formal evaluation of VPTs in the UK.

Objective 1

Analysis of primary outcome data is on a conservative Intention to Treat (ITT) basis. Not all ARAs will choose to engage with the VPT, and therefore a secondary per-protocol (PP) analysis will be undertaken. Descriptive analyses will characterise participants included in the ITT population, but not the PP population. Engagement is defined as a patient agreeing to engage with the VPT, and a patient's or responsible guardian's signature is required on the VPT patient referral form to that effect.

We hypothesise that the intervention reduces the recurrence of unscheduled ED attendance, the primary outcome. Recognising that there are also socio-economic characteristics associated with violence (27-31), that are less amenable to change, it is therefore necessary to ensure analyses are balanced for age, gender, ethnicity, deprivation, and urban/rural location. We do this in two ways. In primary analyses by using residential characteristics (e.g., urban/rural) and features prognostic of violence to match case and control patients, and in secondary analyses including these features to control for their influence on outcomes.

Objective 2

Our second hypothesis is that the implementation of the intervention improves ARA ascertainment.

It is feasible that some patients might be reluctant to disclose the reason for any injury. This might be a lifestyle choice or because they are fearful of reprisals. In the context of the VPT, an increase in ascertainment would imply more patients are receiving healthcare support for underlying need. As

processes involved in the management of patients are standardised in Wales and EDs use the same EDDS codes to record an ARA, we assume that any change in the proportion of ARAs identified is attributable to patients' and ED staffs' willingness to discuss the reasons for an injury. While reporting standards are expected to change (work by VS with the Welsh Government stalled due to the pandemic), these would be common across EDs in Wales and not unique to one hospital. We therefore propose a time series (38, 39) of the weekly proportion of injuries identified as assault injuries for each ED in Wales. Analyses can identify any initial change in ascertainment when the intervention was implemented and any subsequent "bedding-in" period. If the VPT fulfils the WSMA approach to violence and encourages clinical staff and patients to disclose injuries that are a result of violence, then the expectation is an increase in the proportion of injuries identified as an ARA in intervention sites. This is further explored in secondary analyses where we consider the referral of ED patients across the healthcare estate.

Objective 3

We aim to determine whether the VPT represents value for money. While the primary outcome concerns ED reattendance, the nature of the intervention means that there are other costs to the NHS, due to referral, which we can capture and include in analyses. There are also additional costs across social care, the police and the third sector. Which we will explore through existing links with these networks and for both control and comparator groups.

Secondary Analyses

We aim to co-produce study protocols with collaborators and provide opportunities for them to shape secondary and additional epidemiological analyses. This facilitates opportunities to realise and contribute to what is a rapidly changing policy area. One example is our inclusion of school attainment, exclusions, and attendance in analyses, which have been highlighted in these early discussions. VPU and VRUs have made little headway working with the education system to challenge the causes of violence, and this has been identified as a priority (40).

Control/comparator group

Control patients will be those attending a Welsh ED with an assault-related injury. Control patients will be propensity score matched to case patients. They are eligible if they are normally resident in Wales, aged 11 years and older and attended non-intervention Type I ED with an assault-related injury. They will become ineligible if they move their residence out of Wales, or do not have a minimum 12-month follow-up period available for analysis. Welsh residents who sustain injury and attend ED outside of Wales, but within the UK, are eligible as these healthcare data are available for analysis. Participants will not be eligible if they were not resident in Wales for three years before becoming eligible for inclusion, in order that baseline characteristics can be included in secondary analyses. Up to the implementation of the Swansea VPT, Swansea patients will be eligible as controls, so long as there is no evidence of contamination.

Progression criteria

This is a definitive study. As the primary focus of the study uses routinely collected data, which is available for analysis subject to information governance permissions and extraction, progression criteria are not applicable.

Sampling

Across Wales, the number of ARAs were 8,272 in 2018, 7,874 in 2019, and 4,466 in 2020.

Between October 2019 and September 2020, the Cardiff VPT engaged with 454 patients (mean age 26.5 years, range 11-86 years; 78.6% male; approximately 86% white British), in ED and emergency admissions of whom 97% accepted VPT support; 20% had sustained injuries due to the use of a weapon, 5% were street homeless, 18% were referred to children's multiagency support services; and 20% were referred to and made a statement to the police. Numbers reduced during the pandemic but are expected to increase substantially as pandemic mitigations relax, except for ARAs where injury occurred in a residential address, where numbers have remained stable across the pandemic (41). We conservatively estimate that there will be 1,800 patients from the four years (2019-2023) of VPT operation in Cardiff, and 900 from two years (2021-2023) operation in Swansea.

Initial estimates from the Cardiff VPT suggest that 3% of those engaging with the VPT reattended ED at least once within one year, compared to 23% patients who did not engage with the VPT. Data from 2015 and 2016 suggest that the frequency of unscheduled attendances for patients with at least one ARA (mean = 2.35 attendances) is greater than patients making an unscheduled attendance without evidence of an assault (mean attendances = 1.73). For a simple Cox survival model, ($\alpha = 0.05$, $\beta = 0.90$) and a hazard ratio of 0.8 a total N of 845 is required. To realise the recurrent nature of analyses, simulation (42) (1,000 estimates per point estimate) was used across varying follow-up periods (Figure), which suggests a 12 month follow-up period and total N of 300 is adequate to identify a significant effect. By increasing the number of controls, statistical power will be further enhanced (43). A similar approach can be used to assess sample size considerations for linear ITSA (44). In Cardiff there is an average of 31.8 (SD = 7.4) ARAs and 347.4 (SD = 82.1) injuries each week. Identifying an additional five injuries as ARAs each week would yield a significant ($p < 0.05$) initial effect for a single group ITSA.

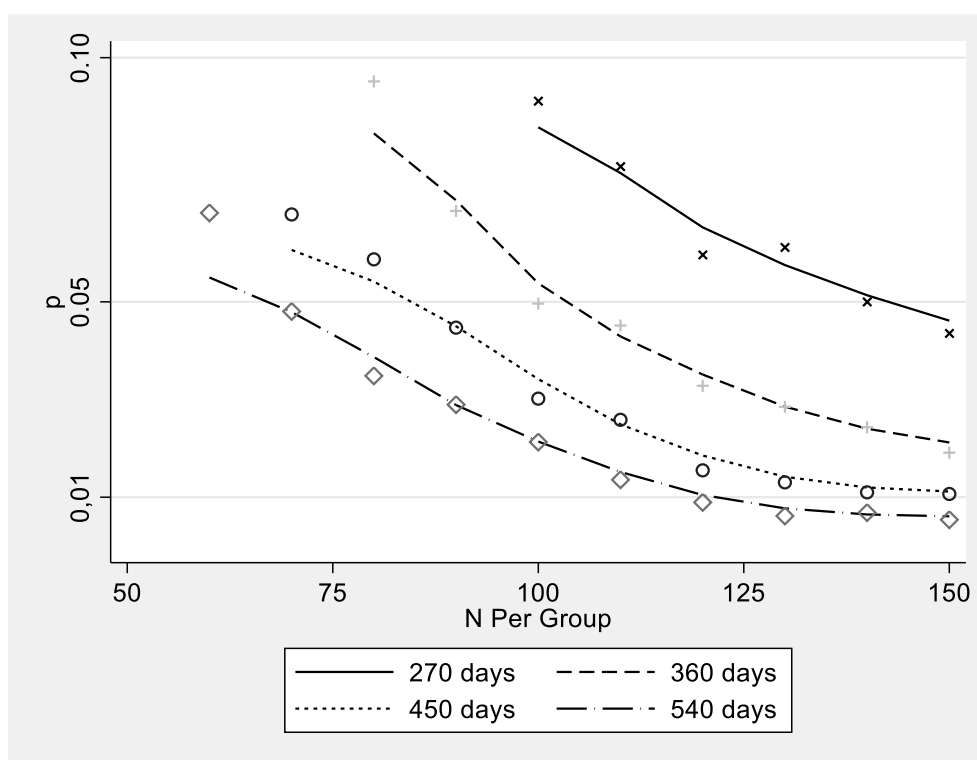


Figure - Simulated Andersen-Gill Models by Follow-up Period and Group Size

Public and Patient Involvement

We have developed an extensive PPI group. Our rationale, reflected in PPI engagement while developing this proposal, is that many of the patients included will be vulnerable. Given that point of contact with the VPT, for some, might be the beginning of their journey, expectations these patients could reflect meaningfully on the VPT within the study timeline is unlikely. Coupled with our experience that follow-up qualitative work with young adults in Emergency Healthcare, the dominant group in ED, requires considerable resources and suffers from high levels of attrition (45), we therefore aim to develop PPI engagement in order that those with experience of the emergency healthcare system are able to feed into the project, co-produce methods, provide their interpretation of the results and assist with interpretation and dissemination. This includes survivors of domestic violence, carers, those who have experienced alcohol and drug dependence, homelessness, sexual exploitation, and mental health issues. Subject to funding, we will also include ALPHA, a PPI group involving young people available through DECIPHer (Centre for Development, Evaluation, Complexity, and Implementation in Public Health Improvement), Cardiff University. One PPI lead, AB, will be responsible for monitoring equality and diversity across PPI groups. We do not involve ARA patients directly. PPI involvement will be captured and reported using GRIPP2 (46) and we include two PPI advocates as co-investigators.

Glossary

ALF	Anonymised Linking Field
ARA	Assault-related Injury
CMD	Common mental disorder
DMEC	Data monitoring and ethics committee
DNA	Did not attend
EDDS	Emergency Department Data Set
ED	Emergency Department
EMRTS	Emergency Medical Retrieval and Transfer Service
HVIP	Hospital-Based Violence Intervention Programme
ICD10	10 th revision of the International Statistical Classification of Diseases
IGRP	Information Governance Review Panel
ITT	Intention to treat
ITU	Intensive Therapy Unit
LSOA	
NHS	National Health Service
NWIS	National Health Service Wales Informatics Service
ONS	Office for national Statistics
PEDW	Patient Episode Database Wales
PP	Per-protocol
Q	Question
QALY	Quality Adjusted Life Year
RALF	Residential Anonymised Linking Field
SAIL	Secure Anonymised Information Linkage
TARN	Trauma Audit and Research Network
UK	United Kingdom
VPT	Violence Prevention Team
VPU	Violence Prevention Unit (Wales)
VRU	Violence Reduction Unit (England)

WIMD	Welsh index of multiple deprivation
WSMA	Whole system multi-agency
YEF	Youth Endowment Foundation

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