Administration of Methoxyflurane (Penthrox™) as a Pre-Hospital Analgesic by Specialist Police Officers; A Retrospective Audit of Patient Report Forms.

Background

Since 2010 specialist firearms police officers have had a medical component as an integral part of their training, a module known as D13. It is recognised that the time directly after trauma or injury is vitally important and there may be times where specialist police officers are on scene with patients and can perform basic, life-saving treatment before medical assistance arrives. The D13 module was formed in collaboration with the Faculty of Pre Hospital Care to set a national standard of training which recognised the need for these officers to have enhanced training in first aid and trauma care to allow them to look after these patients while awaiting arrival of health care professionals. It is important to note that a medically trained police officer is not a registered health care professional and their primary job is as a police officer at all the scenes they attend. The D13 curriculum program has since been renamed as Clinical Skills for Police Officers in Specialist Role and is now undertaken by some officers outside the firearms role.

Since the initiation of this clinical program four audits[1-4] have taken place to ensure standards of care and documentation are being fulfilled. In these it has been noted that most patients attended have a traumatic mechanism of injury, with road traffic collisions (RTCs) and assaults being the most commonly reported, and that pain is the most frequently reported symptom. It was also noted that officers were sometimes spending a significant amount of time on scene with patients before medical help arrived.[1-3] Feedback from these officers highlighted that they thus often had to attend to patients for long periods of time, without the means to provide pain relief to casualties. As a result it was decided to initiate the introduction of an analgesic medication, methoxyflurane, into the training for the officers and review its effectiveness.

Methoxyflurane, better known by its brand name Penthrox™, is an inhaled analgesic "indicated for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain."[5] Penthrox™ is self-administered by the patient under close supervision via disposable handheld inhalers in 3mL vials.[6] It has been licenced in the UK since late 2015 but has been used by emergency services in Australia and New Zealand for over 30 years[5] and accumulated over 6 million uses worldwide.[7]

The training to allow officers to use Penthrox™ is assessed and authorised by a registered doctor and goes beyond the curriculum of the Clinical Skills for Police Officers in Specialist Role program. They follow a strict protocol of how and when it is deemed appropriate for them to use Penthrox™ and the steps taken to document the process. The "Train the Trainer" course is provided by the Anaesthesia Trauma and Critical Care Group (ATACC)[8], who are the official training partners of the drug distributor (Galen Pharmaceuticals). The course is delivered to police force medical instructors who are assessed in their capability to administer Penthrox™ to appropriate patients, understand the clinical governance surrounding its use and to teach these skills to their units. This training is quality assured by their clinical governance lead who then signs off the individual officers' competencies. 25% of the officers from each unit are randomly reviewed for proficiency by clinical governance leads each year, as well as every officer coming through the training program for the first time.

The protocol the officers adhere to is a document developed to "enable a trained person, who has been assessed as competent, to safely administer Penthrox™ inhalation in a non-permissive environment. This will be for emergency relief of moderate to severe acute pain in conscious patients following accidents, burns or other trauma when there is no easy access to medical care."[9] It was developed by the clinical governance leads for the units involved with input from an

independent consultant pharmacist. All the clinical skills learnt by the officers are monitored under strict clinical governance frameworks[10] of training and reporting, and the Penthrox™ protocol was deliberately designed to be more restrictive than might be clinically needed in order to reduce any risks in spreading its use to this group of responders in the UK.

Not all units had access to Penthrox™ at the same, the first unit having its protocol approved in 2017 and the latest in February 2019 (in total one in 2017, four in 2018 and five in 2019/20), though the content is the same for each force. The protocol sets out the inclusion and exclusion criteria of patients for the officers to use Penthrox™, as well as indications, contraindications and the documentation required by officers and the service.

There are two stock logbooks kept in each unit which record the stock of medications as they arrive into the unit and are then disseminated, to either individual officers or specific medical kits. These are kept by trained personnel and also used as an audit trail. The order for the drugs must be signed by a registered doctor.

The protocol specifically states the following;

"NEVER use on a patient if:

- *They have no radial pulse; or a Respiratory Rate > 30 and/or a radial pulse rate > 120*
- *Penthrox™ (or other inhalation anaesthetic) has knowingly been used within the previous 3 months;*
- *There is a change in the level of consciousness due to any cause including head injury, drugs, or alcohol;*
- *They have shallow breathing or difficulty in breathing.*

Do not use on patients known to;

- *Be allergic to Penthrox™ (methoxyflurane), any other anaesthetic given by inhalation or any of the ingredients in the product;*
- *Have a history or family history of severe side effects to Penthrox™ (methoxyflurane);*
- *Have a history or family history of malignant hyperthermia (a condition where symptoms such as a very high fever, fast, irregular heartbeat, muscle spasms and breathing problems have occurred after being given an anaesthetic);*
- *Have previously had liver damage after using Penthrox™ (methoxyflurane) or any inhalation anaesthetics;*
- *Have significant kidney impairment."*[9]

The Officers are taught to use the "A-BACK-PACK" method of quickly assessing suitability to administer;

"A BACK - PACK"
A *- Adult*
B *- Breathing OK*
A *- Anaesthetic adverse reaction or allergy*
C *- Conscious*
K *- Kidney or Liver Disease*
P *- Previous* ***PENTHROX™*** *within 6 months*
A *- Antibiotics*
C *- Confirm safe to use with second provider*
K *- Keep record of use and effectiveness for audit reporting"*

Developed by the ATACC Group[11]

The limitations placed on the officers regarding the use of Penthrox™ are deliberately more restrictive than the guidelines for trained health care professionals. For example in this protocol it specifies the respiratory rate and pulse rate ranges and that any difficulty or shallow breathing should be a "never use" situation[9], while in the administration guide for health care professionals its states to "only administer methoxyflurane to patients that do not have clinically evident respiratory depression / cardiovascular instability"[12]. This allows a health care professional to use clinical acumen to make a judgement, whereas this medical decision making is reduced for the specialist officers using Penthrox™ under high pressure situations.

In terms of reporting use of Penthrox™ the officers use Patient Report Forms to report all medical interventions, and the protocol states they must specifically include the following when Penthrox™ is administered;

- *Date of record;*
- *Date and reason for administration;*
- *Pre dose and post dose pain scores*
- *Patient's name, address, date of birth;*
- *Details of consent given;*
- *Dose administered including date, times, batch number and expiry date (every dose administered to be documented);*
- *Advice given to patient (including side effects);*
- *Observations of patient with details of any side effects or adverse drug reactions experienced including time and date;*
- *Confirmation that details of any side effects have been reported to a doctor with name of doctor and date reported recorded;*
- *Signature/name of staff who administered or supplied the medication, and also, if relevant, signature/name of staff who removed/discontinued the treatment;*
- *Referral arrangements (including self-care);*
- *Name of staff receiving the patient if handed over to a doctor or emergency medical care.*[9]

It is specified that the standard to audit is 100% with no exceptions.[9]

Objectives/aims;

This audit is the first since the introduction of Penthrox™ for use by police officers and aims to;

1. Identify the circumstances under which Penthrox™ is being used
2. Discover how well the protocol is being adhered to
3. Audit the effectiveness, or otherwise, of Penthrox™ administered in these circumstances
4. Note any areas for developing the protocol and further training

Method;

Patient Report Forms (PRFs) are documents which require officers to retrospectively record their medical input at scene. They are comprised of tick boxes to state demographics, mechanism of injury (MOI), injuries and actions taken using the Catastrophic Bleeding, Airway, Breathing, Circulation, Disability, Exposure (<C>ABCDE) structure, as well as space to note patient observations and a free text area. The forms are then all externally reviewed by the clinical governance lead, a registered health care professional, to ensure actions taken and documentation was appropriate. We have gathered PRFs from five different forces under the same clinical governance system and

anonymised this data to retrospectively analyse both as a whole and any specific notes for individual force's feedback. It is worth noting that although the PRFs are very similar they are not standardised across all units and within those audited there are differences and changes to the layout.

In total 37 PRFs were audited that documented consideration or administration of Penthrox™, out of a total of 493 in the same time period, from late 2017 until March 2020. Currently on average only 7.5% (range 2% to 18% in the different forces) of patients receiving treatment from officers are being administered or documented as considered for Penthrox™.

Results;
Analysis for a total of 37 PRFs.

Mechanism of Injury;

Out of the 37 PRFs discussed the mechanisms of injuries fell into the following categories, which are determined by check boxes on the PRF; RTC (14), Assault (9), Other (8), Fall less than 6ft (4), Pedestrian (3) (*Figure 1*). The total adds to 38 owing to one patient having mechanisms of injury in two categories. All the mechanisms of injury fall under the umbrella of trauma.

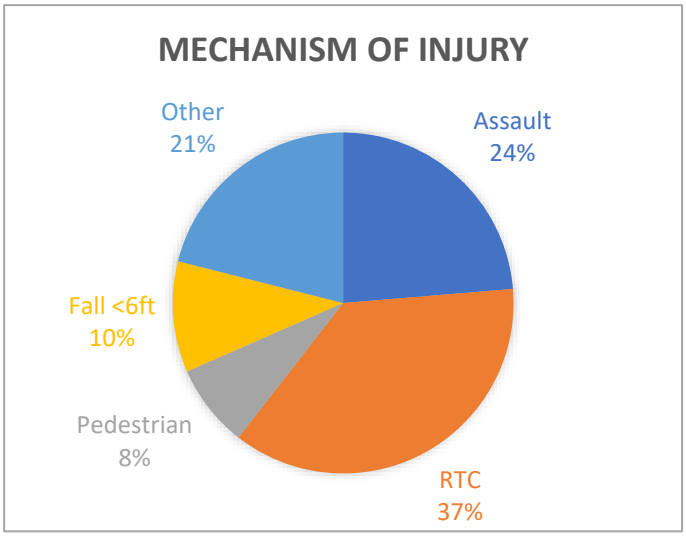


Figure 1; Proportions of mechanisms of injuries, as reported on PRF

The "Other" category included; Twisted leg (1), Bicycle crash (3), Fall/Trip (2) and Self-Harm (2). Two of the bicycle crashes did not involve other traffic while one involved collision with a car. The latter could have been counted in RTC as another similar incident was, or vice versa, as the MOI categories not always discrete.

Within the RTC category; 12 were drivers of the vehicle, one a front seat passenger and one a cyclist, and of the 14 there were seven cars, five motorcycles, one moped and one cyclist.

The nature of the assaults fell into the following categories; Shooting (4), Punched/Kicked (3), Stabbing (2), Domestic Violence (1). One patient also fell less than six feet and two of the incidents fell into more than one of the categories.

Of the pedestrians; two were hit by a car and one by a lorry.

Injuries;

On the PFRs there are 12 options for injuries to be ticked, as well as a body map to describe the location of the injuries and free text. Of the check boxes the following injuries and number of times they are recorded are detailed in *Figure 2*.

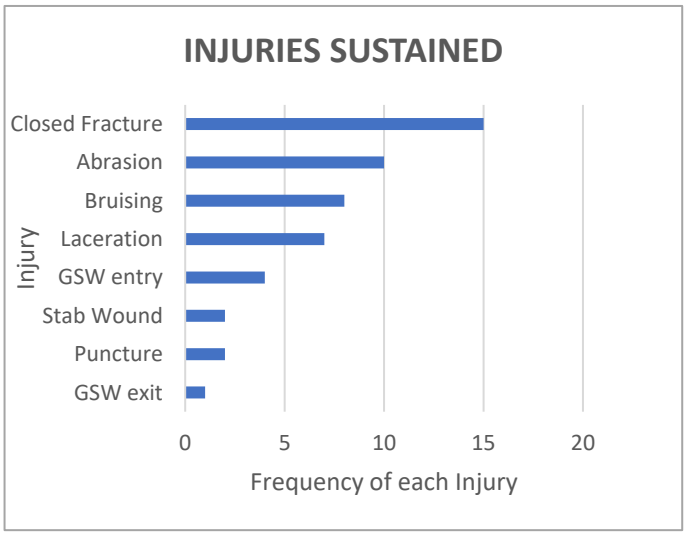


Figure 2; Types of injuries sustained, as reported on PRF

62% (n=23) of PRFs had checked multiple injuries; four PRFs had just one injury, gunshot wound (GSW) or puncture wound but not pain, and ten PRFs marked no injuries and only pain. Of those marking only pain most described an injury in the free text, for example twisted leg or a pre-existing back injury triggered by a fall that didn't fit easily into the check boxes.

Pain;

Although only 86% (n=32) had pain checked in the initial part of the form, all the PRFs had MOI suggestive of pain and all had pre Penthrox™ administration pain scores recorded or pain noted in the free text. This suggests an issue with form filling, rather any of the patients not being in pain.

On the PRF pain scores for each patient should be recorded before and after administration of Penthrox™. Most of the PRFs (86%, n=32) include either check boxes for 0-3, 4-7 and 8-10 out of 10 or the Wong Baker Faces Scale with a space to note the specific pain score. Five of the PRFs didn't have a specific space anywhere on the form for pain scores so the score had to be recorded purely in free text. Many officers also noted the specific pain scores in the free text area.

For the purposes of this audit scores 0-3, 4-7 and 8-10 correspond with pain categories mild, moderate and severe respectively.

Pre Penthrox™ Administration Pain Scores;

86% (n=32) of patients were in the severe pain category, 11% (n=4) of patients were in the moderate category and one was not recorded numerically (*Figure 3*).

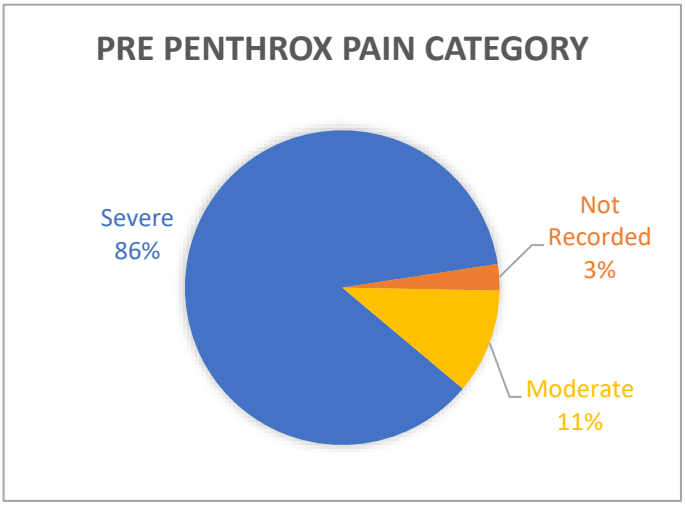
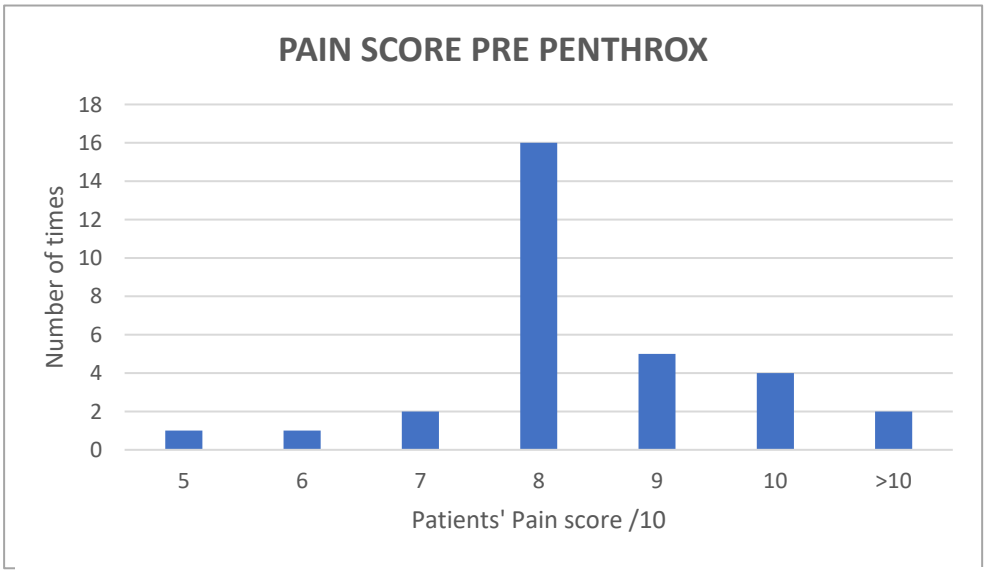


Figure 3; Category of pain score reported by patient prior to administration of Penthrox

The one who didn't record a numerical score at all noted that due to patient's extreme pain and shouting they could not determine a pain score, but as there was an unknown ambulance time of arrival an off-duty doctor on scene authorised that Penthrox™ could be administered.

84% (n=31) of PRFs recorded a specific pre pain score, detailed in *Figure 4*. Of the two that are recorded as >10 one was quoted as "one million" and the other "11".



Mean 8.32
SD 1.17

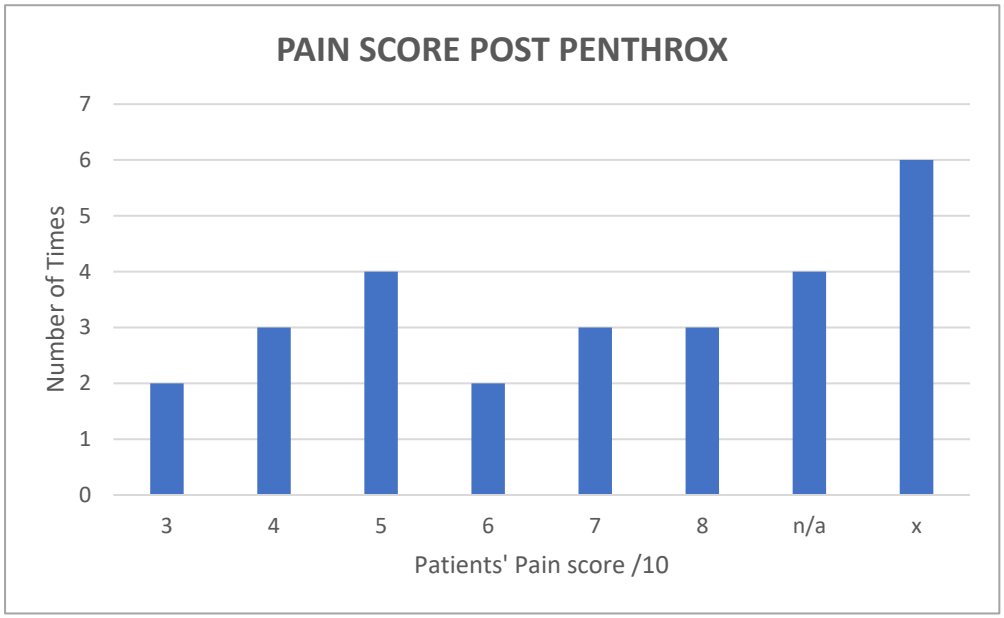
Median 8
LQ 8, UQ 9
IQR 1

Figure 4; Patients' pain scores prior to administration of Penthrox, in those that recorded a specific value

Post Penthrox™ Administration Pain Scores:

Pain scores post Penthrox™ were; moderate 51% (n=19), not recorded 16% (n=6), mild 14% (n=5), not applicable 11% (n=4) and severe 8% (n=3) (*Figure 5*).

There is a much lower rate of recording a specific pain score after Penthrox™ administration, with only 46% (n=17) having a specific score and 16% (n=6) not recording at all. The 'not applicable' group was due to either medication not being administered as an ambulance arrived (n=3) or the drug being refused by the patient (n=1).



Mean 5.59
SD 1.7

Median 5
LQ 4, UQ 7
IQR 3

Figure 5; Patients' pain scores after administration of penthrox, in those that recorded a specific value

n/a = not applicable; due to medication not being administered / not taken
x = not recorded with no documented reason

Change in pain scores after administration of Penthrox™;

Of the PRFs which had both a pre and post pain score (n=27, 73%) there was a drop in pain category in 19 (70%), either from severe to moderate (n=13, 48%) or severe to mild (n=6, 22%). There was no drop in category in eight (30%), six (22%) and two (7%) respectively remained in severe and moderate pain (*Figure 6*).

However, of the eight patients (30%) who didn't experience a drop in pain enough to bring them down a category, six (75%) of them suggested some sort of drop in pain score. Of these six; three dropped from 10 to 8; one from >10 to 8-10, one from 7 to 4-7 and one specified that although both 8-10 the patient stated that the 'edge was taken off'.

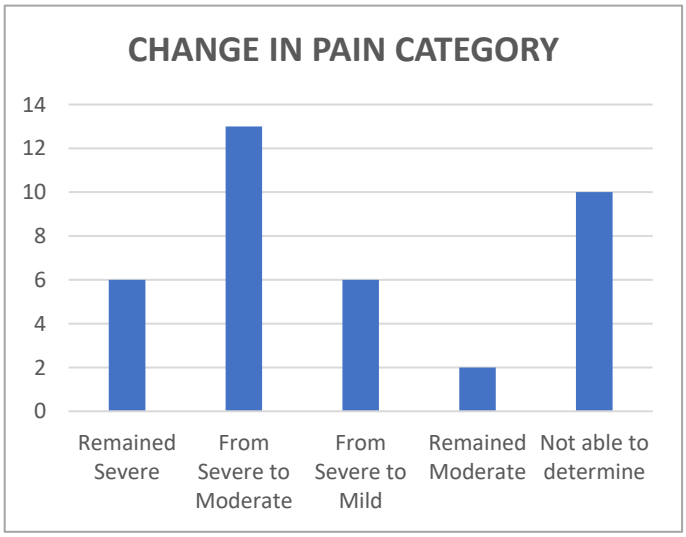


Figure 6; Numbers of patients whose pain scores did and did not change categories after administration of Penthrox

One patient recorded that the medication was not working at all and that the pain was unbearable, and one was marked initially at 5 then subsequently 4-7, so it is difficult to determine if there was any change.
Of the 17 PFRs marked with a specific pain score for both pre and post (46%) the mean change in pain score is by -3 (range -1 to -5) with a Standard Deviation (SD) of 1.27. (*Figure 7*).

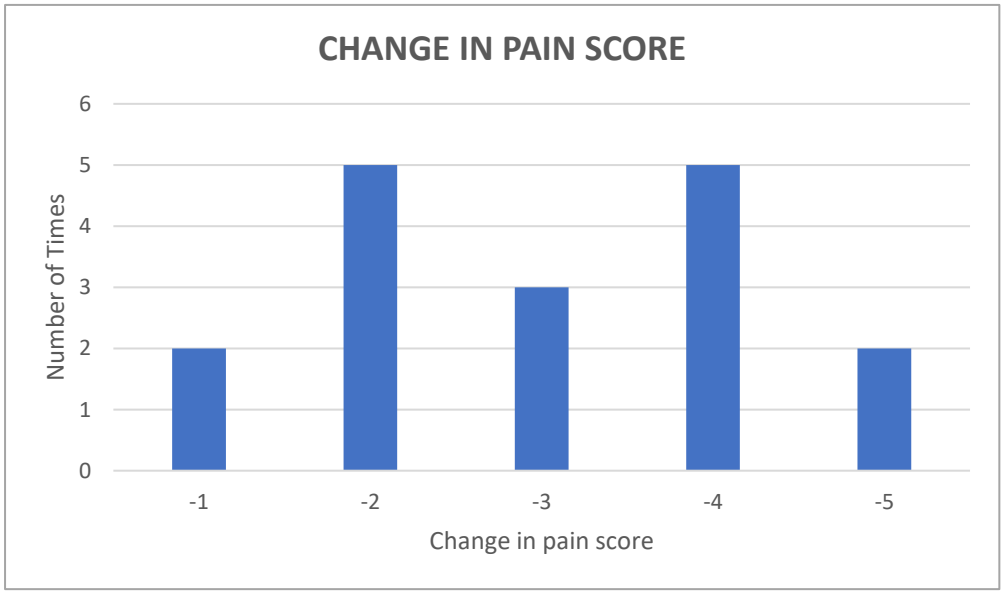


Figure 7; Numerical values for the change in pain score experienced by patients in those that recorded a specific pre and post administration pain score

Statistical Analysis;

To determine whether the drop in pain score was statically significant we used the Wilcoxon Signed Rank Test, a non-parametric statistical test chosen to reflect the small sample size and non-normally distributed data. (See *Appendix A* for full analysis). This analysis showed that, as expected, this analgesic medication caused a decrease in pain score, but also that this decrease was statistically significant. This combined with a very small P value (p=0.01), shows that there is very limited probability that the result is due to chance alone, meaning we can be confident that the officers using Penthrox™ are significantly reducing the pain of their patients and effectively filling a therapeutic vacuum while waiting arrival of medical professionals.

Patient Demographics;

The age / date of birth of the patients was only recorded in 22% (n=8) of PRFs. Of those that did, the range of ages was between 31 and 88 years old. The gender of all patients was recorded and was predominantly male (70%, n=26).

Vials Given;

Doses come in 3mL vials, but we are unable to determine exactly how much of each vial is used per patient. In the majority (84%, n=31) of cases it was recorded as only one vial given and there was only one case of a second vial being given. This was given 25 minutes after the initial vial and it was also noted that the team was informed the ambulance crew were unsure how long it would take to get to them.
There were three occasions (8%) where the officers were preparing to give Penthrox™ when an ambulance arrived and took over, so the medication wasn't given. There was one occasion where the patient refused the treatment after one breath due to an unpleasant taste. Data from those that were not given Penthrox™ for these reasons was still included in this audit, as it is important to analyse all situations where officers thought Penthrox™ use could be appropriate.
There were two PRFs that didn't record the number of vials given which is an important point regarding complete form filling and protocol adherence. However, there are other systems in place to monitor the number of doses that go out with the officers and are returned to provide stock logs.

Respiratory Rate, Nature of Breathing and Oxygen Given;

95% (n=35) of patients had respiratory rate checked that was between 10-30 breaths per minute, this is a check box on the form. One rate was not marked but the PRF stated this was due to patient shouting in pain and one was only marked as being checked by paramedics on handover. Of these the majority, 73% (n=27), were classified as "normal" breathing, with one marked as difficulty breathing. The remaining 24% (n=9) were not specified.
Of these approximately a third of PRFs (35%, n=13) recorded a specific respiratory rate in the free text, ranging from 10 to 30 breaths per minute (mean 16, mode 10).

Around half the patients (49%, n=18) received oxygen at some point during the treatment.

Heart Rate;

Heart rate was specified in 62% (n=23) of patients with a range of 54-118 beats per minute (mean 85.5 beats per minute). This is an important area for improvement as it should be recorded on every form. Many of them had checked that they had a radial pulse but did not record a value.

Consciousness and Alcohol or Drugs;

Consciousness is marked using the Alert, Verbal, Pain, Unresponsive scale (AVPU) and almost all (95%) were marked as Alert for the whole time the officers were on scene. There was one occasion where a patient deteriorated from alert to verbal and one occasion from alert to unresponsive. In both PRFs the reasons for deterioration were unclear; one had a leg injury and the patient refused Penthrox™ after one breath and then a short time afterwards consciousness reduced slightly, from A to V, as they waited for medical help. The patient was fully alert by the time they handed over to paramedics and all other vitals were within appropriate ranges. The second became unresponsive whilst being treated following an RTC with severe injuries – the patient had two vials of Penthrox™ administered whilst alert, in line with the protocol, over 35 minutes and subsequently had a brief

period of unresponsiveness accompanied by a reduction of oxygen saturations. This could have been in response to the two doses of Penthrox™ or due to the patient's injuries, we are unable to determine exactly, but within five minutes the patient returned to alert and care was taken over by the ambulance crew. This PRF was reviewed by the clinical governance lead and it was stated that although unclear as to the cause for the change in conscious level the patient was handled well. Within those that were marked as Alert one was stated to have a "serious head injury" and one that recorded that colleagues first on scene reported the patient had been "initially unconscious" but was conscious and alert when officers arrived on scene, recorded within the free text. The serious head injury was from a pedestrian hit by a car and stated to not lose consciousness but was confused and aggravated. These PRFs were requested for feedback and debriefing at the time to discuss the use of Penthrox™ in these situations.

Of all the PRFs only one was marked as involving alcohol or drugs but there was no mention of this in the free text and was A on AVPU the whole time.

First ten compared to second ten PRFs;

The first five PRFs from two forces (all 2018) were compared to the second five from the same two forces (all 2019), ten from 2018 and ten from 2019 in total, to see if there was any difference in form filling. We looked at this as there was immediate feedback provided to the forces on a form by form basis after the first few uses of Penthrox™.

Table 1; Data demonstrating quality of form fill for 10 PRFs in 2018 compared to the first 10 PRFs in 2019 from two forces

	2018	**2019**
Age	2 (20%)	4 (40%)
Gender	All	All
AVPU	All	All
Alcohol or Drugs	All	All
Pulse Rate (recorded as a specific number)	5 (50%)	8 (80%)
Respiratory Rate	100% range / 30% specific	90% range / 30% specific
Oxygen	50% received	70% received
Pre Penthrox™ Pain Score	All	9 (90%)
Post Penthrox™ Pain Score	5 (50%)	7, out of 8 doses given (87.5%)*

**2019 Post Penthrox™ Pain Scores; only eight out of ten of the PRFs gave the medication, with two preparing to give when medical help arrived. Seven out of the eight doses given recorded a Post Penthrox™ Pain Score (87.5%).*

One of the 2019 PRFs stated that the observations could not be completed due to patient's extreme pain and shouting, but as there was an unknown ambulance time of arrival an off-duty doctor on scene authorised that Penthrox™ could be administered. Two of the 2019 PRFs stated that paramedics were present and applied an electrocardiogram (ECG) which is why they didn't record specific pulse rates.

Of the 2018 PRFs discussed in *Table 1* five of the forms did not have specific areas for the officers to record patients pain scores, relying on use of the free text area for this information. Of the five after the addition of a checkbox for pain score 80% (n=4) recorded a post Penthrox™ pain, score

compared with 20% (n=1) for the five without a specific box. 50% (n=5) of all ten PRFs recorded a post Penthrox™ pain score in the first 10 forms.

Other;

Other interventions that could potentially have assisted with reduction in pain were; splinting of fractures (used five times), applying a pelvic binder (used twice) and manual in line stabilisation (used six times).
In the free text area of 15 PRFs officers documented that the patient had been asked Penthrox™ or "A-BACK-PACK" questions to determine suitability of administration, with five recording the second colleague who witnessed this check. This varied between forces, as all five who recorded witnesses were from the same force. There was one PRF that specifically noted the other medications the patient was taking. Only two forms documented any side effects (light-headedness and nausea), however these were the only two forms that specifically asked for side effects.

The average time on scene for the PRFs that recorded both time they arrived and time they left the scene (n=29) was 1hour 16minutes (range 25minutes to 3hours 15minutes). This is longer than the average for all PRFs included in past audits; 2018 was 48 minutes [(1)] and in 2019 was 51 minutes (range: 3 to 245 minutes)[(4)]. The time recorded on scene does not always reflect the time officers spent with the patient. For example, the second longest time recorded (3 hours 13 minutes) was an RTC where the ambulance crew arrived within 10 minutes of police arrival. The longest time officers spent on scene (3 hours 15 minutes) was at a shooting, but the PRF did not record how long ambulance took to arrive. One PRF specifically noted that the ambulance arrived over 2 hours after the RTC occurred and this was 45 minutes after the officers arrived on scene. Another recorded 2 hours 21 minutes on scene and this was the only case where two doses of Penthrox™ were given, it was also recorded that the officers were updated that the ambulance would not arrive for over an hour due to other incidents.

Discussion;

This audit has shown that officers competently identify appropriate situations in which to use Penthrox™, i.e. all are trauma patients with moderate to severe pain scores. The use of Penthrox™ produced a statistically significant (at p=0.01) decrease in pain score for patients. This outcome was expected, and we have shown that officers trained in the use of Penthrox™ are able to provide effective and safe pain relief to their patients, filling the therapeutic vacuum while awaiting medical help to arrive.

The scenarios, defined by the current protocol, in which an officer should never administer Penthrox™ are dependent on the recording of; respiratory rate, radial pulse rate, level of consciousness and nature of breathing.

The measurement of respiratory rate was generally well documented as a range (95%) and many (35%) also included a specific rate. Of those who documented a respiratory rate no officers used Penthrox™ outside the range of 10-30 breaths per minute. The nature of breathing was generally marked as normal, although some didn't specify, except one occasion where breathing was marked as difficult. This was an incident involving an RTC with significant injuries where the patient had to be moved out of the car due to safety considerations. It was unclear exactly why the breathing was difficult but when reviewing the PRF in detail it is likely that this was due to injuries to the chest or collar bone causing pain. The respiratory rate was 10-30 breaths per minute throughout and the only other consideration was that the officers had been informed the patient had previously been unconscious, although was alert at present. Penthrox™ was not actually given in this scenario, but as this was due to ambulance arrival rather than the officers deciding against the medication, we thought it was still important to discuss with the officers whether using Penthrox™ would have been suitable for the patient and whether they would have been adhering to the protocol.

Heart rate was not recorded in over a third of patients (38%) which is an important area to feedback to forces and to be emphasised in future training. Of those where heart rate was recorded, no officers used Penthrox™ where patients had a pulse rate of above 120 beats per minute. Many officers use the "A BACK PACK" acronym to remind of the checks to be done prior to administering Penthrox™, however this covers both breathing and consciousness but neglects to remind of pulse rate/cardiovascular state, which could be a useful addition for memory aide. The limited recording of pulse rate is consistent with audits of all PRFs, not just those with Penthrox™.[1-4]

Consciousness level was recorded in all PRFs and 95% of patients were alert throughout. There were two PRFs which had circumstances where the patient had either a head injury or had been quoted as "unconscious" before officers arrived. The protocol states Penthrox™ should not be used in patients with "a change in the level of consciousness". However, it is not entirely clear whether this refers to consciousness levels at the point of which the officers are giving the medication or if this extends to changes, for example, prior to officers' arrival on scene.

The delivery of oxygen was an area that was identified in previous audits for potential improvement[1-3] as the officers are trained that "all trauma patients require oxygen"[4]. However, given that the officers don't have the use of nasal cannula to deliver oxygen and that Penthrox™ is an inhaled medication they cannot currently be given simultaneously. This means whether oxygen is used or not may partially depend on other factors, such as how long before they give the medication, how quickly the patient uses the inhaled medication and how long after they are waiting for medical help to arrive.

In line with the Penthrox™ protocol the following points should have been recorded on every PRF which uses Penthrox™;

- *Date of record and signature/name of staff and Patient's identifiers and date of birth;* Due to data protection each PRF now has a unique reference number which leads to a log of patient and officer details, but these are not recorded on the PRF itself anymore.
- *Date and reason for administration;* All forms stated MOI, injuries and pain.
- *Pre dose and post dose pain scores;* All bar one (97%), and this had their reasoning explained, recorded a score pre giving Penthrox™ and 84% a post Penthrox™ score or recorded that the drug wasn't given.
- *Details of consent given*; Very few officers specifically noted the details of consent, however as this medication is self-administered by the patients there is a nature of implied consent. For example, one officer documented that they "handed it to patient to administer themselves".
- *Dose administered including date, times, batch number and expiry date;* Batch number and expiry date were not recorded in the PRFs but records of this are kept by the medical training lead for the service who organises the logbook and ordering of medications. Most (95%) recorded dose given, or if not given, and the two that did not record dose on the PRF would have been recorded in logbooks. Four recorded the exact time Penthrox™ was given *(*6 to 17 minutes after arrival).
- *Advice given to patient (including side effects);* Alert cards come with the medication and should be given to each patient, but this was only recorded three times.
- *Side effects or adverse drug reactions;* Very few officers reported the presence of absence of side effects. The only two forms that had a specific box for this, however, both declared mild side effects (nausea/dizziness). Neither specified whether this was handed over to a medical professional.
- *Referral arrangements / Name of staff receiving the patient;* There is space on the form to note where the ambulance was taking patient and many also were able to record updates from hospital later too. Very few recorded specific names, which would potentially be difficult to obtain in pressured situations.

Officers' body worn video (BWV) footage has been reviewed from a number of those that administered Penthrox™ which has shown that often the officers are often fulfilling the criteria above but not always documenting in the PRFs. On the PRFs it was also noticed that the initial checkboxes to mark injuries, the body map to add injuries location and the free text did not always have the corresponding information. Both issues could be improved by editing the PRF itself, to make it easier for officers to record the essential information.

<u>Overall Penthrox Data;</u>

Data from the most up to date audit of all PRFs shows that in total for 2019 there were 298 PRFs and 106 (36%) of them recorded pain as an injury, while only 23 (8%) for the same time documented considering / administering Penthrox™.[(4)] However, the figure for pain is assumed to be much higher as not all MOIs that would have caused pain were recorded as in pain. For example, only 18% of those stabbed and 30% of those hit by a road vehicle were marked as in pain.[(4)] Seeing as only those using Penthrox™ recorded the pain scores of the patients, it is impossible to know how many of these patients would have been in the moderate or severe pain category, as well as some of these patients recording pain for medical reasons, such as chest pain, so being unsuitable under the current protocol. The high levels of alcohol or drugs involved in the total PRFs (n=66, 22%) would have been another potential reason for excluding the patient from using Penthrox™.[(4)] It is also not

frequently documented how long it takes for medical assistance to arrive, which may be another factor affecting whether Penthrox™ is used, especially given that the time on scene for those using Penthrox™ is longer on average then all incidents attended.

However, it is clear that only a small percentage of each forces' medical interventions use Penthrox™ currently, and this is out of relatively small number of medical interventions made by officers on a yearly basis, ranging from 1 to 116 (mean 53) PRFs being recorded in a year for different forces. These figures do not consider the number of officers providing this care or the size of the different forces but do put into perspective the relatively infrequent exposure and use of clinical skills and Penthrox™ each officer will get. The infrequent usage of Penthrox™ by forces, and individual officers, means that although the Penthrox™ itself is straightforward to administer the documentation, which is an essential part of being able to administer medication, is not as second nature as it would be if doing on a regular basis.

Data showed that for two forces who had use of Penthrox™ throughout the whole of 2018 and 2019 the average use of Penthrox™, out of all PRFs, rose from 6% to 9%. Although the numbers are small this could suggest that as the officers become more comfortable and confident using the medication they are more likely to consider administering it. However, there are many factors that may influence the amount of times Penthrox™ is used. For example, the force with the smallest use of Penthrox™ is an inner city unit which perhaps will often be on scene for less time before medical help arrives, compared with some of the more rural forces who potentially have longer waiting times with the patient.

Conclusion

Remembering that medical care is not the officer's primary role at these incidents is important when looking at these PRFs and that overall the circumstances under which Penthrox™ was given was appropriate and a reasonable number of patients benefited from significant reduction in their pain levels.

Penthrox™ in this audit has been shown to be efficacious, easy to administer and safe to use under the current protocol's restrictions. Through this audit we hope to promote more widespread consideration of the use of Penthrox™ as analgesia for patients across trauma incidents attended by specialist officers. Furthermore, in line with other protocols and studies across the world we feel able to consider relaxing some aspects of the protocol that may now be regarded as overly restrictive. For example, the "Pain Management Certificate (Methoxyflurane) Learner Guide"[13] for the Australian Lifesaving Academy and "Surf Life Saving New Zealand – Lifesaving Policy Statement"[14], who, like the specialist officers discussed in this audit, are both groups trained in first aid and use of Penthrox™ but are not medical professionals. The former permits the use of methoxyflurane in casualties who "responds to voices and remains alert"[13] and contraindicates the administration of the drug in patients "with inadequate respiratory effort or rate"[13] without specifying a range of rates. The latter specifies that in terms of consciousness the patient must be "able to obey commands"[14] and doesn't specify respiratory rate or cardiovascular state in its five listed contraindications. These groups have been using methoxyflurane under the guidance detailed since 2012 and 2017 respectively, and to our knowledge have had no issues with the adverse reactions to the medication. In terms of vital sign parameters, a paper from St John Ambulance in Western Australia gathered data on over 500 patients who were given methoxyflurane[15]. The paper concludes that the use of methoxyflurane in the doses used for analgesia "did not produce any deleterious effect on cardiovascular or respiratory parameters"[15] in the patients reviewed. The paper noted that there were some changes in vital signs seen over the measurements taken post

administration of Penthrox™ but suggested this was in line with expected changes with a decrease in pain.[15]

Considering the findings of this audit, as well as looking into other similarly trained groups using Penthrox™, the main changes to the current protocol we are considering reviewing are as follows;

- The current restriction on giving Penthrox™ to patients with previously reduced Consciousness level could be reviewed to allow delivery of Penthrox™ to any patients who is currently alert and can obey commands, even if having previously had a reduced level of consciousness
- It might be made clear that patients under the influence of alcohol / drugs who are alert and able to obey commands at the current time can receive Penthrox™
- The current restrictions on respiratory rate and heart rate parameters may be edited so that patients in the following categories are excluded from administration of Penthrox™ by specialist officers;
    - Respiratory rate under 10 breaths per minute
    - Patients with no radial pulse

In addition to this, and in conjunction with the most up to date audit looking at all PRFs from 2019, we are proposing that changes to the PRF form itself, to create a standardised PRF that could be used across all the forces, could be beneficial. A standardised PRF would not only allow for better comparison of audited data in the future but the addition of more specific areas for vital signs or interventions and a detailed section for the use of Penthrox™ would potentially prompt better documentation, especially in reference to the Penthrox™ protocol.

The changes to the PRF we are proposing relating to Penthrox™ use include the following;

- Check boxes for pain score of 0-10, for pre Penthrox™, after the first dose and after the second dose
- Number of vials used
- Specific sections for breathing rate, radial pulse, age and currently alert in line with the protocols restrictions
- Time, batch number and expiry date for both first and second dose
- Confirmed that there are;
    - No contraindications
    - Past medical history / Medication
    - No use of Penthrox™ in last 3 months
    - Alert card given & discussed
    - Consent obtained
- Space to record any adverse reaction to Penthrox™, the specific reaction and who the clinical governance lead reported to was
- Handover to EMS and the name of the staff receiving patient / EMS call sign
- Any other notes specifically to do with Penthrox™ use

We will also share findings of this audit with instructors delivering the training, showing that overall the use is safe and effective, but to encourage them to emphasise the recording of vital signs, especially heart rate, and the importance of documentation when training and refreshing their officers.

With these changes we plan to re-audit the use of Penthrox™ in the future and hope to see that a wider group of patients gain access to the benefits of Penthrox™ used by specialist police officers adhering to the developed protocol, and that it remains safe and effective.

Appendix A – Statistical Analysis

To determine whether the mean difference of the two sets of observations, pre and post administration of Penthrox™, was statistically different from zero we used a Wilcoxon Signed Rank Test. We chose these due to the small sample size (n=17) and non-normally distributed data.

We hypothesised that;

- H_0= There was no significant change in pain scores pre and post Penthrox™ administration.
- H_1=There is a decrease in pain score post Penthrox™ administration.

Wilcoxon Signed Rank Test;

N	PRE PAIN SCORE	POST PAIN SCORE	DIFFERENCE	ABSOLUTE DIFFERENCE	RANKED *(LOWEST TO HIGHEST)*	RANKED WITH AVERAGES	SIGN
1	8	7	-1	1	1	1.5	-
2	8	7	-1	1	2	1.5	-
3	10	8	-2	2	3	5	-
4	10	8	-2	2	4	5	-
5	8	6	-2	2	5	5	-
6	10	8	-2	2	6	5	-
7	*8*	*6*	-2	2	7	5	-
8	8	5	-3	3	8	9	-
9	8	5	-3	3	9	9	-
10	*10*	*7*	-3	3	10	9	-
11	9	5	-4	4	11	13	-
12	8	4	-4	4	12	13	-
13	9	5	-4	4	13	13	-
14	8	4	-4	4	14	13	-
15	*8*	*4*	-4	4	15	13	-
16	8	3	-5	5	16	16.5	-
17	8	3	-5	5	17	16.5	-

W+ = 0 and W- = 153

W- + W+ = 153

$$\frac{N(N+1)}{2} = \frac{17 \times 18}{2} = 153$$

From tables using One Tailed Test:[16]

Critical value 0.5 = p=41, Critical value 0.01 = p=27

W = 0 is the minimum W value, 0 <27 so is significant at P=0.01

The W(min) value is less than the critical value at n=17, therefore the decrease in pain score is significant at P=0.01 and we can reject the H0.

The analysis shows that, as expected, Penthrox™ given by officers causes a decrease in pain score as any analgesic should but this analysis shows that this is a statistically significant decrease which is thus filling a therapeutic vacuum before the arrival of medical professionals.

References;

1. Hartley F, Howells A, Thurgood A, Hall F, Porter K. Medical training for police officers in specialist role (D13): A retrospective review of patient report forms from 2010–2015. Trauma. 2018;Volume 20 (Issue 1).
2. Rhimes P, Williams S, Hall J, Porter K. Retrospective Audit of Patient Report Forms (PRFs) from semi rural specialist police firearms units January to December 2017 2020 [Accessed On 01/06/2020] Available from: https://fphc.rcsed.ac.uk/media/2883/retrospective-audit-of-patient-report-forms-prfs-from-semi-rural-specialist-police.pdf.
3. Serebriakoff P, Hartley F, Hall J, Porter K. An update on firearm police medical response. Trauma. 2020;Vol 22(Issue 1).
4. Elford J, Franklin M, Elford A, Hall J, Porter K. Clinical Skills for Police Officers in Specialist Role: An Audit of Patient Report Forms in 2019. Pending Publication. 2020. Available at: https://fphc.rcsed.ac.uk/media/2899/clinical-skills-for-police-officers-in-specialist-role-an-audit-of-patient-report-forms-in-2019-final.pdf
5. Galen Ltd. Penthrox for Healthcare Professionals 2019 [Accessed On 08/06/2020] Available from: https://www.penthrox.co.uk/hp/.
6. Medicines. PENTHROX 3mL inhalation vapour liquid 2018 [Accessed On 08/06/2020] Available from: https://www.medicines.org.uk/emc/product/1939/smpc.
7. Porter KM, Dayan AD, Dickerson S, Middleton PM. The role of inhaled methoxyflurane in acute pain management. Open Access Emerg Med. 2018;Volume 10.
8. ATACC Group. Offically Approved Training for Penthrox [Accessed On 08/06/2020] Available from: https://www.ataccgroup.com/training/course-listing/officially-approved-training-for-penthrox/?t=medical-in-hospita.
9. Harding J, Hall F, Porter K. Protocol for the administration of Penthrox vapour liquid using a Penthrox inhaler for the emergency relief of moderate to severe pain in conscious adult patients with trauma and associated pain in a hostile environment.
10. Williams C. Police Clinical Governance. 2010;Version Three.
11. ATACC Group. Police Penthrox Assessment Method.
12. Galen Pharmaceuticals. PENTHROX® (methoxyflurane) Administration Guide 2015 [Accessed On 10/06/2020] Available from: https://www.medicines.org.uk/emc/rmm/396/Document.
13. Australian Lifesaving Academy. Pain Management Certificate (Methoxyflurane) Learner Guide 2012 [Version 2.3]
14. Surf Life Saving New Zealand. Lifesaving Policy Statement 2017 [Version 3]
15. Oxer HF. Effects of Penthrox®(methoxyflurane) as an analgesic on cardiovascular and respiratory functions in the pre-hospital setting. Journal of Military and Veterans' Health. 2016;Volume 24(Issue 2).
16. Department of Statistics University of Florida. Critical Values of the Wilcoxon Signed Rank Test [Accessed On 08/06/2020] Available from: http://users.stat.ufl.edu/~winner/tables/wilcox_signrank.pdf.

Authors

Corresponding Author
Maggie Franklin, Medical Student, University of Liverpool
M.Franklin2@student.liverpool.ac.uk

Dr Jane Elford, Foundation Year One Doctor, Ysbyty Gwynedd, Bangor.

Dr J Hall MBE, Hon Secretary FPHC RCS Ed

Prof. Sir K Porter, Professor of Clinical Traumatology, University Hospital Birmingham