Abstract of dissertation entitled

“An evidence-based guideline for nurse-initiated paracetamol for patient presenting minor trauma pain at emergency department”

Submitted by

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Background: Pain is the most frequent chief complaints by patient attending Accident and Emergency Department (AED) worldwide, whereas trauma patients reported a high prevalence of pain. Undertreatment of pain has been recognised as a common problem in AEDs. Triage nurses have an important role to play in assessing and managing this pain as the first contact for patients. Studies report that nurse-initiated paracetamol is effective in reducing pain intensity resulted from minor trauma.
**Objective:** This translational study aims to develop an evidence-based guideline for nurse-initiated paracetamol for patients presenting minor trauma pain at Accident and Emergency Department (AED).

**Methods:** Three electronic databases including CINHAL, Pubmed, and PsycInfo were used for searching relevant literatures. The outcome measure was found as reducing pain intensity for patients presenting minor trauma pain in AED by setting inclusion and exclusion criteria. The selected studies were then reviewed and synthesized best evidences for developing an evidence-based guideline. Transferability, feasibility of carrying out those suggested recommendations as well as costs-benefits ratio for the whole programme were considered.

**Results:** According to the selection criteria and all outcome measures for these studies were focused on reduction of pain intensity in patient presenting minor trauma pain, six selected reviewed studies were retrieved. In quality assessment, most of the selected reviewed studies (n=5) were rated as high quality. Ample supports and evidences illustrated that this proposed nurse-initiated paracetamol guideline was highly transferrable, feasible and cost-effective and seven practice recommendations were developed.

**Conclusion:** The proposed nurse-initiated paracetamol guideline is effective to reduce patients’ pain resulted from minor trauma. Without the innovative guideline, patients’ biological and psychological aspects may be affected.
Declaration

I declare that this dissertation represents my own work, except where due acknowledgement is made, and it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualifications.

Signed__________________________________________

Cheung Pui Yu
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I take this opportunity to express gratitude to my colleagues for their help and support. Last but not the least; I would like to thank my family for supporting me spiritually throughout writing this dissertation and my life in general.
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# Abbreviations

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<tr>
<td>AED</td>
<td>Accident and Emergency Department</td>
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<td>AEIS</td>
<td>Accident and Emergency Information System</td>
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<td>APN</td>
<td>Advance Practice Nurse</td>
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<td>CINAL</td>
<td>Cumulative Index to Nursing and Allied Health Literature</td>
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<td>CI</td>
<td>Confidence level</td>
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<td>CMS</td>
<td>Clinical Management System</td>
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<td>CONS</td>
<td>Consultants</td>
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<td>COS</td>
<td>Chief of Service</td>
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<td>DOM</td>
<td>Department Operational Manager</td>
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<tr>
<td>ECMO</td>
<td>Extracorporeal membrane</td>
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<td>EBP</td>
<td>Evidence-based practice</td>
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<td>HA</td>
<td>Hospital Authority</td>
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<td>LOS</td>
<td>Length of stay</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>NO</td>
<td>Nursing Officer</td>
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<td>QMH</td>
<td>Queen Mary Hospital</td>
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<td>Abbreviation</td>
<td>Description</td>
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<tr>
<td>RCT</td>
<td>Randomised controlled trial</td>
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<td>RN</td>
<td>Registered nurse</td>
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<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Networks</td>
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<td>DTC</td>
<td>Drug and Therapeutic Committees</td>
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<td>VAS</td>
<td>Visual Analog Scale</td>
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<td>Ward Manager</td>
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Chapter 1: Introduction

In this chapter, the background information, affirming needs, objectives and significance will be included.

1.1 Background

Pain is the most frequent chief complaint by patient attending Accident and Emergency Departments (AEDs) worldwide (Cordell et al., 2002; Ducharme, 2000; Tanabe, 1999; McCaig & Burt, 2001), whereas trauma patients reported a high prevalence of pain (Johnston, Gagnon, Fullerton, & Common, 1997; Berben et al., 2007; Berbe, Schoonhoven, Meijs, van Vugt, & van Grunsven, 2011; Tanabe & Buschmann, 2000; Tcherny-Lessenot, 2003). Under-treatment of pain has been recognised as a common problem for all AEDs (Jones, Johnson, & McNinsh, 1996; Rupp & Delaney, 2004; Todd et al., 2007; Wilson & Pendleton, 1989). Untreated pain was associated with biological and psychological problems. Fosnocht, Heaps, and Swanson (2004) found that timely analgesia was expected by patient; it also linked to improve biological outcomes and reduced anxiety (Ducharme, 2000; Singer et al., 2008). For the biological aspects, the phenomenon pain is uncontrolled; the patients become more sensitive to painful stimulus. Uncontrolled pain and increased irritation will stimulate nerve fibres other than pain nerve fibres (Ducharme, 2000). Delay and untreated pain will stimulate more nerve fibres, and hence recruit more spinal neurotransmitter release lead to increased pain
sensitivity, as a result patients suffered from more pain than normally expected (Ikeda, 2006). Moreover, untreated pain will activate biological inflammatory and stress response (Singer et al., 2008). As for psychological aspects, pain is often accompanied with anxiety or feeling loss of control (Ducharme, 2000).

Patients had perception towards AED staff ignoring their pain because of inadequacy in analgesia prescription. Triage nurses, as the first health provider to contact patients, have an important role in assessing and managing the pain condition. However, it is a traditional practice that medication including analgesia has to be prescribed by doctor. The long waiting time to see doctor contributed to the delay in receiving analgesia timely. According to Forero et al. (2008) and Mitchell, Kelly, and Kerr (2009), timely administration of analgesia relieved patients’ pain quickly. In Hong Kong, there is lacking a comprehensive guideline for nurse-initiated paracetamol for patient’s present minor trauma pain in AED. The study in Hong (Wong, et al., 2007) only recruited patients with minor isolated single limb injury. Moreover, effectiveness of paracetamol for patient presenting minor trauma pain in AED also investigated in this reviewed study which not mentioned in the Wong, et al.’s study (2007). Therefore, more patients will be benefit from this translational study.

Studies suggested that timely delivery of analgesia to patients by triage nurse could decrease length of stay (LOS) in AED and increase patient satisfaction (Campbell, Dennie, Dougherty, Iwaskiw, & Rollo, 2004; Krett-Dougherty, 2003; Seguin, 2004). According to Accident and Emergency Information System (2014), average waiting time for patients presenting minor
trauma pain in AED is more than 120 minutes. Paracetamol is the first choice of analgesic using in Accident and Emergency Department of Hong Kong (Lee, Tse, Tang, & Wong, 2011). Therefore; nurse-initiated paracetamol at triage considered as an early intervention for patients presenting minor trauma pain in AED.

According to the Hong Kong Accident and Emergency Department clinical guideline for pharmacological approach in pain management (Lee, Tse, Tang, & Wong, 2011), paracetamol is a suitable first choice analgesic for most patients who present with mild to moderate pain in AED. It is because paracetamol is a well-tolerated, effective and inexpensive analgesic. In London, paracetamol is prescribed by emergency nurse practitioners for pain relief (Summers, 2007). Some studies have found that paracetamol was effective for patients with soft tissue injury, strains and sprains, and low back pain. This kind of pain is referred to minor trauma pain (Muchie, 1986; Indelicato, 1986; Palangio, 2002). Therefore, it is believed that more patients will be benefit from this translational study.

In this translation study, evidenced-based nurse-initiated paracetamol for patients with minor trauma pain in a local public hospital is going to be investigated.

**Definition of minor trauma**

Trauma is caused by external force or energy transferral which exceeds the injury threshold of the body tissue (Greaves, Porter, & Garner, 2009). The
external force is an energy which can be in form of kinetic energy, thermal energy, electrical energy, chemical energy, and nuclear energy (Greaves, Porter, & Garner, 2009). Blunt trauma and penetrating trauma caused by kinetic energy; burns caused by thermal energy or electrical energy; electric shocks caused by electrical energy (Greaves, Porter, & Garner, 2009). Minor trauma is caused by low-energy trauma (Greaves, Porter, & Garner, 2009). In emergency department, understanding of the mechanism of injury will inform the individual patient care. According to AED triage guideline, minor trauma including recent minor headache without symptoms, sprain or injury with no fracture or dislocation suspected, and minor abrasion (Hospital Authority, 2011).

**Prevalence of pain in AEDs**

Cordell et al. (2002) found out that 52.2% of AED attendants’ chief complaint was pain in an urban and tertiary-care AED in America. Another American study also stated that more than half of the patients reported pain during AED attendance (Johnston et al., 1997). According to Tanabe and Buschmann (1999), a prevalent rate of 78% of patients had a chief complaint related to pain. Amongst 78% of patients of chief complaint of pain, 54% of them complained of intense pain in AED (Tchemy-Lessenot et al., 2003). Berben et al. (2008) has found 60% of trauma patients reported moderate and severe pain at discharge and only few patients received analgesia during their stay in AED.
Evidence of oligoanalgesia in AEDs

Oligoanalgesia is defined as under-treatment of acute pain (Wilson & Pendleton, 1989). Guru and Dubinsky (2000) stated that nearly 49% of patients felt their pain had not been relieved before discharge from AEDs. According to Albrecht et al. (2013), more patients (66%) not receiving analgesic felt under-treatment of acute pain when compared with patients (39%) received analgesic.

Clinical background

In Hong Kong, the total number of attendances at the Accident and Emergency Departments of the Hospital Authority was more than 2.2 million in 2012-2013 (Hong Kong Hospital Authority Annual Plan 2012-2013). For my serving Hong Kong West clusters, there were 127,800 attendances targeting in 2014-2015 (Hong Kong Hospital Authority Annual Plan 2015). The AED attendances had an increasing trend arising from an ageing and growing population (Lai & Ho, 2015). There were 254,711 cases of trauma by year of 1991, which equal to 25% of all attendances at AEDs (Rainer et al., 2000). In view of a large population of AED attendances, AEDs operates on a 5-level triage scales system to determine priority of care, appropriate venue for intervention, and intensity of care (Fan & Leung, 2013). According to A&E triage guidelines (Hospital Authority, 2011), patients were sorting into five categories:
Category 1: Critical patient, who suffers from a life-threatening condition caused by a major event and needs immediate treatment response.

Category 2: Emergency patient, who suffers from a potentially life-threatening condition and needs treatment response within 15 minutes.

Category 3: Urgent patient, who suffers from a major condition with potential risk of deterioration, and needs treatment response within 30 minutes.

Category 4: Semi-urgent patient, who suffers from an acute incident with a stable condition.

Category 5: Non-urgent patient, who has a minor and stable condition and can afford to wait without deterioration.

In my current working AED, average waiting-time of triage category 4 and 5 are 95 minutes and 160 minutes respectively to be assessed by doctor in year 2013-2014 (Accident and Emergency Information System, 2014).

1.2 Affirming the need

According to the record from the Accident and Emergency Information System (AEIS, 2014), 19,528 of AED attendances were related to trauma from September 2013 to August 2014. And, 10,425 traumatic patients had category 4 or 5 (AEIS, 2014). In view of triage guidelines (Hospital Authority, 2011), severity of trauma had to be assessed according to the anatomical site of the injury, mechanism of injury, and evidence of high energy impact, for example gun shoot, pedestrian thrown or run over, by triage nurses. For patients presenting trauma
pain in AED, triage nurses can initiated arm slings for upper limbs injury, Sam-splints for affected extremities and wound dressing for the wounds. Moreover, a Visual Analogue Scale had implemented in the documentation part for triage nurses assessing and documenting patients' pain intensity in January, 2015 in my working AED. Triage nurses had responsibilities to assess patients' pain level, however, nurses did not had right to initiate pharmacological interventions. Studies had found out that nurse manage pain early, at triage not only benefit to patients' well-being, but also could decrease waiting times and length of stay in AED, and, increased patients’ satisfaction (Campbell, Dennie, Dougherty, Iwaskiw, & Rollo, 2004; Krett-Dougherty, 2003; Seguin, 2004). Thus, an evidence-based guideline for nurse-initiated paracetamol for patients presenting minor trauma pain at AED would be developed and recommended in order to accommodate the needs of patients with minor trauma.

1.3 Study Objectives and Significance

This study aims to find out whether there are any differences for nurse-initiated paracetamol for patients presenting pain as a result of minor trauma compared to the usual nursing care which including arm slings for upper limbs injury, Sam-splints for affected extremities and wound dressing for the wounds. This research question guides the critical appraisal, translation, application, implementation, evaluation parts of the clinical guideline in this translational research. The objectives of this study are as follow:
1. To conduct a systematic literature review regarding to the effectiveness of nurse-initiated paracetamol for patients presenting minor trauma pain in AEDs.

2. To develop an evidence-based guideline conducted by nurses for minor trauma patients upon arrival AEDs to reduce their pain intensity.

As nurses are the first health care professionals to assess AED attendances, they are the most appropriate people to provide pharmacological pain management to bridge this gap of prolong delivery of analgesia. Based on the best available evidence or practice, a nurse-initiated paracetamol guideline would be developed so as to offer a higher standard of pain management in AEDs.

The research question is “Whether there are any pain intensity differences for nurse-initiated paracetamol compared with usual nursing care for patients presenting minor trauma pain in AED?”
Chapter 2: Critical Appraisal

In this chapter, the method of identifying and analyzing evidences from relevant literatures will be illustrated. It includes the description on the selection criteria and search strategy for the relevant studies, quality assessment and summary, and data synthesis of the selected reviewed studies.

2.1 Inclusion and Exclusion Criteria

In this systematic literature review, a number of selection criteria were set for recruiting relevant studies. They included: (1) primary studies; (2) studies written in English; (3) studies on adults who suffered from minor trauma pain; and (4) studies focused on paracetamol for minor trauma patients. Studies were excluded if they focused on non-pharmacological interventions.

2.2 Search strategy

The search strategy for this review study included electronic search and manual search from the reference lists. Three electronic databases were used; they are CINHAL, Pubmed, and PsycInfo. Throughout the searching process, year limit did not set so as to recruit relevant literatures as many as possible. Thus, 1,234 literatures were found using the keywords: ‘nurse initiated’, ‘emergency department’, ‘analgesic’ ‘paracetamol’, ‘pain analgesia’, and ‘minor trauma’. The initial search was done by recruiting literatures in which their titles resemble the above keywords. Meanwhile, the title and abstracts of these identified literatures was then scanned to decide whether they eligible for inclusion into the review. The numbers of selected literatures were further refined
by scanning the abstracts that met the inclusion and exclusion criteria. Finally, a manual search according to the reference lists of these selected literatures was done for identifying the relevant studies that might not be included in the three electronic databases adopted. After searching all databases and combining the results, six relevant studies were identified. The PRISMA chart and summary of search history and results was presented in Appendix A.

2.3 Table of evidence

A table of evidence was developed to extract and compile data from the six selected studies. The data is grouped into categories for utilization namely: study type, evidence level, patients’ characteristics, interventions, outcome measures, effect size and results of study. The table of evidence is modified by the evidence table from Scottish Intercollegiate Guidelines Networks (SIGN) (Sleith, 2012). Details of the 6 tables of evidence are attached in Appendix B.

In view of different research study designs, the level of evidence for all selected reviewed research studies was assessed and determined by the hierarchies from Melnk & Fineout-Overholt (2005). The table for hierarchies on level of evidence was attached in Appendix C. Five of the reviewed studies (Bondarsky, et al., 2013; Craig, Jeavons, Probert, & Benger, 2015; Ridderikhof, et al., 2013; Vahdati, Baghi, Ghobadi, Ghafouri, & Habibollahi, 2014; Woo, Man, Lam, & Rainer, 2005) are Level II of evidence from at least one well-designed randomized controlled trial, while one reviewed study (Wong, Chan, Rainer, &
Ying, 2007) is Level IV evidence from well-designed case-control and cohort studies.

2.4 Quality Assessment

The quality of the six selected studies was also assessed using appraisal tool called Scottish Intercollegiate Guidelines Networks (SIGN) developed by National Health Service (NHS) in Scotland in 1993. SIGN guidelines are derived from a systematic review of literature, and are simple and clear to use in critical appraisal. The first section uses key questions about the methodology, to judge how well the study meets key criteria. This is important that methodology can make a significant difference on the conclusion of the study. Section 2 of the SIGN guidelines relates to the overall assessment of the studies which bases on the questions replied in section 1. Each study is assigned one of 3 codes to conclude how well the studies fulfil of the criteria in section 1. Details of the quality assessment for each of the six selected studies are illustrated in Appendix D.

To begin with the appraisal, a clearly-focused research question should be considered. All Studies (n=6) did state clearly-focused research questions and provided details of population studied, intervention given and the outcomes in addressing the research objectives or purpose. Five out of six studies were randomised controlled trial (RCT) which three major characteristics of randomized controlled trial were present in these studies (Bondarsky, et al., 2013; Craig, Jeavons, Probert, & Benger, 2015; Ridderikhof, et al., 2013; Vahdati,
Baghi, Ghobadi, Ghafouri, & Habibollahi, 2014; Woo, Man, Lam, & Rainer, 2005). They were intervention, randomization, and control group. One study was a prospective cohort study (Wong, Chan, Rainer, & Ying, 2007). All the studies aimed at comparing the effect of paracetamol on the trauma patients in Accident and Emergency Department (AED) (n=6). The majority of studies (n=5) using RCT research design was good and appropriated in establishing the cause and effect relationship in studies. In randomization, five studies (n=5) showed that participants were randomly assigned to either intervention or control groups. The details about the method of allocation was not described in any of these studies, four studies stated clearly the method of randomization for participants such as computer-generated randomization list (Woo, et al., 2005), randomization list created by clinical research unit (Ridderikhof, et al., 2013), computerized random numbers table (Bondarsky, et al., 2013), and excel software (Vahdati, et al., 2014). For the baseline demographic variables, it explicitly stated that all studies (n=6) showed no significant difference and well-balanced between intervention and control groups at the entry to the trial. This means, baseline measures were considered and that would not affect the effectiveness of the interventions to the outcome measures. On the aspect of blinding, five studies (n=5) considered the double blinding which neither the staff nor patient knew which treatment was being given (Bondarsky, et al., 2013; Craig, et al., 2015; Ridderikhof, et al., 2013; Vahdati, et al., 2014; Woo, et al., 2005). The double blinding method was to eliminate the biases stemming from subjective assessment of outcomes. One study did not use blinding method (Wong, et al., 2007). In view of loss to follow
up, only two studies (Wong, et al., 2007 & Woo, et al., 2005) indicated 24% and 2% dropout rate respectively. A dropout rate of 20% or less was classified as at acceptable level (Melnyk & Fineout-Overholt, 2005) and hence, only one study (n=1) with clearly stated dropout rate of less than 20% was considered as acceptable (Woo, et al., 2005). And, other four studies did not have information to evaluate whether dropout rate was well-addressed in these studies or not. A higher drop-out rate will normally lead to downgrading the study. As for the follow up, most of the studies (n=5) were reviewed in the same time intervals whereas one study (Wong, et al., 2007) did follow up both intervention and control group in different time schedule. For the data collection, all studies stated that they were collected in the same way for both groups. For instance, the blinded investigators, research assistants or assessors (n=5) were responsible for obtaining the outcome information. Likewise, all the relevant outcomes between two groups in all studies (n=6) were measured by the same, standard, valid and reliable measuring tools in order to increase the validity of results. In power analysis, it should be done at the outset to each study so as to estimate the minimum numbers of study participants need in the study which contributing to achieve the significant results. Only three reviewed studies (Ridderkhof, et al., 2013; Craig, et al., 2015; Vahdati, et al., 2014) did the power calculation. The researcher did not state the sample size calculation in other studies (n=3) and therefore, it was questionable and rather hard to assess whether enough participants involved in the study in order to minimize the play of chance as well as showing the significant results. On the result session, it explicitly indicated that
statistical analysis were done in all studies (n=6). Initially, majority of studies (n=4) summarized the demographic or baseline characteristic of study participants in both groups in tables which allowed the readers to assess for the selection bias of participants (Bondarsky, et al. 2013; Craig, et al., 2015; Woo, et al., 2005, & Wong, et al. 2007). Four out of six studies reported and presented numbers of statistical analysis and results in form of tables as mean and standard deviation or range (Bondarsky, et al. 2013; Craig, et al., 2015; Woo, et al., 2005, & Wong, et al. 2007). Apart from tables, there were two researchers showed their finding in the form of bars (Bondarsky, et al. 2013, & Woo, et al., 2005) for better generating the information on phenomenon over time and easier comparison between the intervention and control groups. Meanwhile, four studies set the significant test at 5% level of significance (Bondarsky, et al. 2013; Craig, et al., 2015; Vahdati, et al., 2014 & Woo, et al., 2005) and two studies (Wong, et al., 2007 & Ridderikhof, et al., 2013) set 1% as the level of significance in the testing. All studies except one study (Ridderikhof, et al., 2013) showed the p-value whereas only two studies (Ridderikhof, et al., 2013 & Woo, et al., 2005) presented 95% confidence interval (CI) for identifying the precision of results. Finally, one of the studies (Wong, et al., 2007) considered that the outcome could be applied to other Hong Kong AED with similar patients and settings. For the remaining studies (n=5), they did not mention the generalizability of results in other clinical settings.

as high quality studies as they meeting criteria of RCT which including a clearly-focused research question, intervention, randomization, and control group. While one study graded as medium quality as it is a prospective cohort study without randomization (Wong, et al., 2007).

2.5 Summary and synthesis of findings

The description of findings for all six selected studies are discussed and summarized as follows.

Study population

Four of reviewed studies were carried out in Western countries while two studies carried out in Hong Kong (Wong, et al., 2007; Woo, et al., 2005); one in Netherlands (Ridderkhof, et al., 2013); one in America (Bondarsky, et al. 2013); one in United Kingdom (Craig, et al., 2015); and one in Iran (Vahdati, et al, 2014).

Number of Participants

In view of sample size, all studies clearly stated the number of eligible participants in each arm of intervention and control groups. According to the findings, the sample size of these studies varied from 55 to 547 subjects. Two of the reviewed studies reported sample size around 300 study participants (Wong, et al., 2007; Woo, et al., 2005) and one study reported more than 500 participants (Ridderkhof, et al., 2013) involved in research study. More than three studies involved sample less than 100 participants (Bondarsky, et al. 2013; Craig,
et al., 2015; Vahdati, et al, 2014). For the dropout rate of these six studies, only two studies explicitly stated out the dropout rate of 2% and 24% respectively (Wong, et al., 2007; Woo, et al., 2005). Only one study stated out the reasons of dropout (Wong, et al., 2007). The reasons of dropout are incomplete data record, left to consult private doctors.

**Participants’ characteristics**

Five studies (Bondarsky, et al. 2013; Craig, et al., 2015; Vahdati, et al, 2014; Wong, et al., 2007; Woo, et al., 2005) indicated the mean age for both groups of study participant. The mean age for the intervention group ranged from the age of 34 to 41 and from 32.9 to 44 for the control group. In other words, the average age for intervention group was 37.2 and 36.6 for control group. The age range from aged 16 to aged 55. The six studies explicitly illustrated that all participants suffered from pain resulted from minor trauma who were attending AED. Since any difference of baseline factors might affect the interpretation of findings, five studies (n=5) did compare the baseline characteristics and reported no significant statistical difference between intervention and control groups. In wong et al 2007 study, patient characteristics (age, sex, and type of injury) was assessed by using t-test and p –value <0.0001. The mean age and gender of patients in intervention and control groups had p-value=0.46 and p-value=0.09 respectively (Vahdati, et al, 2014). Two studies (Craig, et al., 2015 &Woo, et al., 2005), baseline characteristics are compared using \( \chi^2 \) test and with similar results. There was no difference in baseline characteristic of the patients by using standard deviations (Bondarsky, et al. 2013)
Interventions

In all interventional studies, most of the interventions were carried out by emergency nurses or research nurses (Craig, et al., 2015; Vahdati, et al, 2014; Wong, et al., 2007; Woo, et al., 2005). Two of them were conducted by emergency physicians or study investigators (Bondarsky, et al. 2013; Ridderkhof, et al., 2013). In view of the intervention content, all studies showed administering paracetamol to patients (n=6). Four studies stated the use of oral paracetamol (Bondarsky, et al. 2013; Ridderkhof, et al., 2013; Wong, et al., 2007; Woo, et al., 2005). The other two studies used of intravenous paracetamol (Craig, et al., 2015; Vahdati, et al, 2014). Four studies specified the dosage of one gram paracetamol (Craig, et al., 2015; Ridderkhof, et al., 2013; Vahdati, et al, 2014; Woo, et al., 2005). Two reviewed studies stated that the patients can receive additional analgesia from doctor if 1 gram paracetamol is not enough for their pain control. (Ridderikhof, et al., 2013; Woo, Man, Lam & Rainer, 2005). The doctor can prescribe tramadol (Ridderikhof, et al., 2013). In Craig, et al.’s study (2015), patients are advised to take no more than three grams of paracetamol in the next 24 hours. If the patient was admitted, an inpatient drug chart was written so that no more than three grams of paracetamol could be administered over the next 24 hours.

Comparison

All studies stated explicitly the presence of both intervention and control groups for comparing the effect of paracetamol for patients presenting minor
trauma pain to reduce their pain intensity. The content of comparison group comprised of routine AED treatment including arm slings for upper limbs injury, Sam-splints for affected extremities and wound dressing for the wounds. (Wong, et al., 2007), non-steroidal anti-inflammatory drugs including indomethacin, diclofenac, ibuprofen (Bondarsky, et al., 2013; Ridderikhof, et al., 2013; Woo, et a., 2005), and morphine (Vahdati, et al, 2014; Craig, et al., 2015).

**Evaluation**

All studies (n=6) arranged evaluation after intervention given. Four studies indicated the evaluation time is 30 minutes and 60 minutes after paracetamol commencement to reassess patient’s pain intensity (Craig, et al., 2015; Ridderikhof, et al., 2013; Vahdati, et al., 2014; Woo, et al., 2005); whereas one study indicated the evaluation time is 60 minutes after paracetamol commencement (Wong, et al., 2007).

**Outcome Measure**

All studies presented the main outcome measure on pain intensity. The measuring tools for pain intensity was either visual analogue scale (VAS) or numeric rating scale (NRS). Most of the studies (n=4) used VAS as measuring tool. Two studies used NRS as measuring tool (Bondarsky et al., 2013; Ridderikhof, et al., 2013).
**Effect Size**

Five studies (n=5) indicated that paracetamol was effective in minimizing pain intensity for patient suffering from minor trauma. One study Craig et al. (2015), indicated that paracetamol has the same analgesic effect as morphine (P=0.16). According to Todd, et al. (1996), a reduction of 13mm or more on VAS has to been shown to represent a clinically significant reduction in pain. In Woo et al.’s study (2005), it revealed that a reduction of 13 mm of VAS in 95% confidence interval. Meanwhile, Wong et al.’s study (2007) found that overall median reduction in VAS by 20mm at discharge (p<0.001). In the effect size of Bondarsky et al.’s study (2013), paracetamol group had 17 mm reduction in VAS (p<0.001). In Vahdati et al.’s study (2014), intervention group significantly mitigated in comparison with control group (p<0.005). In Bondarsky et al.’ s study (2013) found out 17 mm reduction in verbal numeric pain score for oral paracetamol group (p<0.001).

**Result of Review**

All reviewed studies (n=6) documented a statistically reduced pain scores in the intervention group (Bondarsky et al., 2013; Craig et al., 2015; Ridderikhof et al., 2013; Vahdati et al., 2014; Wong et al., 2007; Woo et al., 2005). Five studies found out that the pain score reduced 13mm or more on VAS which shown clinically significant (Bondarsky et al., 2013; Craig et al., 2015; Ridderikhof et al., 2013; Vahdati et al., 2014; Wong et al., 2007; Woo et al., 2005). All studies (n=6) reported participants suffered from pain resulted from minor trauma. Four
studies reported oral paracetamol as the intervention (Bondarsky et al., 2013; Ridderikhof et al., 2013; Wong et al., 2007; Woo et al., 2005). Five studies (n=5) had reviewed patients’ pain intensity on 30 minutes and 60 minutes after commencement of paracetamol (Bondarsky et al., 2013; Craig et al., 2015; Ridderikhof et al., 2013; Vahdati et al., 2014; Woo et al., 2005). Nearly all studies (n=5) reported the results with effect size (Bondarsky et al., 2013; Craig et al., 2015; Vahdati et al., 2014; Wong et al., 2007; Woo et al., 2005).

2.6 Synthesis and implications

Based on the evidences from reviewed studies, it suggested that one gram of paracetamol showed positive effect on reducing patient’s pain intensity resulted from the minor trauma. The follow up time is 30 minutes and 60 minutes after paracetamol commencement to reassess patient’s pain intensity using VAS. Patients can request tramadol from doctor if one gram of paracetamol is not enough. Patients are advised to take no more than three grams of paracetamol in the next 24 hours. From the synthesis of the reviewed studies, the mode of follow-up can be telephone responding to questionnaire to assess patient’s health-related quality of life. Therefore, it is the high time for us to consider the use of effective paracetamol intervention in developing an evidence-based guideline for minor trauma patients.
Chapter 3: Assessment of Implementation Potentials

The six studies reviewed in Chapter 2 collectively concluded that paracetamol was effective in reducing minor trauma pain. It is worthwhile to translate the corresponding evidence and apply it in AEDs. In order to implement paracetamol intervention at triage to reduce minor trauma pain intensity of adult patients in the AED, there should be a thorough assessment of its implementation potential so as to develop an evidence-based practice (EBP) guideline. In this chapter, transferability of findings, the feasibility of implementation, and the cost to benefit ratio of the innovation will be assessed (Pilot & Beck, 2004).

3.1 Transferability of the findings

3.1.1 Target audience

Selection of Target Audiences

In literature review, it suggested that paracetamol was effective to reduce minor trauma pain including extremity pain; pain resulted from strains, sprains and contusions; and headache caused by pure trauma. In local AED triage guidelines for minor trauma injury included sprain, injury with no fracture or dislocation suspected, recent minor head injury without symptoms, and minor abrasion with triage category 4 or 5 (Hospital Authority, 2011). The characteristics of audience in the literature review and the local setting were nearly the same. Therefore, the intervention was fit into local clinical setting. To
be specific, it targeted at patients who suffered from pain resulted from minor trauma injury with category 4 or 5 during their initial triage assessments in AED.

**Characteristics of Target Audience**

This innovative paracetamol intervention at triage by nurses target at all patients with minor trauma attends AED. They all triaged with category 4 or 5 after triage nurse assessment. In view of the six reviewed studies, the age group was considered as one of the characteristics for the study participants. The mean ages for both intervention groups and control groups ranged from 34 to 41 and from 32.9 to 44 respectively. Moreover, two studies (n=2) stated that nurse-initiated paracetamol was targeted to patients who aged of 18 or above (Ridderikhof et al., 2013; Wong et al., 2007); or between aged from 18 to 55 (Vahdati et al., 2014); or, between aged from 16 to 65 (Craig et al., 2015). Therefore, when taking the reference of the age group from the studies, study participants aged from 18 to 55 is suggested. Based on the reviewed studies (n=6) no previous analgesia taken for the minor trauma pain was set as one of the characteristics of study participants (Bondarsky et al., 2013; Craig et al., 2015; Ridderikhof et al., 2013; Vahdati et al., 2014; Wong et al., 2007; Woo et al., 2005). Participants should also be free of physical, visual, or cognitive impairment, since all these characteristics may affect the clinical assessments and lead to invalid and false results on the visual analogue scale. Moreover, patients with hepatic or renal problems, and alcoholism should be excluded as paracetamol used with caution in these group of patients (Summers, 2007).
Pharmacological Approach in Pain Management in AED

The intervention in all reviewed studies is prescribing paracetamol for patients presenting minor trauma pain. Four studies stated the use of oral paracetamol (Bondarsky, et al. 2013; Ridderkhof, et al., 2013; Wong, et al., 2007; Woo, et al., 2005). Paracetamol is a well-tolerated, effective, and inexpensive analgesia. Therefore in Hong Kong AED, it is always be the first choice simple analgesic for most patients with mild to moderate pain (Lee, Tse, Tang, & Wong, 2011). In the oral analgesic ladder, paracetamol 1g is the first step for adult patient of AED pain management (Lee, Tse, Tang, & Wong, 2011). When prescribing paracetamol to patients, triage nurse should follow the current practice of “5 Rights”: right patient, right drug, right dose, right time, and right route. In addition, a 6th right was introduced, right to refuse (Goh, CHoo, Lee & Tham, 2007).

3.1.2 Target Setting

With reference to the six reviewed studies, all interventions about prescription of paracetamol for minor trauma patients were conducted in AED. Therefore, AED is an appropriated place to implement this innovated practice. My working AED is located in Hong Kong Island which is a public acute hospital and managed by the Hospital Authority (HA). In AED, there is a triage station with two areas for triage nurses assessing patients who are walk-in with or without wheelchair. Each of the area located with one computer for capturing triage time by AEIS system and viewing patient past medical history by Clinical
Management System (CMS). Essential equipments and medication like normal saline are stored in a four-stored drawer. Moreover, another triage area inside the AED, five cubicles are provided for patient come with stretches or wheelchairs; each cubicle can accommodate 2 stretches or 2 wheelchair-bound patients and therefore ten patients in total. Five computers located inside AED health care staff station for the triage nurses to assess AEIS and CMS. There is a medication cupboard and three drawers for storage of top-up medication inside the station. Triage nurses are the first health care professionals to assess and contact the AED attendant in the triage station and the five cubicles. In short, the environment is appropriate to launch such innovative interventions in AED.

3.1.3. Philosophy of care

According to the guideline for specialty nursing services for Accident and Emergency care, the philosophy of emergency nursing are based on timely care to patients suffering from life-threatening conditions or injuries resulted from accident that is urgently in needs of medical and nursing interventions (Hospital Authority, 2012). The emergency nursing delivery model emphasizes the individual as a primary focus. Nursing care is provided through nursing process by team nursing and named nurse (Hospital, 2012). This approach supports the whole person in promoting physical, psychological and spiritual health. Most importantly, Hospital Authority supports the extended role of emergency nurse who can prescribes medications according to endorsed protocol, such as paracetamol, which shortens consultation time for patient whose condition is not life-threatening but requires initial treatment as soon as possible. This extended
role of nurse would enhance patient care; improve nurses’ job satisfaction (Hospital Authority, 2012). According to Hospital Authority (2005), nurse-initiated medications approved by hospital Drug and Therapeutic Committees (DTC) specify registered nurses or above rank allowed to initiate medications on the approved list of medication including paracetamol. Furthermore, Hospital Authority has been actively supporting evidence-based nursing practice. AED has a rise of evidence-based movement over the past two decades. In the same time, nurse initiating paracetamol showed positive effects in reducing pain intensity for the minor trauma patients as reported from the reviewed studies (Bondarsky et al., 2013; Craig et al., 2015; Ridderikhof et al., 2013; Vahdati et al., 2014; Wong et al., 2007; Woo et al., 2005). The proposed innovation is a nurse-initiated paracetamol protocol supported with best evidence for physical and psychosocial care to patients with minor trauma in AED. That is to say, the philosophy of care underlying this innovation is fundamentally similar to the philosophy of care in the prevailing practice setting.

3.1.4 Estimated benefit to patients

The average number of attendance in my working AED is approximately 320 daily. About 85% patients are adult, 70% categorized 4 or 5, and 15% are traumatic patients (AEIS, 2014). By calculation using 365 days, the estimated number of adult minor trauma patients eligible for nurse initiating paracetamol is 10,425 (320 x 365 x 85% x 70% x15%= 10,425) annually.
3.1.5 Estimated schedule for implementation and evaluation

It takes about 34 weeks for the implementation period. It starts with guideline and proposal development. Sending the proposal to Chief of Service (COS); Department Operational Manager (DOM), Ward Manager (WM) and Drug and Therapeutic Committees (DTC) for approval and applies grant for this innovation will be about 8 weeks. After setting up an organization committee, the committee will execute and review the innovation over the next 10 weeks. After approval, the pilot program will be executed from 9am-5pm over 8 weeks, as most of the committee members’ work in this shift. The patients’ pain intensity, waiting time for analgesia, and acceptance and preference of nurse initiated paracetamol will be evaluated. A survey will be sent to nursing staff for the intervention evaluation. This process of the data collection, analysis and evaluation will take about 8 weeks.

3.2 Feasibility

According to Pilot and Beck (2004), the importance of nursing autonomy in the feasibility of the intervention includes the resource and staff availability; the departmental atmosphere and administrative support, and resistance to and consensus of the innovation.
3.2.1 Resource and staff availability

Interference with current staff functions and workload

In the proposed AED, there are 38 registered nurses (RNs) and 15 Nursing Officers (NO) or Advanced Practice Nurses (APNs), total 53 qualified practice nurses who have at least one year AED experiences and has attended structured triage training such as workshop on Triage Assessment (Hospital Authority, 2011). Each AM and PM shift has around 9 nursing staff and night shift duty has 6 nursing staff. Two Registered Nurses (RNs) and one Advanced Practice Nurse (APN) responsible for triage, three RNs responsible for resuscitations, one RN responsible for dressing and simple suture, and one RN responsible for walk-in clinic during AM and PM shift. Except triage nurses, all other nurses are responsible for carrying out doctors’ prescribed treatments and discharge of patients. Currently, triage nurses will assess and give intervention to minor trauma patients at triage station or in cubicles. The interventions include dressing and immobilization by arm slings or Sam splint. In fact, the proposed practice is the extension of existing triage services to cover both non-pharmacological and pharmacological aspects. Implementing the new innovation of nurse-initiated paracetamol will extend the role of nurses. But it is expected that the modification of the intervention components will cause minimal interference to current staff workload.
Equipment and facilities for innovation

Equipments and facilities such as conference room, computers, projectors and photocopiers are readily available in the department for any training purpose. Clerks and secretaries in the department can prepare pain scale rating cards and photocopying.

3.2.2 The departmental atmosphere and administrative support

Freedom to carry out the innovation

Generally, AED nurses have autonomy to conduct any evidence-based practice once it is approved by administrative level. Firstly; the proposer shows the available evidences and information to one of the APNs who is the clinical guideline developer in AED. After getting the support and agreement from APN, a well-planned and detailed proposal will be presented to the administrative level such as Department Operations Manager (DOM) and Ward Manager (WM), Chief of Service (COS), Consultant (CONS), for getting their endorsements and consensus. As nurse-initiated paracetamol involved medication, the proposal will also be presented to Drug and Therapeutic Committees of Hong Kong West Cluster for getting support and endorsements. During the discussion, any suggestions for adjustments and feedback would be received from the DOM and other managerial member for better addressing the practical concerns and meeting the patients’ needs. After it is approved by DOM and other members, briefing session of the innovated practice will be given to all nurses before pilot testing and any termination of intervention if necessary can be decided by DOM.
Administrative support

In general, administrator like DOM has been supportive in adopting evidence-based nursing practices within the department. It is common that staff training workshops or seminars will be given before implementation of new practice. To cite an example, the Nurse Specialist from Intensive Care Unit will be invited to share the extracorporeal membrane (ECMO) care to staff prior to the use of ECMO in resuscitation patients within department. Therefore, departmental administrators have to allocate resources to facilitate the proposed innovation once it is assessed as a worthwhile practice.

Resistance against the innovation

Practice nurses including RNs, NOs, and APNs may resist this innovation. However, a number of benefits from this programme in view of patients, nurses and departments can gain nurses’ support. It is supposed that nurses will be willing to conduct it in their daily practice with minimal resistance.

Need for availability of external assistance

The most suitable providers for prescribing paracetamol are qualified practices nurses including RNs, NOs, and APNs with at least one year AED working experiences. Therefore, staff training to them in terms of pain assessment, use of pain rating tools, paracetamol medication knowledge will be provided by the pain nurses form Department of Anaesthesiology.
3.3 Cost/Benefit ratio of the intervention

3.3.1 Costs of Implementation

Both material costs and non-material costs are taken into consideration when implementing the nurse-initiated paracetamol guideline. As for the material costs of implementation, printing expenses, equipments, facilities, nurses training, and pain nurse from Department of Anaesthesiology expenses, whereas stress from triage nurses is the non-material costs.

Printing material including training manuals and all VAS cards are necessary in this nurse-initiated paracetamol innovation. Furthermore, expenses for photocopying evaluation questionnaires for both patients and nurses are also essential for getting feedback and comments.

Training expense is also one of the material costs. Three identical sessions, each session three hours, will be conducted by the pain nurse from the Department of Anaesthesiology to all AED practice nurses including RNs, NOs and APNs. The estimated mean monthly salary for RN and NO or APN in AED are $3,626.4 and $52,018 respectively according to Hospital Authority Pay Adjustment Scale 2014 (Hospital Authority, 2014). The hourly salary is approximately $206 and $296 respectively and hence, the estimated expenses for 38 RNs and 15 NOs or APNs to attend training in 3 hours are $36,804. For the workshop, it is part of the pain nurse’s duty and will be conducted within her working hours. So, the expenses for pain nurse to offer three identical sessions of 3 hours’ training workshop are also counted into the budget plan. Based on the
Hospital Authority Pay Adjustment Scale 2014 (Hospital Authority, 2014), the estimated mean monthly salary for pain nurse who is nurse specialist is $50,593 and his/her hourly salary is $287. Thus, the expenses for 3 identical 3-hour training workshop are $2583.

Another material cost is paracetamol. According to Department of Pharmacy in Queen Mary Hospital, each tablet of 500mg paracetamol is $0.03 and every patient will receive two tablets (Hospital Authority, 2011). The estimation of 10,415 trauma patient annually, $62.7 will be the expense. No extra cost is incurred in using the existing computers, projectors, photocopiers as well as the conference room. In general, all these equipments and facilities are the properties of the department and easily available for training purpose once it is booked in advance. In summary, the estimated total expenses for this nurse-initiated paracetamol protocol are about $51,014.7. In Appendix E, detailed calculation for estimated material cost of the nurse-initiated paracetamol programme is attached.

As for the non-material costs, the nurses may be stressful about the extended role and functions. Nurses’ satisfaction may decrease with the unfamiliar protocol at the beginning. By providing training programme, nurses can familiar with the protocol and more adaptable to the new protocol. In the long run, it hope that nurse-initiated paracetamol can enhance nurses’ autonomy, and hence staff’s satisfaction.
3.3.2 Benefits of implementation

The potential benefits of implementation this nurse-initiated paracetamol are to reduce the pain intensity and the waiting time to paracetamol of the patients presenting minor trauma pain in AED categorized 4 or 5. According to the record from the Accident and Emergency Information System (AEIS), the average medical waiting time of categorized 4 and 5 patients is 120 minutes, whereas, the nursing waiting time for triage were 5 minutes (AEIS, 2014).

Considering the non-material side of the potential benefits, all three parties, patients, nurses and department, can be benefited from this innovated practice.

For patients, the nurse-initiated paracetamol can reduce minor trauma patients’ pain intensity. Based the study of Wong et al. (2007), the findings demonstrated both a statistical and clinical significance in reduction in pain scores in the nurse-initiated paracetamol group, with a overall median reduction in visual analogue scale by 20 mm at 60 minutes post-triage. In Woo et al.’s study (2005), it revealed that a reduction of 13 mm of VAS in 95% confidence interval. In the effect size of Bondarsky et al.’s study (2013), paracetamol group had 17 mm reduction in VAS (p<0.001). In Bondarsky et al.’ s study (2013) found out 17 mm reduction in verbal numeric pain score for oral paracetamol group (p<0.001).

For nurses, the potential benefits for this new practice is the extended role of emergency nurses would improve nurses’ job satisfaction. At the same time, nurses will increase autonomous decisions regarding analgesic with safe
outcomes for the patients. Moreover, reputation of AED will be increased by providing such holistic nursing care to minor trauma pain patients.

3.3.3 Cost-benefit ratio

The costs for implementation the innovation is $51,014. The benefit is intangible by improving patients’ biological and psychological aspects. By striking the balance between the costs and benefits for the proposed innovation, the estimated benefits outweigh the expenses. Therefore, it is cost-effective and rewarding to carry out this practice in AED in order to let more minor trauma patients enjoy the benefits of the service.
Chapter 4:

Evidence-based practice guideline

4.1 Introduction

Findings from the reviewed studies suggested that nurse-initiated paracetamol at triage showing positive and significant effect in reducing pain scores for patients with minor trauma pain in AED. Meanwhile, ample and convincing evidences support the transferability and feasibility of implementing such intervention in local setting. Calculation of the costs and benefits of the proposed nurse-initiated paracetamol showed that its potential benefits outweigh the estimated expenses. It is confident to say that the innovated practice is cost-effective, highly transferrable and feasible in the local setting. An evidence-based practice guideline for patients presenting minor trauma pain in AED is developed and described in this Chapter.

4.2 Purpose of practice guideline

Title

An evidence-based practice guideline for nurse-initiated paracetamol for patients presenting minor trauma pain at Accident and Emergency Department.

Aim

Reduce the pain intensity of patients with minor trauma pain through the nurse-initiated paracetamol at triage.
Objectives for the nurse-initiated paracetamol guideline

- To guide AED triage nurses on using paracetamol for minor trauma patients based on best available evidence;

- To standardize the nursing care and maintain the quality of service to patients;

- To increase quality pain management for patients presenting minor trauma pain in the AED.

Target setting

- An AED in Hong Kong

Target population

- Adult patients with minor trauma pain who are triaged with category 4 or 5

Inclusion criteria:

- Between the aged 18 to 55

- Able to read and see

- Cantonese, Mandarin or English-speaking patients

Exclusion criteria:

- Allergy to paracetamol

- Cognitive disability
- Alcoholism

- Hepatic diseases

- Renal diseases

- Previous treatment with an analgesic for the same injury

**Intended users**

AED qualified practice nurses including RNs, NO, and APNs with at least one year AED experience who received training from pain nurse specialist can carry out the nurse-initiated paracetamol intervention according to this guideline.

**4.3 Outline for practice guideline**

The nurse-initiated paracetamol guideline is targeted to AED attendants who suffered from minor trauma pain and triaged with category 4 or 5 AED management. Nurse can initiated and administer one gram paracetamol for the target patients who can walk or wheelchair-bound at triage station or patient who are come with stretches in the cubicle. Meanwhile, patients’ pain scores are recorded in visual analogue scales (VAS) in AED card at triage phase. After 30 minutes and 60 minutes of paracetamol administration, patients’ pain intensity will be reassessed VAS and recorded in AED cards to see the effectiveness of paracetamol by nurses. Patents are advised not to take more than three gram of paracetamol and return the self-designed questionnaire before discharge form AED.
4.4 Development of Practice Guideline

Grades of recommendations

The grades of recommendations were developed by the Scottish Intercollegiate Guidelines Network (2012) and range from A to D. Each recommendation is supported by the 6 reviewed studies with their level of evidence. All recommendations are Grade A. The criteria of recommendations are attached in Appendix F.

Recommendations

Recommendation 1: Trained triage nurses are responsible for carrying out this protocol. (Grade A)

Evidence:

Four of reviewed studies reported that the paracetamol was initiated by nurses. (Craig, et al., 2015 [2+]; Vahdati, et al, 2014[2+]; Wong, Cahn, Rainer & Ying, 2007 [2+]; Woo, Man, Lam & Rainer, 2005 [1+]). Besides, one of the studies stated that the responsible nurses for conducting this intervention were well trained in communication skills and care of patients with minor trauma injury (Wong, Cahn, Rainer & Ying, 2007 [2+]).

Recommendation 2: Minor trauma patients are recruited as eligible study participants who are categorized as 4 or 5 AED management (Grade A).
Evidence:

All reviewed studies (n=6) recruited patients with minor trauma pain resulted from minor traumatic mechanism (Bondarsky, et al., 2013 [1+]; Craig, Jeavons, Probert & Benger, 2015 [1+]; Ridderikhof, et al., 2013 [1+]; Vahdati, Baghi, Ghobadi, Ghafouri & Habibollahi, 2014 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). Three of the reviewed studies had patients of painful isolated limb injuries (Craig, Jeavons, Probert & Benger, 2015 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). One of the study reported that the new triage pain management protocol was mainly focused on isolated limb injury patients with triage category 4 (Wong, Cahn, Rainer & Ying, 2007 [2++]).

Recommendation 3: Administered 1g paracetamol orally to patient presenting minor trauma pain. (Grade A)

Evidence:

All reviewed studies (n=6) administered paracetamol to patients with minor trauma injury (Bondarsky, et al., 2013 [1+]; Craig, Jeavons, Probert & Benger, 2015 [1+]; Ridderikhof, et al., 2013 [1+]; Vahdati, Baghi, Ghobadi, Ghafouri & Habibollahi, 2014 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). More than half of the studies (n=4) administered oral paracetamol to patients (Bondarsky, et al., 2013 [1+]; Ridderikhof, et al., 2013 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). One study conducted in Accident and Emergency Department of Hong
Kong stated that the dose of 1g paracetamol chosen first because they are in accordance with British National Formulary recommendations and second because it is the dosage used in emergency physicians’ practice (Wong, Cahn, Rainer & Ying, 2007 [2++]).

Recommendation 4: Using 100mm numbered and horizontal Visual Analogue Scale (VAS) to measure patients’ pain intensity. (Grade A)

Evidence:

More than half reviewed studies (n=4) used VAS to measure minor trauma pain intensity (Craig, Jeavons, Probert & Benger, 2015 [1+]; Vahdati, Baghi, Ghobadi, Ghafouri & Habibollahi, 2014 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). One of them utilise a specially designed 100mm VAS, A4 sized laminated chart for triage nurses rating patients’ pain intensity (Wong, Cahn, Rainer & Ying, 2007 [2++]). One of them used numbered and horizontal VAS for baseline measurement and subsequent intervals (Woo, Man, Lam & Rainer, 2005 [1+]). A4-paper sized VAS will be used in the guideline because it is easier visualized by patients.

Recommendation 5: Patients’ pain score are taken at 0, 30, and 60 minutes after the start of paracetamol. (Grade A)

Evidence:

Four studies indicated the evaluation time is 30 and 60 minutes after paracetamol given to reassess patients’ difference of pain intensity injury (Craig,
Jeavons, Probert & Benger, 2015 [1+]; Ridderikhof, et al., 2013 [1+]; Vahdati, Baghi, Ghobadi, Ghafoori & Habibollahi, 2014 [1+]; Woo, Man, Lam & Rainer, 2005 [1+]). Half of the reviewed studies (n=3), the median reduction in VAS after 60 minutes in the post-test period, was 20mm (Bondarsky, et al., 2013 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]) and 23mm (Craig, Jeavons, Probert & Benger, 2015 [1+]) respectively. A reduction of 13mm or more on VAS scoring has been shown to represent a clinically significant reduction in pain (Craig, Jeavons, Probert & Benger, 2015 [1+]; Ridderikhof, et al., 2013 [1+]; Woo, Man, Lam & Rainer, 2005 [1+]).

Recommendation 6: The doctor on duty was free to give extra or alternative doses of analgesia if clinically required, and this was documented. (Grade A)

Evidence:

Two reviewed studies stated that the patients can receive additional analgesia from doctor if 1g paracetamol is not enough for their pain control. (Ridderikhof, et al., 2013 [1+]; Woo, Man, Lam & Rainer, 2005 [1+]). The doctor can prescribe tramadol (Ridderikhof, et al., 2013 [1+]).

Recommendation 7: Patients were advised to take no more than 3g of paracetamol in the next 24 hours. (Grade A)

Evidence:

The patients discharged following the study were advised to take no more than 3g of paracetamol in the next 24 hours. If the patient was admitted, an
inpatient drug chart was written so that no more than 3g of paracetamol could be
administered over the next 24 hours (Craig, Jeavons, Probert & Benger, 2015 [1+]).
Chapter 5: Implementation plan

Many evidences and supports are demonstrated in the transferability, feasibility, cost-benefit ratio of the proposed new triage pain protocol for minor trauma patients in Accident and Emergency Department (AED) as described in the previous chapters. And hence, seven practice recommendations for using the nurse-initiated paracetamol protocol had been developed (Appendix G). Before implementing the nurse-initiated paracetamol in AED, the project’s proposer has to identify, plan and adopt a number of strategies in communicating with the potential stakeholders in order to avoid the unnecessary objections. In this chapter, the communication plan and pilot study plan for this proposed nurse-initiated paracetamol protocol will discuss.

5.1 Communication Plan

Effective communication with the stakeholders is necessary and important before implementation of this innovated practice in AED. Stakeholders are those who may be affected by the proposed changes. Therefore, identification and communication with the potential key stakeholders will enhance the smooth running of the proposed innovation successfully.

Identification of Stakeholders

As for the proposed nurse-initiated paracetamol protocol, decision makers such as Department of Manager (DOM) and Ward Managers (WMs) are the stakeholders at the administrative level. They develop clinical department plan and allocate budgets for implementing the innovation.
Practice nurses including Nursing Officer (NO), Advanced Practice Nurse (APN) and Registered Nurse (RN) are the stakeholders in this proposed protocol. In current AED practice, paracetamol is prescribed by doctors. As the proposed nurse-initiated paracetamol protocol is prescribed by nurses, the protocol would extend nursing role and increase workload on nurses, thus imposing extra pressure on NO, APN and RN when they carry out the new practice in the AED.

Another potential stakeholder is the doctors in AED. If clinically required, the doctors on duty were responsible to give extra or alternative doses of analgesia. Therefore, this change of new practice may also have doctors’ involvement.

Patients are the last stakeholders of this proposed practice as they will receive the nurse-initiated paracetamol directly from nurses. As the proposed innovation is a extend role of practice nurses, it is, therefore the patients’ acceptance of prescribing paracetamol from nurses also a concern in implementation of the innovation.

**Communication with Administrators**

In my AED, an evidence-based practice group was form by DOM, 2 WMs, 2 APNs and 2 RNs. The proposer will explain the nurse-initiated paracetamol protocol to one of the APNs who will introduce the protocol during the evidence-based practice group meeting. After discussion with the evidence-based practice group members and agreed by DOM, the proposed protocol will be submitted to
Chief of Service (COS) of the Accident and Emergency Department and the Drug Therapeutic Committees (DTC) of Hong Kong West Cluster.

Before the evidence-based practice group meeting, the proposer will explain the insufficiency of current pain management at triage and provided best available evidences from the selected literature to support the need of change on the current pain management to one of APNs in the evidence-based practice group. According to career progression model for nurses (Hospital Authority, 2008), APN served as an advocator for evidence-based practice and a promoter for its implementation. Moreover, APN is responsible for initiating and participating in evidence-based practice and research. As a result, APN can give her expertise advice as well as her collaboration for the proposed change of practice in AED.

During evidence-based practice group meeting, APN initiate the new protocol of pain management at triage by providing best available evidences and the need of change on current pain management in AED. The members of the group will discuss and provide comments for the new practices.

After getting the support and collaborations from the evidence-based practice group and all evidence-based group members including WM and DOM consider the new practice is appropriate, WM and DOM will plan and facilitate nursing research activities. DOM has to manage all operational activities and planning for implementation of nursing research activities and evidence-based practice in the AED (Hospital Authority, 2008). Moreover, he is a decision maker
in allocating resources and manpower for launching this new practice. Therefore, any change of practice in the AED must be approved by DOM.

Both COS and DTC will approach for getting endorsements and consensus on the proposed change after DOM’s agreement. DOM will provide detailed explanation for the proposed change during the formal meeting with COS and DTC. By the multi-discipline approach from nurses and doctors, it is anticipated that the transferability and feasibility of the proposed innovation will be further discussed.

**Communication with Frontline**

After the proposed innovation endorsed by COS and DTC, a formal nursing staff meeting will be held. In the meeting, the proposer will explain the proposed innovation’s advantages are far outweighing the disadvantages by providing relevant information and evidences as described in Chapter 2. With support of evidences from selected studies, the proposer can further explain to all nursing staff the rationales for the change of current practice as reasonable and justifiable. As a result, all nurses are understandable about the importance and needs for change of current practice. At the same time, they are encouraged to voice out their opinions and concerns in the meeting. After the meeting, a training session is provided by pain nurse from Department of Anaesthesiology. Furthermore, modification for the new practice will be made for addressing their needs and reassurance.

**Approach for Sustaining the Change of Practice**
The evidence-based practice group will hold meeting every month. Besides the members of the evidence-based practice group, all practice nurses in AED are welcome to join the meeting in order to raise their concerns and comments about the new practice. Moreover, once the nurse-initiated paracetamol protocol is completed, the responsible nurse will mark patients’ pre- and post-test pain scores with time on the AED cards. In current practice, all AED cards will be checked by the in-charge NO or APN in each shift to ensure all prescribed treatments are given to patients upon their discharge. That is to say, this serves as an auditing procedure for checking nurses’ compliance on the nurse-initiated paracetamol protocol.

5.2 Pilot Testing

A pilot test will be conducted before the actual implementation of the proposed guideline. Two objectives of this pilot test for nurse-initiated paracetamol. To find out the feasibility of subject enrolment, the intervention, and data collection plan is the first objective. The second objective is monitoring and preliminarily evaluating the effectiveness of innovation. The ultimate goal is to identify the weaknesses and unexpected problems of conducting the nurse-initiated paracetamol protocol, and thus, based on the preliminarily findings and feedback from the pilot test, further revision can be made before its actual implementation in the AED.
Study Participants

The pilot test for this nurse-initiated paracetamol protocol is targeted to all minor trauma patients with categorized as 4 or 5, aged 18 to 55, able to speak and read, speak Cantonese, Mandarin, or English, with no paracetamol allergy, cognitive disability, hepatic diseases, and previous treatment of an analgesic with the same injury (Bondarsky, et al., 2013; Craig, Jeavons, Probert & Benger, 2015; Ridderikhof, et al., 2013; Vahdati, Baghi, Ghobadi, Ghafouri & Habibollahi, 2014; Wong, Cahn, Rainer & Ying, 2007; Woo, Man, Lam & Rainer, 2005).

Responsible Staff and Staff Training

Currently, the qualification of triage nurse should be Registered Nurses (RNs) or above grade such as NOs or APNs with minimum of one year AED experience; and has attended structured triage training such as workshop on Triage Assessment (Hospital Authority, 2011). WM arranges job assignments to all nurses in AED. Normally, two practice nurses including one NO or APN and one RN will be assigned as triage nurses in AM and PM shifts. Under the proposed new nurse-initiated paracetamol protocol, it is planned that two assigned triage nurses in AM and PM shifts will be responsible for the programme at the triage station and two triage nurses responsible for patients come with stretches. Two nurses are responsible for checking medications in my AED. Therefore, one triage nurse responsible for prescribing and administering of paracetamol and the other nurse as the checker.
Flow-Chart and staff training

The pilot test for the nurse-initiated paracetamol at triage will be implemented when guideline is well prepared and staff training is completed. Based on the information from the selected reviewed studies, the new triage flow chart for the minor trauma pain patient at triage in Appendix H is developed by the proposer. Basically, it will design to be simple and easy to follow so as to enhance the comprehensibility of the triage nurses. Any amendments of flow chart will be made based on the comments from the COS, Consultant, DOM, WMs, APNs, practice nurses in the AED and minor trauma pain patients. Copies will be made and placed in the triage station once the flow chart is ready. Moreover, the VAS card will be printed on an A4-paper size and put in triage area for easier visualized by patients. For the staff training, it is planned that one session of 1-hour training will be held by the pain nurse from the Department of Anaesthesiology during the AED training day as most nurses and doctors will attend the training. In the training session, knowledge on minor trauma pain signs and symptoms, assessment skills and briefing on using 100mm Visual Analogue Scale will be included. Furthermore, any concerns can be shared at the end of the training session.

Setting and Duration

The pilot test will be carried out at triage station and cubicles. Two consultation areas in the triage station will be available to conduct the new practice. As more practice nurses in AM and PM shift, the pilot test will run from
9am to 5pm so that each practice nurse can make an adoption into new innovation to 24-hours service afterwards. Currently, 53 qualified triage practice nurses (NOs, APNs and RNs) are working in the AED and the pilot test expected that all triage nurses including NOs, APNs and RNs can practice the innovation before the actual implementation. It is anticipated that around 4 weeks for all practice nurses to be assigned as triage nurses in this pilot testing. As for data collection and programme refinement, approximately 4 weeks are needed. This pilot test duration will roughly last for 8 weeks in total.

**Procedure and Data Collection**

When the patients arriving AED and assessed by nurses at the triage station. According to the standardized triage guideline (Hospital Authority, 2011) triage nurses will categorize patients and recruit eligible patients into the study. The target patients will be assessed their pain intensity by using 100mm Visual Analogue Scale (VAS) and prescribe 1g oral paracetamol. After triage assessment, the triage nurses will place those AED cards of minor trauma patients onto the assigned reassessment tray. After 30 minutes and 60 minutes, nurses will reassess minor trauma patients' pain intensity again. Afterward, the minor trauma pain patients' AED card will place to doctor’s tray for doctors' assessment. Meanwhile, nurses will concern about patients' waiting time on the waiting queue to ensure the protocol will not delay medical consultation. If the patients wait less than 30 minutes or 60 minutes for medical consultation, patient will be assessed by doctor first. As for the primary process evaluation, each patient will complete the questionnaire after doctors’ consultation; to get patients’
feedback and evaluate their level of satisfaction towards this nurse-initiated paracetamol protocol, a self-designed questionnaire for patients in Appendix I will be distributed by triage nurses and returned to any AED nurses during the discharge. After completion of the pilot test, the proposer will collect information of staff’s perceived feasibility of the programme for the health care provider outcomes.

**Evaluation**

Both process and outcome evaluations will be considered in this pilot test of nurse-initiated paracetamol protocol. The process evaluation is to collect both patients’ and nurses’ viewpoints towards the innovation by using a self-designed questionnaire in Appendices J and K. As a result, both patients and nurses can give feedback to the innovation. As for the patients’ outcome evaluation, the pain intensity of minor trauma patient will be assessed by VAS at 0, 30 and 60 minutes.
Chapter 6: Evaluation Plan

An evaluation plan is evaluating the effectiveness of the proposed nurse-initiated paracetamol protocol in the AED. In this chapter, identification of outcomes and measurements, nature and number of participants to be involved, data analysis and basis of demonstrating the effectiveness of interventions will be illustrated clearly.

6.1 Identification of Outcomes and Measurements

In this nurse-initiated paracetamol protocol, patient outcome, health care provider outcome and system outcome are the three main outcomes have to be identified. For the measurement on these outcomes, few evaluation tools and self-designed questionnaires will be utilized.

Patient Outcomes and Measurements

The outcome of nurse-initiated paracetamol at triage is to reduce the pain intensity among patients with minor trauma pain in AED. The VAS recorded in AED cards will be adopted for measuring the patient outcomes.

The primary outcome for the pain intensity of minor trauma pain patients will be measured at 0, 30 and 60 minutes after paracetamol administered. VAS is a horizontal line, which with 100mm in length (Appendix K). Once the patient has indicated the point on the scale that best represents the current level of pain, a centimetre ruler is placed on the scale and a numeric scale of 0 mm to 100 mm is given, whereas 0 mm represent no pain and 100 mm represent the most pain
intensity. According to Boonstra, Schiphorst, Henrica and Stewart (2014), VAS scores 34 mm corresponded to mild pain, whereas 35 mm to 64 mm implied moderate pain, and 65 mm implied severe pain.

**Process Evaluation**

A self-designed questionnaire for patients (Appendix I) will be used to evaluate patients’ perceptions and comments on the nurse-initiated paracetamol at triage. The questionnaire is designed to measure the following areas: (1) usefulness of nurse-initiated paracetamol at triage; (2) the readiness of reading and understanding the VAS; (3) the appropriate time for administering analgesic; (4) the duration for the reassessment of pain intensity; (5) the knowledge of practice nurses about the protocol. By gathering more information and feedback, further improvement of the nurse-initiated paracetamol protocol can be made. Moreover, patient’s health-related quality of life can be assessed by using follow-up questionnaire (Appendix E). The questionnaire including five areas: (1) mobility; (2) self care; (3) usual activities; (4) pain or discomfort; (5) anxiety or depression.

**Health Care Provider Outcomes and Measurements**

To assess the health care provider acceptance of the innovation, a self-designed questionnaire for nurses (Appendix J) will be used. The questionnaire is focused on the following aspects: (1) nurses’ acceptance on the nurse-initiated paracetamol protocol; (2) useful of training sessions; (3) feasible to continue the protocol; (4) nurses’ job satisfaction; and (5) staff’s stress level, any extra
workload and difficulties in carrying out the programme. Moreover, any comments can be raised for improving the feasibility of nurse-initiated paracetamol protocol. The proposer will gather and analysis the data and information collected.

**System Outcomes and Measurements**

In view of evaluating the system outcome, utilization of the nurse-initiated paracetamol protocol and allocation of manpower and availability of resources will be the two main focuses. As for the utilization of the protocol, the proposer can compare the number of eligible patients who attended AED with the actual number of patients involved in the protocol. The second outcome is the available resources, extra resources such as expenses for nurses training and printing materials should be considered. Furthermore, nursing staff may have extra workload and have a new function when implementing the new innovation. Therefore, discussion between administrative levels including DOM, WM with frontline staff is important to get their feedback and information at the end of nurse-initiated paracetamol protocol for further improvement.

**6.2 Study Participants and Sample Size**

The target of study participants are patients with minor trauma pain in AED, are aged between 18 and 55 years old, and categorized as 4 or 5. Additionally, participants should also be free of physical, visual, or cognitive impairment by checking medical history from CMS or giving information by patients, since all these characteristics may affect the clinical assessments and
lead to invalid and false results on the visual analogue scale. Moreover, patients with hepatic or renal problems, and alcoholism should be excluded as paracetamol used with caution in these group of patients (Summers, 2007).

The sample size calculation for nurse-initiated paracetamol protocol is based on pain intensity which is the primary outcome. Therefore, two-tailed paired t-test was used to analyse the desired sample size. As recommended by Polit and Beck (2004) for power analysis, level of significance as 0.05 and the power as 0.8 are taken. With reference to the study of Woo et al., (2005), the standard deviation (SD) for the VAS of minor trauma pain intensity is taken as 7.32 mm, conservatively; the SD for VAS of minor trauma pain intensity is taken as 20 mm. Studies had found that a reduction of 13 mm or more on VAS scoring has been shown to be clinically significant reduction in pain, and hence the true value set as 13 (Craig, et al., 2015; Ridderikhof, et al., 2013; Woo, et al., 2005). By using the analysis software to calculate the sample size (Lenth, 2011), the required sample size for this nurse-initiated protocol is 19.

**6.3 Data Analysis**

Statistical Package for Social Science (SPSS) version 19 will be used to analyze quantitative data in McNemar test. The quantitative data of McNemar test will be the VAS scores recorded on 0, 30 and 60 minutes after paracetamol commencement. Questionnaires about patients’ and nurses’ feedback and satisfaction will also be analysed by measuring the percentage of each item.
6.4 Basics for effective conducting the nurse-initiated paracetamol

Reducing pain intensity by using nurse-initiated paracetamol at triage is the foremost important indication of an effective change of practice. From the reviewed studies, taking the conservative estimation, mean VAS reduction by 13 mm (Craig, et al., 2015; Ridderikhof, et al., 2013; Woo, et al., 2005) or more will be regarded as effective.

The nurses will act as the user level in the innovation. In the nursing staff questionnaire about nurse-initiated paracetamol at triage, the results are considered to be positive if nursing staff cross the column from 1 to 3, whereas 1 means strongly agree; 2 means agree; and 3 means neutral (Appendix J). Nurse-initiated paracetamol protocol will be considered effective when 50% or more of the nursing staff give a positive response to each question.

6.5 Ethical approval

Ethical approval has to be obtained from Hospital’s Human Research Ethics Committee before the implementation of the innovation. Given that the intervention was deemed to be a quality improvement activity and the data required for the study was already collected as part of normal clinical practice. The data collected were initially identifiable, but only de-identified data were used for data manipulation and analysis.
Chapter 7: Conclusion

In summary, this translational study described a nurse-initiated paracetamol protocol at triage for all adult patients presenting minor trauma pain with category 4 or 5. This innovation can reduce target patients’ pain intensity.

There is a need to increase pharmacological pain management at triage by triage nurses. All the reviewed studies indicated a positive effect of nurse-initiated paracetamol for patients presenting minor trauma pain. The evidences from the reviewed studies used to develop evidence-based guidelines for triage nurses to initiate paracetamol for patients presenting minor trauma pain in AED. Ample evidences demonstrated that the new practice is highly transferrable, feasible and cost-effective.

It is hoped that the proposed nurse-initiated paracetamol guideline is effective and helpful to reduce pain intensity, and hence, improve overall outcome on physical and psychological among the patients presenting minor trauma pain in local clinical setting.
References


Hospital Authority. (2008, March). *Hospital Authority career progression model for nurses*. 69

Hospital Authority. (2011). *Department of Pharmacy: Drug Formulary in Queen Mary Hospital*. Hong Kong.


steroidal anti-inflammatory drugs in treating acute musculoskeletal trauma. BioMed Central Emergency Medicine, 13(19), 1-9


Appendix A

Search strategy and Results

Pubmed → CINAHL → PsyInfo

By Keywords search: "nurse initiated", "emergency department", "analgesic", "paracetamol", "panadol", "pain analgesia" or minor trauma

1,234 literatures

Pubmed: 957 articles
CINAHL: 208 articles
PsyInfo: 69 articles

Reviewed by titles

Pubmed: 8 articles
CINAHL: 15 articles
PsyInfo: 13 articles

Reviewed by abstracts

Pubmed: 6 articles
CINAHL: 3 articles
PsyInfo: 2 articles

Reviewed by full papers and reference lists

Pubmed: 6 articles
CINAHL: 1 article
PsyInfo: 1 article

Total articles for review after elimination of duplication: 6 articles
Table of Evidence


<table>
<thead>
<tr>
<th>Study type</th>
<th>Evidence level</th>
<th>Sample</th>
<th>Interventions</th>
<th>Comparison</th>
<th>Evaluation</th>
<th>Outcome measures</th>
<th>Effect size</th>
<th>Result of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>A prospective cohort study</td>
<td>Level IV</td>
<td>No. of Patients</td>
<td>Responsible staff</td>
<td>Responsible staff</td>
<td>Pain scores recorded on 0 and 60 minutes after analgesia started</td>
<td>Primary 1. Pain reduction</td>
<td>1. Overall median reduction in VAS by 20mm at triage and at discharge (p&lt;0.001)</td>
<td>1. A rapid triage pain protocol resulted in an increased rate in pain assessment, earlier administration of analgesics, and greater reduction in pain score in the first hour after arrival in AED.</td>
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<tr>
<td>Pre-test and post-test control group</td>
<td></td>
<td>Total (n=295)</td>
<td>Research nurses</td>
<td>Research nurses</td>
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<td>Primary 2. Time to initial oral Paracetamol administration</td>
<td>2. A 84 minutes time reduction to oral Paracetamo (p&lt;0.001)</td>
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<tr>
<td>A quality research design for process evaluation</td>
<td></td>
<td>Intervention group (n=199); non-intervention group (n=96)</td>
<td>Content</td>
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<tr>
<td>Hong Kong</td>
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<td>Drop out:24%</td>
<td>Nurses to administer oral Paracetamol</td>
<td>Standard triage care consisted of triage assessment and routine triage interventions, such as wound care and immobilisation</td>
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<td>Reasons for drop out</td>
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<td>1. incomplete data record</td>
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<td>2. left to consult private doctors</td>
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<td>3. poor mood and feeling discomfort</td>
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<td>4. upgraded to category 3</td>
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<td>Patients’ characteristics</td>
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<td>-Mean age: Intervention group=41 years; non-intervention group=44 years</td>
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<td>-Socio-demographic characteristics, intelligence and mechanism of injury variables are similar</td>
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General comments: This study is relevant to AEDs in Hong Kong and is likely to be applicable to other AEDs with similar patient profiles and settings.

**Table of evidence (Continued)**

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<th>Study type</th>
<th>Evidence level</th>
<th>Sample</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Evaluation</th>
<th>Outcome measures</th>
<th>Effect size</th>
<th>Result of study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized double-blind control trial (RCT)</td>
<td>Level II</td>
<td>No. of patients -Total (n=300) Intervention group (n=66); control group (n=234) -Drop out: 2% -Reasons for dropout: Not mention</td>
<td>Responsible staff -triage nurses -research nurses</td>
<td>Content Received oral indomethacin 25 mg Or Oral diclofenac 25mg Or Oral paracetamol 1g and oral diclofenac 25mg</td>
<td>Pain scores recorded 30,60,90,120 minutes after the start of analgesia</td>
<td>1. Mean pain scores reduction at rest and with movement</td>
<td>1. Reduction of 13mm of VAS in 95% CI at 90 minutes with initial pain scores from 30mm (at rest) to 70mm (with movement)</td>
<td>1. Oral paracetamol appears to be effective in management of pain in musculoskeletal syndrome of minor to moderate severity</td>
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<td>Randomization: Computer-generated randomization list</td>
<td>-Single center -Hong Kong</td>
<td>Patients’ characteristics -Mean age: intervention group=36; control group=38 -Baseline characteristics of the participants in two groups were well-balanced -Patients with pain after musculoskeletal injury</td>
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General comments: Nurse-initiated oral paracetamol is as effective as nonsteroidal antiinflammatory drugs for musculoskeletal pain patient in Accident and Emergency Department.

**Table of Evidence (Continued)**

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<th>Study type</th>
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<th>Outcome measures</th>
<th>Effect size</th>
<th>Result of study</th>
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<td>Level II</td>
<td>No. of patients Total (n=547) - Drop out: not mentioned</td>
<td>Responsible staff - General practitioners - Research assistances</td>
<td>Pain score recorded 30, 60 and 90 minutes after the start of analgesia</td>
<td>1. Pharmacological pain management for adult patients with acute musculoskeletal trauma</td>
<td>1. A decrease in NRS of more than 33% and Number Needed to Treat to achieve 33% decrease in NRS are used.</td>
<td>1. Paracetamol was not inferior to diclofenac or paracetamol + diclofenac in the treatment of pain sustained from acute musculoskeletal trauma.</td>
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<tr>
<td>Randomization: Randomization list created by Clinical research unit</td>
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<td>Patients’ characteristics Age ≥18 Acute musculoskeletal trauma including strains, sprains and contusions Baseline characteristics are similar between two groups</td>
<td>Content - Received oral paracetamol 1g</td>
<td>1. Pharmacological pain management for adult patients with acute musculoskeletal trauma</td>
<td>2. Safety and adverse events 3. Patient satisfaction</td>
<td>Measurement tools 1. Numeric rating scale (NRS) 3. 5-point Likert scale</td>
<td>1. Paracetamol was comparatively effective as non-steroidal anti-inflammatory drug in treating acute musculoskeletal trauma.</td>
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General comments: Paracetamol was comparatively effective as non-steroidal anti-inflammatory drug in treating acute musculoskeletal trauma.
Table of evidence (Continued)


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<th>Study type</th>
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<th>Comparison</th>
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<th>Outcome measures</th>
<th>Effect size</th>
<th>Result of study</th>
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<td>No. of patients&lt;br&gt;- Total (n=96)&lt;br&gt;- Intervention group (n=30); control group (n=60)&lt;br&gt;- Drop out: not mentioned</td>
<td>Responsible staff&lt;br&gt;- Study investigators&lt;br&gt;- Content&lt;br&gt;- Received oral paracetamol</td>
<td>Responsible staff&lt;br&gt;- Study investigators&lt;br&gt;- Content&lt;br&gt;- Received oral ibuprofen or oral paracetamol and ibuprofen</td>
<td>Pain score recorded 20, 40 and 60 minutes after start of analgesia</td>
<td>1. Pain decreased over 60 minutes&lt;br&gt;<strong>Measurement tools</strong>&lt;br&gt;1. Verbal numeric pain score (VNPS)</td>
<td>1. 17 mm reduction in VNPS for oral paracetamol group (p&lt;0.001)</td>
<td>1. Oral combination of paracetamol ibuprofen was more effective at relieving the pain associated with acute musculoskeletal injuries in adults patients</td>
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General comments: Oral combination of paracetamol ibuprofen was more effective at relieving the pain associated with acute musculoskeletal injuries in adults patients.

### Table of evidence (Continued)

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<tr>
<th>Study type</th>
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<th>Sample</th>
<th>Interventions</th>
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<th>Outcome measures</th>
<th>Effect size</th>
<th>Result of study</th>
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<tbody>
<tr>
<td>Randomised double-blind controlled trial (RCT)</td>
<td>Level II</td>
<td>No. of patients - Total (n=55) - Intervention group (n=27); control group (n=28) - Drop out: not mentioned</td>
<td>Responsible staff - Doctors - Nurses - Emergency nurse practitioners</td>
<td>Responsible staff - Doctors - Nurses - Emergency nurse practitioners</td>
<td>Pain score recorded 5, 15, 30, 45, and 60 minutes after infusion was commenced</td>
<td>1. Pain scores for both groups</td>
<td>1. Mean pain score at 0 minutes (paracetamol vs morphine=76.4 mm Vs 70.1mm) And at 60 minutes (paracetamol vs morphine=52.9 mm Vs 44mm) (p=0.16; p=0.28)</td>
<td>1. Paracetamol give less adverse effect as compared with morphine</td>
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<td>Randomization: Not mentioned</td>
<td></td>
<td>Patients’ characteristics - Mean age: intervention group =38years; control group=35 years - Acute traumatic limb pain on upper and lower limbs; fracture and soft tissue injuries - Baseline characteristics between two group were well-balanced</td>
<td>Content Received intravenous paracetamol 1g</td>
<td>Content Received intravenous morphine 10mg</td>
<td>2. Patient satisfaction</td>
<td>2. No significant difference about patient satisfaction was found between two group (p=0.44)</td>
<td>2. Paracetamol gave a comparable analgesic effect as compared with morphine</td>
<td></td>
</tr>
<tr>
<td>- Single centre</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
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</tr>
<tr>
<td>- United Kingdom</td>
<td></td>
<td></td>
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<td></td>
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</tr>
</tbody>
</table>

General comment: Intravenous paracetamol appeared to provide a level of analgesia comparable to intravenous morphine in isolated limb trauma, while causing less side effects than morphine.
### Table of evidence (Continued)


<table>
<thead>
<tr>
<th>Study type</th>
<th>Eviden ce level</th>
<th>Sample</th>
<th>Interventions</th>
<th>Comparison</th>
<th>Evaluation</th>
<th>Outcome measures</th>
<th>Effect size</th>
<th>Result of study</th>
</tr>
</thead>
</table>
| Randomised double-blind control trial | Level II | No. of patients  
-Total (n=60)  
-Intervention group (n=30); Control group (n=30)  
-Drop out: not mentioned | Responsible staff  
-Emergency physicians  
-Emergency nurses | Responsible staff  
-Emergency physicians  
-Emergency nurses | Pain scores recorded 30 and 60 minutes after start of analgesia | 1. Pain reduction of headache | 1. Intravenous paracetamol and morphine had comparable analgesia effect on pure head trauma headache  
2. Administered intravenous paracetamol was quicker than morphine | |
| Randomization: Excel software  
-Single centre  
-Iran | Patients’ characteristics  
-Mean age: intervention group=38 years; control group=33 years  
-Pure head trauma headache  
-Baseline characteristics: not mentioned | Content  
-Received intravenous paracetamol 1g | Content  
-Received intravenous morphine 0.1mg/kg | | | | |

**General comments:** Paracetamol is a rapid and effective treatment for headache due to trauma.
Hierarchies on Level of Evidence

Level I Evidence from systematic review of meta-analysis of all relevant randomized controlled trials (RCTs), or evidence-based clinical practice guidelines based on systematic reviews of RCTs

Level II Evidence from at least one well-designed RCT

Level III Evidence from well-designed controlled trials WITHOUT randomization

Level IV Evidence from well-designed case-control and cohort studies

Level V Evidence from systematic reviews of descriptive and qualitative studies

Level VI Evidence from a single descriptive or qualitative study

Level VII Evidence from the opinion of authorities and/or reports of expert committees

Source:
Quality assessment using SIGN guidelines

Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>Study identification (Include author, title, year of publication, journal title, pages)</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Guideline topic: An evidence-based guideline for nurse-initiated pain management for patient presenting pain at emergency department</th>
<th>Key Question No:</th>
<th>Reviewer:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

**Before** completing this checklist, consider:

1. Is the paper a *randomised controlled trial* or a *controlled clinical trial*? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a *controlled clinical trial* questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.¹</td>
<td>Yes ✔️</td>
</tr>
<tr>
<td></td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.²</td>
<td>Yes ✔️</td>
</tr>
<tr>
<td></td>
<td>Can’t say ☐</td>
</tr>
</tbody>
</table>

¹ Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

² Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study.
1.3 | An adequate concealment method is used.³ | Yes ✓ | No □ | Can't say □
1.4 | Subjects and investigators are kept ‘blind’ about treatment allocation.⁴ | Yes ✓ | No □ | Can't say □
1.5 | The treatment and control groups are similar at the start of the trial.⁵ | Yes ✓ | No □ | Can't say □
1.6 | The only difference between groups is the treatment under investigation.⁶ | Yes ✓ | No □ | Can't say □
1.7 | All relevant outcomes are measured in a standard, valid and reliable way.⁷ | Yes ✓ | No □ | Can't say □

³ Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%.

⁴ Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the clinician nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, clinicians, nor those conducting the analysis are aware of which patients received which treatment. The higher the level of blinding, the lower the risk of bias in the study.

⁵ Patients selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin, or co-morbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

⁶ If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. If groups were not treated equally, the study should be rejected unless no other evidence is available. If the study is used as evidence it should be treated with caution.

⁷ The primary outcome measures used should be clearly stated in the study. If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected. Where outcome
1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? Drop out not mentioned in the study

1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). Yes ☑ No ☐ Can’t say ☐ Does not apply ☐

1.10 Where the study is carried out at more than one site, results are comparable for all sites. Yes ☐ No ☐ Can’t say ☐ Does not apply ☑ (single centre study)

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias? Code as follows: High quality (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. Acceptable (+): Most criteria met. Some flaws in the study with an associated risk of bias. Conclusions may change in the light of further studies. Low quality (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.

measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

8 The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop out rate may be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.

9 In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention to treat analysis.) If it is clear that analysis was not on an intention to treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

10 In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

11 Rate the overall methodological quality of the study, using the following as a guide: High quality (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. Acceptable (+): Most criteria met. Some flaws in the study with an associated risk of bias. Conclusions may change in the light of further studies. Low quality (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.
<table>
<thead>
<tr>
<th></th>
<th></th>
<th>Acceptable (+) ✓</th>
<th>Unacceptable – reject 0 □</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>Yes, p-value 5% level of significance</td>
<td></td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
<td></td>
</tr>
<tr>
<td>2.4</td>
<td><strong>Notes.</strong> Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
<td>Oral combination of paracetamol ibuprofen was more effective at relieving the pain associated with acute musculoskeletal injuries in adults patients</td>
<td></td>
</tr>
</tbody>
</table>
Methodology Checklist 2: Controlled Trials

<table>
<thead>
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<th>Study identification</th>
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</tr>
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<tbody>
<tr>
<td>(Include author, title, year of publication, journal title, pages)</td>
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<td></td>
</tr>
</tbody>
</table>

Guideline topic: An evidence-based guideline for nurse-initiated pain management for patient presenting pain at emergency department

Before completing this checklist, consider:

1. Is the paper a *randomised controlled trial* or a *controlled clinical trial*? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a *controlled clinical trial* questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study…**

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes ✓</td>
</tr>
<tr>
<td>Can’t say ☐</td>
</tr>
</tbody>
</table>

1.1 The study addresses an appropriate and clearly focused question.  

1.2 The assignment of subjects to treatment groups is randomised.

---

12 Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

13 Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study.
1.3 | An adequate concealment method is used.  
| | | Yes ☑ | No ☐  
| | | Can't say ☐

1.4 | Subjects and investigators are kept ‘blind’ about treatment allocation.  
| | | Yes ☑ | No ☐  
| | | Can't say ☐

1.5 | The treatment and control groups are similar at the start of the trial.  
| | | Yes ☑ | No ☐  
| | | Can't say ☐

1.6 | The only difference between groups is the treatment under investigation.  
| | | Yes ☑ | No ☐  
| | | Can't say ☐

1.7 | All relevant outcomes are measured in a standard, valid and reliable way.  
| | | Yes ☑ | No ☐  
| | | Can't say ☐

14 Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%.

15 Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the clinician nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, clinicians, nor those conducting the analysis are aware of which patients received which treatment. The higher the level of blinding, the lower the risk of bias in the study.

16 Patients selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin, or co-morbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

17 If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. **If groups were not treated equally, the study should be rejected unless no other evidence is available.** If the study is used as evidence it should be treated with caution.

18 The primary outcome measures used should be clearly stated in the study. **If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected.** Where outcome
1.8 | What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?[^19] | Drop out not mention in study
---|---|---
1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).[^20] | Yes ☑ No ☐ Can’t say ☐ Does not apply ☐
1.10 | Where the study is carried out at more than one site, results are comparable for all sites.[^21] | Yes ☐ No ☐ Can’t say ☐ Does not apply ☐

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

2.1 | How well was the study done to minimise bias?  
*Code as follows.*[^22] | High quality (++)

---

[^19]: The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop out rate may be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.

[^20]: In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention to treat analysis.) If it is clear that analysis was not on an intention to treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

[^21]: In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

[^22]: Rate the overall methodological quality of the study, using the following as a guide: **High quality** (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. **Acceptable** (+): Most criteria met. Some flaws in the study with an associated risk of bias. Conclusions may change in the light of further studies. **Low quality** (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.
<table>
<thead>
<tr>
<th></th>
<th>Acceptable (+)</th>
<th>Unacceptable – reject 0</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>2.2</strong></td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>Power of 80% with type I error at 5% p-value</td>
</tr>
<tr>
<td><strong>2.3</strong></td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>2.4</strong></td>
<td><strong>Notes.</strong> Summaries the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
<td>Intravenous paracetamol appeared to provide a level of analgesia comparable to intravenous morphine in isolated limb trauma, while causing less side effects than morphine.</td>
</tr>
</tbody>
</table>
Appendix D

Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>Study identification</th>
<th>Key Question No:</th>
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</tr>
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<tbody>
<tr>
<td>(Include author, title, year of publication, journal title, pages)</td>
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</tbody>
</table>

Guideline topic: An evidence-based guideline for nurse-initiated pain management for patient presenting pain at emergency department

Before completing this checklist, consider:

1. Is the paper a randomized controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyze using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question 2. Other reason (please specify):

SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study...</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.(^23)</td>
<td>Yes (✓) () No () () Can't say ()</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomized.(^24)</td>
<td>Yes (✓) () No () () Can't say ()</td>
</tr>
</tbody>
</table>

\(^23\) Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

\(^24\) Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study.
1.3 An adequate concealment method is used.\(^{25}\)  

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<table>
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<tr>
<td>Yes</td>
<td></td>
<td>No</td>
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<tr>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Can’t say</td>
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</table>

1.4 Subjects and investigators are kept 'blind' about treatment allocation.\(^{26}\)  

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<tbody>
<tr>
<td>Yes</td>
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<td>No</td>
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<tr>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Can’t say</td>
<td></td>
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</table>

1.5 The treatment and control groups are similar at the start of the trial.\(^{27}\)  

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<tbody>
<tr>
<td>Yes</td>
<td></td>
<td>No</td>
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<tr>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Can’t say</td>
<td></td>
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</table>

1.6 The only difference between groups is the treatment under investigation.\(^{28}\)  

<p>| | | |</p>
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<tr>
<td>Yes</td>
<td></td>
<td>No</td>
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<tr>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
<tr>
<td>Can’t say</td>
<td></td>
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</tbody>
</table>

1.7 All relevant outcomes are measured in a standard, valid and reliable way.\(^{29}\)  

<p>| | | |</p>
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<tbody>
<tr>
<td>Yes</td>
<td></td>
<td>No</td>
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<tr>
<td>Yes</td>
<td></td>
<td>No</td>
</tr>
<tr>
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<td></td>
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\(^{25}\) Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%.

\(^{26}\) Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the clinician nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, clinicians, nor those conducting the analysis are aware of which patients received which treatment. The higher the level of blinding, the lower the risk of bias in the study.

\(^{27}\) Patients selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin, or co-morbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

\(^{28}\) If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. **If groups were not treated equally, the study should be rejected unless no other evidence is available.** If the study is used as evidence it should be treated with caution.

\(^{29}\) The primary outcome measures used should be clearly stated in the study. **If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected.** Where outcome
1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? \(^{30}\)  
Drop out did not mention in study

1.9 All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). \(^{31}\)  
Yes ✔ No □  
Can’t say □ Does not apply □

1.10 Where the study is carried out at more than one site, results are comparable for all sites. \(^{32}\)  
Yes □ No □  
Can’t say □ Doesn’t apply □ (single centre study)

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias?  
Code as follows. \(^{33}\)  
High quality (++)

measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

\(^{30}\) The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop out rate may be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.

\(^{31}\) In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention to treat analysis.) If it is clear that analysis was not on an intention to treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

\(^{32}\) In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

\(^{33}\) Rate the overall methodological quality of the study, using the following as a guide: High quality (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. Acceptable (+): Most criteria met. Some flaws in the study with an associated risk of bias. Conclusions may change in the light of further studies. Low quality (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.
<p>| | | |</p>
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<tbody>
<tr>
<td>Acceptable (+)</td>
<td></td>
<td>Unacceptable – reject 0</td>
</tr>
<tr>
<td><strong>2.2</strong></td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>95% CI p-value</td>
</tr>
<tr>
<td><strong>2.3</strong></td>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>2.4</strong></td>
<td><strong>Notes.</strong> Summaries the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
<td>Paracetamol is a rapid and effective treatment for headache due to trauma.</td>
</tr>
</tbody>
</table>
# Methodology Checklist 3: Cohort studies

**Study identification**  *(Include author, title, year of publication, journal title, pages)*


**Guideline topic:** An evidence-based guideline for nurse-initiated pain management for patient presenting pain at emergency department

<table>
<thead>
<tr>
<th>Key Question No:</th>
<th>Reviewer:</th>
</tr>
</thead>
</table>

**Before** completing this checklist, consider:

1. Is the paper really a cohort study? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist..

**Reason for rejection:** 1. Paper not relevant to key question □ 2. Other reason □ (please specify):

*Please note that a retrospective study (ie a database or chart study) cannot be rated higher than +.*

## SECTION 1: INTERNAL VALIDITY

### In a well conducted cohort study:

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question.<em>34</em></td>
</tr>
<tr>
<td>Yes ✓</td>
</tr>
<tr>
<td>No □</td>
</tr>
<tr>
<td>Can't say □</td>
</tr>
</tbody>
</table>

### SELECTION OF SUBJECTS

<table>
<thead>
<tr>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.2</strong> The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation.<em>35</em></td>
</tr>
<tr>
<td>Yes ✓</td>
</tr>
<tr>
<td>No □</td>
</tr>
<tr>
<td>Can't say □</td>
</tr>
<tr>
<td>Does not apply □</td>
</tr>
</tbody>
</table>

---

*34 Unless a clear and well defined question is specified in the report of the review, it will be difficult to assess how well it has met its objectives or how relevant it is to the question you are trying to answer on the basis of the conclusions.

*35 This relates to selection bias.* It is important that the two groups selected for comparison are as similar as possible in all characteristics except for their exposure status, or the presence of specific prognostic factors or prognostic markers relevant to the study in question.
| 1.3 | The study indicates how many of the people asked to take part did so, in each of the groups being studied. \(^{36}\) | Yes ☑ | No □ | Does not apply □ |
| 1.4 | The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis. \(^{37}\) | Yes ☑ | No □ | Can't say □ | Does not apply □ |
| 1.5 | What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed. \(^{38}\) | 24% of dropout |
| 1.6 | *Comparison is made between full participants and those lost to follow up, by exposure status.* \(^{39}\) | Yes ☑ | No □ | Can't say □ | Does not apply □ |

**ASSESSMENT**

\(^{36}\) This relates to *selection bias.* The participation rate is defined as the number of study participants divided by the number of eligible subjects, and should be calculated separately for each branch of the study. A large difference in participation rate between the two arms of the study indicates that a significant degree of *selection bias* may be present, and the study results should be treated with considerable caution.

\(^{37}\) If some of the eligible subjects, particularly those in the unexposed group, already have the outcome at the start of the trial the final result will be subject to *performance bias.* A well conducted study will attempt to estimate the likelihood of this occurring, and take it into account in the analysis through the use of sensitivity studies or other methods.

\(^{38}\) This question relates to the risk of *attrition bias.* The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but in observational studies conducted over a lengthy period of time a higher drop out rate is to be expected. A decision on whether to downgrade or reject a study because of a high drop out rate is a matter of judgement based on the reasons why people dropped out, and whether drop out rates were comparable in the exposed and unexposed groups. Reporting of efforts to follow up participants that dropped out may be regarded as an indicator of a well conducted study.

\(^{39}\) For valid study results, it is essential that the study participants are truly representative of the source population. It is always possible that participants who dropped out of the study will differ in some significant way from those who remained part of the study throughout. A well conducted study will attempt to identify any such differences between full and partial participants in both the exposed and unexposed groups. This relates to the risk of *attrition bias.* Any unexplained differences should lead to the study results being treated with caution.
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.7</td>
<td>The outcomes are clearly defined. 40</td>
<td>Yes ☑</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.8</td>
<td>The assessment of outcome is made blind to exposure status. If the study is retrospective this may not be applicable. 41</td>
<td>Yes ☐</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.9</td>
<td>Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome. 42</td>
<td>Yes ☑</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.10</td>
<td>The method of assessment of exposure is reliable. 43</td>
<td>Yes ☑</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say ☐</td>
</tr>
<tr>
<td>1.11</td>
<td>Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable. 44</td>
<td>Yes ☑</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Can’t say ☐</td>
</tr>
</tbody>
</table>

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40 This relates to the risk of detection bias.* Once enrolled in the study, participants should be followed until specified end points or outcomes are reached. In a study of the effect of exercise on the death rates from heart disease in middle aged men, for example, participants might be followed up until death, or until reaching a predefined age. **If outcomes and the criteria used for measuring them are not clearly defined, the study should be rejected.**

41 This relates to the risk of detection bias.* If the assessor is blinded to which participants received the exposure, and which did not, the prospects of unbiased results are significantly increased. Studies in which this is done should be rated more highly than those where it is not done, or not done adequately.

42 This relates to the risk of detection bias.* Blinding is not possible in many cohort studies. In order to assess the extent of any bias that may be present, it may be helpful to compare process measures used on the participant groups - e.g. frequency of observations, who carried out the observations, the degree of detail and completeness of observations. If these process measures are comparable between the groups, the results may be regarded with more confidence.

43 This relates to the risk of detection bias.* A well conducted study should indicate how the degree of exposure or presence of prognostic factors or markers was assessed. Whatever measures are used must be sufficient to establish clearly that participants have or have not received the exposure under investigation and the extent of such exposure, or that they do or do not possess a particular prognostic marker or factor. Clearly described, reliable measures should increase the confidence in the quality of the study.
| 1.12 | Exposure level or prognostic factor is assessed more than once. | Yes □ No □ Can't say □ Does not apply ✓ |
| CONFOUNDING | |
| 1.13 | The main potential confounders are identified and taken into account in the design and analysis. | Yes ✓ No □ Can't say □ |
| STATISTICAL ANALYSIS | |
| 1.14 | Have confidence intervals been provided? | Yes □ No □ ✓ (only p-value) |

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

| 2.1 | How well was the study done to minimize the risk of bias or confounding? | High quality (+++) □ |

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44 This relates to the risk of detection bias.* The primary outcome measures used should be clearly stated in the study. If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected. Where outcome measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

45 This relates to the risk of detection bias.* Confidence in data quality should be increased if exposure level is measured more than once in the course of the study. Independent assessment by more than one investigator is preferable.

46 Confounding is the distortion of a link between exposure and outcome by another factor that is associated with both exposure and outcome. The possible presence of confounding factors is one of the principal reasons why observational studies are not more highly rated as a source of evidence. The report of the study should indicate which potential confounders have been considered, and how they have been assessed or allowed for in the analysis. Clinical judgement should be applied to consider whether all likely confounders have been considered. If the measures used to address confounding are considered inadequate, the study should be downgraded or rejected, depending on how serious the risk of confounding is considered to be. A study that does not address the possibility of confounding should be rejected.

47 Confidence limits are the preferred method for indicating the precision of statistical results, and can be used to differentiate between an inconclusive study and a study that shows no effect. Studies that report a single value with no assessment of precision should be treated with extreme caution.
<table>
<thead>
<tr>
<th>Section</th>
<th>Question</th>
<th>Acceptable (+)</th>
<th>Unacceptable – reject 0</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.2</td>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, do you think there is clear evidence of an association between exposure and outcome?</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td>2.3</td>
<td>Are the results of this study directly applicable to the patient group targeted in this guideline?</td>
<td>Yes ☑</td>
<td>No ☐</td>
</tr>
<tr>
<td>2.4</td>
<td><strong>Notes.</strong> Summarizes the authors conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>This study is relevant to AEDs in Hong Kong and is likely to be applicable to other AEDs with similar patient profiles and settings.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

---

48 Rate the overall methodological quality of the study, using the following as a guide: **High quality** (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. **Acceptable** (+): Most criteria met. Some flaws in the study with an associated risk of bias, Conclusions may change in the light of further studies. **Low quality** (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.
### Methodology Checklist 2: Controlled Trials

**Study identification (Include author, title, year of publication, journal title, pages)**


**Guideline topic:** An evidence-based guideline for nurse-initiated pain management for patient presenting pain at emergency department

**Key Question No:**

**Reviewer:**

Before completing this checklist, consider:

1. Is the paper a **randomized controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyze using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

**Reason for rejection:**

1. Paper not relevant to key question □
2. Other reason □ (please specify):

#### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study...**

**Does this study do it?**

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>The study addresses an appropriate and clearly focused question.</td>
<td>Yes □</td>
</tr>
<tr>
<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomized.</td>
<td>Yes □</td>
</tr>
</tbody>
</table>

---

49 Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

50 Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study.
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
</table>
| **1.3** | An adequate concealment method is used.\(^{51}\) | Yes ☑   No ☐  
|     |   | Can't say ☐ |
| **1.4** | Subjects and investigators are kept ‘blind’ about treatment allocation.\(^{52}\) | Yes ☑   No ☐  
|     |   | Can't say ☐ |
| **1.5** | The treatment and control groups are similar at the start of the trial.\(^{53}\) | Yes ☑   No ☐  
|     |   | Can't say ☐ |
| **1.6** | The only difference between groups is the treatment under investigation.\(^{54}\) | Yes ☑   No ☐  
|     |   | Can't say ☐ |
| **1.7** | All relevant outcomes are measured in a standard, valid and reliable way.\(^{55}\) | Yes ☑   No ☐  
|     |   | Can't say ☐ |

\(^{51}\) Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%.

\(^{52}\) Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the clinician nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, clinicians, nor those conducting the analysis are aware of which patients received which treatment. The higher the level of blinding, the lower the risk of bias in the study.

\(^{53}\) Patients selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin, or co-morbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

\(^{54}\) If some patients received additional treatment, even if of a minor nature or consisting of advice and counseling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. **If groups were not treated equally, the study should be rejected unless no other evidence is available.** If the study is used as evidence it should be treated with caution.

\(^{55}\) The primary outcome measures used should be clearly stated in the study. **If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected.** Where outcome
What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed? \(^{56}\)

Adequately addressed: 2% of drop out, reason of drop out not mentioned

All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). \(^{57}\)

Yes \(\checkmark\)  No \(\square\)

Can’t say \(\square\)  Does not apply \(\square\)

Where the study is carried out at more than one site, results are comparable for all sites. \(^{58}\)

Yes \(\square\)  No \(\square\)

Can’t say \(\square\)  Does not apply \(\square\)

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

**2.1** How well was the study done to minimise bias? Code as follows. \(^{59}\)

High quality (++) \(\checkmark\)

measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

\(^{56}\) The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop out rate may be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.

\(^{57}\) In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention to treat analysis.) If it is clear that analysis was not on an intention to treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

\(^{58}\) In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

\(^{59}\) Rate the overall methodological quality of the study, using the following as a guide: **High quality** (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. **Acceptable** (+): Most criteria met. Some flaws in the study with an associated risk of bias, Conclusions may change in the light of further studies. **Low quality** (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.
### 2.2
*Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?*

<table>
<thead>
<tr>
<th>Acceptable (+) □</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unacceptable – reject 0 □</td>
</tr>
</tbody>
</table>

- Yes, 95%CI used for data analysis
- Power of 80% with type I error at 5%

### 2.3
*Are the results of this study directly applicable to the patient group targeted by this guideline?*

- Yes

### 2.4
*Notes. Summaries the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.*

Nurse-initiated oral paracetamol is as effective as nonsteroidal antiinflammatory drugs for musculoskeletal pain patient in Accident and Emergency Department.
Methodology Checklist 2: Controlled Trials

Study identification  (*Include author, title, year of publication, journal title, pages*)


Guideline topic: An evidence-based guideline for nurse-initiated pain management for patient presenting pain at emergency department

<table>
<thead>
<tr>
<th>Key Question No:</th>
<th>Reviewer:</th>
</tr>
</thead>
</table>

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.[^60]</td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised.[^61]</td>
<td>Yes ☑ No ☐ Can’t say ☐</td>
</tr>
</tbody>
</table>

[^60]: Unless a clear and well defined question is specified, it will be difficult to assess how well the study has met its objectives or how relevant it is to the question you are trying to answer on the basis of its conclusions.

[^61]: Random allocation of patients to receive one or other of the treatments under investigation, or to receive either treatment or placebo, is fundamental to this type of study.
<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.3</td>
<td>An adequate concealment method is used. <strong>62</strong></td>
<td>Yes [✓]  No [☐]  Can't say [☐]</td>
</tr>
<tr>
<td>1.4</td>
<td>Subjects and investigators are kept ‘blind’ about treatment allocation. <strong>63</strong></td>
<td>Yes [✓]  No [☐]  Can't say [☐]</td>
</tr>
<tr>
<td>1.5</td>
<td>The treatment and control groups are similar at the start of the trial. <strong>64</strong></td>
<td>Yes [✓]  No [☐]  Can't say [☐]</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation. <strong>65</strong></td>
<td>Yes [✓]  No [☐]  Can't say [☐]</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way. <strong>66</strong></td>
<td>Yes [✓]  No [☐]  Can't say [☐]</td>
</tr>
</tbody>
</table>

**62** Allocation concealment refers to the process used to ensure that researchers are unaware which group patients are being allocated to at the time they enter the study. Research has shown that where allocation concealment is inadequate, investigators can overestimate the effect of interventions by up to 40%.

**63** Blinding refers to the process whereby people are kept unaware of which treatment an individual patient has been receiving when they are assessing the outcome for that patient. It can be carried out up to three levels. Single blinding is where patients are unaware of which treatment they are receiving. In double blind studies neither the clinician nor the patient knows which treatment is being given. In very rare cases studies may be triple blinded, where neither patients, clinicians, nor those conducting the analysis are aware of which patients received which treatment. The higher the level of blinding, the lower the risk of bias in the study.

**64** Patients selected for inclusion in a trial must be as similar as possible. The study should report any significant differences in the composition of the study groups in relation to gender mix, age, stage of disease (if appropriate), social background, ethnic origin, or co-morbid conditions. These factors may be covered by inclusion and exclusion criteria, rather than being reported directly. Failure to address this question, or the use of inappropriate groups, should lead to the study being downgraded.

**65** If some patients received additional treatment, even if of a minor nature or consisting of advice and counselling rather than a physical intervention, this treatment is a potential confounding factor that may invalidate the results. **If groups were not treated equally, the study should be rejected unless no other evidence is available.** If the study is used as evidence it should be treated with caution.

**66** The primary outcome measures used should be clearly stated in the study. **If the outcome measures are not stated, or the study bases its main conclusions on secondary outcomes, the study should be rejected.** Where outcome
What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?  

All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).

Where the study is carried out at more than one site, results are comparable for all sites.

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

How well was the study done to minimise bias?  
*Code as follows:*  

<p>| | | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>How well was the study done to minimise bias?</td>
<td>High quality (++)</td>
</tr>
</tbody>
</table>

measures require any degree of subjectivity, some evidence should be provided that the measures used are reliable and have been validated prior to their use in the study.

The number of patients that drop out of a study should give concern if the number is very high. Conventionally, a 20% drop out rate is regarded as acceptable, but this may vary. Some regard should be paid to why patients dropped out, as well as how many. It should be noted that the drop out rate may be expected to be higher in studies conducted over a long period of time. A higher drop out rate will normally lead to downgrading, rather than rejection of a study.

In practice, it is rarely the case that all patients allocated to the intervention group receive the intervention throughout the trial, or that all those in the comparison group do not. Patients may refuse treatment, or contra-indications arise that lead them to be switched to the other group. If the comparability of groups through randomisation is to be maintained, however, patient outcomes must be analysed according to the group to which they were originally allocated irrespective of the treatment they actually received. (This is known as intention to treat analysis.) If it is clear that analysis was not on an intention to treat basis, the study may be rejected. If there is little other evidence available, the study may be included but should be evaluated as if it were a non-randomised cohort study.

In multi-site studies, confidence in the results should be increased if it can be shown that similar results were obtained at the different participating centres.

Rate the overall methodological quality of the study, using the following as a guide: **High quality** (++): Majority of criteria met. Little or no risk of bias. Results unlikely to be changed by further research. **Acceptable** (+): Most criteria met. Some flaws in the study with an associated risk of bias. Conclusions may change in the light of further studies. **Low quality** (0): Either most criteria not met, or significant flaws relating to key aspects of study design. Conclusions likely to change in the light of further studies.
|   |   | Acceptable (+) □
|   | Unacceptable – reject 0 □ |
|---|---|---|
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes, 85% power to reject the null hypothesis |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
| 2.4 | **Notes.** Summaries the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | Paracetamol was comparatively effective as non-steroidal anti-inflammatory drug in treating acute musculoskeletal trauma. |
### Appendix E

Table for Cost and Benefits of Implementation

<table>
<thead>
<tr>
<th>Expense</th>
<th>Quantity</th>
<th>Amount</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Printed materials for staff training</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Teaching manual</td>
<td>38 nurses</td>
<td>$10/nurse × 38</td>
</tr>
<tr>
<td></td>
<td></td>
<td>=$380</td>
</tr>
<tr>
<td><strong>Printed material for nurse implementation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Numeric Rating Scale card</td>
<td>38 nurses</td>
<td>$20/nurse × 38</td>
</tr>
<tr>
<td>- Self-designed questionnaire for nurses (1 set)</td>
<td></td>
<td>=$760</td>
</tr>
<tr>
<td><strong>Printed material for patient</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Self-designed questionnaire for patient (1 set)</td>
<td>10,425 patients</td>
<td>$1/patient × 10,425</td>
</tr>
<tr>
<td></td>
<td></td>
<td>=$10,425</td>
</tr>
<tr>
<td><strong>Expenses for nurse to attend training</strong></td>
<td>38 nurses</td>
<td>($206/hour × 38 RNs+</td>
</tr>
<tr>
<td>- Workshop by Pain Nursing Specialist from Dept. of Anaesthesia</td>
<td></td>
<td>$296/hour × 15 APNs)</td>
</tr>
<tr>
<td>(3 hours of 1 session)</td>
<td></td>
<td>× 3 hours</td>
</tr>
<tr>
<td></td>
<td></td>
<td>=$36,804</td>
</tr>
<tr>
<td><strong>Expenses for Pain Nursing Specialist from Dept. of Anaesthesia to</strong></td>
<td>1 NS</td>
<td>$2583/all nurses</td>
</tr>
<tr>
<td>provide training**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>- Training workshop to AED nurses NO or APN &amp; RN (hrs of 3 identical sessions)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Expenses for paracetamol</strong></td>
<td></td>
<td>$62.7/year</td>
</tr>
<tr>
<td><strong>Expenses for equipments &amp; facilities</strong></td>
<td></td>
<td>No extra cost</td>
</tr>
<tr>
<td><strong>Total Estimated Expenses</strong></td>
<td></td>
<td>$51,014.7</td>
</tr>
</tbody>
</table>

With reference to HA General Pay Scale (HGPS) in 2014 (Hospital Authority, 2014)

*Estimated mean monthly salary for Registered Nurses (RNs) in AED = $36,264

Hourly salary = $36,264 ÷ (44 hours × 4 weeks) = $206 / hour

Estimated mean monthly salary for Nursing Officer or Advanced Practice Nurses (APNs) in AED= $52,018

Hourly salary= $52,018 ÷ (44 hours × 4 weeks) = $296/hour

Expenses for nurse to attend training ($) = hourly salary × no. of hours for workshop: $206 × 3 hours= $618 / nurse
**Estimate mean monthly salary for Nursing Specialist = $ 50,593**

Hourly salary = $50,593 \div (44 \text{ hours} \times 4 \text{ weeks}) = $287/ \text{hour}

Expenses for Pain Nursing Specialist to provide training workshop ($) = hourly salary no. of hours for workshop: $287 \times 9 \text{ hours} = $2583

***Estimate expenses for paracetamol: $0.03/\text{tablet} \times 2 \text{ tablets} \times 10,425 \text{ patients/ year} = $62.7/\text{year}
## Level of Evidence (SIGN, 2012)

<table>
<thead>
<tr>
<th>Level of evidence</th>
<th>Evidence Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
</tbody>
</table>
| 2++               | High quality systematic reviews of case control or cohort or studies  
High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal |
| 2+                | Well conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal |
| 2-                | Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal |
| 3                 | Non-analytic studies, e.g. case reports, case series |
| 4                 | Expert opinion |
### Grades of Recommendations (SIGN, 2012)

<table>
<thead>
<tr>
<th>Grade</th>
<th>Statements</th>
</tr>
</thead>
</table>
| A     | At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or  
A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results |
| B     | A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+ |
| C     | A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++ |
| D     | Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+ |
Appendix G

Practice Recommendations:
Instructions in Using the Nurse-Initiated Paracetamol Protocol

**Recommendation 1:** Trained triage nurses are responsible for carrying out this protocol. (Grade A)

Evidence:

Four of reviewed studies reported that the paracetamol was initiated by nurses. (Craig, et al., 2015 [2++]; Vahdati, et al, 2014[2++]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). Besides, one of the studies stated that the responsible nurses for conducting this intervention were well trained in communication skills and care of patients with minor trauma injury (Wong, Cahn, Rainer & Ying, 2007 [2++]).

**Recommendation 2:** Minor trauma patients are recruited as eligible study participants who are categorized as 4 or 5 AED management (Grade A).

Evidence:

All reviewed studies (n=6) recruited patients with minor trauma pain resulted from minor traumatic mechanism (Bondarsky, et al., 2013 [1+]; Craig, Jeavons, Probert & Benger, 2015 [1+]; Ridderikhof, et al., 2013 [1+]; Vahdati, Baghi, Ghobadi, Ghafouri & Habibollahi, 2014 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). Three of the reviewed studies had patients of painful isolated limb injuries (Craig, Jeavons, Probert & Benger, 2015 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). One of the study reported that the new triage pain management protocol was mainly focused on isolated limb injury patients with triage category 4 (Wong, Cahn, Rainer & Ying, 2007 [2++]).
**Recommendation 3:** Administered 1g paracetamol orally to patients with minor trauma pain. (Grade A)

Evidence:

All reviewed studies (n=6) administered paracetamol to patients with minor trauma injury (Bondarsky, et al., 2013 [1+]; Craig, Jeavons, Probert & Benger, 2015 [1+]; Ridderikhof, et al., 2013 [1+]; Vahdati, Baghi, Ghobadi, Ghafoori & Habibollahi, 2014 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). More than half of the studies (n=4) administered oral paracetamol to patients (Bondarsky, et al., 2013 [1+]; Ridderikhof, et al., 2013 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). One study conducted in Accident and Emergency Department of Hong Kong stated that the dose of 1g paracetamol chosen first because it is in accordance with British National Formulary recommendations and second because it is the dosage used in emergency physicians’ practice (Wong, Cahn, Rainer & Ying, 2007 [2++]).

**Recommendation 4:** Using 100mm numbered and horizontal Visual Analogue Scale (VAS) to measure patients’ pain intensity. (Grade A)

Evidence:

More than half reviewed studies (n=4) used VAS to measure minor trauma pain intensity (Craig, Jeavons, Probert & Benger, 2015 [1+]; Vahdati, Baghi, Ghobadi, Ghafoori & Habibollahi, 2014 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++]; Woo, Man, Lam & Rainer, 2005 [1+]). One of them utilise a specially designed 100mm VAS, A4 sized laminated chart for triage nurses rating patients’ pain intensity (Wong, Cahn, Rainer & Ying, 2007 [2++]). One of them used numbered and horizontal VAS for baseline measurement and subsequent intervals (Woo, Man, Lam & Rainer, 2005 [1+]). A4-paper sized VAS will be used in the guideline because it is easier visualized by patients.
Appendix G

**Recommendation 5**: Patients’ pain score are taken at 0, 30, and 60 minutes after the start of paracetamol. (Grade A)

**Evidence:**

Four studies indicated the evaluation time is 30 and 60 minutes after paracetamol given to reassess patients’ difference of pain intensity injury (Craig, Jeavons, Probert & Benger, 2015 [1+]; Ridderikhof, et al., 2013 [1+]; Vahdati, Baghi, Ghobadi, Ghafoori & Habibollahi, 2014 [1+]; Woo, Man, Lam & Rainer, 2005 [1+]). Half of the reviewed studies (n=3), the median reduction in VAS after 60 minutes in the post-test period, was 20mm (Bondarsky, et al., 2013 [1+]; Wong, Cahn, Rainer & Ying, 2007 [2++] and 23mm (Craig, Jeavons, Probert & Benger, 2015 [1+]) respectively. A reduction of 13mm or more on VAS scoring has been shown to represent a clinically significant reduction in pain (Craig, Jeavons, Probert & Benger, 2015 [1+]; Ridderikhof, et al., 2013 [1+]; Woo, Man, Lam & Rainer, 2005 [1+]).

**Recommendation 6**: The doctor on duty was free to give extra or alternative doses of analgesia if clinically required, and this was documented. (Grade A)

**Evidence:**

Two reviewed studies stated that the patients can receive additional analgesia from doctor if 1g paracetamol is not enough for their pain control. (Ridderikhof, et al., 2013 [1+]; Woo, Man, Lam & Rainer, 2005 [1+]). The doctor can prescribe tramadol (Ridderikhof, et al., 2013 [1+]).

**Recommendation 7**: Patients were advised to take no more than 3g of paracetamol in the next 24 hours. (Grade A)
Evidence:

The patients discharged following the study were advised to take no more than 3g of paracetamol in the next 24 hours. If the patient was admitted, an inpatient drug chart was written so that no more than 3g of paracetamol could be administered over the next 24 hours (Craig, Jeavons, Probert & Benger, 2015 [1+]).
Intervention Flow of Nurse-Initiated Paracetamol

*Nurses will concern about patients’ waiting time on the waiting queue to ensure the protocol will not delay doctor consultation. If the patients wait less than 30 or 60 minutes for doctor consultation, patient will be assessed by doctor first.

Inclusion criteria:
- Between aged 18 and 55
- Able to read and see
- Cantonese, Mandarin or English-speaking patients

Exclusion criteria:
- Allergy to Panadol
- Cognitive disability
- Alcoholism
- Hepatic diseases
- Renal diseases
- Previous treatment with an analgesic for the same injury
# Self-designed Questionnaire for Minor Trauma Patients

## Evaluation of a Nurse-initiated Paracetamol for Minor Trauma Patients in Accident and Emergency Department

Thanks for involving this nurse initiating programme. The programme organizer would like to gather your comments and suggestions for improvement and future directions of the programme. Please spend a few minutes to complete this questionnaire. Thanks for your generous cooperation and participation.

Please **CROSS (X)** the item you find most appropriate.


<table>
<thead>
<tr>
<th>1. You find the nurse-initiated paracetamol useful.</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. You find the Visual Analogue Scale easy to use.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>3. You find the Visual Analogue Scale representing your real pain.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>4. Is it the right time to receive paracetamol at triage stage.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5. The duration (60mins) for reassess the pain intensity is too not long.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6. The triage nurse is competent to administer paracetamol.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
</tr>
</tbody>
</table>

Answer the following questions.

7. What are the strengths of this nurse-initiated paracetamol programme?

_____________________________________________________________________
_____________________________________________________________________

8. What are the weaknesses or limitation of this nurse-initiated paracetamol programme?

_____________________________________________________________________
_____________________________________________________________________

9. What suggestions or comments do you have for further improvement of this nurse-initiated paracetamol programme in future?

_____________________________________________________________________
_____________________________________________________________________
分流護士為輕度創傷病人處方撲熱息痛後問卷調查

您好！此問卷目的是透過了解輕度創傷病人在急症室所提供的分流護士處方撲熱息痛後的意見，藉以檢討流程和運作，從而作出適當的改善方法和服務質素，請用數分鐘去填寫問卷，多謝您的寶貴意見和參與。

請選出最適合的答案填上 (X)

1. 十分有用  2. 有用  3. 沒有意見  4. 没有用  5. 完全沒有用

<table>
<thead>
<tr>
<th>項目</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. 您對本急症室提供的分流護士處方撲熱息痛感到有用。</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. 這「疼痛視覺程度量表」是否簡單易明。</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. 您覺得「疼痛視覺程度量表」能夠表達您真正的痛楚。</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. 您認為病人在分流時，給予撲熱息痛藥物是適當的時間。</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. 您認為 60 分鐘後再量度病人的疼痛程度，不是太長可以接受。</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. 您認為分流護士能勝任處方撲熱息痛。</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

請回答以下問題

7. 您認為這分流護士為輕度創傷病人處方撲熱息痛，您最欣賞哪一部份？

___________________________________________________________________________________
___________________________________________________________________________________

8. 您認為這分流護士為輕度創傷病人處方撲熱息痛，您覺得哪一部份有待改善？

___________________________________________________________________________________
___________________________________________________________________________________

9. 您對這分流護士為輕度創傷病人處方撲熱息痛有任何建議，意見可作日後改善之用？

___________________________________________________________________________________
___________________________________________________________________________________
Self-designed Questionnaire for Nurses

Evaluation of a Nurse-initiated Paracetamol for Minor Trauma Pain Patients in Accident and Emergency Department

Thanks for conducting this educational programme. The programme organizer would like to gather your comments and suggestions for improvement and future directions of the programme. Please spend a few minutes to complete this questionnaire. Thank you for your generous cooperation and participation.

Please CROSS (X) the item you find most appropriate.


<table>
<thead>
<tr>
<th></th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you agree with the nurse-initiated paracetamol programme?</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2. The training session provided by the Department of Anaesthesia is useful to you to implement the new programme in AED.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3. The feasibility to continue the nurse-initiated paracetamol programme.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4. You feel sense of job satisfaction once you conducted the nurse-initiated paracetamol at triage.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5. You face extra stress when conducting the nurse-initiated paracetamol programme.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. You have encountered difficulties when carrying the nurse-initiated paracetamol programme.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. You are willing to conduct the nurse-initiated paracetamol programme even after the trial.</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please answer the following questions.

8. What are the strengths of this nurse-initiated paracetamol programme?

______________________________________________________________________________

______________________________________________________________________________

9. What are the weaknesses or limitation of this nurse-initiated paracetamol programme?

______________________________________________________________________________

______________________________________________________________________________

10. What suggestions or comments do you have for further improvement of this nurse-initiated paracetamol programme in future?

______________________________________________________________________________

______________________________________________________________________________
Visual Analogue Scale (VAS) Ruler

English version of VAS

![VAS Ruler](image)

Chinese version of VAS

![Chinese VAS](image)