# PRE-HOSPITAL PAIN MANAGEMENT IN CHILDREN:

# A MIXED METHODS STUDY

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**Abstract**

*Background*

Pain is a highly complex sensory and emotional experience; the biological, psychological and social aspects must each be considered. The intersection between the phenomenon of pain, the unpredictable pre-hospital environment and children is highly convoluted. Studies have shown that pre-hospital pain management in children is poor, despite access to pain management being considered a fundamental human right. Without effective pain treatment, children may suffer long-term psychological changes (e.g. altered pain perception) and are at risk of developing post-traumatic stress disorder. The aim of this thesis was to identify predictors, barriers and facilitators associated with effective pre-hospital pain management in children suffering acute pain and to identify ways to improve the quality of care.

*Methods*

A postpositivist paradigm was adopted for the study, with a critical realist ontology and a modified objectivist epistemology. A mixed methods sequential explanatory design was adopted, informed by a systematic mixed studies review. The initial quantitative study employed a multivariable logistic regression analysis using routinely collected clinical data to identify predictors of effective pain management. The final qualitative study used face-to-face semi-structured interviews with ambulance clinicians to help explain the identified predictors, identify barriers and facilitators and explore ways to improve the quality of care. Interviews were audio recorded and transcribed verbatim with thematic analysis used to analyse the data.

*Results*

The systematic mixed studies review included 13 studies (8 quantitative and 5 qualitative) and highlighted the importance of analgesic administration. The initial quantitative study included 2312 clinical records; only 39% of children suffering acute pain achieved effective pain management. Predictors of effective pain management included children who were younger, administered analgesics, attended by a paramedic or living in an area of low or medium deprivation. The final qualitative study included 12 ambulance clinicians (9 paramedics and 3 emergency medical technicians) who provided possible explanations for these disparities. Novel barriers and facilitators were also identified along with ways to improve pain management. Meta-inferences were developed which provided a more comprehensive understanding of this complex phenomenon. To improve pre-hospital pain management in children, the following recommendations were made; 1) explore methods to increase rates of analgesic administration, perhaps by utilising the intranasal and inhaled route; 2) reduce fear and anxiety in children, perhaps by using child friendly uniform, non-pharmacological techniques and more public interaction and 3) reduce fear and anxiety in clinicians, by enhancing training, optimising crew mix and developing a more pragmatic pain assessment tool. A theoretical model of pre-hospital pain management in children was developed as part of this thesis.

*Conclusion*

Pre-hospital pain management in children may be improved by increasing rates of analgesic administration and reducing the fear and anxiety experienced by children and clinicians. Future research should explore the experience of the child and determine the most important outcome measures. Robust clinical trials are needed to determine the efficacy and safety of intranasal (fentanyl/ketamine) and inhaled (methoxyflurane) analgesics in the pre-hospital setting. Investment in future research and intervention development is imperative; we need to make children's pain in the pre-hospital setting matter.

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# List of abbreviations

| Abbreviation | Definition |
|---|---|
| ARC | Applied Research Collaboration |
| ARS | Adjective Response Scale |
| DCA | Double Crewed Ambulance |
| ED | Emergency Department |
| EMAS | East Midlands Ambulance Service NHS Trust |
| FLACC | Face, Legs, Activity, Crying and Consolability |
| GRADE | Grading of Recommendations, Assessment, Development and Evaluation |
| HRA | Health Research Authority |
| IRAS | Integrated Research Application System |
| IN | Intranasal |
| IV | Intravenous |
| JRCALC | Joint Royal Colleges Ambulance Liaison Committee |
| NIHR | National Institute for Health Research |
| NPRS | Numeric Pain Rating Scale |
| PRISMA | Preferred Reporting Items for Systematic Reviews and Meta-Analyses |
| RCT | Randomised Controlled Trial |
| RRV | Rapid Response Vehicle |
| VAS | Visual Analogue Scale |
| WHO | World Health Organisation |

## List of publications associated with this thesis

Whitley, G.A., Hemingway, P., Law, G.R. & Siriwardena, A,N. 2021. Ambulance clinician perspectives of disparity in pre-hospital child pain management: A mixed methods study. **Health Science Reports**. 4:e261 https://doi.org/10.1002/hsr2.261

Whitley, G.A., Munro, S., Hemingway, P., Law, G.R., Siriwardena, A,N., Cooke, D. & Quinn, T. 2020. Mixed methods in pre-hospital research: understanding complex clinical problems. **British Paramedic Journal** 5(3) 45–52 https://doi.org/10.29045/14784726.2020.12.5.3.44

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Whitley, G.A., Hemingway, P., Law, G.R. & Siriwardena, A,N. 2019. The complexity of pain management in children. **Journal of Paramedic Practice** 11(11):466-468 https://doi.org/10.12968/jpar.2019.11.11.466

Whitley, G.A. & Pilbery, R. 2019. Pre-hospital intranasal analgesia for children suffering pain: a rapid evidence review. **British Paramedic Journal** 4(3):24-34 https://doi.org/10.29045/14784726.2019.12.4.3.24

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Whitley, G,A. & Lord, B. 2018. Discerning the age of a child. **Journal of Paramedic Practice**. 10(9):383-385 https://doi.org/10.12968/jpar.2018.10.9.383

Whitley, G,A., Siriwardena, A,N., Hemingway, P. & Law GR. 2018. What are the predictors, barriers and facilitators to effective management of acute pain in children by ambulance services? A mixed-methods systematic review protocol. **British Paramedic Journal** 3(2):22-28 https://doi.org/10.29045/14784726.2018.09.3.2.22

## List of presentations from this thesis

| Presentation | Location | Date |
|---|---|---|
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| Research Visit<br>*PhD Overview* | Kokushikan University<br>Tokyo, Japan | 11th Sept 2018 |
| Training Seminar<br>*Systematic Mixed Studies Review Methods* | University of Lincoln<br>UK | 19th Feb 2019 |
| College of Paramedics National Research Conference<br>*Systematic Mixed Studies Review (Poster)* | Bristol<br>UK | 24th Sept 2019 |
| College of Paramedic National Research Conference<br>*Cross-sectional Study (Oral)* | Bristol<br>UK | 24th Sept 2019 |
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| Critical Reading and Writing for Research Students | UoL | 15-Feb-2018 |
| Systematic Review Training (Session 1) | UoL | 30-Apr-2018 |
| Implementation Science | ARC-EM | 03-May-2018 |
| Systematic Review Training (Session 2) | UoL | 04-Jun-2018 |
| Mixed Methods Research | UoL | 05-Jun-2018 |
| Systematic Review training (Session 3) | UoL | 24-Jul-2018 |
| Epistemology and Philosophy of Science | UoL | 02-Oct-2018 |
| The Collection and Analysis of Qualitative Data | UoL | 13-Feb-2019 |
| 'In House' STATA training by CaHRU members | UoL | 2019 |

UoL: University of Lincoln, ARC-EM: Applied Research Collaboration – East Midlands.

# Chapter 1 – Introduction

## 1.1 Personal statement

My career in the ambulance service started in 2010 when I joined the West Midlands Ambulance Service NHS Foundation Trust as a student paramedic. During the initial two years of training my interest in research was sparked by the PARAMEDIC trial (Perkins et al., 2015) which compared mechanical to manual chest compressions in out of hospital cardiac arrest in adults. Mechanical chest compression (LUCAS-2) devices were on some ambulances, but not others. I initially thought this was due to a lack of funding, but I later came to realise this was the method of randomisation. This intrigued me, I wanted to learn more and get involved in research, therefore I enrolled onto a master's degree after qualifying as a paramedic in 2012.

I then joined the East Midlands Ambulance Service NHS Trust in 2014. In 2015 I joined the AIRWAYS-2 clinical trial (Taylor et al., 2016, Benger et al., 2018) study team as a research paramedic. AIRWAYS-2 compared tracheal intubation to the i-gel supraglottic airway device in out of hospital cardiac arrest in adults. This was my first experience of working on a clinical trial and confirmed my desire to become more involved in research.

The final component of my master's degree was to undertake a dissertation. In my search to find an appropriate topic, I found a Delphi study undertaken by Professor Helen Snooks in conjunction with the 999 Emergency Medical Service (EMS) research forum (Snooks et al., 2008). A total of 96 research priorities were identified, with 'nasal route for administration of pain relief' ranking 8$^{th}$. I knew that Australian paramedics were using intranasal fentanyl as a pain management tool in children. Before exploring this option further, I felt it would be difficult to change UK practice without evidence demonstrating a need for intranasal analgesics, especially in children. I performed a service evaluation assessing the effectiveness of current analgesics at reducing pain in children suffering traumatic

injury within a UK ambulance service. This study sparked my interest in the field of pre-hospital pain management in children.

The results of this dissertation were submitted to the 999 EMS Research Forum 2017 where I presented in Bristol. I also submitted an abstract to the EMS2017 conference in Copenhagen, which was accepted and subsequently nominated as a top 8 abstract out of 138 submissions worldwide. I developed and submitted the manuscript to the British Paramedic Journal (BPJ) which was accepted and published in March 2017 (Whitley and Bath-Hextall, 2017). The College of Paramedics hosted a competition for the five highest quality articles published in the BPJ at their national conference in 2017. My paper was selected, I was invited to present my study and I won first prize. This allowed me to present my study at the EMS EXPO in Las Vegas in October 2017.

This success motivated me to undertake further research; I developed a research proposal on the topic of pre-hospital pain management in children and applied for funding to undertake a PhD. I was successful in securing funding from the National Institute for Health Research (NIHR) Applied Research Collaboration, East Midlands (ARC-EM). I then negotiated a part-time paramedic contract with the East Midlands Ambulance Service NHS Trust to work one week per month for the duration of this PhD to maintain my clinical competencies.

In addition to this clinical commitment, the novel coronavirus (SARS-CoV-2) was declared a pandemic during the final year of my PhD by the World Health Organisation on the 11th March 2020 (World Health Organisation, 2020). This made my final year write up extremely difficult as lockdown was in place across the UK for many months, placing significant stress on my family, including my two young children and wife. During the pandemic I volunteered for extra shifts where needed to assist with staff shortfalls, as many clinicians were self-isolating. I felt I was able to overcome the challenges of the COVID-19 pandemic both clinically and academically with the support of my family, academic supervisors and work colleagues.

## 1.2 Context

The context of this research fell within three broad areas; the ambulance service setting, pain as the phenomenon of interest and children as the patient group. The focus of this PhD combined these three areas; pre-hospital pain management in children. Each of these contextual areas will be discussed in relation to this research.

### 1.2.1 Ambulance service

The need for remote health care was realised on the battlefield during the Siege of Malaga in 1487 in order to transport injured soldiers; the concept of the ambulance was born (Ciottone, 2006). The incorporation of treatment during transport was developed during Napoleon times under the instruction of Dr Dominique-Jean Larrey during the 1790s (Caroline, 2007). Larry created the 'ambulances volantes', or flying ambulance, essentially a carriage staffed with medical personnel (Ciottone, 2006). Civilian ambulance services were first created in the 1860s in the US and UK (Ciottone, 2006, Caroline, 2007), the 1880s in Canada (Ontario Paramedic Association, 2015) and the 1890s in Australia (Queensland Ambulance Service, 2018, Ambulance Service of New South Wales, 2018).

Ambulance services have developed significantly since the late nineteenth century and have moved away from the traditional transport model where ambulance personnel were viewed as 'drivers' (Newton, 2012). Modern health care demands have fundamentally changed the way ambulance services work. UK ambulance services are less involved with emergency calls and more involved in urgent care calls; approximately 10% of 999 calls to UK ambulance services are for life-threatening emergencies, the remainder are for urgent primary or social care needs (Association of Ambulance Chief Executives, 2011). In England during 2017, 38% of calls to ambulance services were attended by an ambulance, but not transported to hospital (Coster et al., 2019).

Within the UK, double-crewed ambulances (DCAs) have two members of staff and can include paramedics, emergency medical technicians (EMTs) and emergency

care assistants (ECAs) (NHS, 2020c). Any variation of staff mix can occur on a DCA, however they normally have at least one qualified clinician (an EMT or paramedic). EMTs are typically trained within the ambulance service, have a broad range of skills, can work independently or support a paramedic but they are not currently registered with a professional body (NHS, 2020b). Paramedics must gain registration with the Health and Care Professions Council (HCPC) in order to practice within the UK. From September 2021 new paramedics must register with a Bachelor's degree (Health and Care Professions Council, 2018), therefore the training of a paramedic is more extensive than that of an EMT. ECAs are an integral part of the ambulance crew and assist paramedics and EMTs with patient care (NHS, 2020a).

Ambulance service clinicians attend patients of all ages, suffering both traumatic injuries and medical illnesses within a variety of environments (Lord et al., 2016). They must be dynamic and prepared to face any situation. This can be challenging, especially when dealing with children because the exposure rates are relatively low; approximately 9% of ambulance service patients are under 18 years of age (Lord et al., 2016, Shah et al., 2008, Whitley et al., 2020b, Lord et al., 2019). By comparison, up to 25% of UK general practice consultations are for children (Gill and Thompson, 2015). This lack of exposure to children within the ambulance service presents unique challenges.

#### 1.2.1.1 International perspective

Ambulance services around the world vary in terms of their level of professional development, clinical practice and autonomy. Australian ambulance services employ different levels of paramedic, including qualified paramedics, mobile intensive care ambulance paramedics, air ambulance paramedics, bicycle response paramedics, wilderness response paramedics and aquatic paramedics (Ambulance Victoria, 2020).

Variation exists across Europe, with the French and German ambulance services being more 'physician led' (Adnet and Lapostolle, 2004, Lechleuthner, 2019, Fischer

et al., 2011), Sweden being more 'nurse led' (Lederman et al., 2019) and Denmark, Ireland, the Netherlands and the UK being more 'paramedic led' (Lindskou et al., 2019, National Ambulance Service Ireland, 2020, Timm et al., 2014).

The ambulance services in the United States are difficult to gauge due to the number of states, compounded by the number of emergency medical services within each state following their own individual guidelines and policies. The United States Department of Transportation estimated that in 2011, there was median of 249 EMS agencies per state, with a total of 21,283 EMS agencies in operation (United States Department of Transportation, 2014).

### 1.2.2 Pain

Pain is a highly complex phenomenon with several definitions, two of the most notable being:

> *'Pain is whatever the experiencing person says it is, existing whenever he says it does'*
>
> (McCaffery, 1968) pg95

> *'An unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage'*
>
> (International Association for the Study of Pain, 2020)

The International Association for the Study of Pain (IASP) recently updated their definition of pain (Raja et al., 2020) from the previous version published in 1979. It now includes six key notes to supplement the definition; it was deemed pertinent to this thesis to quote these in full:

1. '*Pain is always a personal experience that is influenced to varying degrees by biological, psychological, and social factors.*
2. *Pain and nociception are different phenomena. Pain cannot be inferred solely from activity in sensory neurons.*
3. *Through their life experiences, individuals learn the concept of pain.*
4. *A person's report of an experience as pain should be respected.*
5. *Although pain usually serves an adaptive role, it may have adverse effects on function and social and psychological well-being.*
6. *Verbal description is only one of several behaviours to express pain; inability to communicate does not negate the possibility that a human or a nonhuman animal experiences pain.*'

(International Association for the Study of Pain, 2020)

These key notes were discussed in more detail throughout this chapter and referred to throughout this thesis.

#### 1.2.2.1 Types and causes of pain

Pain can be divided into two major categories: nociceptive and neuropathic. In 2007, IASP updated their definitions of basic pain terminology (Loeser and Treede, 2008), which included an update to the definitions of nociceptive and neuropathic pain.

Nociceptive pain was defined as '*pain arising from activation of nociceptors'* (Loeser and Treede, 2008); a nociceptor being a sensory receptor that is capable of transducing and encoding noxious stimuli. Nociceptor activation and pain should be considered separate phenomena according to the International Association for the Study of Pain (2020), as this helps to explain phenomena such as phantom limb pain (Amputee Coalition, 2020). Nociceptor activation acts as an alarm system, initiating protective withdrawal reflexes and focuses our immediate attention and can result in sensations of sharp, dull, aching or burning pain (Prescott and Ratté, 2017). Nociceptive pain is associated with tissue damage or inflammation (Loeser and Treede, 2008) and can be caused by traumatic injuries such as burns, wounds,

fractures and dislocations or by medical illnesses such as cardiac ischemia and appendicitis (Prescott and Ratté, 2017).

Neuropathic pain was defined as '*pain arising as a direct consequence of a lesion or disease affecting the somatosensory system*' (Loeser and Treede, 2008) and can affect the peripheral (peripheral neuropathic pain) and central (central neuropathic pain) nervous system. Neuropathic pain affects approximately 7-10% of the population (van Hecke et al., 2014). Common causes of central neuropathic pain include cardiovascular diseases such as stroke, neurodegenerative diseases such as Parkinson's disease, spinal cord abnormalities caused by injury and demyelinating diseases such as multiple sclerosis (Colloca et al., 2017). Peripheral neuropathic pain can be caused by diabetes mellitus, infectious diseases such as HIV and leprosy, postsurgical neuropathy and cancer, as chemotherapy can affect sensory fibres (Colloca et al., 2017).

The nociceptive and neuropathic dichotomisation is one way of categorising pain, however for the purpose of pre-hospital emergency care, pain is often dichotomised into acute and chronic. Acute pain is caused by a specific nociceptive event (illness or injury) and is defined as pain <12 weeks in duration; whereas chronic pain is considered that which has persisted beyond the normal healing time and is defined as pain over 12 weeks in duration (British Pain Society, 2019, Stevens and Zempsky, 2013). Acute pain is a common reason for calling an ambulance (Galinski et al., 2010, Jennings et al., 2011, McLean et al., 2002) and will be the focus of this PhD, rather than chronic pain. Considering the acute setting and limited time frame for assessing and managing patients, the impact of ambulance service intervention on chronic pain is likely to be much less than for acute pain. This is due to the increased complexity of chronic pain with its multifactorial aetiology that requires different diagnostic approaches and management strategies (Mao, 2017).

1.2.2.2 Theory of pain

Several theories have been proposed since the 17th century in an attempt to explain how people experience pain. Two individuals suffering the exact same painful stimulus may not *experience* the pain in the same way. Further to this, phenomena such as phantom limb pain (Amputee Coalition, 2020) and referred pain make theory development convoluted, because explaining these phenomena are challenging.

Specificity theory, originally developed in the 17th Century by Descartes (1901), argued the existence of a fixed communication system, direct and uninterrupted from the tissue to the brain, therefore identical painful stimuli to the tissue would elicit equal pain perceptions in ourselves and others. Simply put, stimulation and sensation are directly connected and uninterrupted. Melzack and Wall (1965) argued the unlikeliness of this model as it failed to explain several clinical, physiological and psychological phenomena, including but not limited to phantom limb pain (Amputee Coalition, 2020), battlefield injuries (Beecher, 1946) (soldiers experiencing reduced pain perception at the time of injury) and referred pain (Murray, 2009) (pain in jaw/teeth during a heart attack for example).

It was thought that soldiers in the battlefield may not experience pain from injuries the same as a civilians would (Beecher, 1946), and it was found that 57% of severely injured soldiers reported no pain or mild pain in a field hospital several hours after injury. Beecher (1946) concluded that strong emotions can block pain. Aldington et al. (2011) however found that two thirds of soldiers, when recalling pain from the time of injury, recalled moderate to severe pain.

Pattern theory (Goldscheider, 1894) argued that pain is perceived based on the 'pattern' of stimulus intensity, for example high frequency versus low frequency, localised versus widespread, sudden versus gradual stimulation of neurones. Melzack and Wall (1965) argued that this theory alone did not constitute a satisfactory general theory of pain, therefore aspects of specificity and pattern theory were merged to create gate control theory.

1.2.2.2.1 Gate control theory

Arguably the most accepted theory of pain to date is gate control theory, proposed by Melzack and Wall (1965). This theory accepted the pathway from periphery to brain as argued by specificity theory, however, explained that the pathway was not direct and uninterrupted. The signal (or stimulus) must pass through a number of 'gates' which can be opened or closed through several different mechanisms. Firstly, the theory accepted that stimuli travel via short-diameter fibres (pain and injury, itch, hot and cold) *and* large-diameter fibres (motor, touch, vibration and balance) (Massachusetts General Hospital: Neuropathy Commons, 2018). The balance of these stimuli can open or close the 'gate'; rubbing a painful area (stimulating large-diameter fibres via touch / vibration) can reduce pain perception as the large-diameter fibres out-compete the small-diameter fibres, closing the 'gate' via a negative feedback mechanism. In contrast to this, large quantities of small-diameter activation, for example a sharp penetrating injury would significantly outweigh any large-diameter stimulation in the form of touch or vibration, therefore the mechanism would create a positive-feedback loop exaggerating the effect of the painful stimuli. This occurs via a process of inhibition within the substantia gelatinosa, where increased large-diameter fibre activation increases the inhibition of pain perception (closes the 'gate') while increased small-diameter fibre activation decreases the inhibition of pain perception (opens the 'gate') (Melzack and Wall, 1965). Once the substantia gelatinosa has influenced the stimulus, it then proceeds to the first central transmission cells.

Before reaching the first central transmission cells, 'central control' can influence the perception of this stimulus (Melzack and Wall, 1965). It was argued that several central nervous system activities can influence the input of sensory stimuli such as pain. These activities include emotion, attention and memories of prior experience. This second 'gate' could explain why soldiers on the battlefield may experience no pain or reduced pain when injured (Beecher, 1946), as their attention and emotion is thought to override any incoming new stimuli, including pain (McGrath, 1994).

Once the stimulus has passed through the gate control system and central control, it is perceived by the central nervous system and once a certain threshold is

reached, the stimulus requires a response, or action. This action system involves mechanisms such as a flexion reflex, vocalisation, startle response, examination of the damaged area, autonomic responses and recollection of prior experience of similar situations to determine potential consequences (Melzack and Wall, 1965).

Gate control theory (Melzack and Wall, 1965) was used within this thesis to help understand the highly complex phenomenon of pre-hospital pain management in children. It was used because it is currently the most accepted theory of pain (Moayedi and Davis, 2013) and explains physiological and psychological aspects of pain perception. These aspects (physiological and psychological), along with social aspects (discussed, in part, as cultural aspects in section *1.2.2.3 Culture of pain*) were recognised in the updated IASP definition of pain through key point number 1 (see section *1.2.2 Pain*).

### 1.2.2.3 Culture of pain

'Culture' is difficult to define and highly contested (Prinz, 2020). Edward Tylor provided an early definition of culture: '*that complex whole which includes knowledge, belief, art, law, morals, custom, and any other capabilities and habits acquired by man as a member of society.*' (Tylor, 1871). A myriad of definitions have been proposed since this early version, with heated debate among anthropologists (Prinz, 2020). For the purpose of this thesis, the accepted definition of culture aligned close to the initial version developed by Edward Tylor, with specific emphasis on shared knowledge, belief, morals and custom within a specific community.

The relationship between culture and pain is extremely complex as it influences not only the perception and expression of pain, but also has clinical implications (The British Pain Society, 2010). Culture is adaptive; it continually changes to meet environmental and social changes and it is heterogeneous; cultural groups have internal variation with regards to gender, age, socioeconomic class, education and religion (Clemente, 2013). This cultural influence was acknowledged in the IASP

definition of pain key point number 1, which recognised that social factors influence the personal experience of pain (see section *1.2.2 Pain*).

The experience of pain is private; no one can share the experience. Patients decide how to translate their private pain into public pain behaviour, this is influenced by social norms and culture and by the perceived normality of the pain (Peacock and Patel, 2008, McGrath, 1994). Some cultures expect stoicism and restraint in the presence of pain; nearly half of Australian aboriginals from one study experienced long-term private spinal pain but did not make this pain public due their cultural beliefs (Honeyman and Jacobs, 1996). In another study, publicly expressed pain behaviours were more acceptable for Euro-American participants than for Japanese participants (Hobara, 2005), further illustrating the stoicism embedded in some cultures.

An individual's culture determines how they perceive pain, offering a different 'lens' though which they make sense of the world (Hoka, 2004, Peacock and Patel, 2008). Pain might be perceived as a punishment, or in a negative light by some, whereas others may view pain in a more positive light due to its protective nature; pain causes withdrawal from sources of injury and promotes self-splinting, reducing further damage to injured parts of the body (Givler and Maani-Fogelman, 2019). The Japanese culture may view pain in a positive light (Hoka, 2004) which might explain the difference in culture observed by Hobara (2005).

#### 1.2.2.4 Consequences of poor pain management

IASP recognised that pain has adverse effects on function and social and psychological well-being (International Association for the Study of Pain, 2020), as described in their fifth key point (see section *1.2.2 Pain*). If acute pain is left untreated, several consequences may arise. In the post-operative surgical setting, quality of life may be reduced (Wu et al., 2003) along with patient satisfaction, recovery may be delayed and the risk of developing persistent pain is higher (Joshi and Ogunnaike, 2005). Inadequate pain management may also result in increased health care costs due to prolonged hospital stays or readmissions (Fortier et al.,

1998, Pavlin et al., 2002). Reduced quality of life was also found by Sinatra (2010) to be a consequence of poor management of acute pain, along with other consequences such as; impaired sleep, impaired physical function, high economic cost and physiological consequences such as the development of chronic pain.

Specific consequences of poor pain management in children in the acute setting include post-traumatic stress disorder (Sheridan et al., 2014, Saxe et al., 2001) and altered pain perception (Taddio et al., 1997, Weisman et al., 1998). Therefore, effective management of acute pain has several personal and socioeconomic benefits.

### 1.2.3 Children

Within the UK it is well established that people aged 18 years and above are termed adults. There are several terms used to describe individuals under the age of 18 years, including but not limited to; neonate, baby, infant, toddler, child, teenager, adolescent and minor, with the age range of each often blurred and overlapping between domestic and foreign settings. For the purpose of this thesis, all individuals under the age of 18 years will be termed 'child[ren]' (United Nations, 1989), unless otherwise explicitly stated.

Children are unique, especially when compared with adults and must be considered separately. This is due to the complex physical, mental and emotional stages of development children experience as they grow (Whitley and Lord, 2018). This growth is not identical in all children, as some develop faster than others. When including children in research projects there are two initial considerations:

1. *Age*: What age range should be included?
2. *Consent*: How is consent gained from children?

#### 1.2.3.1 Age

The United Nations convention of the rights of a child, article 1, defines a child as any person under the age of 18 years (United Nations, 1989). This however is not

reflected in recent pre-hospital literature (Whitley and Lord, 2018), with age ranges varying from 'under 15 years' to 'under 21 years' for studies of 'children'. According to Whitley and Lord (2018) the physical, mental, emotional and legal age of a child have to be taken into consideration when deciding the age range of children to include.

#### 1.2.3.1.1 Physical age

The physical age, or size of a child is determined by their rate of growth, of which there are many influencing factors (Rogol et al., 2000). The size of a child at birth is influenced by maternal nutrition, mother's metabolism, placental and intrauterine factors more so than the genetic makeup of a child (Rogol et al., 2000). In addition to this, birth weight is also influenced by maternal age, birth order and season, with birth weight generally increasing with increased maternal age, increased birth order and during the months of March, April and May (study performed in New York, US) (Selvin and Janerich, 1971).

After birth, rates of growth vary between male and female children, with females starting puberty on average two years earlier than their male counterparts (Rogol et al., 2000). Ethnicity also influences growth rates in children, with black female children tending to be taller and heavier during puberty than their white female counterparts and are more likely to have a greater body mass index (Rogol et al., 2000). Arguably one of the most influential factors is nutrition, with poverty-related malnutrition being the most common cause for childhood 'stunting' (Rogol et al., 2000). 149 million children less than five years of age suffered from stunted growth worldwide in 2018 (Unicef, 2019). The most affected area being South Asia with 34.4% of all children under 5 years suffering from stunted growth, with the United States and Australia having relatively low rates (2.6% and <2.5%, respectively) (Unicef, 2019). Stunted growth is associated with impaired cognitive ability (Unicef, 2019), this could directly influence a child's ability to interpret pain assessment tools to provide accurate pain reporting, therefore physical age is an important consideration.

Within the national UK ambulance service clinical guidelines (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019b) there was a 'page for age' section ranging from birth to 11 years. Each page listed expected vital signs, energy levels for defibrillation, airway sizes and drug dosages. This information relied on the anticipated correlation between size (height and weight) and age. The pharmacokinetics and pharmacodynamics of administered drugs also relied on this correlation, as UK paramedics do not calculate drug dosages by weight. As such, children whose weight is well below the 25$^{th}$ percentile or well above the 75$^{th}$ percentile weight for age *may* have a sub-therapeutic response to drug therapy or a dose that exceeds the safe threshold. Charlton et al. (2020) explored the correlation between child age and weight, with reference to UK ambulance service 'page for age' clinical guidelines (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019a) and found that observed weight was greater than 'page for age' estimated weight. Charlton et al. (2020) concluded that drug dosages and defibrillation charges guided by 'page for age' differed from those guided by weight.

The UK clinical practice guideline definition of a 'child' in terms of drug dosages refers to any patient aged less than 12 years. This definition is consistent with the Ambulance Victoria guideline definition (<12 years), but not the Queensland Ambulance Service definition of a child (which is anyone aged less than 13 years) (Whitley and Lord, 2018). When clinicians cross or move between jurisdictions, any variation in definition could create confusion when treating children, potentially resulting in incorrect drug dosages being administered or procedural errors when a child is treated as an adult. While the clinical consequences may be unclear, clinical audit systems are likely to flag care that is inconsistent with the jurisdiction's guidelines, and this may have performance management consequences for the paramedic.

Physical age of the child is therefore an important consideration when determining the age range to include in studies and the area of the world in which the study is to take place.

1.2.3.1.2 Mental age

Piaget (1964) identified four stages of cognitive development in children, namely the sensory-motor (pre-verbal) stage (0-2 years), pre-operational stage (2-7 years), concrete operational stage (7-11 years) and formal operational stage (12 and over). The progression between stages relies on four factors; maturation, experience, social transmission and equilibration (Piaget, 1964). Depending on these factors, the correlation between patient age and cognitive ability is likely to vary. Some children may have a cognitive ability that supersedes their age, yet others may have reduced cognitive ability. Therefore, it is difficult to state an upper age limit where all patients will have the level of cognitive function to interact effectively with clinicians undertaking assessments and treatments. This could influence patient reported outcomes such as pain scores, quality of life assessments and patient experiences.

1.2.3.1.3 Emotional age

According to Saarni (2011) there are several stages of emotional development in children ranging up to age 13 years. Saarni (2011) stated that individuals aged over 13 years have *'increasing integration of moral character and personal philosophy in dealing with stress and subsequent decisions'* (pg3). This ability is a useful consideration for pre-hospital clinical studies as patients unable to deal with stress may not give accurate or reliable patient reported outcome measures. The term 'increasing' implies a lack of emotional competence as this ability has not fully been achieved, therefore this should be considered when including children under 13 years of age.

1.2.3.1.4 Legal age

The United Nations convention on the rights of the child (United Nations, 1989) Article 1 defines a child as anyone under the age of 18 years. Within the UK, adulthood is achieved at the age of 18 years (Family Law Reform Act 1969 c.46).

Considering many adult studies use an age range of 18 years and over, and many child studies use an age range of under 16 years (Jennings et al., 2015, Watkins, 2006, Galinski et al., 2011, O'Donnell et al., 2013, Murphy et al., 2017), it appears that 16 and 17-year-old patients may be grossly under-represented within the literature.

In addition to the underrepresentation of adolescents in pre-hospital child pain research, adolescents have been excluded from other key research areas including HIV vaccine trials (Jaspan et al., 2008) and cancer trials (Ferrari et al., 2008), with one study finding that children <15 years of age had much higher rates of cancer trial enrolment (>94%) than adolescents aged 15-19 years (21%) (Bleyer et al., 1997). This systemic underrepresentation of adolescents aged 16 and 17 years in clinical research requires urgent attention.

#### 1.2.3.2 Consent

Once a child reaches the age of 18 years in the UK, mental capacity is assumed and the individual is considered capable of making independent decisions regarding their health care (Mental Capacity Act 2005 c.9).

Research involving children must normally be carried out with the consent of the parent/guardian and/or the child depending on the competency of the child (Medical Research Council, 2004). Children aged 16 and 17 can consent to surgical, medical or dental treatment which, without consent, would result in 'trespass to person' (assault or battery) (Family Law Reform Act 1969 c.46). According to case law children under 16 years of age can be deemed Gillick competent (House of Lords AC 112, 1986). If a child has *'sufficient understanding and intelligence to enable him or her to understand fully what is proposed'* (House of Lords AC 112, 1986) then consent from the child is deemed sufficient; in cases of insufficient maturity, parental consent must be sought (Paediatrics RCO, 2000).

In some observational research, where children are not directly involved in a study and their management has not changed, but their routine clinical data are used, if

the records are anonymised and appropriate ethical approval is gained, consent from the child or parent to use their data is not required (Paediatrics RCO, 2000).

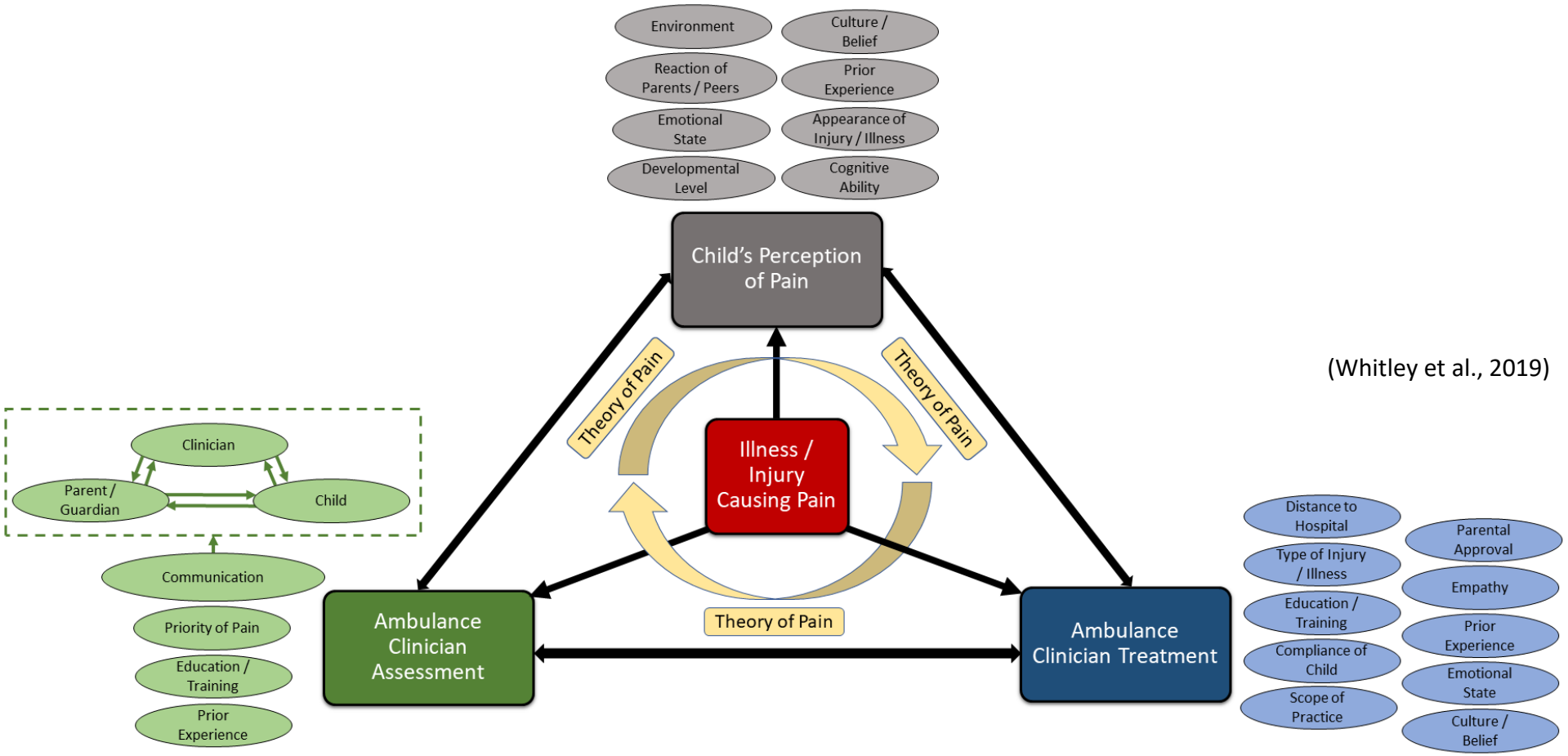
### 1.2.4 Pre-hospital pain management in children

Pain is a common symptom suffered by children who present to ambulance services; Lord et al. (2016) found that 41.3% of children attended by Ambulance Victoria suffered pain and Lerner et al. (2014) found that 42.1% of children suffered a painful complaint, such as traumatic injury, abdominal pain or chest pain.

It was important to consider the whole process of pre-hospital pain management in children to visualise and further understand this complex phenomenon. A process map was developed utilising an iterative approach incorporating current literature, clinical experience and expert opinion (Whitley et al., 2019), see Figure *1* (pg18). The map was developed over several months whilst gaining feedback from my supervisors along with my clinical and research peers; this process facilitated numerous revisions where a consensus of expert opinion was reached and the final version was produced (see *Figure 1* pg18).

Having an appreciation for the theory of pain, as discussed in section *1.2.2.2.1 Gate control theory*, was fundamental to the process. It was clear from Figure *1* (pg18) that four facets of the pain management process should be considered; the illness or injury causing the pain, the child's perception of the pain, the ambulance clinician's assessment and the ambulance clinician's management of the pain. Each of these four facets had influencing factors, as discussed below.

Figure 1 – Flow diagram illustrating the factors influencing the pre-hospital pain management process in children




(Whitley et al., 2019)

1.2.4.1 Illness/injury causing pain

Typically, acute pain is categorised as traumatic or medical in the pre-hospital setting (Lord et al., 2016). For example, a child may present with a fracture, laceration to the skin or sustain a thermal injury, all of which would be classified as a traumatic injury. Traumatic injuries may influence the child's perception of pain as the child can visually see an abnormality, perhaps the presence of blood or a deformed limb, potentially creating a higher level of traumatic stress (defined as '*exposure to traumatic events or situations [that] overwhelms a child's or adolescent's ability to cope*' Kao et al. (2017) pg249). Kao et al. (2017) stated that there may be an association between traumatic stress and pain in children; whether traumatic stress is higher in traumatic or medical sources of pain is to be determined. McGrath (1994) stated that situational factors, such as those involved in acute pain caused by severe trauma, can intensify perceived pain. Lord et al. (2016) found that 67.7% of children suffering pain in the pre-hospital setting suffered traumatic injury, including musculoskeletal injuries, burns and other trauma. Trauma differs from medical pain caused by abdominal complaints for example, as the child cannot visually see any abnormality, they can only feel the pain (Whitley et al., 2019).

Children in these different sub-groups may have varying perceptions of pain and their coping mechanisms may be different. A child may be more likely to self-soothe or rub the site of medical pain, such as abdominal pain or growing pains, than they would traumatic pain from a burn or broken limb. This could be explained by gate control theory (Melzack and Wall, 1965), as non-painful stimuli such as rubbing activates large diameter fibres, closing the 'gate', reducing perceived pain.

Different aetiologies also affect the clinician's perception. For example, children who suffer traumatic pain versus medical pain are more likely to receive effective pain management (Bendall et al., 2011a, Jennings et al., 2015, Lord et al., 2019). Therefore, the aetiology of pain is an important consideration.

1.2.4.2 Child's perception of pain

The child's perception of pain is likely to be influenced by many factors, including the child's developmental level and cognitive ability (McGrath and Craig, 1989, McGrath, 1994), their prior experience of pain (as pain is considered a learned experience, see section *1.2.2 Pain*) (McGrath and Craig, 1989, Raja et al., 2020), the reaction of the people around them (friends and/or family) (Hadjistavropoulos et al., 2011, Goubert and Simons, 2013) and the appearance of the illness/injury (Whitley et al., 2019) as discussed above. Prior experience has a significant potential to influence pain perception, therefore pain can be considered a learned phenomenon (Linton and Shaw, 2011, McGrath, 1994); illustrated by key point number 3 in the IASP definition of pain (see section *1.2.2 Pain*). However, as each child's prior experience will differ, so will their perception and resultant behaviour, therefore clinicians should interpret behaviour with caution when assessing pain. Self-reported pain intensity and direct observation of pain behaviour was found to be moderately correlated, but showed great variability across studies (Labus et al., 2003); therefore associations should be not be made between a patients behaviour of pain and their perceived level of pain.

The culture and belief system of the child is important to consider (see section *1.2.2.3 Culture of pain*), for example some cultures (Givler and Maani-Fogelman, 2019) believe pain to be beneficial and is viewed in a positive light rather than a negative one, as pain prevents further injury and promotes self-splinting. Paramedics in Japan for example did not carry analgesics and were restricted to life-saving interventions such as advanced life support procedures along with fluid and glucose administration (Igarashi et al., 2018, Tanigawa and Tanaka, 2006), illustrating this alternative culture around pain. The environment (hot, cold, crowded, calm) in which the child experiences pain along with their emotional state is likely to influence their perception of pain (Strigo et al., 2000, Peters, 2015).

The assessment and management of pain by the clinician may influence the overall perception of pain by the child. For example, when a child is suffering abdominal pain, the clinician may perform an abdominal assessment which may involve palpation (Joint Royal Colleges Ambulance Liaison Committee. Association of

Ambulance Chief Executives, 2019a). This may influence the perception of pain by increasing or decreasing its intensity. Also, the child may experience heightened states of emotion such as fear and anxiety during assessment (Lerwick, 2016), potentially influencing the child's perception of pain. Interventions such as analgesics and non-pharmacological techniques including slings and splints, distraction techniques and comfort may also influence the perception of pain (Jennings et al., 2015, Lord et al., 2016).

#### 1.2.4.3 Ambulance clinician assessment of pain

The clinician's assessment of pain may be influenced by prior clinical experience, education and training (Beltramini et al., 2017), the priority of the pain within the clinical situation (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019a) and the level of communication between the patient, the parent/guardian and the clinician. For example, if a child was suffering hypovolaemic shock from an amputated limb, the highest priority would be to stop the bleeding and reverse the shock (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019a). Pain assessment would be less of a priority in this situation. Communication is a significant factor during the assessment of pain. Where verbal communication is limited (pre-verbal/poor cognitive function) clinicians should use behavioural pain scales such as FLACC (face, legs, activity, crying and consolability scale) (Whitley, 2018, Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019b). Communication can be challenging especially when a pre-hospital clinician has little exposure to children in a professional capacity (see section *1.2.1 Ambulance service*). Clinicians may not have sufficient education and training in paediatric pre-hospital care or are not exposed to children frequently from a social/family life perspective.

The clinician's assessment of pain is influenced by the child's perception, the source of pain and the clinician's initial management of pain (Whitley et al., 2019). For example, if the child has suffered multiple injuries in the past or has previously suffered cancer and undergone chemotherapy, it is likely that their perception of

pain maybe different to that of a child experiencing pain for the first time, due to the 'learnt' phenomenon (Cafasso, 2018). This may result in a higher or lower pain score when using assessment tools; McGrath (1990) stated that the intensity and unpleasantness of mild injuries in children generally decreases with age.

Rates of documented pain assessment for children in the pre-hospital setting vary, with Pilbery et al. (2019) stating that for children suffering pain, only 24% of records had two pain scores documented and Lord et al. (2016) stating that 59% had two documented pain scores. This highlights disparity in rates of pre-hospital child pain assessment.

#### 1.2.4.4 Ambulance clinician management of pain

Pain management is likely to be influenced by a clinician's level of education, training and scope of practice (Williams et al., 2012, Murphy et al., 2014), the clinician's level of empathy (Goubert et al., 2005), their culture and belief system (*1.2.2.3 Culture of pain*), their emotional state, prior experience of managing pain in children and the relative distance to hospital (Williams et al., 2012, Murphy et al., 2014). Qualitative research has found one of the barriers to effective pain management in children is fear perceived by the clinician (Williams et al., 2012). Clinicians fear children having an allergic reaction to morphine, for example. Murphy et al. (2014) found that another barrier was inhaled analgesics, as they are difficult to administer to distressed and uncooperative children.

The clinician's management of pain is influenced by the type of pain; Lord et al. (2016) found that clinicians were significantly more likely to administer analgesics to children suffering traumatic pain versus medical pain.

Pain management in children within the ambulance service consists of pharmacological and non-pharmacological interventions (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019b). Lord et al. (2016) found that 55% of children suffering severe pain did not receive analgesics, however 85% of all children with an initial pain score >3 out of 10 achieved effective pain management, with a reduction of 2 or more points. It was

concluded that non-pharmacological techniques were probably responsible for this disparity. Within the UK, Whitley and Bath-Hextall (2017) found that 38.8% of children reporting pain received no analgesic and no alternative treatments such as slings, splints, dressings or bandages. For children suffering pain in the pre-hospital setting, Pilbery et al. (2019) found that 14.4% received analgesics, Lord et al. (2016) found that 39.5% received analgesics and Whitley and Bath-Hextall (2017) found that 51.6% received analgesics. This variation in rates of analgesic administration illustrate the challenges of pain management, with the route of analgesic administration identified as a major barrier (Murphy et al., 2014).

### 1.2.5 Wider context

Pre-hospital pain management in children is a very specific context and population. There might be valuable lessons learnt in wider contexts and populations, such as children who receive pain management in-hospital and adults who receive pain management in the pre-hospital setting. This may help develop a *broader* understanding of pain management.

#### 1.2.5.1 In-hospital pain management in children

In-hospital pain management in children includes several different contexts, including specialist neonatal and paediatric wards, surgical wards and acute emergency departments. For the purpose of this thesis, the acute emergency department context was most applicable, therefore I focussed on child pain management in the emergency department for this 'wider context' section.

Pain is a common symptom of children who attend emergency departments, which is often under-treated in younger children, those in developing countries and those with cognitive impairment (Krauss et al., 2016). There are several notable differences when comparing pain management in children in emergency departments and ambulance services. Clinicians working in emergency departments with a separate paediatric area/department have much higher exposure to children compared to ambulance service staff; typically only 9% of

ambulance clinicians' workload involve children (see section *1.2.1 Ambulance service*). There are typically more staff to share the decision-making load in emergency departments. Emergency departments have a wide variety of analgesics available for administration via different routes including oral, intravenous and nasal (Krauss et al., 2016), whereas relatively few analgesics (four: paracetamol, ibuprofen, Entonox® and morphine) are available for ambulance clinicians in the UK (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019a). Some ambulance services have more analgesics available, such as intranasal fentanyl in countries such as Australia (Lord et al., 2016) and Ireland (Murphy et al., 2017).

Pope et al. (2018) explored the perceptions of children aged 4-8 years who attended an emergency department with acute pain. A 'draw, write and tell' technique was used to gather data which highlighted the importance of listening to the child, being honest and developing trust. One of the main findings was the importance of fostering a secure environment; the presence of a parent, primarily the mother, was important along with the actions of hospital staff, including having things explained, being read to, tickled or massaged all created a sense of security. This concept of fostering a secure environment was considered transferable to the pre-hospital setting, however this could be challenging, especially when not in the child's own home as pre-hospital environments are often unpredictable, making assessment and management more challenging (Abelsson and Lindwall, 2012).

A recent study in UK emergency departments showed that pain scoring may not accurately reflect patient experience and staff often recorded their own judgement of pain (Sampson et al., 2019). This raised doubt over the accuracy of pre-hospital pain scoring and questioned whether the obtained pain scores reflected the patient's true experience of pain. This is a potential limitation to any pain study using pain scoring tools as the outcome measure.

One study attempted to improve rates of pain assessment and treatment in children attending the emergency department by implementing a 'paediatric pain bundle' (Scott et al., 2013). This bundle consisted of formal and informal education sessions, the introduction of a new behavioural observational pain scoring tool

(Alder Hey Triage Pain Score, (Stewart et al., 2004)) and a new analgesia guideline. There was no statistically significant change between assessment rates or analgesic administration rates before and after implementation (Scott et al., 2013). Scott et al. (2013) concluded by stating that pain assessment and management in emergency departments was challenging, in part due to organisational and system requirements that increase time to analgesia. In addition to this, assessing pain for all children aged 0-15 years using a behavioural observational tool might not accurately reflect the patient's true experience of pain, as the use of self-report pain scales where children are old enough to comply effectively are considered the gold standard (Krauss et al., 2016). A similar study was performed recently in the UK, introducing a care bundle to improve pain management in children in emergency departments and minor injury units, however the authors concluded that although small improvements were made, overall the level of pain management still fell below expected standards (Treadgold et al., 2019). Both these studies add to the argument that pain management in children is extremely complex and requires a deeper understanding to improve clinical practice.

#### 1.2.5.2 Pre-hospital pain management in adults

Pain is a common symptom suffered by adults presenting to ambulance services (Jennings et al., 2011). Despite easier assessment (generally) due to enhanced patient communication skills and cognition, rates of effective pain management and analgesic administration are still low.

In one Australian pre-hospital study, 34.5% of all patients experienced pain of traumatic (40.1%), medical (39.1%) and cardiac (17%) origin (Jennings et al., 2011). Two pain scores were available for 86% of the patients reporting pain and of these patients, 40.7% achieved a pain score reduction of 3 or more using the verbal numeric rating scale. 51% of patients reporting pain received an analgesic.

In the United States, 34% of all patients (90% adult >18 years) attended by the ambulance service reported pain (McLean et al., 2002). Narcotic analgesics were administered to 21% of patients reporting pain. McLean et al. (2002) stated that

pain was likely under-reported as narcotic analgesics were administered to 13% of patients who did not have pain documented.

In Denmark, 27.7% of patients transported to hospital reported moderate to severe pain (≥4 out of 10 on the numeric pain rating scale) and only 7.9% of these received intravenous fentanyl (the primary analgesic of choice for EMTs in this study) (Friesgaard et al., 2018).

The rate of analgesic administration for pre-hospital adult patients varies hugely from 51% (Jennings et al., 2011) to 8% (Friesgaard et al., 2018), highlighting disparity in ambulance service care internationally.

## 1.3 Research Question

*What are the predictors, barriers and facilitators to effective management of acute pain in children by ambulance services?*

This question was developed over several months having been reviewed by colleagues and academics. The 'what' nature of the question implied a process of identification, representing an initial stage of inquiry, as opposed to a later stage such as 'how' or 'why' do barriers and facilitators impact pain management in children. It was deemed necessary to start with this initial inquiry due to the limited evidence base and calls for further research by leading academics in the field (Lord et al., 2019, Williams et al., 2012).

'Predictors' were perceived as objective quantifiable factors that indicate the likelihood of a child achieving effective pain management. Such factors could be identified quantitatively through analysing clinical record data and performing an appropriate analysis. Such factors may include for example the patient's sex, age or ethnicity, type of pain, distance to hospital and clinician demographics such as age, sex and years of experience.

'Barriers and facilitators' were perceived as subjective qualitative factors that cannot be measured. They exist through the experience, culture and belief systems of individual clinicians. Barriers may include for example a fear of side effects from the use of analgesics or the experience of failed intravenous access attempts in small children.

'Effective management' can be considered difficult to define due to the subjective nature of pain and the subsequent perceived impact of pain relief interventions. For the purpose of this research, effective management of pain was defined objectively as the abolition or reduction of pain by ≥2 out of 10 on the numeric pain rating scale (NPRS), Wong-Baker FACES® scale or the face, legs, activity, crying and

consolability (FLACC) scale (Myrvik et al., 2013, Bulloch and Tenenbein, 2002, Bailey et al., 2010, Powell et al., 2001, Voepel-Lewis et al., 2011, Tsze et al., 2015).

It should be stated that in the literature, variation exists in the reporting of the number of points on respective pain scales; for example some authors describe the numeric pain rating scale (0-10) as a ten point scale (Pilbery et al., 2019, Whitley and Bath-Hextall, 2017, Andolfatto et al., 2019) while others describe it as an eleven point scale (Jennings et al., 2015, Siriwardena et al., 2019). Technically, there are eleven points on the scale, including the zero, however the maximum score is ten, which is why some authors describe it as a ten-point scale. To prevent confusion, the numeric pain rating scale was described as a ten-point scale in this thesis. This decision was informed in part by peer-review feedback from the publication of the cross-sectional study (Whitley et al., 2020b) as the initial reference to an eleven-point scale created confusion, therefore was subsequently changed to ten-point scale.

One of the challenges of this PhD, for the identification of predictors, was the selection of an appropriate outcome measure. Two main measures have previously been cited: analgesic administration (Schauer et al., 2018, Browne et al., 2016b) and pain score reduction (Jennings et al., 2015, Bendall et al., 2011a, Lord et al., 2019). The decision to adopt pain score reduction as the outcome measure was discussed further in section *4.2.1.4 Outcome of interest*.

'Acute pain' was selected to fit the context of this study. The British Pain Society (2019) defined acute pain as pain lasting less than 12 weeks. Ambulance service clinicians normally deal with unplanned, unexpected, emergency medical/traumatic conditions. When considering traumatic injuries and medical illness such as abdominal pain in children, acute pain is normally present, rather than chronic pain. Therefore, these patients would not have a pre-existing pain treatment regime or plan for breakthrough pain, as would be expected with children suffering cancer or long-term degenerative conditions for example. The inclusion of such chronic pain patients would make the research more convoluted, potentially weakening any inferences made as the assessment and management of chronic pain is more complex (*1.2.2.1 Types and causes of pain*). Considering the frequent presentation

of acute pain to pre-hospital clinicians compared to the relatively infrequent presentation of chronic pain (Murphy et al., 2016, Lord et al., 2016), acute pain was deemed the most appropriate type of pain in this context.

'Children' can be difficult to define, particularly when specifying an age range (Whitley and Lord, 2018), as discussed in section *1.2.3.1 Age*. Most adult studies include patients aged 18 years and above. Therefore, it seemed logical to include all patients aged less than 18 years. The United Nations convention of the rights of a child, article 1 defines a child as any person under the age of 18 years (United Nations, 1989), therefore this decision was justified.

'Ambulance service' was chosen to fit the context of the research problem. Variation of terminology exists across the continents. Emergency medical service is often used in the Americas and Asia, whilst ambulance service is more common in Europe and Australasia. Both terminologies are acceptable and interchangeable, however for the purpose of this thesis the term ambulance service was used.

## 1.4 Research Aim and Objectives

### 1.4.1 Aim

The aim of this research was to identify predictors, barriers and facilitators associated with effective pre-hospital pain management in children suffering acute pain and to identify ways to improve the quality of care.

The results of this research may be used to inform an educational intervention for ambulance service clinicians which could be implemented into clinical practice. This PhD may also inform future research.

### 1.4.2 Objectives

1. Systematically review the evidence on predictors, barriers and facilitators associated with effective pre-hospital management of acute pain in children by ambulance services.
2. Identify predictors associated with effective pre-hospital pain management in children by ambulance services.
3. Explain identified predictors associated with effective pre-hospital pain management in children by ambulance services.
4. Identify barriers and facilitators to the pre-hospital pain management process in children by ambulance services.
5. Explore how pre-hospital pain management in children by ambulance services could be improved.

## 1.5 Overview of Thesis

This thesis has been structured in the following order: Introduction (Chapter 1), Philosophy and Methodology (Chapter 2), Systematic Mixed Studies Review (Chapter 3), Mixed Methods Sequential Explanatory Study (Chapter 4) and Discussion and Conclusion (Chapter 5). It was necessary to incorporate the components of the mixed methods sequential explanatory study (cross sectional study and generic qualitative study) along with the discussion of integration into the same chapter (Chapter 4) to illustrate the single overall nature of the study. This however created a long chapter, therefore within Chapter 4 each study along with the discussion of integration was clearly labelled and segregated.

This structure provided logic and ease of reading, with full studies confined within their individual chapter, allowing the reader to break between chapters without losing momentum or context.

# Chapter 2 – Philosophy and Methodology

## 2.1 Philosophy

### 2.1.1 A brief history of philosophy

Western philosophy has evolved over the last 2400 years since the time of Plato (429-347 BCE), Socrates (470-399 BCE) and Aristotle (384 – 322 BCE) (Lincoln and Guba, 1985, Johnson and Gray, 2010).

The scientific revolution of the sixteenth and seventeenth century and the eighteenth century period of Enlightenment were major turning points in scientific and intellectual history which brought significant philosophical advances (Johnson and Gray, 2010). During this time period, some of the major philosophical influencers were Francis Bacon (1561-1626), René Descartes (1596-1650), John Locke (1632-1704), David Hume (1711-1776) and Immanuel Kant (1724-1804) (Johnson and Gray, 2010).

The scientific method and classical positivism saw advances with William Whewell (1794-1866) and Auguste Comte (1797-1857) (Johnson and Gray, 2010). Whewell created the term 'scientist' in 1833, prior to this the term 'natural philosopher' or 'man of science' was used (Snyder, 2019). Comte described the six sciences; mathematics, astronomy, physics, chemistry, biology, sociology and stated that in this order, generality decreases and complexity increases (Bourdeau, 2018).

Positivism was heavily criticised by the likes of Karl Popper (1902-1994) and Thomas Kuhn (1922-1996), mainly because of the difficulty in 'verifying' a hypothesis of a law. Consider the black swan analogy; a theory that all swans are white can easily be disproved by identifying one black swan (rather than attempting to verify that all swans are white), therefore it is easier to falsify than to verify (Taleb, 2007). Popper recommended a model of 'falsification' rather than 'verification' (Popper, 1962), whereby theories stood for as long as they were not disproved/falsified (Johnson and Gray, 2010). This led to the modification of logical positivism, first to logical empiricism and then to postpositivism.

Thomas Kuhn was one of the most influential philosophers of all time, his most notable work being *The Structure of Scientific Revolutions* (Kuhn, 2012), originally published in 1962. Kuhn developed the concept of the 'paradigm shift' and stated that scientific and philosophical advances did not occur in a linear fashion, but instead made significant advanced at certain points in time (Bird, 2018).

Philosophy is considered to have three broad divisions; metaphysics (the nature of existence), epistemology (the nature of knowledge) and axiology (the nature of value) (Feaver, 1975). Within these broad divisions, several sub-divisions, or branches, exist. Ontology (the nature of 'being' and reality) is closely related to metaphysics (van Inwagen and Sullivan, 2020). Logic (the study of correct reasoning) is closely related to epistemology (Shapiro and Kouri Kissel, 2018). Ethics (the study of morality) and aesthetics (the study of beauty) are both closely related to axiology, and religion is closely related to all three divisions of philosophy (Taliaferro, 2019).

The combination of a set of beliefs about the nature of 'being' and reality (ontology) and the nature of knowledge (epistemology) is said to be a 'paradigm', a 'lens' or a worldview (Teddlie and Tashakkori, 2009, Lincoln and Guba, 1985). The main paradigms in social science research include positivism, postpositivism, critical theory and constructivism/interpretivism, each of which have specific ontological and epistemological views (Guba and Lincoln, 1994, Lincoln and Guba, 1985). Pragmatism is also considered one of the main paradigms (Teddlie and Tashakkori, 2009), however is constrained by a lack of ontological and epistemological positioning (Biesta, 2010). Niglas (2010) argued for the concept of a philosophical and methodological continuum, stating that paradigms and their underlying methodologies overlap to varying degrees. This is highly relevant to mixed methods research, as a single paradigm may not suit the research question.

### 2.1.2 Philosophical paradigm

The philosophical paradigm adopted for this thesis was postpositivism. There were several driving forces behind this decision, including the beliefs and assumptions of the researcher and the nature of the research question.

#### 2.1.2.1 Researcher beliefs and assumptions

My personal journey leading to this research project has been discussed in section *1.1 Personal statement*. I consider myself emotional, compassionate and caring; this facilitates holistic clinical practice (Zamanzadeh et al., 2015) where the emotional needs of the children and parents I attend are a priority. The ability to relate to patients and parents on a personal level and acknowledge that their past experiences and emotions influence their perception of pain along with my assessment and management of pain indicates that a constructivist/interpretivist paradigm would be a useful 'lens' to conduct this research through.

However, the combination of being a clinical paramedic and having undertaken research in the field of child pain management has led me to understand that macro trends and disparities exist. As a practising paramedic I have managed children with traumatic and medical sources of pain, therefore I understand the differences between these two patient groups and the tendency to treat pain caused by trauma more proactively than pain caused by medical illness, a phenomenon that has previously been identified (Jennings et al., 2015, Bendall et al., 2011a). Similarly, I understand the challenges in assessing and managing children of different ages. This personal experience, coupled with the knowledge gained from examining the literature during my previous research (Whitley and Bath-Hextall, 2017) has led me to believe that disparity in clinical care for children suffering pain exists at a broader level. This belief and assumption did not lend itself to a constructivist/interpretivist paradigm, but rather a positivist or postpositivist paradigm where quantitative enquiry would be the desirable approach. This was because macro trends and broad disparity are better identified using large sample sizes via quantitative techniques, rather than small sample sizes via qualitative techniques (Johnson and Onwuegbuzie, 2004).

This conflict between the constructivist/interpretivist and positivist/postpositivist paradigm has resulted in some interesting debate, resulting in contemporary issues of philosophical paradigms in mixed methods research, discussed by Tashakkori and Teddlie (2010) and discussed in section *2.1.5 Philosophy in mixed methods research*. Considering my personal beliefs and assumptions, the perceived validity and benefit of both quantitative and qualitative methods was evident.

#### 2.1.2.2 Research question

The research question was discussed in detail in section *1.3 Research Question*. The question aimed to identify three key aspects of the pre-hospital child pain management phenomenon; predictors, barriers and facilitators. In order to identify predictors of effective pain management, quantitative methods were needed to perform a statistical analysis on a large sample size of children suffering pain (Law and Pascoe, 2013, Katz, 2011). To identify barriers and facilitators, qualitative methods were needed to elicit the experiences, beliefs and culture of the clinicians attending children in pain (Green and Thorogood, 2018). It was clear that quantitative and qualitative methods were needed to answer the research question, therefore the paradigms of choice leaned towards postpositivism (Creswell, 2014, Guba and Lincoln, 1994) and pragmatism (Teddlie and Tashakkori, 2009).

It was challenging to select between postpositivism and pragmatism, and it could be argued that both were suitable paradigms. The selection of postpositivism occurred as part of an iterative process, as the interplay between paradigm and methodology was considered. Given that quantitative and qualitative methods were both needed, it was useful to consider the methodology and decide whether a mixed methods or multi methods study would be more appropriate (discussed later in section *2.3 Methodology*). It was clear that a mixed methods approach was suitable, specifically the sequential explanatory design. This led back to the paradigm where Creswell et al. (2003) argued that postpositivism may be the most appropriate paradigm for the sequential explanatory mixed methods design. This was due to the postpositivist paradigm lean towards a predominantly quantitative

approach (Niglas, 2010) and the reliance on quantitative methods within the sequential explanatory approach to build a strong foundation (Creswell, 2014, Whitley et al., 2020c) on which the qualitative strand could be conducted. In addition to this, Biesta (2010) stated that pragmatism can be considered a set of philosophical tools rather than a specific paradigm due to its lack of ontological and epistemological positioning. The culmination of my personal beliefs and assumptions, the research question and the interplay between paradigm and methodology resulted in the decision to adopt postpositivism as the choice paradigm for this thesis.

### 2.1.3 Postpositivism

The ontological stance of postpositivism is considered to be critical realism (Guba and Lincoln, 1994), a philosophical movement most closely associated with Bhaskar (1975). Critical realism arose from the amalgamation of Bhaskar's 'critical naturalism' and 'transcendental realism' (Archer et al., 2013). The view of critical realism is that one reality exists, it is real, but we can only apprehend and understand it imperfectly and probabilistically due to flawed human intellect and the complexity of nature (Guba and Lincoln, 1994, Teddlie and Tashakkori, 2009). Bhaskar stated:

> '*we are not imprisoned in caves, either of our own or of nature's making. We are not doomed to ignorance. But neither are we spontaneously free. This is the arduous task of science: the production of the knowledge of those enduring and continually active mechanisms of nature that produce the phenomena of our world.*'
>
> Bhaskar (1975) pg37

It was claimed by Bhaskar that this was the way to freedom from ignorance (Bhaskar and Hartwig, 2010). Enduring and continually active mechanisms of nature were perceived to play a role in the complex phenomenon of pre-hospital

pain management in children. Considering the complexity of the phenomenon (Whitley et al., 2019), illustrated in Figure *1* (pg18), the task of attempting to unpack and delineate this convoluted process can indeed be considered arduous, but this thesis seeks to illuminate this problem and extend the body of knowledge on this topic.

Critical realism complements the research question and the complex phenomenon of pre-hospital child pain management. It acknowledges that whilst we can observe differences quantitatively and identify predictors of effective pain management, we struggle to explain or understand the observed disparity because nature, particularly human nature, is highly complex. To further our understanding of observed disparity, it is necessary to adopt qualitative methods to help delineate and explain, to some extent, the complexity of human nature. It is therefore clear, under this ontological position, that the adoption of quantitative and qualitive methods is acceptable, demonstrating congruence between paradigm and methodology.

The epistemological stance of postpositivism is considered to be modified objectivism (Guba and Lincoln, 1994). The relationship between the knower and the known, or the researcher and the participant is objective; objective knowledge is sought through replication (Weaver and Olson, 2006). The belief is that replicated findings are probably true, but are always subject to falsification (Guba and Lincoln, 1994). The postpositivist considers knowledge as conjectural; subject to conjecture (an opinion or conclusion formed on the basis of incomplete information) (Phillips et al., 2000). Popper stated:

> '*There are no ultimate sources of knowledge. Every source, every suggestion, is welcome; and every source, every suggestion, is open to critical examination.*'
>
> Popper (1962) pg 27

The epistemological stance of postpositivism, whilst it is considered to lean towards objective, quantitative approaches, does accommodate qualitative approaches; as Popper stated, every source of knowledge is welcome. Further to this, the ontological stance of critical realism accepts that contextual factors influence observation, therefore qualitative approaches are valued within postpositivism to help further our understanding and knowledge of phenomena.

The lean towards objective knowledge that comes with postpositivism suits this thesis and research question and particularly suits the sequential explanatory mixed methods approach adopted (Creswell et al., 2003). The qualitative, subjective aspect of the research question allows for a much deeper understanding of the contextual factors. This may help explain any observed disparity in pre-hospital child pain management as well as offer understanding of subjective phenomena, such as fear and experience.

### 2.1.4 Other paradigms

Positivism, critical theory, constructivism (interpretivism) and pragmatism were not considered suitable for adoption for the purpose of the research question and this thesis. These will briefly be discussed along with the reason for not adopting them.

#### 2.1.4.1 Positivism

Classical positivism was founded by Auguste Comte in the nineteenth century (Bourdeau, 2018, Johnson and Gray, 2010). This original version of positivism was somewhat different to the version of positivism known by most today, which is called logical positivism or neopositivism (Bourdeau, 2018). The ontological stance of positivism is considered naïve realism; reality is 'real' and apprehendable (Guba and Lincoln, 1994). The epistemological stance of positivism is objectivist; objective generalisable theories are sought (Weaver and Olson, 2006) and findings are considered true (Guba and Lincoln, 1994). A useful visualisation of positivism, according to Alderson (1998), is a scientist looking through a microscope; this represents the distance between the observer and observed and the resultant

exclusion of the surrounding context along with the use of reliable, visible 'hard' data.

Positivism was not deemed appropriate to answer the research question because the identification of barriers and facilitators necessitated a qualitative approach. From my personal beliefs and assumptions (*2.1.2.1 Researcher beliefs and assumptions*), when research involves humans, contextual factors such as culture, social norms and beliefs should be considered to gain a complete picture. A key example of this lies within the field of pain and is therefore highly relevant to this thesis. The theory of pain was discussed in section *1.2.2.2 Theory of pain* where Descartes theorised a model of pain during the scientific revolution in the seventeenth century. Descartes hypothesised specificity theory (Descartes, 1901) which was a mechanistic model influenced simply by cause and effect with no mediators of influencing contextual factors. This theory was later incorporated into the broader gate control theory (Melzack and Wall, 1965), hypothesising that pain perception is influenced by contextual factors. Gate control theory is now the most widely accepted theory of pain and illustrates the paradigmatic shift in health care research from positivism to other inclusive paradigms such as postpositivism. Therefore, the reason positivism was not adopted as the overarching paradigm was because it did not allow for the accommodation of contextual factors.

#### 2.1.4.2 Critical theory

Critical theory is concerned with countering oppression, redistributing resources and power and includes feminist and emancipatory movements (Weaver and Olson, 2006). The ontological view of critical theory is considered to be historical realism, where reality is considered true and 'taken for granted' (Weaver and Olson, 2006) and is formed and shaped over time from social, cultural, ethnic, political, economic and gender values (Guba and Lincoln, 1994). The epistemological view of critical theory is considered to be subjectivist, and that findings are value-mediated (Guba and Lincoln, 1994).

The research question did not align well to the critical theory paradigm. The concepts of countering oppression and redistributing resources and/or power did not resonate with the research question as these were not issues. The perceived issue was disparity in quality of care, and the aim was to identify predictors of disparity along with barriers and facilitators to the pain management process, therefore this paradigm was not adopted.

#### 2.1.4.3 Constructivism (interpretivism)

The ontological stance of constructivism is relativism (Teddlie and Tashakkori, 2009) where the concept of multiple realities is accepted as they are considered 'constructed' by each individual. The concept of these multiple realities is important for the epistemological assumption, as knowledge is considered co-constructed between participant and researcher and this intersubjectivity is fostered and valued (Weaver and Olson, 2006). Therefore the epistemological stance of constructivism is subjectivism; findings are created (Teddlie and Tashakkori, 2009, Guba and Lincoln, 1994).

Whilst constructivism was considered a good paradigm for the qualitative aspect of the research question, it would not allow for the objective, quantitative methods that were required for the identification of predictors.

#### 2.1.4.4 Pragmatism

Pragmatism was developed initially by Charles Sanders Peirce (1839–1914) and further developed by John Dewey (1859–1952) (Legg and Hookway, 2020). Biesta (2010) argued that Deweyan pragmatism made a significant contribution to mixed methods research by attempting to settle the objectivism/subjectivism dualism. Dewey argued that different types of knowledge (objective or subjective) cannot offer a deeper or truer account of the world, instead these different types of knowledge are simply a result of different ways in which we engage with the world (Biesta, 2010).

According to Biesta (2010) pragmatism is not strictly a paradigm due to the lack of prescribed ontological, epistemological and methodological stance, but more a set of philosophical tools that provide useful insights into the philosophical underpinnings of mixed methods research. Johnson and Onwuegbuzie (2004) argued for pragmatism as a solution to the philosophical debate within mixed methods research, however they admitted that one of the weaknesses of pragmatism was that under scrutiny, it failed to solve many of the philosophical disputes. For these reasons, pragmatism was not adopted as the philosophical stance within this thesis, however as pragmatism develops over time it may be a viable option in the future.

### 2.1.5 Philosophy in mixed methods research

When considering philosophical paradigms within the context of mixed methods research, complications occur. For example, some paradigms are considered incommensurable, that is, they share nothing in common, they do not overlap and they cannot be combined (Tashakkori and Teddlie, 2010). An example would be to compare positivism and constructivism. The ontological stance of positivism is one that holds reality as 'real' and believes in realism, whereas constructivism holds reality as 'constructed' and believes in relativism. These ontologies have direct implications on their respective epistemologies. The positivist realist believes knowledge is gained objectively and that findings are true, versus the constructivist relativist who believes knowledge is subjective, and the findings are created (Denzin and Lincoln, 1994). The natural methodology for the positivist realist who believes in objective knowledge would be quantitative by nature, with the aim of research being prediction or control. Conversely, the constructivist relativist who believes in subjective knowledge would naturally undertake qualitative research, with the aim of research being understanding or reconstruction (Denzin and Lincoln, 1994). To undertake the opposite research methodology would defy their belief system and be ontologically and epistemologically redundant.

Having considered this, an important question arises. How can methodologies be mixed without compromising their underlying philosophical (ontological and

epistemological) assumptions? Possible solutions to this problem are discussed in the next section.

#### 2.1.5.1 Conceptual stances

Tashakkori and Teddlie (2010) proposed several conceptual stances that aim to address the contemporary issue described above. One solution is to adopt an a-paradigmatic stance. This argues the irrelevance of paradigms within 'real world' settings such as applied research. Another solution is the substantive theory stance, which argues again that a paradigm is less important, but a relevant theory should be adopted to support the research. Multiple paradigms could be used within mixed methods research, specifically a paradigm for each type of mixed methods design, for example postpositivism for the sequential explanatory approach or constructivism for the sequential exploratory approach (Creswell et al., 2003). The dialectic stance is one that argues multiple paradigms can be used within a single study type to provide greater understanding of the phenomenon of interest. Finally, a single paradigm stance is proposed, where one paradigm could suit all mixed methodologies, for example pragmatism. The solution adopted for this thesis was to adopt the 'multiple paradigms' approach, where postpositivism was considered suitable for the mixed methods sequential explanatory approach (Creswell et al., 2003, Tashakkori and Teddlie, 2010).

## 2.2 Theoretical Framework

Green and Thorogood (2018) stated that all research is framed by theory, whether it is made explicit or not. The use of theory within research should strengthen the purpose or rationale for conducting the research (Lederman and Lederman, 2015, Green, 2014) and is useful to help place research within broader fields of knowledge, aiding validity and contributing to generalisability (Green and Thorogood, 2018).

Different levels of theory exist, including macro/grand theory and middle-range theory (Green and Thorogood, 2018). Macro/grand theories, are formulated at a high level of abstraction and make broad generalisations that apply across many domains at a global level (Davidoff et al., 2015). Middle-range theories act as an intermediate and link grand theory to minor working hypotheses (Davidoff et al., 2015, Green and Thorogood, 2018).

The grand theory used to frame this research stems from the postpositivist paradigm of reality and knowledge (Guba and Lincoln, 1994). This argues that pain perceived by children is separate to that perceived by the clinician and would exist without the observation of the clinician. The distance between the perceived pain of the patient and the pain assessment by the clinician mean that the phenomenon can be investigated objectively, as the reality of this phenomenon is not considered co-constructed, but real (realism). Postpositivism argues that we must be critical of this realism (critical realism), and that experience, culture and social norms are important considerations. This is because reality is 'real', but only imperfectly and probabilistically (Guba and Lincoln, 1994), as discussed in section *2.1.3 Postpositivism*. Therefore, the perception of pain by the child and the ability of the clinician to understand the pain and manage it effectively is likely to be influenced by contextual factors such as emotion, experience and culture. This theoretical understanding strengthened the rationale for the research question, as the identification of predictors, barriers and facilitators were perceived as equally important. This was one of the reasons for adopting a sequential explanatory mixed methods approach (Creswell, 2014).

Kolcaba's theory of comfort (Kolcaba, 1994) was used as a middle-ranged theory during the analysis of qualitative data, specifically in relation to the four contexts of patient comfort; physical, social, psychospiritual and environmental. Although this theory was developed in the context of nursing palliative care patients, the theory was considered broadly applicable to children suffering acute pain.

In addition to this theory, the biopsychosocial model of health (Engel, 1977) was used to help analyse the qualitative data and frame this thesis more broadly, ensuring that the biological, psychological and social needs of children were all considered. This was particularly important when considering the psychological influences on patients, specifically emotions such as fear and anxiety for example. In addition to this, the social influences on children suffering pain were highlighted in this thesis with the findings of the cross-sectional study (see *Table 9* pg120), where level of deprivation was identified as a predictor of effective pain management. The biological, psychological and social aspects of pain were paramount considerations in this thesis, highlighted by IASP key point number one (see section *1.2.2 Pain*).

Finally, the most widely accepted model/theory of pain, gate control theory (Melzack and Wall, 1965), was used to frame this thesis. Gate control theory was discussed in section *1.2.2.2 Theory of pain* and is highly relevant to this thesis because it argues that the pathway from nociceptor activation to central perception can be influenced by non-noxious stimuli and other factors such as level of attention and emotion (McGrath, 1994). This is useful to consider as children suffering acute pain often suffer emotions of fear and anxiety, discussed further in section *4.3 Generic Qualitative Study*.

## 2.3 Methodology

The paradigm adopted for a research project directly influences what methods are likely to be employed (Guba and Lincoln, 1994), therefore the justification for the methods (methodology) is founded within the philosophical underpinnings of said paradigm. Postpositivism was adopted as the paradigm (or 'lens') through which this thesis was conducted. The method chosen for this thesis was a mixed methods sequential explanatory approach, including a quantitative cross-sectional study and a generic qualitative study. The mixed methods study was informed by a systematic mixed studies review. Justification for the adoption of these methods can be found below in sections *2.3.1 Systematic mixed studies review*, *2.3.2 Mixed methods sequential explanatory approach*, *2.3.3 Cross-sectional study* and *2.3.4 Generic qualitative study.*

### 2.3.1 Systematic mixed studies review

A review of the literature was needed to inform the development of the quantitative and qualitative studies within the mixed methods approach adopted for this thesis. It was essential that existing knowledge was incorporated into the mixed methods study because previously identified predictors would feed into the multivariable logistic regression analysis, as discussed in section *4.2.1.5 Data analysis*. If previously identified predictors were not identified, and therefore not considered for inclusion in the regression model, the analysis may have been jeopardised (Katz, 2011). It was also important to ensure that this research was not duplicating previous research. If a high-quality mixed methods study answering the same research question as proposed in this thesis had already been published, its identification may have influenced the trajectory of this thesis.

There were several potential methods for reviewing the literature, including literature (narrative) review, rapid review, scoping review and systematic review (Boland et al., 2017) amongst several others (Grant and Booth, 2009). The systematic review method was chosen for several reasons. Primarily, it was to maximise the identification of studies that had previously identified predictors of

effective pre-hospital pain management in children. Systematic reviews employ rigorous and exhaustive search strategies to identify relevant papers (Boland et al., 2017, Centre for Reviews and Dissemination, 2008, Grant and Booth, 2009) whereas literature reviews may be less exhaustive in their search strategy and rapid reviews may have their search strategy constrained by time (Grant and Booth, 2009).

Systematic reviews *'aim to minimize bias by using explicit, systematic methods documented in advance with a protocol'* (Chandler et al., 2020). The development and publication of a protocol and registering the review ensures transparency (Mallett et al., 2012). The combination of a systematic, rigorous, transparent approach makes the systematic review method more reliable than the literature review method. Literature reviews are susceptible to a number of biases during identification and selection of relevant papers (Haddaway et al., 2015). This increases the likeliness of missing important papers; in the context of this thesis, it was important to identify all predictors of effective pain management, therefore the systematic review method was preferable over the literature review method.

Scoping reviews are useful to identify and map the available evidence, particularly when little is known about a topic (Munn et al., 2018, Grant and Booth, 2009). They do have clearly defined research questions but are much broader in focus and therefore lack the depth of a standard systematic review (Boland et al., 2017). The aim of the review was not to understand the nature and extent of the available literature, but to identify specific studies, therefore the systematic review method was more appropriate.

Rapid reviews aim to provide evidence to policy-makers in a short timeframe (Khangura et al., 2012, Garritty et al., 2020). This reduced timeframe is often achieved by reducing or omitting some of the steps involved in a formal systematic review, for example only searching one or two databases or omitting the quality assessment (Boland et al., 2017, Garritty et al., 2020) or limiting the search by date or language and only performing a narrative summary of results (Tricco et al., 2015). The rapid review method was not suitable for this thesis due to the lack of exhaustive search strategy.

The systematic review method was the most suitable review method for this thesis, however quantitative and qualitative studies were required for the review, therefore a systematic mixed studies review was performed (Sandelowski et al., 2006, Joanna Briggs Institute, 2014, Pearson et al., 2015).

### 2.3.2 Mixed methods sequential explanatory approach

The justification for adopting a mixed methods sequential explanatory approach was founded within the philosophical underpinnings of the paradigm used and the research purpose.

In section *2.1.2 Philosophical paradigm*, the interplay between paradigm and methodology was discussed. Quantitative and qualitative methods were needed to address the research question, therefore a mixed methods and a multi-methods approach was considered. Due to initial scoping searches on the topic, I was aware that predictors (Jennings et al., 2015), barriers and facilitators (Williams et al., 2012, Murphy et al., 2014) had already been identified. Considering that individual quantitative and qualitative studies had already been performed, performing a multi-methods study would arguably add less value to the evidence base than performing a mixed methods study. This was because of the benefits of adopting a mixed methods approach; the integration inherent in mixed methods studies may produce more than the sum of its parts (Teddlie and Tashakkori, 2009, Barbour, 1999). This led to the adoption of a mixed methods approach.

The mixed methods convergent and sequential designs were then considered (Creswell, 2014, Teddlie and Tashakkori, 2009). The convergent mixed methods design was not adopted because qualitative and quantitative studies are performed and analysed separately and simultaneously to save time in the 'field', followed by 'merging' of the data which may or may not involve data transformation (Creswell, 2014, Teddlie and Tashakkori, 2009, Pluye and Hong, 2014). Whilst the simultaneous conduct of studies saves time, the downside is that if one study generates novel findings, the opportunity to fully explore the findings with the other study may have passed. A solution may be to extend the study and perform

more interviews in order the capture the additional data required. Fetters et al. (2013) described an 'interactive' approach to convergent design studies, where iterative data collection and analysis can lead to real-time changes in data collection. Convergent designs are considered more technically challenging to conduct than sequential designs due to the complexity of running both strands of the study simultaneously (Teddlie and Tashakkori, 2009, Creswell, 2014). For a novice researcher such as myself, the simultaneous collection and analysis of both types of data would have been extremely challenging. The 'interactive' approach where real-time adjustments are made to data collection may not have been achieved or executed to its full potential and therefore useful insights may have been missed. This thesis was conducted over three years; time was not restricted. Keeping the strands separate and allowing the study to unfold in a slower more predictable way was deemed to be advantageous (Teddlie and Tashakkori, 2009). For these reasons, the sequential design was adopted.

There are two main mixed methods sequential designs; explanatory and exploratory (Pluye and Hong, 2014, Creswell, 2014, Teddlie and Tashakkori, 2009). The decision to adopt the explanatory approach was based on data availability. Clinical record data from the ambulance service was limited (due to electronic clinical record data fields being pre-determined), therefore it was logical to exhaust the limited clinical data first, identifying predictors of effective pain management, followed by seeking possible explanations (explanatory approach). If this was performed in reverse (exploratory approach), clinical data would likely not be available to refute, confirm or complement themes arising from the initial qualitative study.

Having concluded that the mixed methods sequential explanatory approach was the most appropriate method for this thesis, the necessary paradigm through which to conduct the research became clearer. The research question dictated which types of data were necessary to answer the question, which informed the selection of methods, which led to the philosophical positioning, or 'lens'. In this sense, the research question drove the paradigm.

Whilst discussing the problem of conceptual stances in mixed methods research, Tashakkori and Teddlie (2010) stated that multiple paradigms may useful (a paradigm for each type of mixed methods study). Creswell et al. (2003) stated that postpositivism may be the best paradigm for sequential explanatory designs and interpretivism for sequential exploratory designs. As discussed in section *2.1.2 Philosophical paradigm*, postpositivism was considered as the paradigm of choice. In section *2.1.3 Postpositivism* it was explained that the epistemology of postpositivism leaned towards objective, quantitative knowledge. Considering that the mixed methods sequential explanatory approach places a greater emphasis on quantitative data, due to the quantitative study informing the qualitative study and the qualitative study explaining the quantitative study findings, the paradigm of postpositivism was well suited.

In addition to the philosophical underpinning and the research purpose, prior research had called for a mixed methods approach to *'better clarify, quantify and delineate these perceived barriers and enablers'* Williams et al. (2012) pg526. Lord et al. (2019) stated that there might be unrecognised barriers to the pre-hospital pain management process in children. These statements strengthened the decision to adopt a mixed methods approach.

### 2.3.3 Cross-sectional study

The two broad types of quantitative study design are observational and experimental (Law and Pascoe, 2013). The research question aimed to identify predictors of effective pain management. This inquiry was not experimental because it did not involve a change to clinical practice, therefore an observational design was necessary.

Quantitative observational studies are often labelled differently. For example, all of the following studies were retrospective in nature and analysed clinical record data from a set time period, yet Jennings et al. (2015) and Lord et al. (2016) reported a 'cohort study', Bendall et al. (2011a) reported a 'comparative study' and Murphy et al. (2017) and Siriwardena et al. (2019) reported a 'cross-sectional study'.

Common quantitative observational methods include cross-sectional, case-control and cohort designs (Law and Pascoe, 2013). An inherent feature of cohort studies is that patients are followed-up over a period of time, for example the British Doctor's study (Doll et al., 2004). Follow-up was not required in this thesis, as the assessment period was during one point in time (the pre-hospital phase of the patient's care). The cross-sectional design was best suited to this thesis due to the assessment taking place at one point in time and there being no need for cases and controls.

### 2.3.4 Generic qualitative study

Qualitative research has traditionally been categorised as one of the following established approaches; phenomenology, ethnography or grounded theory (Cooper and Endacott, 2007, Teherani et al., 2015, Green and Thorogood, 2018). However, many forms of qualitative research do not fit well within these categories, particularly within the field of applied health care research (Cooper and Endacott, 2007) and often results in authors claiming allegiance to one of the above established approaches, when in fact a more descriptive approach has been taken (Caelli et al., 2003). This has led to a number of authors attempting to clarify this more descriptive approach, with Thorne et al. (1997) proposing 'interpretive description' and Sandelowski (2000) proposing 'qualitative description'. In an attempt to merge these ideas and provide greater clarity towards this broader more descriptive approach, Caelli et al. (2003) proposed the 'generic qualitative' approach.

One of the reasons for adopting a generic qualitative approach, as explained by Caelli et al. (2003) is that applied clinical questions can only be answered through such a broad approach. Cooper and Endacott (2007) argue for the generic qualitative approach as an appropriate design for applied emergency care research but stress the importance of reflexivity, rigor and clear methods.

Within this thesis I aim to satisfy three objectives within the qualitative study (*1.4.2 Objectives*). One objective is to explain identified predictors from the cross-

sectional study, completing the mixed methods sequential explanatory approach. It seemed sensible to also identify barriers and facilitators and explore ways to improve pain management during the same interview. This was because the participants would be focussed on the specific population and context and it was likely that barriers, facilitators and methods of improvement would inadvertently be discussed during the explanation phase of the interview. The combination of explanation, identification and exploration required an approach that was broad in nature with the capacity to accommodate a broad philosophical lens such as postpositivism.

The requirement to accommodate broad objectives within the same study along with a postpositivist lens leant itself to a generic qualitative approach. The generic qualitative approach (Caelli et al., 2003) argues for clarity and transparency in four key areas in order to maintain credibility, namely; a) the theoretical positioning of the researcher, b) the congruence between methodology and methods, c) strategies used to establish rigor and d) the theoretical framework through which the data are examined.

#### 2.3.4.1 Theoretical positioning

Caelli et al. (2003) argued that as a minimum, authors utilising generic qualitative approach should identify their disciplinary affiliation, explain what brought them to the question and be clear about any assumptions they have on the topic.

My disciplinary affiliation lies within applied health care research. Unlike the social sciences, for example psychology and sociology, applied health care research, specifically within ambulance service research, seems less immersed in theory and philosophy, perhaps due to the dominance of quantitative research and the implicit assumption of a positivist approach. As discussed in section *2.3.2 Mixed methods sequential explanatory approach*, the research question creates the driving force in the field of applied health care research, as clinical research in particular seeks pragmatic answers to practical 'real world' problems. The reason I arrived at this research question has been explained in section *1.1 Personal statement* and my

assumptions on the topic are that a) pain management in children is poor within ambulance services and requires improvement (Samuel et al., 2015, Lord et al., 2016) and b) reduction of acute pain is a desirable outcome for children and parents in the ambulance service setting (discussed during a patient and public involvement group meeting, see section *5.2.5 Patient and public involvement*).

#### 2.3.4.2 Congruence between methodology and methods

The interplay between philosophical paradigm, methodology and method has been discussed previously (see sections *2.1.2 Philosophical paradigm* and *2.3.2 Mixed methods sequential explanatory approach*). The generic qualitative approach is well suited to mixed methods research (Percy et al., 2015) due to its ability to accommodate broad objectives (explanation, identification and exploration) within a wide philosophical lens (postpositivism). The justification for the specific methods employed within the generic qualitative study are discussed later in section *4.3.1 Methods*.

#### 2.3.4.3 Strategies used to establish rigor

Cooper and Endacott (2007) and Caelli et al. (2003) suggested a number of ways to establish rigor within the generic qualitative approach. These included; a) when the concept of data saturation is used, be explicit about how it was achieved, b) use triangulation to ensure legitimacy, c) be reflexive to ensure transparency regarding representation and d) consider the use of respondent feedback. Each of these are discussed in detail within the qualitative methods section (see section *4.3.1 Methods*).

#### 2.3.4.4 Theoretical framework through which data are examined

I engaged with the data using a combination of knowledge gained both clinically and through the findings of the systematic mixed studies review, in particular the thematic synthesis (*3.3.5 Qualitative synthesis*) and also the biopsychosocial model

of health (Engel, 1977) and the theory of comfort (Kolcaba, 1994) (see section *2.2 Theoretical Framework*).

# Chapter 3 – Systematic Mixed Studies Review

## 3.1 Introduction

Pain is 'an unpleasant sensory and emotional experience associated with, or resembling that associated with, actual or potential tissue damage' (International Association for the Study of Pain, 2020). Considering that access to pain management is considered a fundamental human right (Brennan et al., 2019) pre-hospital pain management in children is poor (Samuel et al., 2015, Lord et al., 2016). This is despite effective pain management being recently identified as a key quality outcome measure for ambulance services (Turner et al., 2019). The management of pain is known to be complex, especially in children, as age, developmental level, cognitive and communication skills, and associated beliefs must be considered (Srouji et al., 2010, Whitley et al., 2019). Without effective pain treatment, children are at risk of adverse consequences including post-traumatic stress disorder (Sheridan et al., 2014, Saxe et al., 2001) and altered pain perception (Taddio et al., 1997, Weisman et al., 1998).

Effective pain management consists of pharmacological and non-pharmacological interventions (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019b). Analgesic administration rates for pre-hospital children suffering acute pain have been low (Lerner et al., 2014, Whitley and Bath-Hextall, 2017, Lord et al., 2016). For example, one Australian study (Lord et al., 2016) found that more than half (55%) of children with severe pain (verbal numeric rating scale 8–10) did not receive any analgesic. One United States study (Lerner et al., 2014) found that from 55,642 pre-hospital patients aged <19 years, 42.1% suffered a traumatic injury or pain, yet only 0.3% received analgesics. Non-pharmacological interventions such as slings, splints, bandages and dressings are often missing from data sets or not extracted for analysis and are subsequently cited as a limitation in published research (Lord et al., 2016, Murphy et al., 2017). Other non-pharmacological approaches such as distraction, staying close to relatives and creating a calm environment are rarely documented or extracted for

analysis (Pilbery et al., 2019). This lack of data, coupled with the complexity of pre-hospital pain management in children (Whitley et al., 2019) causes uncertainty when attempting to improve quality of care for children suffering pain.

A review of pre-hospital child pain management was completed by Samuel et al. (2015) which focussed on pharmacological interventions. Whilst a useful review, a broader review was required to gain a more complete understanding of this complex and convoluted process. A comprehensive evidence synthesis was required to provide focus and clarity for future clinical practice interventions and research. This will identify areas of disparity in clinical practice along with known barriers and facilitators. This review was also required to inform the development and undertaking of a subsequent mixed methods study (see *Chapter 4 – Mixed Methods Sequential Explanatory Study*).

The aim of this systematic mixed studies review was to identify predictors, barriers and facilitator to effective management of acute pain in children by ambulance services.

## 3.2 Methods

This systematic mixed studies review was registered with PROSPERO (CRD42017058960), the protocol was published (Whitley et al., 2018) and the final version of this review has been published (Whitley et al., 2020a).

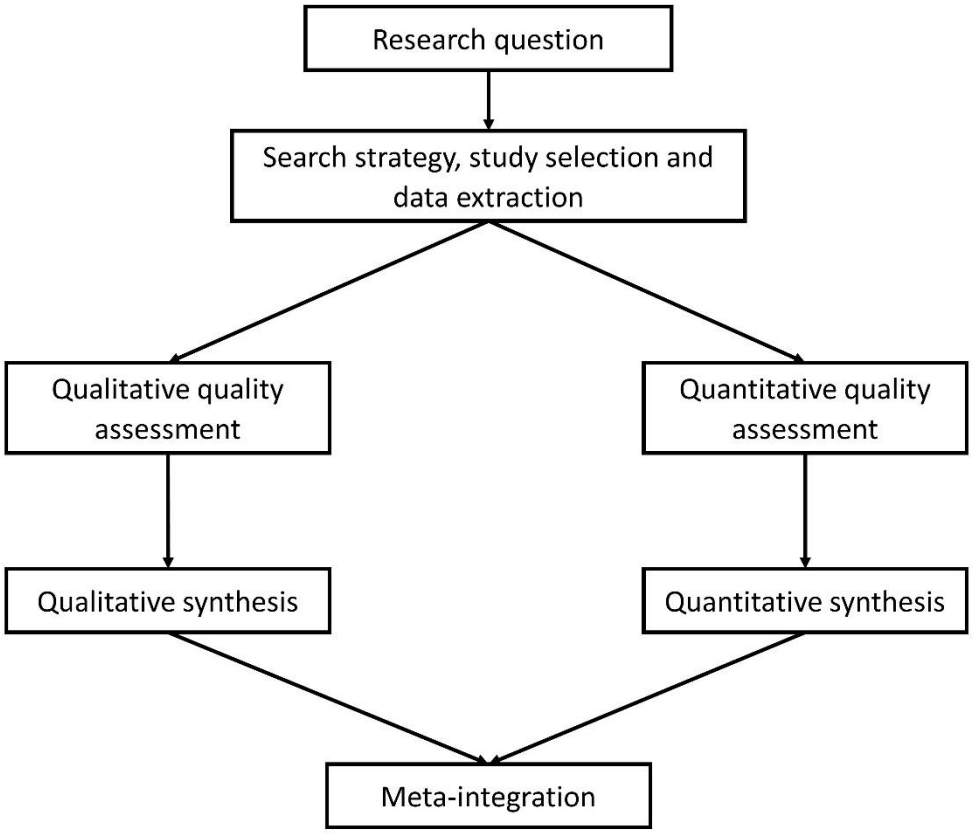
### 3.2.1 Study design

A modified segregated approach was taken for this systematic mixed studies review, based on the guidance of Sandelowski et al. (2006), the Joanna Briggs Institute (JBI) (2014) and the Preferred Reporting Items for Systematic review and Meta-Analysis (PRISMA) guidelines (Moher et al., 2009). The approach was modified to combine the research question, search strategy, study selection and data extraction, which were proposed as separate procedures by Sandelowski et al. (2006). See *Figure 2* (pg57) for the diagram of procedures.

The segregated approach was adopted over other methods such as the integrated design (Sandelowski et al., 2006) due to the differing nature of the quantitative and qualitative data. It was felt that predictors identifying disparity in rates of effective pain management and barriers and facilitators of effective pain management addressed different aspects of the target phenomenon. Sandelowski et al. (2006) argued that in such cases, complementarity should be assessed rather than confirmation/refutation. Complementarity can be assessed when performing a segregated mixed studies review, however when performing an integrated review data are transformed and combined and their ability to confirm or refute each other are assessed. Therefore, a segregated approach was adopted to enable complementarity to be assessed.

The justification for performing a systematic mixed studies review over single study systematic reviews or other types of review was provided in section *2.3.1 Systematic mixed studies review*.

Figure 2 – Systematic mixed studies review: Diagram of procedures




3.2.2 Eligibility criteria

3.2.2.1 Inclusion criteria

- Participants: children (patients aged <18 years), relatives and ambulance service staff.
- Phenomena of interest: studies identifying predictors of effective pain management or barriers and facilitators to the pain management process in children suffering acute pain treated by ambulance services.
- Context: international pre-hospital ambulance services.
- Types of study: empirical quantitative (e.g. interventional, observational, survey) or qualitative designs. Multi-methods studies were considered where their component parts could be separated into their respective arm.
    - No language restrictions were placed on the review.

The chosen age range for children was justified in section *1.2.3.1 Age*. The inclusion of children enabled the identification of both quantitative studies identifying predictors of effective pain management and qualitative studies identifying barriers and facilitators. The inclusion of relatives and clinical staff aimed to capture qualitative studies identifying barriers and facilitators. Effective pain management was defined in section *3.2.7.1.2 Measurement of treatment effect*. Identifying international evidence is one of the aims of performing a systematic review (Munn et al., 2018), therefore this justified the chosen context of international pre-hospital ambulance services and the decision to include any language paper.

3.2.2.2 Exclusion criteria

- Participants: None
- Phenomena of interest: None.
- Context: In-hospital studies.
- Types of study: Animal studies, reviews, audits, service evaluations, simulated studies, letters, Best Evidence Topics (BestBETs), case studies, self-efficacy studies, opinion pieces and studies only reporting an abstract were excluded. Quantitative studies including children and adults where the child specific data could not be extracted were excluded.

To maintain a higher quality of data, several study types were excluded, including service evaluations, case studies and self-efficacy studies (studies where clinicians rated their own level of confidence in dealing with children suffering pain). Self-efficacy studies were considered low quality because they lacked objective outcome measures (effective pre-hospital child pain management determined via clinical record assessment) and relied on the clinician's report of their perceived confidence. It can be difficult to determine an association between confidence and improved outcomes, a limitation discussed by Travers et al. (2013).

### 3.2.3 Search strategy

The search strategy was developed with the assistance of an academic librarian. Pilot searches were performed during the process of refining the search criteria. Keywords for the search were developed and listed in the protocol (Whitley et al., 2018).

The initial search was performed on the 13th March 2018. The search was updated in August 2019 due to submission of the systematic mixed studies review manuscript for publication. A final search update was performed on the 30th June 2020 due to reviewer comments and for the purpose of providing up to date findings in this thesis.

The initial and second search used only keywords, as the inclusion of MeSH and subject headings returned an excessive number of articles (approximately 26,000). In hindsight, this was due to the high number of MeSH and subject headings included. In the final search, only a small number of MeSH and subject headings were included (n=3-6 depending on database). No new studies were identified through the addition of MeSH and subject headings in the search strategy.

Only the final worked search strategy (including MeSH and subject headings) for MEDLINE and the final PRISMA flow diagram are presented in this thesis. See *Appendix 1* for search terms used, *Appendix 2* for the worked MEDLINE search and Figure *3* (pg65) for the PRISMA from diagram.

The following databases were searched from inception to 30th June 2020:

- MEDLINE via EBSCOhost
- CINAHL Complete via EBSCOhost
- PsycINFO via EBSCOhost
- EMBASE via Ovid SP
- Web of Science Core Collection
- Scopus

These databases were chosen because of their relevance to the body of biomedical/health care literature and as a result of recommendation by an

academic librarian. Database searching was supplemented with internet searching (e.g. Google Scholar), forward and backward citation tracking from systematic reviews and included studies, and contact with study authors, experts and research groups.

### 3.2.4 Study selection

Two reviewers (myself and Professor A. Niroshan Siriwardena) independently undertook the screening and selection process and resolved any differences in opinion by discussion.

Duplicates were initially removed by using the EndNote X8 duplicate recognition function, followed by manual screening for duplicates. Titles and abstracts were exported to Microsoft Excel and then screened against the inclusion and exclusion criteria. Potentially eligible studies then received a full-text screen, and non-eligible studies at that stage had the reason for exclusion documented.

### 3.2.5 Data collection

The Cochrane data extraction template for randomised controlled trials was adapted (The Cochrane Collaboration, 2018) and used. See *Appendix 3* for the data extraction tool used. Data extraction was performed by myself and then verified by Professor A. Niroshan Siriwardena. There were no disagreements.

A data extraction tool was developed and used to ensure the systematic process of extracting all necessary data, minimising the risk of missing important data. The first step of data extraction is identifying the data that you need to extract (Boland et al., 2017), for this review the focus was quantitative data identifying predictors of effective pain management and qualitative data identifying barriers and facilitators. The Cochrane data extraction template was used due to its comprehensive structure and was adapted to include appropriate qualitative sections.

### 3.2.6 Risk of bias assessment

Risk of bias/quality assessment of included studies was performed in duplicate by myself and Professor A. Niroshan Siriwardena. Assessment tools used were the Cochrane Quality and Intervention Methods Group guidance (Hannes, 2011), the Critical Appraisal Skills Programme Qualitative Checklist (Critical Appraisal Skills Programme, 2013), the appraisal tool for cross-sectional studies (AXIS tool) (Downes et al., 2016) and the Scottish Intercollegiate Guidelines Network (SIGN) methodology checklist for cohort and case-control studies (Scottish Intercollegiate Guidelines Network, 2017). The results were displayed in a risk of bias table (See *Appendix 4*). Risk of bias was not used as a reason for exclusion.

The mixed methods appraisal tool (MMAT) (Hong et al., 2018) was considered as the choice quality assessment tool, however it was felt that using individual assessment tools specific to each study type would provide a more comprehensive assessment. MMAT has the ability of assess qualitative, quantitative and mixed methods studies and was designed specifically for systematic mixed studies reviews; considering the growing adoption of mixed methods approaches, MMAT will be considered again for future systematic mixed studies reviews.

### 3.2.7 Synthesis

#### 3.2.7.1 Quantitative studies

Where predictors were identified using regression analysis, odds ratios with their 95% confidence intervals were incorporated into the synthesis. Where studies evaluated the effectiveness of analgesics, mean/median pain score reductions were incorporated into the synthesis, along with the percentage of patients achieving effective pain management.

##### 3.2.7.1.1 Assessment of heterogeneity

Heterogeneity was assessed within STATA version 15 using the 'metan' module, incorporating odds ratios and 95% confidence intervals. The $I^2$ statistic was used to

determine heterogeneity. Where substantial heterogeneity was found ($I^2$ = ≥50%) (Deeks et al., 2020), a narrative synthesis was performed.

3.2.7.1.2 Measurement of treatment effect

The outcome measure was effective pain management (pain score reduction of ≥2 out of 10 on the numeric pain rating scale, Wong-Baker FACES® scale or the faces, legs, activity, crying and consolability [FLACC] scale) (Bulloch and Tenenbein, 2002, Bailey et al., 2010, Voepel-Lewis et al., 2011, Myrvik et al., 2013, Tsze et al., 2015). This was deemed to be the minimum clinically significant difference in pain and has previously been used in this context as the primary outcome measure (Jennings et al., 2015, Siriwardena et al., 2019).

3.2.7.1.3 Subgroup and sensitivity analysis

Subgroup and sensitivity analyses were not performed due to the low number of studies suitable for meta-analysis (n=3), as described in the systematic review protocol (Whitley et al., 2018).

3.2.7.1.4 Meta-bias(es)

No interventional studies were included therefore reporting bias could not be assessed. Publication bias could not be assessed due to the small number of studies suitable for meta-analysis (n=3).

3.2.7.2 Qualitative studies

Thematic synthesis, as described by Thomas and Harden (2008), was used to synthesise eligible qualitative studies. This process involved three steps; 1) coding text from the published quotations of eligible studies; 2) developing descriptive themes and 3) generating analytical themes. Thomas et al. (2003) used thematic synthesis to better understand the barriers and facilitators of healthy eating (fruit and vegetables) in children.

Several methods of qualitative synthesis were available, including meta-ethnography, grounded theory, thematic synthesis, textual narrative synthesis, meta-narrative and critical interpretive synthesis, amongst others (Barnett-Page and Thomas, 2009). Thematic synthesis was chosen as it combined and adapted approaches from meta-ethnography and grounded theory (Barnett-Page and Thomas, 2009) and enabled the researcher to go beyond the primary studies to develop new insights (Thomas and Harden, 2008).

### 3.2.8 Meta-integration

Quantitative and qualitative data often address different aspects of a target phenomenon, therefore they may not be capable of confirming or refuting each other, instead their complementarity can be assessed (Sandelowski et al., 2006). Complementarity is found where data are related to each other linking observations with explanations (Sandelowski et al., 2006), strengthening the understanding. Where observations and explanations seemed to oppose each other, the term 'conflict' was used and further research was recommended to explain the disparity. Following the methods of Frantzen and Fetters (2016), the meta-integration was displayed in tabular format to illustrate the complex inter-relational connections.

### 3.2.9 Confidence in the cumulative evidence

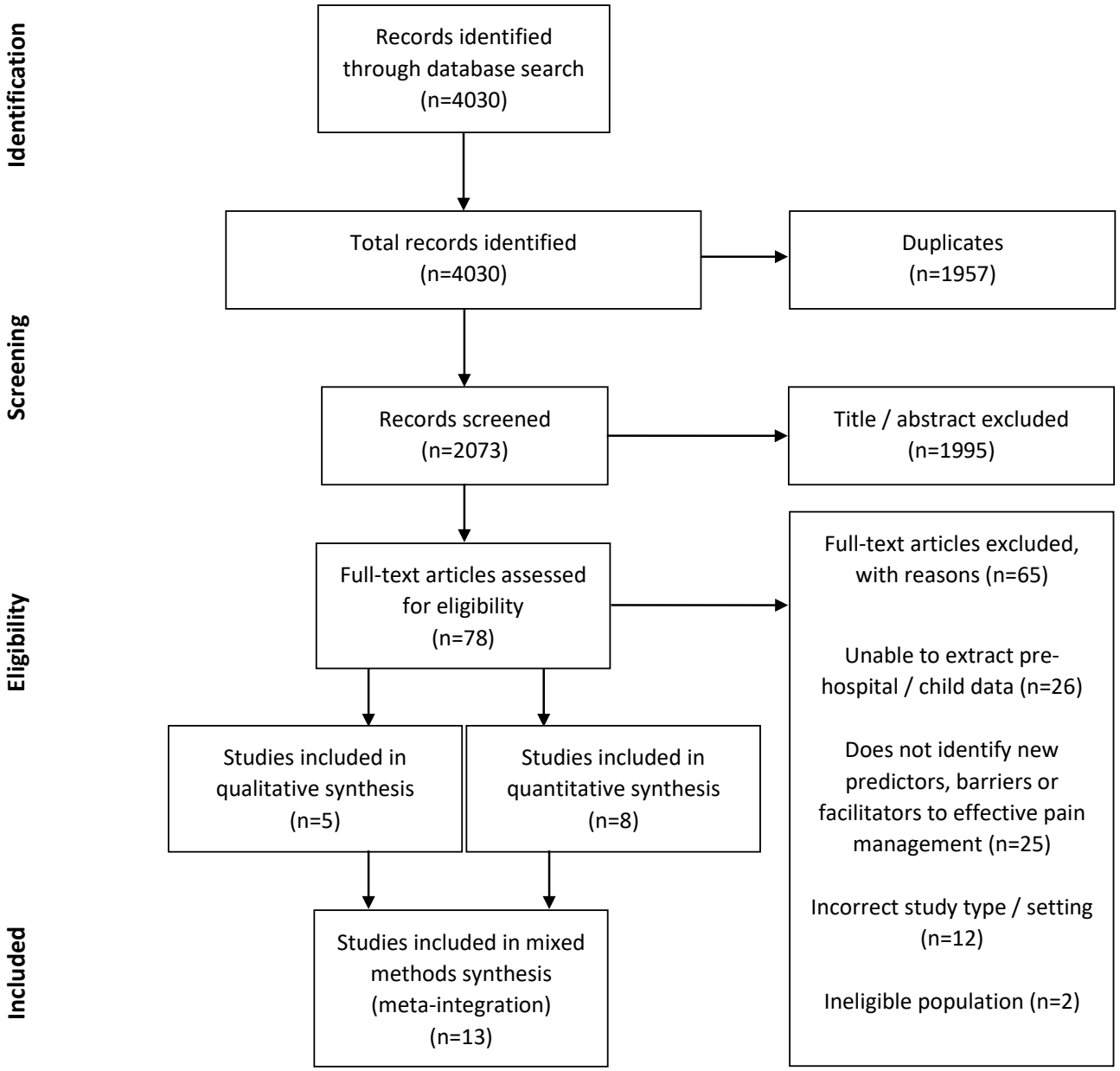
The Grading of Recommendations Assessment Development and Evaluation (GRADE) approach (Atkins et al., 2004) was used to assess the findings from the quantitative synthesis. The GRADE Confidence in the Evidence from Reviews of Qualitative research (GRADE CERQual) approach (Lewin et al., 2018) was used to assess the findings from the qualitative synthesis. Overall quality was adjudicated as *High* (further research unlikely to change conclusions), *Moderate* (further research may change conclusions), *Low* (further research likely to change conclusions) or *Very Low* (very uncertain about current conclusions).

## 3.3 Results

From 4030 articles screened, 78 were selected for full text review, with 8 quantitative and 5 qualitative studies included, see *Figure 3* (pg65). A complete list of studies excluded from the full-text screen can be found in section *3.3.1 Excluded studies*. All included studies can be found in *Table 1* (pg67).

Interestingly, the timely publication of the cross-sectional study within this thesis (*4.2 Cross-sectional Study*) has resulted in this systematic review identifying the paper (Whitley et al., 2020b) during the search update in June 2020. For the purpose of this thesis, it was important for the review to be inclusive of all eligible studies. Although the initial review was performed before the cross-sectional study, and the initial draft of this review informed the decision to move forward with the cross-sectional study and ultimately the full mixed methods study, the cross-sectional study has been included in this final version of the systematic mixed studies review for the purpose of inclusiveness, as it met the inclusion/exclusion criteria. It was deemed important to follow the systematic mixed studies review protocol inclusion and exclusion criteria (Whitley et al., 2018), ensuring methodological rigor within this thesis, along with ensuring that the published version of the systematic mixed studies review and the version within this thesis were an accurate reflection of each other.

Figure 3 – Systematic mixed studies review: PRISMA flow diagram



### 3.3.1 Excluded studies

65 studies were excluded from the full text screen for the following reasons:

- Unable to extract pre-hospital/child data (n=26) (Walsh et al., 2013, Eidenbenz et al., 2016, Garrick et al., 2011, Baartmans et al., 2016, Fleischman et al., 2010, Asghar et al., 2016, Frakes et al., 2009, Oberholzer et al., 2017, Johnston et al., 2011, Ansem et al., 1994, Kelly and Guly, 1999, Stene et al., 1988, Chambers and Guly, 1994, Hollis et al., 2017, Browne et al., 2016b, Swor et al., 2005, Rutkowska and Skotnicka-Klonowicz, 2015, Rogovik and Goldman, 2007, Kanowitz et al., 2006, Thal et al., 1979, Lebon et al., 2016, Ellerton et al., 2013, Bakkelund et al., 2013, Michael et al., 2007, Galinski et al., 2018, Zietlow et al., 2019).
- No new predictors, barriers or facilitators to effective pain management identified (n=25) (Galinski et al., 2005, Hennes et al., 2005, van der Velde et al., 2013, Svenson and Abernathy, 2007, Clendaniel, 2009, Häske et al., 2014, Bendall et al., 2011b, DeVellis et al., 1998, Bredmose et al., 2009, Franck et al., 2004, Browne et al., 2016a, Galinski et al., 2011, Hewes et al., 2018, Johnson et al., 2014, Lord et al., 2016, Murphy et al., 2016, O'Donnell et al., 2013, Watkins, 2006, Whitley et al., 2017, Roggenkamp et al., 2018, Teefy et al., 2019, Helm et al., 2020, Lourens et al., 2020, Dworkin et al., 2020, Finch et al., 2020).
- Incorrect study type/setting (n=12) (Cole et al., 2009, Schauer et al., 2018, Sadeghi Bazargani et al., 2013, Murphy et al., 2013, Kaziny et al., 2012, Rahman et al., 2015, Edmonds and Twycross, 2018, Whitley and Bath-Hextall, 2017, Pope et al., 2018, Crandall et al., 2002, Lynde and Zorab, 2015, Montero et al., 2019).
- Did not include children (n=2) (Young et al., 2013, Forrest et al., 2019).

3.3.2 Included studies

Table 1 – Systematic mixed studies review: Summary of included studies

| Study | Design | Country | Number of participants | PICo | Primary outcome measure | Key findings |
|---|---|---|---|---|---|---|
| Bendall et al. (2011a) | Cross-sectional (Retrospective) | Australia | 3312 | **Participants:** Paediatric patients aged 5 to 15 years. **Phenomena of interest:** To compare the effectiveness of intravenous morphine, intranasal fentanyl, and inhaled methoxyflurane for managing moderate to severe pain (NPRS ≥5 out of 11). **Context:** Prehospital EMS system. | Pain score reduction ≥30% | Intranasal fentanyl and intravenous morphine were equally effective analgesic agents in paediatric patients with moderate to severe acute pain in the out-of-hospital setting. Methoxyflurane was less effective in comparison with both morphine and fentanyl, but was an effective analgesic in the majority of children. |
| Jennings et al. (2015) | Cross-sectional (Retrospective) | Australia | 15,016 | **Participants:** Children aged <15 years. **Phenomena of interest:** To identify the factors associated with clinically meaningful pain reduction in children. **Context:** Prehospital EMS system. | Clinically meaningful pain reduction defined as 2 or more out of 11 | Patients older than 9 years were less likely and boys were more likely to have a clinically meaningful reduction in pain. Patients with pain classified as musculoskeletal were more likely to achieve a clinically meaningful reduction in pain when compared with other medical causes. |

| Study | Design | Country | Number of participants | PICo | Primary outcome measure | Key findings |
|---|---|---|---|---|---|---|
| Whitley et al. (2020b) | Cross-sectional (Retrospective) | United Kingdom | 2312 | **Participants:** Children aged <18 years. **Phenomena of interest:** To identify predictors of effective management of acute pain in children. **Context:** Prehospital EMS system. | Effective pain management, defined as the abolition or reduction of pain by 2 or more out of 10. | Predictors included children who were younger, administered analgesics, attended by a paramedic or living in an area of medium or low deprivation. |
| Karlsen et al. (2014) | Cross-sectional (Prospective) | Denmark | 903 (63 were less than 18 years of age) | **Participants:** Adults and children older than 8 years. **Phenomena of interest:** To assess the safety profile and apparent analgesic effect of intranasal fentanyl. **Context:** Prehospital EMS system. | Occurrence of adverse effects and change in numeric pain score from before fentanyl administration until the last recording before arriving at the hospital. | The out-of-hospital administration of intranasal fentanyl in doses of 50 to 100 mcg was safe and appeared effective. |
| Murphy et al. (2017) | Cross-sectional (Prospective) | Ireland | 94 | **Participants:** Children aged between 1 and 16 years. **Phenomena of interest:** To describe the clinical efficacy and safety of INF when administered by advanced paramedics in the treatment of acute severe pain. **Context:** Prehospital EMS system. | Effective reduction in pain, defined as 2 or more out of 11 at 10 minutes following single dose of intranasal fentanyl. | INF at a dose of 1.5 µg/kg appeared to be a safe and effective analgesic in the prehospital management of acute severe pain in children. |

| Study | Design | Country | Number of participants | PICo | Primary outcome measure | Key findings |
|---|---|---|---|---|---|---|
| Lord et al. (2019) | Interrupted time-series analysis (Retrospective) | Australia | 9833 | **Participants:** Children aged <15 years. **Phenomena of interest:** To measure the effect that a change to practice guidelines (introduction of INF) for the management of pain in children had on the reduction of pain severity scores in cases receiving analgesics. **Context:** Prehospital EMS system. | Odds of achieving a 2-point or greater reduction in pain severity score using an 11-point verbal numeric rating scale where any analgesic (morphine, fentanyl, or methoxyflurane) was given before and after intervention. | Before the intervention, 88.1% (n = 3114) of children receiving analgesics had a reduction of pain severity of 2 or more points, with 94.2% (n = 5933) achieving this benchmark after intervention (P < 0.0001). |
| Babl et al. (2006) | Case Series (Prospective) | Australia | 102 | **Participants:** Children aged 15 months to 17 years. **Phenomena of interest:** To prospectively describe the use pattern of methoxyflurane in children transported to the ED by ambulance. **Context:** Prehospital EMS system. | Indications for use, verbal numerical pain scores, adverse events and depth of sedation based on paramedic, patient, parent and emergency department staff surveys and review of ambulance care records. | Methoxyflurane appeared to be an efficacious analgesic with a low adverse events profile. In young children in particular it can briefly lead to deep sedation. |

| Study | Design | Country | Number of participants | PICo | Primary outcome measure | Key findings |
|---|---|---|---|---|---|---|
| Johansson et al. (2013) | Case Series | Sweden | 9 (6 were less than 18 years of age) | **Participants:** Patients aged 7 to 36 years. **Phenomena of interest:** To describe the use of nasally administered S-Ketamine in 9 cases. **Context:** Prehospital rural air ambulance. | Pain score reduction 5 - 10 minutes after administration of nasal s-ketamine | VAS-score decreased from a median of 10 to 3. Side-effects in these 9 cases were few and non-serious. The effect and safety of this treatment should be further studied. |
| Williams et al. (2012) | Qualitative | United States of America | 16 | **Participants:** Paramedics currently in clinical practice. **Phenomena of interest:** To identify and investigate the barriers and enablers perceived by paramedics regarding the administration of analgesics to paediatric emergency medical services patients. **Context:** Prehospital EMS system. | To identify and investigate the barriers and enablers perceived by paramedics regarding the administration of analgesics to paediatric emergency medical services patients. | There was a preference to defer administration of analgesic agents. A number of educational and EMS system changes could be made to address these barriers and increase the frequency of appropriate paediatric prehospital analgesia. |

| Study | Design | Country | Number of participants | PICo | Primary outcome measure | Key findings |
|---|---|---|---|---|---|---|
| Murphy et al. (2014) | Qualitative | Ireland | 16 | **Participants:** Advanced paramedics with at least 3 years of experience. **Phenomena of interest:** To identify the barriers, as perceived by a national cohort of advanced paramedics, to achieving optimal prehospital management of acute pain in children. **Context:** Prehospital EMS system. | To identify the barriers, as perceived by a national cohort of advanced paramedics, to achieving optimal prehospital management of acute pain in children. | The pathway to improving care must include an emphasis on improvements in practitioner education and training, offering alternatives to assessing pain in preverbal children, exploring the intranasal route of drug delivery in managing acute severe pain, and robustly developed evidence-based guidelines that are practitioner friendly and patient-focused. |
| Gunnvall et al. (2018) | Qualitative | Sweden | 8 | **Participants:** Prehospital emergency nurses with at least 3 years of experience. **Phenomena of interest:** To examine prehospital emergency nurses' (PENs') experiences of pain management during prehospital care of preverbal children. **Context:** Prehospital EMS system. | To examine PENs' experiences of pain management during prehospital care of preverbal children, based on PENs' given mission to alleviate patients' suffering. | A lifeworld perspective with a family-centred approach may support PENs in alleviating pain and suffering in preverbal children. What is required to meet children's specific needs and security are customised prehospital guidelines consisting of both medical and care guidelines; collaboration within a multidisciplinary team; clinical skills and education. |

| Study | Design | Country | Number of participants | PICo | Primary outcome measure | Key findings |
|---|---|---|---|---|---|---|
| Holmström et al. (2019) | Qualitative | Sweden | 18 | **Participants:** Swedish-speaking prehospital emergency nurses with 2 years clinical experience and experience of managing children (0-18 years) in pain. **Phenomena of interest:** To describe nurses' experiences of prehospital care encounters with children in pain and specific related challenges. **Context:** Prehospital EMS system. | To describe nurses' experiences of prehospital care encounters with children in pain and specific related challenges. | Caring for children in pain was stressful for the nurses. The nurses described how they had to shift focus and used different methods to build trust, such as playfulness, making eye contact, attracting curiosity, and using the parents to create trust. The also had to adjust to the child regarding dosages and materials. |
| Jepsen et al. (2019) | Qualitative | Sweden | 14 | **Participants:** Swedish- or English-speaking parents, whose children had been cared for by the ambulance team. **Phenomena of interest:** To explore the experiences of the caring encounter in the ambulance service among parents to children aged 0–14 years. **Context:** Prehospital EMS system. | To explore the experiences of the caring encounter in the ambulance service among parents to children aged 0–14 years. | There is a need to strengthen the family-centred care in the ambulance service. Not inviting the parents in the care and use of equipment that was non-functioning or not adjustable for the children's age caused lack of trust and increased the level of stress among the parents. |

PICo – participants, phenomena of interest, context, NPRS – numeric pain rating scale, VAS – visual analogue scale, EMS – emergency medical service, IV – intravenous, IN – intranasal, INF – intranasal fentanyl, ED – emergency department.

### 3.3.3 Quality/risk of bias assessment

See *Appendix 4* for quality/risk of bias assessments. The reporting of study design varied, with Jennings et al. (2015) reporting a cohort study, Bendall et al. (2011a) reporting a comparative study, Karlsen et al. (2014) reporting an observational study and Murphy et al. (2017) and Whitley et al. (2020b) reporting a cross-sectional study. These five studies were better categorised as cross-sectional studies, and along with Lord et al. (2019) (reporting an interrupted time series analysis) were all assessed using the cross-sectional AXIS tool. None of the cross-sectional studies justified the sample size used. There were some concerns regarding the appropriateness of the target population, as Karlsen et al. (2014) excluded children under 9 years of age and Murphy et al. (2017) recruited advanced paramedics; the findings of these studies may not be representative of the wider EMS clinician or patient population. There was also a concern with the relationship between the researcher and participants for one of the qualitative studies (Murphy et al., 2014); it was felt the implications of utilising a paediatric emergency medicine specialist moderator were not discussed adequately (see *Appendix 4*).

### 3.3.4 Quantitative synthesis

Eight quantitative observational studies were synthesised; four identified predictors of effective pain management in children by using regression analysis and calculated adjusted odds ratios (Jennings et al., 2015, Bendall et al., 2011a, Lord et al., 2019, Whitley et al., 2020b) and the remaining four studies evaluated the effectiveness and safety of specific analgesics (Babl et al., 2006, Johansson et al., 2013, Karlsen et al., 2014, Murphy et al., 2017). Thus, the quantitative synthesis was split into two sections; predictive factors and predictive analgesics.

#### 3.3.4.1 Predictive factors

Several predictors of effective pain management were identified, see *Table 2* (pg75).

Child sex was the only predictor capable of being incorporated into a meta-analysis, as the comparator was the same for all included studies (male versus female). Child age and others could not be assessed because the comparator groups were different for each study, therefore a narrative analysis was performed for these predictors. A meta-analysis was performed in Stata version 15 for child sex using the following syntax:

***gen lnor = ln(or)***

***gen lnlci = ln(lci)***

***gen lnuci = ln(uci)***

***metan lnor lnlci lnuci, eform xlabel(0.75, 1.0, 1.25, 1.5, 1.75, 2.0) effect(or) scale (1.9) random***

Table 2 – Systematic mixed studies review: Predictive factors

| **Predictors** (Odds of achieving effective* pain reduction) | **Study** | | | |
|---|---|---|---|---|
| | Bendall et al. (2011a) AOR (95% CI) | Jennings et al. (2015)** AOR (95% CI) | Lord et al. (2019)** AOR (95% CI) | Whitley et al. (2020b) AOR (95% CI) |
| **Child sex** | | | | |
| Male | 1.42 (1.19–1.71) | 1.1 (1.0-1.3) | | 1.17 (0.98-1.39) |
| **Child age, years** | | | | |
| 5-9 (compared to 10-15) | 1.33 (1.00–1.75) | | | |
| 5-9 (compared to 0-4) | | 0.7 (0.6-0.95) | | |
| 10-14 (compared to 0-4) | | 0.5 (0.4-0.6) | | |
| >9 (compared to <3) | | | 0.49 (0.23-1.06) | |
| 0-5 (compared to 12-17) | | | | 1.53 (1.18-1.97) |
| 6-11 (compared to 12-17) | | | | 1.49 (1.21-1.82) |
| **Type of pain** | | | | |
| Abdominal pain/problems (compared to trauma) | 0.69 (0.50-0.96)[#] | | | |
| Musculoskeletal (compared to medical) | | 1.7 (1.5-1.9) | | |
| Burns (compared to medical) | | 1.6 (1.1-2.5) | | |
| Trauma (other) (compared to medical) | | 1.4 (1.1-1.9) | | |
| Cardiac (compared to musculoskeletal) | | | 0.22 (0.08-0.60) | |
| Trauma (compared to medical) | | | | 1.18 (0.97-1.43) |
| **Initial pain score** | | | | |
| Moderate (4-7/10) (compared to 3/10) | | 3.9 (3.3-4.6) | | |
| Severe (8-10/10) (compared to 3/10) | | 7.5 (6.2-9.0) | | |

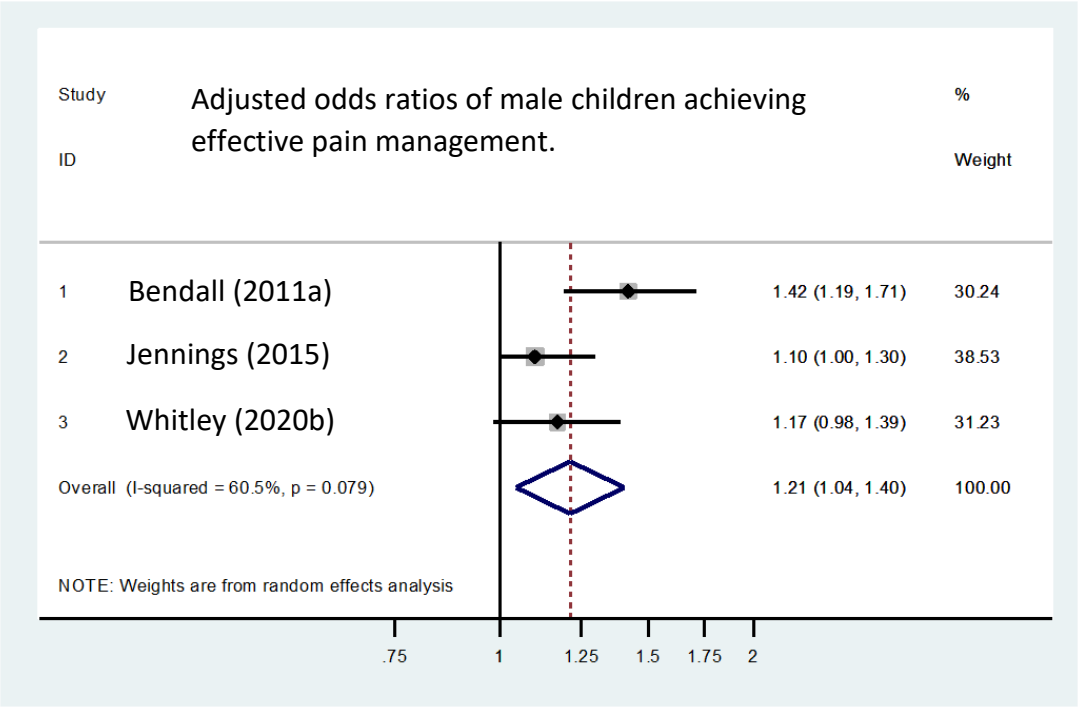
| Predictors (Odds of achieving effective* pain reduction) | Study | | | |
|---|---|---|---|---|
| | Bendall et al. (2011a) AOR (95% CI) | Jennings et al. (2015)** AOR (95% CI) | Lord et al. (2019)** AOR (95% CI) | Whitley et al. (2020b) AOR (95% CI) |
| **Analgesic agent** | | | | |
| Methoxyflurane (compared to IV morphine) | 0.52 (0.36–0.74) | | | |
| Methoxyflurane (compared to IN fentanyl) | 0.43 (0.29–0.62) | | | |
| Methoxyflurane (compared to no analgesic) | | 5.3 (4.8-5.9) | | |
| Fentanyl (IN & IV) (compared to no analgesic) | | 2.8 (2.3-3.3) | | |
| Morphine (IV) (compared to no analgesic) | | 2.8 (2.2-3.6) | | |
| Any analgesic (compared to no analgesic) | | 6.6 (5.9-7.3) | | |
| Analgesic administered (compared to no analgesic) | | | | 2.26 (1.87-2.73) |
| **Index of multiple deprivation[##]** | | | | |
| Low deprivation (compared to high deprivation) | | | | 1.37 (1.04-1.80) |
| Medium deprivation (compared to high deprivation) | | | | 1.41 (1.11-1.79) |
| **Clinician rank** | | | | |
| Paramedic crew (compared to non-paramedic crew) | | | | 1.46 (1.19-1.79) |
| **Implementation of IN fentanyl** | | | | |
| After implementation of IN fentanyl (compared to before implementation) | | | 2.33 (1.71-3.17) | |
| Trend after intervention on IN fentanyl (compared to before implementation) | | | 0.97 (0.95-1.0) | |

*Bendall 2011 (reduction ≥30%), Jennings 2015, Lord 2019 and Whitley 2020 (reduction ≥2/10)
**Jennings 2015 & Lord 2019 used the same base dataset, therefore the predictor 'child sex' was excluded for Lord 2019.
[#]Unadjusted odds ratio
[##]Index of multiple deprivation data from UK ministry of housing, communities and local government (2015) (deciles used and categorised as 1-3 (low), 4-7 (medium) and 8-10 (high).
AOR – Adjusted odds ratio, CI – Confidence interval, IN – Intranasal, IV – Intravenous.

This created a random-effects as opposed to a fixed-effects meta-analysis. Random-effects meta-analyses distribute weight more evenly across studies, reducing the impact of large scale studies (Deeks et al., 2020). This generally provides a more conservative estimate of the effect. Figure *4* (pg78) shows the random-effects meta-analysis. The heterogeneity, as calculated by the $I^2$ statistic, was 60.5%. This may represent substantial heterogeneity (Deeks et al., 2020). Considering the substantial heterogeneity, a narrative quantitative synthesis was performed.

*Table 2* (pg75) shows that child sex (male), child age (younger), type of pain (traumatic), high initial pain score, analgesic administration, index of multiple deprivation (low/medium), clinician rank (paramedic) and implementation of intranasal fentanyl were all predictors of effective pain management, however the trend after implementation of intranasal fentanyl, which demonstrated a downward slope, was not associated with effective pain management.

Figure 4 – Systematic mixed studies review: Meta-analysis




Adjusted odds ratios taken from *Table 2* (pg75) for 'Child sex (male)'.

3.3.4.2 Predictive analgesics

Four studies evaluated the effectiveness and safety of specific analgesics (Babl et al., 2006, Johansson et al., 2013, Karlsen et al., 2014, Murphy et al., 2017), see *Table 3* (pg80). Considering an effective or 'clinically meaningful' reduction in pain as ≥2 out of 10 on the NPRS (numeric pain rating scale), VAS (visual analogue scale) and Wong & Baker faces scale (Powell et al., 2001, Bulloch and Tenenbein, 2002, Bailey et al., 2010, Voepel-Lewis et al., 2011, Myrvik et al., 2013, Tsze et al., 2015), *Table 3* (pg80) shows that intranasal fentanyl, methoxyflurane and nasal s-ketamine all produced a clinically meaningful reduction in pain. However, caution should be exercised when interpreting these results due to the observational nature of the studies and small sample sizes, with Johansson et al. (2013) including only 6 patients aged under 18 years.

For the purpose of this analysis, the results regarding analgesics from *Table 2* (pg75) along with *Table 3* (pg80) were combined and defined as 'analgesic administration'. Therefore, one of the predictors of effective pain management in children was the administration of analgesics.

Table 3 – Systematic mixed studies review: Predictive analgesics

| **Predictors** (Analgesic) | **Study** | | | |
|---|---|---|---|---|
| | Babl et al. (2006)* (administration to 10 minutes) | Johansson et al. (2013)* (administration to final score) | Karlsen et al. (2014)† (administration to final score) | Murphy et al. (2017)† (administration to 10 minutes) |
| INF alone | | | | 5 (88%‡) |
| INF with other analgesic | | | 4 (87%‡) | 4 (79%‡) |
| Methoxyflurane with other analgesic | 4.7 | | | |
| Nasal s-ketamine with other analgesic | | 6.9 (100%‡) | | |

INF: Intranasal Fentanyl

*mean pain score reduction out of 10

†median pain score reduction out of 10

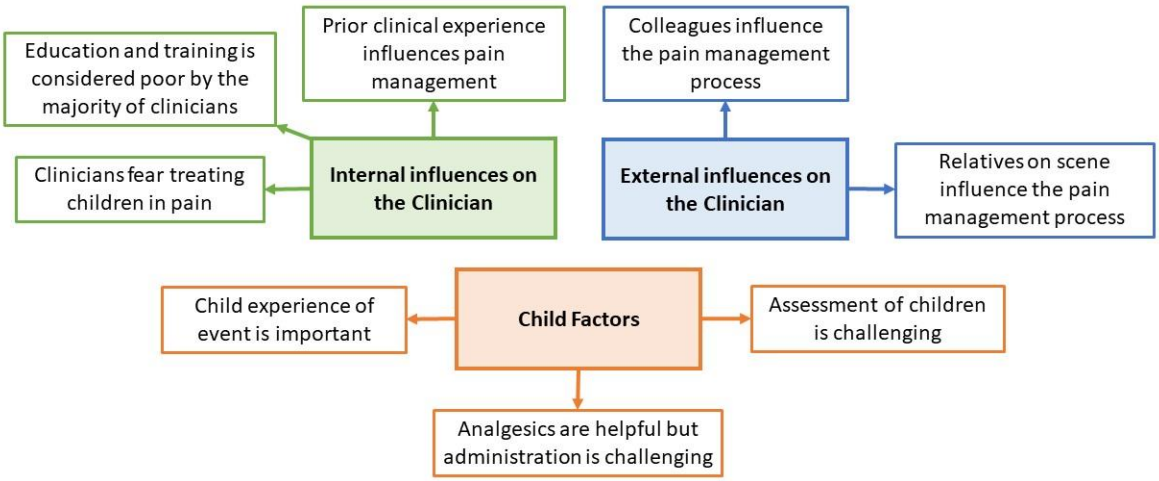
‡Percentage of patients achieving clinically meaningful reduction in pain (≥2 out of 10)

### 3.3.5 Qualitative synthesis

Five studies were included in the qualitative synthesis, interviewing paramedics (Williams et al., 2012), advanced paramedics (Murphy et al., 2014), prehospital emergency nurses (Gunnvall et al., 2018, Holmström et al., 2019) and parents of children (Jepsen et al., 2019).

Thematic synthesis resulted in the generation of three analytical themes: internal influences on the clinician, external influences on the clinician and child factors. These analytical themes were generated from eight descriptive themes (See *Figure 5* pg81) which in turn were linked to 36 initial codes (see *Appendix 5*). For a complete list of known barriers and facilitators, see initial codes within *Appendix 5*.

Figure 5 – Systematic mixed studies review: Thematic synthesis




The three analytical themes illustrated in *Figure 5* (pg81), internal influences on the clinician, external influences on the clinician and child factors were all discussed further in the following sections.

3.3.5.1 Internal influences on the clinician

A major theme arising from the evidence was the element of fear within the clinician:

*'. . .you know if you give an adult too much morphine for example and you make them hypotensive and you depress their respiratory rate and effort, you can fix that pretty quickly in an adult, but the repercussions of doing that in a little kid? The risk is higher.'*

Williams et al. (2012) pg523

In addition to fearing the side-effects of strong analgesics, clinicians feared making mistakes due to insufficient experience or insecurity (Gunnvall et al., 2018) and feared potential punishment for such errors (Williams et al., 2012), all of which necessitated increased vigilance and extra supervision of drug doses (Holmström et al., 2019).

Clinicians felt unprepared, as many deemed their education and training inadequate:

*'I think from the training point of view, its two or three days in the paediatric A&E, in comparison to over two weeks in an adult A&E, with much more actual interaction with the staff and obviously clinical practice in terms of interventions…'*

Murphy et al. (2014) pg495

Clinicians reported receiving very little time on placement within paediatric emergency departments and formal clinical assessments on children were restricted due to fear of further distressing the child (Murphy et al., 2014). Some clinicians received no specific training and education for children in the prehospital setting (Gunnvall et al., 2018). Education was sparse for child pain assessment tools

(Holmström et al., 2019) and some clinicians even recalled being taught to look for reasons not to give morphine during their education and training (Williams et al., 2012). A facilitator was identified by Murphy et al. (2014) in the form of e-learning, which could be used to overcome some of these educational barriers.

Prior clinical experience was found to influence the pain management process, with many clinicians experiencing a lack of exposure:

*'When it comes to a paediatric emergency or an obstetric emergency, and it's just the exposure, we're not doing five of them a day, so I think we have to try and make up for that deficit somehow again be it in placements, be it in simulation…'*

Murphy et al. (2014) pg495

Clinicians experienced higher rates of stress when attending children, likely exaggerated by the lack of clinical experience and low rates of exposure (Holmström et al., 2019, Williams et al., 2012). Prior clinical experience may be beneficial, allowing clinicians to recognise painful presentations faster, speeding up the assessment process (Williams et al., 2012). However, experience could facilitate clinicians to adopt social and cultural norms where traumatic pain is treated more readily than medical pain (Murphy et al., 2014).

3.3.5.2 External influences on the clinician

The level of support from colleagues and relatives on scene varied hugely among clinicians. Many felt that colleagues were unsupportive:

*'Calling medical control at certain places around here and getting orders for pain control is an almost impossible task . . .. I have never successfully argued for a pain control order out of [hospital]. I have never successfully argued for a pain control order out of [hospital] for kids.'*

Williams et al. (2012) pg523

However, many found colleagues to be supportive:

*'I think I may be more inclined to call for help from specialised units and the helicopter and such, as compared to when it's an adult.' 'Seek assistance from the resources at hand. We have good resources, we have specialised units and units with doctors in them and doctors on the phone.'*

Gunnvall et al. (2018) pg42

There seemed to be a conflict of opinion with regards to perceived level of support from colleagues. Some clinicians wanted to administer analgesics when a GP had withheld them (Murphy et al., 2014), some were concerned about what the hospital staff would say with regards to their treatment (Murphy et al., 2014, Williams et al., 2012), some were inspired by a mentor to be more liberal with their management of pain (Williams et al., 2012) and others stated that their crewmate was helpful to either manage 'hysterical' parents (Holmström et al., 2019) or switch to attending the child (Gunnvall et al., 2018).

Similarly, there appeared to be conflict with perceived support of relatives on scene, with some describing relatives on scene as helpful:

*'Talk to the parent first, take that detour, and try to keep the parent calm because how the parents are is reflected so much in the children, it's reflected a whole lot in the child.'*

Gunnvall et al. (2018) pg42

From the parent's perspective, they found that being involved helped the assessment of their child:

*'He measured my blood oxygen (saturation)… Then he explained that it was really good, and then my son easily cooperated with the assessment…'*

[Jepsen et al. (2019) pg5]

Other clinicians however felt that relatives hindered the pain management process:

*'I've never had a parent get in the way as far as tellin' us how to treat, but I think maybe when they're upset because their child's hurt it does hinder our ability to take care of the patient in the way we're supposed to.'*

Williams et al. (2012) pg523

Some clinicians stated that parents can be 'hysterical' (Holmström et al., 2019) and confrontational (Williams et al., 2012) which can inhibit the clinician's ability to effectively manage pain. Jepsen et al. (2019) explored the parent's perspective of the care encounter with the ambulance service and highlighted the importance of a family-centred approach that included the child and parents. Therefore clinicians should prioritise calming and relaxing the parents as this will likely be reflected in the child (Gunnvall et al., 2018).

3.3.5.3 Child factors

Clinicians felt the experience of the child was an important consideration:

*'It's very important to alleviate children's pain. Especially thinking about their future health care, since they'll remember the second we get there until the second it no longer hurts. If we can make the pain disappear right away, then we've come a long way, then we're the heroes of the day.'*

Gunnvall et al. (2018) pg41

There was a strong appreciation for the holistic approach, particularly from Swedish clinicians who preferred to treat children in their own home (Gunnvall et al., 2018), include them in the decision making process (Gunnvall et al., 2018) and prioritised the development of trust with the child (Gunnvall et al., 2018, Holmström et al., 2019). Clinicians also considered the risk versus benefit of gaining intravenous access, acknowledging the additional pain it would cause (Murphy et al., 2014, Holmström et al., 2019, Williams et al., 2012).

It was clear that analgesic administration was challenging, particularly in younger children:

*'…We have a lot of barriers to IV access in younger children. The older ones wouldn't be a major problem but certainly younger children, which again certainly affects your mind set in relation to using the likes of morphine…'*

Murphy et al. (2014) pg496

There were concerns about the difficulty in gaining IV access (Murphy et al., 2014, Holmström et al., 2019), difficulty administering inhaled analgesics (Murphy et al., 2014) and determining a child's weight (Williams et al., 2012). Many clinicians hinted that the intranasal route was a promising alternative to overcome the

current barriers of analgesic administration (Murphy et al., 2014, Holmström et al., 2019).

It was also clear that assessment of pain was challenging, again more so in younger children:

*'Are you screaming because you're in pain? Are you screaming because you're sad? Are you screaming because you're afraid? Are you screaming because … well, I don't know.'*

Gunnvall et al. (2018) pg42

Some clinicians stated that younger children were more difficult to assess, in part due to communication difficulty (Gunnvall et al., 2018, Murphy et al., 2014), whilst others stated that older children were more difficult to assess (Holmström et al., 2019). Clinicians also relied on other signs to determine a child's severity of pain, such as level of play and curiosity (Gunnvall et al., 2018) along with other signs such as tachycardia (Williams et al., 2012).

### 3.3.6 Meta-integration

Meta-integration was performed following the methods of Frantzen and Fetters (2016). The results can be seen in *Table 4* (pg88). *Table 4* shows that two predictors of effective pain management, 'type of pain' and 'analgesic administration', were complemented by the qualitative data. The predictor 'child age' seemed conflicted by the qualitative data and 'child gender' was unexplored, therefore no conclusion could be drawn.

Table 4 – Systematic mixed studies review: Meta-integration

| **Quantitative synthesis** (predictors) | **Qualitative synthesis** (barriers and facilitators) | | **Integration** (complement* / conflict† / unexplained) |
|---|---|---|---|
| ***Child sex*** Male children were more likely to achieve effective pain management than female children | NULL** | | The predictor of effective pain management 'child sex (male)' was **unexplained** because there was no qualitative data exploring the association between child sex and effective pain management. |
| ***Child age*** Younger children were more likely to achieve effective pain management than older children | Initial codes | Younger children were more difficult to assess | The predictor of effective pain management 'child age (younger)' was **conflicted** by the qualitative synthesis which found that younger children were more difficult to assess, cannulate and administer inhaled analgesics. |
| | | IV access was difficult, especially in younger children | |
| | | Inhaled analgesics were difficult to administer to younger children | |
| | Descriptive themes | Assessment of children was challenging | |
| | | Analgesics were helpful but administration was challenging | |
| | Analytical theme | Child factors | |

| **Quantitative synthesis** (predictors) | **Qualitative synthesis** (barriers and facilitators) | | **Integration** (complement* / conflict† / unexplained) |
|---|---|---|---|
| ***Type of pain*** Traumatically injured children were more likely to achieve effective pain management than those with medical aetiologies | Initial code | Decision making; trauma was treated more readily than medical pain | The predictor of effective pain management 'type of pain (traumatic)' was **complemented** by the qualitative synthesis which found clinicians, as part of the decision-making process, treated traumatically injured children more readily than those with medical pain |
| | Descriptive theme | Prior clinical experience influences pain management | |
| | Analytical theme | Internal influences on the clinician | |
| ***Analgesic administration*** Children who received analgesics were more likely to achieve effective pain management than those who did not | Initial codes | Analgesia improved child anxiety and compliance | The predictor of effective pain management 'analgesic administration' was **complemented** by the qualitative synthesis which mostly explained the decision-making process rather than its effectiveness. The synthesis found that analgesics were helpful but restrictive clinical guidelines hindered effective pain management. |
| | | Restrictive clinical guidelines inhibited effective pain management | |
| | Descriptive themes | Analgesics were helpful but administration was challenging | |
| | | Education and training were considered poor by the majority of clinicians | |
| | Analytical themes | Child factors | |
| | | Internal influences on the clinician | |

*Complement – data are related to each other linking observations with explanation
†Conflict – observations and explanations seem to oppose each other
**NULL – no data
IV - Intravenous

### 3.3.7 Confidence in the cumulative evidence

Having performed the full systematic mixed studies review, it was important to know how much confidence clinicians, policy makers, stakeholders and other researchers should place on the findings. Therefore GRADE (Grading of Recommendations Assessment, Development and Evaluation) (Atkins et al., 2004) and GRADE CERQual (Confidence in the Evidence from Reviews of Qualitative research) (Lewin et al., 2018) were used to provide an overall score; *high* (further research unlikely to change conclusions), *moderate* (further research may change conclusions), *low* (further research likely to change conclusions) or *very low* (very uncertain about current conclusions).

The GRADE assessment can be found in *Appendix 6*, GRADE CERQual evidence profile in *Appendix 7* and GRADE CERQual summary of qualitative findings in *Appendix 8*.

Confidence in the cumulative evidence was deemed low: further research is very likely to have an important impact on the confidence in the estimate of effect and is likely to change the estimate. This was due to the low-quality design (observational) of the studies informing the quantitative findings and the minor concerns regarding the methodological limitations and relevance of the studies informing the qualitative findings.

## 3.4 Discussion

This review included eight quantitative and five qualitative papers which identified predictors of effective pain management along with barriers and facilitators. After synthesising both types of data, two findings complemented each other; 'type of pain (traumatic)' and 'analgesic administration', one finding was conflicted; 'child age (younger)', and one was unexplained; 'child sex (male)'.

The thematic synthesis showed a strong overall theme around analgesics, highlighting concerns around their strength, associated risks and wide dosing regimens. These concerns necessitate more decision making by the clinician, however this may leave clinicians feeling more vulnerable to criticism by peers and senior authorities within the EMS system, which are previously identified phenomena (Williams et al., 2012).

A preference for different routes of administration, in particular the intranasal route, was apparent (Holmström et al., 2019, Murphy et al., 2014), resulting in changes to clinical practice as evidenced by Murphy et al. (2017) and Lord et al. (2019). Analgesic administration showed clear complementarity during meta-integration, strengthening the overall finding, therefore efforts to facilitate this should take priority in clinical practice and future research.

Some studies were excluded for using analgesic administration as the primary outcome measure, however their findings add to the context of the 'analgesic administration' finding within this review. Galinski et al. (2011) used a univariate analysis and found that children reporting severe pain were more likely to receive analgesics. Lord et al. (2016) also found that severe pain was a predictor of receiving analgesics, along with child sex (male), child age (older) and type of pain (trauma). These predictors of analgesic administration were similar to the predictors of effective pain management, except for child age which seemed reversed. Younger children were less likely to receive analgesics but more likely to achieve effective pain management; this highlights the complex nature of pre-hospital pain management in children. Two service evaluations were also excluded due to the study type (Whitley and Bath-Hextall, 2017, Pilbery et al., 2019); these

studies demonstrated an association between analgesic administration and pain score reduction, although Pilbery et al. (2019) showed that 91% of children who did not receive any analgesic achieved effective pain management.

The predictor 'child age' demonstrated conflict during meta-integration, as quantitative data suggested younger children were more likely to achieve effective pain management, yet qualitative data suggested younger children were more difficult to assess and treat. Samuel et al. (2015) concluded that smaller children may face an age bias, placing them at a disadvantage. This conflict may be linked to the difficulty of pain assessment, which is challenging in younger children (Gunnvall et al., 2018, Murphy et al., 2014). Accurate pain assessment in children requires the appropriate use of validated tools; only one tool has been validated in the pre-hospital setting (EVENDOL) (Beltramini et al., 2019). There is potential for inaccuracies in the measurement of pain or inappropriate use of pain scales, potentially overestimating the effect of pain management strategies in younger children who can less clearly verbalise their experience. Clinicians should ensure that they are using pain assessment scales as validated, for example the Wong-Baker FACES® scale should only be used as a self-assessment tool for the child to use.

Meta-integration could not be performed for the predictor 'child sex' due to the lack of qualitative data. The disparity in perceived pain between the two sexes exists from an early age (Guinsburg et al., 2000) and continues through to adolescence (Keogh and Eccleston, 2006). However, explanations for this difference are sparse. In verbal children, this data could be explained by male children acting 'tough' or being 'brave', playing down the pain and more readily reporting pain relief post-intervention than their female counterparts. Equally, unconscious gender bias on the part of the clinician when administering treatments could influence this disparity. Further qualitative research would be required to assess these theories.

There was complementarity of the predictor 'type of pain (traumatic)'. This preferential treatment of children with traumatic injuries should be addressed, as children with medical causes of pain are more likely to suffer unnecessarily.

A lack of patient perspective was evident in this review, discussed later in section *3.4.2 Limitations*. Crandall et al. (2002) explored the pain experience of adolescents after traumatic injury at the scene, in the emergency department and in the hospital setting. This study was excluded as the 'on scene' component of the study could not be associated with the ambulance service context with any certainty. Crandall et al. (2002) identified ways in which adolescents managed their pain on scene in terms of behavioural and cognitive actions. Immobility was identified as a helpful behavioural action, whilst crying was deemed not helpful by the adolescents. Remaining calm, distraction and thought stopping were viewed as helpful cognitive actions, and interrupted sleep along with thinking about the pain or accident were deemed not helpful by the children.

### 3.4.1 Strengths

A strength of this review was its mixed approach, supplying context and enriching the quantitative findings with qualitative data. This has produced novel findings not previously identified, such as the conflict surrounding 'child age'. This was the first systematic review focusing on predictors, barriers and facilitators to effective management of acute pain in children within the pre-hospital setting.

The results were considered generalisable to the UK and other countries with advanced ambulance services because studies of urban, rural and mixed ambulance services from Europe, Australasia and North America were incorporated into this review. The qualitative data was comprised from a broad range of clinicians, including paramedics, advanced paramedics and pre-hospital emergency nurses.

### 3.4.2 Limitations

The concept and process of meta-integration within a systematic mixed studies review is challenging and relatively new in evidence-based medicine (Frantzen and Fetters, 2016); this questions the validity and reliability of the findings from meta-integration techniques. The aims of quantitative and qualitative research are fundamentally different, therefore the results generated from their respective

syntheses are also different. Quantitative and qualitative findings may not be able to confirm or refute each other. Sandelowski et al. (2006) explained this dilemma and coined the term 'complementarity' as a solution. Findings from quantitative and qualitative syntheses can complement each other, in that they can form the same line of argument (configuration). However, a term was not coined by Sandelowski et al. (2006) for when data did not complement each other, or when data seemed to oppose each other. For the purpose of this thesis the term 'conflict' was used when data did not appear to complement each other. Quantitative and qualitative syntheses can confirm or refute each other when data transformation has taken place, for example when an integrated systematic mixed studies review is undertaken (Sandelowski et al., 2006, Frantzen and Fetters, 2016, Joanna Briggs Institute, 2014).

Most of the studies contributing to the predictor 'analgesic administration' were in the context of moderate to severe pain (Jennings et al., 2015, Karlsen et al., 2014, Murphy et al., 2017, Bendall et al., 2011a, Lord et al., 2019), limiting the applicability of these findings to those suffering mild pain.

A limitation was the confidence in the cumulative evidence being deemed low; further research is likely to change the conclusions. This finding was evident after the inclusion of the cross-sectional study within this thesis, but before the qualitative study could be included, which was not published at the time of the last search update. This review should be updated in light of new published evidence.

The voice of the child was not heard in this review, however the diverse group of clinicians along with the parents' perspective provided a balanced account encompassing a wide variety of barriers and facilitators.

### 3.4.3 Implications for clinical practice

During meta-integration two areas of complementarity were identified; 'analgesic administration' and 'type of pain', therefore efforts to improve clinical practice should focus on the following:

1. Explore ways to facilitate analgesic administration; specifically, the intranasal route of administration should be explored within ambulance services. Barriers and facilitators identified within the thematic synthesis of this review should be addressed, perhaps through educational interventions, such as utilising e-learning packages and improving clinical support.

2. Address the culture of managing traumatic pain more readily than pain arising from medical conditions; education and training centres should emphasise the importance of effective pain management for both traumatic and medical sources of pain.

### 3.4.4 Implications for future research

Future research should explore the conflict between the predictor 'child age' as the evidence here appears to lack complementarity. The predictor 'child sex' should also be explored as this remains unexplained. These implications for future research justified the initiation of the mixed methods study within this thesis (see *Chapter 4 – Mixed Methods Sequential Explanatory Study*).

The perceptions and experience of the child should also be explored in research that elicits the child's voice, as this was clearly lacking from the evidence base.

## 3.5 Conclusion

Predictors of effective pain management were identified, along with perceived barriers and facilitators by pre-hospital clinicians and parents of children. Exploring methods to facilitate analgesic administration should take priority, perhaps utilising the intranasal route. Further research is recommended to explore the conflict around 'child age', the unexplained data around 'child sex' and the experience of the child.

# Chapter 4 – Mixed Methods Sequential Explanatory Study

## 4.1 Introduction

The systematic mixed studies review performed in *Chapter 3 – Systematic Mixed Studies Review* produced findings with a low confidence in the cumulative evidence, meaning that further research is very likely to have an important impact on the confidence in the estimate of effect and may change the estimate. In addition to this, there were no qualitative studies explaining why male children were more likely to achieve effective pain management and the qualitative studies which found that younger children were more difficult to assess, cannulate and administer inhaled analgesics conflicted with the finding that younger children were more likely to achieve effective pain management. It would be beneficial to further explain and delineate these gaps in the evidence. Finally, during the meta-integration there were far more qualitative data than quantitative, therefore when assessing complementarity, only a small proportion of the qualitative data was used compared to all of the quantitative data; it would be useful to generate more quantitative data by assessing more variables. This would lead to a richer meta-integration and a deeper understanding of this complex phenomenon. It was felt that a mixed methods sequential explanatory study would help address the above problems.

Some predictors of effective pain management in children within the ambulance service have previously been identified (Jennings et al., 2015, Lord et al., 2019, Bendall et al., 2011a) along with some barriers and facilitators (Murphy et al., 2014, Williams et al., 2012, Gunnvall et al., 2018, Holmström et al., 2019). A mixed methods approach has been called for by Williams et al. (2012) *'to better clarify, quantify and delineate these perceived barriers and enablers'* pg526. To my knowledge, this mixed methods sequential explanatory approach is original and has not previously been performed within this context, therefore the integration of data should provide unique insights.

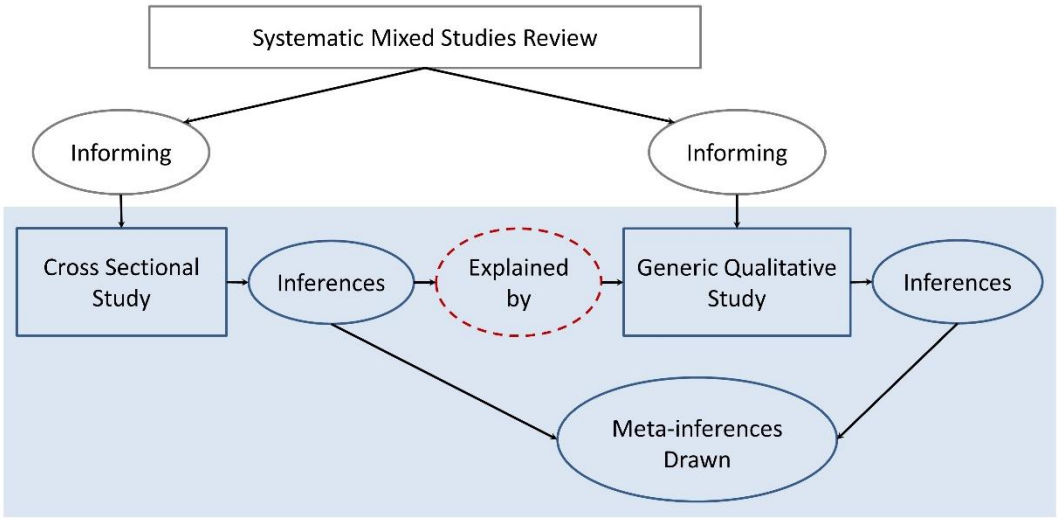
The initial cross-sectional study aimed to satisfy objective two of this thesis (*1.4.2 Objectives*) by identifying predictors of effective pain management in children suffering acute pain within a UK ambulance service. This study aimed to assess a larger number of independent variables than previous studies (Jennings et al., 2015, Lord et al., 2019, Bendall et al., 2011a). It also aimed to avoid the potential error of mathematical coupling, by not including initial pain score as an independent variable, as discussed later in section *4.2.1.5 Data analysis*. The cross-sectional study can be found in section *4.2 Cross-sectional Study.*

The generic qualitative study aimed to satisfy objectives three, four and five of this thesis (see section *1.4.2 Objectives*) by explaining the identified predictors from the cross-sectional study (see section *4.2 Cross-sectional Study*), identifying barriers and facilitators to the pain management process in children and exploring ways to improve pain management in children in the pre-hospital setting. I was also able to explore other factors that may influence the pain management process that could not be assessed within the cross-sectional study, for example, whether the clinician's status as a parent might have influenced care or the impact of ethnicity, because quantitative data for these were not available. The qualitative study can be found in section *4.3 Generic Qualitative Study*.

Integration is considered essential to mixed methods research and is how the quantitative and qualitative results are brought together to produce more than the sum of their parts (Whitley et al., 2020c). The integration of data can be found in section *4.4 Integration*.

Both the quantitative and qualitative studies were informed by the systematic mixed studies review, see Figure *6* (pg99) for the diagram of procedures.

Figure 6 – Mixed methods sequential explanatory diagram of procedures




Adapted from Creswell (2014)

The term 'inference' in this context is not considered the same as 'statistical inference' (Tashakkori and Teddlie, 2010, Rothman and Greenland, 2005). In this mixed methods context, inference is defined as:

*'a conclusion or interpretation in response to a research question, made on the basis of the results of the data analysis'*

Teddlie and Tashakkori (2009) pg336

Meta-inference is defined as:

*'a conclusion generated by integrating the inferences obtained from the qualitative and quantitative strands of a mixed methods study'*

Adapted from Teddlie and Tashakkori (2009) pg338

Tashakkori and Teddlie (2010) highlight a number of issues to consider when attempting to draw meta-inferences from mixed methods research; in particular a)

how meta-inferences are made in mixed methods research and b) how do we know our meta-inferences are credible or believable? These are discussed in section *4.4 Integration*.

.

## 4.2 Cross-sectional Study

The aim of this cross-sectional study was to identify predictors of effective pre-hospital pain management in children by ambulance services (see section *1.4.2 Objectives*). Effective pain management was defined as the abolition or reduction of pain by ≥2 out of 10 on the numeric pain rating scale, Wong-Baker FACES® scale or face, legs, activity, crying and consolability (FLACC) scale. This was discussed further in section *4.2.1.4 Outcome of interest*.

### 4.2.1 Methods

#### 4.2.1.1 Study design

A retrospective cross-sectional study was performed. The decision to adopt a cross-sectional approach has previously been justified within the methodology chapter (see section *2.3.3 Cross-sectional study*). The retrospective approach was utilised for a number of reasons; a) routinely collected data stored from electronic clinical records was abundant and easy to extract in large volumes, b) using non-routinely collected data (a novel dataset) would have required either manipulation of the electronic clinical record software (funding for which was not available) or the distribution and collection of large volumes of paper data collection forms, which logistically is extremely difficult to undertake over a large geographical area and c) a prospective approach would have taken a significantly longer time to collect data and considering the sequential nature of the mixed methods approach, the study would have likely exceeded three years as the qualitative study could not begin before the findings of the cross-sectional study were realised.

#### 4.2.1.2 Setting

Electronic clinical records from one large UK ambulance service (East Midlands Ambulance Service NHS Trust [EMAS]) from 1st October 2017 to 30th September 2018 were used. EMAS served a population of 4.8 million in total, including an estimated 996,348 children (21%) under the age of 18 years (Office for National Statistics, 2019) over an area of 6,435 square miles across six counties covering

both urban and rural areas (East Midlands Ambulance Service NHS Trust, 2017). Approximately 2,500 emergency calls were received per day; during the study period 818,340 calls were received (see flow diagram Figure *7* pg114 in section *4.2.2 Results* for full breakdown of calls received). EMAS employed approximately 2,300 ambulance staff.

#### 4.2.1.2 Participants

No children were directly enrolled into the study, only their anonymised clinical data were used (see section *4.2.1.3 Data collection*).

##### 4.2.1.2.1 Inclusion criteria

- Patients aged 0 - 17 years.
- Attended by the East Midlands Ambulance Service NHS Trust.
- Suffering acute pain (defined as pain <12 weeks in duration (British Pain Society, 2019)).

Ambulance service clinicians attend children of all ages when dealing with pain, therefore research projects involving broad conditions such as pain should reflect this and not be exclusive, as some studies exclude children at the younger (under 5 years) (Bendall et al., 2011a) and older (over 15 years) (Bendall et al., 2011a, Jennings et al., 2015, Watkins, 2006, Bredmose et al., 2009, Galinski et al., 2011, O'Donnell et al., 2013, Johnson et al., 2014, Murphy et al., 2016, Murphy et al., 2017, Lord et al., 2019) age range. Within this thesis, children have been defined as patients under 18 years of age (*1.2.3.1 Age*) and considering the underrepresentation of patients at the lower (0-5 years), but more so the upper age range (16 and 17 years) (Whitley and Lord, 2018) as discussed in section *1.2.3.1.4 Legal age*, it was deemed necessary to incorporate children aged 0 – 17 years in this study.

The justification for only including children suffering acute pain rather than including those with chronic pain has already been provided, see section *1.3*

*Research Question*. Children can suffer acute pain from medical and traumatic causes (Lord et al., 2016), therefore it was important to be inclusive of both types. This also allowed the creation of a variable (type of pain).

4.2.1.2.2 Exclusion criteria

- Patients with a Glasgow Coma Scale (GCS) score <15 at any time or no documented GCS.
- Patients without two pain scores.

Children with a Glasgow Coma Scale score of less than 15 are less likely to provide accurate pain reporting due to the reduced level of consciousness; a score of 14 or less could mean the child's verbal response is 'confused' (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019a). Ambulance service clinicians may ask parents of children for their perceived pain score, however there is no clear way to document this, therefore it would not be possible to distinguish between child and parent pain scores. It was felt that in cases of low GCS, where parents may have been asked for pain scores, exclusion introduced less bias as parents may overestimate (Voepel-Lewis et al., 2005) or underestimate (Chambers et al., 1998) their child's pain.
Two pain scores were essential to the analysis in order to calculate the dependent variable (abolition or reduction of pain by 2 or more out of 10), therefore all clinical records containing less than two pain scores were excluded.

4.2.1.3 Data collection

Data were extracted from 1st October 2017 to 30th September 2018 using anonymised EMAS electronic clinical records. Data were extracted by EMAS onto a Microsoft Excel spreadsheet. This date range was chosen because of the recent implementation (July 2017) of new electronic clinical record hardware and software, therefore initial teething problems had been resolved by October 2017.

Paper clinical records were not included for analysis. At the time of this study the electronic clinical record compliance rate was at least 78%. During this time within

the UK many ambulance services had either fully transitioned from paper to electronic clinical records or were in the process of transitioning. Within the East Midlands Ambulance Service NHS Trust electronic clinical records were mandatory for all staff except where the technology failed or was absent from vehicles, then paper clinical records could be completed. Paper clinical records were scanned digitally and stored as an image file, therefore manual data extraction would have been required; this would have been extremely laborious and subject to human error. Therefore, the decision to exclude these data was justified.

Initially, the clinical impression (pre-hospital diagnosis) of all electronic patient report forms for children aged <18 years were extracted and screened to include only children who were likely to be experiencing acute pain, for example 'abdominal pain' or 'soft tissue injury'. This process also ensured the inclusion criteria 'suffering acute pain' would be met. Patients suffering an anxiety attack, or hypoglycaemia for example were unlikely to be suffering acute pain, and it would not be expected of a clinician to report a pain score. Including such data could skew the analysis of overall pain scoring, therefore the decision to only include patients who were likely suffering acute pain was taken. The alternative approach, to include all clinical records with two pain scores, would have compromised the analysis by violation of the 'suffering acute pain' criteria (*4.2.1.2.1 Inclusion criteria*); including patients suffering acute pain and chronic pain would have disregarded the inclusion criteria of this study. The screening was performed independently and in duplicate by myself and another paramedic researcher, with Cohen's Kappa statistic (Cohen, 1960) calculated to assess inter-rater reliability.

Variables included in the full data extraction included: child sex, age and ethnicity, child's home postcode (this was replaced with the index of multiple deprivation (IMD) category by the East Midlands Ambulance Service NHS Trust prior to receiving the data, therefore maintaining anonymity), clinical impression(s), clinical observations to include all available Glasgow Coma Scale scores and pain scores (documented as numeric or visual), times of observations, medications and non-pharmacological treatments administered, including the times of administration, incident call time, arrival at scene time, left scene time, arrival at hospital time,

clinician rank (paramedic/technician), clinician experience (years of NHS service), clinician age and sex.

IMD codes were generated from the child's home postcode rather than the incident location postcode to provide a more accurate representation of the child's social status.

Medications included all drugs administered by anyone at any time, including prior and during the emergency call. Analgesics were counted when administered by anyone (clinicians, patient or parents/relatives) at any time and included paracetamol (tablets, suspension, intravenous), ibuprofen (tablets, suspension), Entonox®, morphine sulphate (oral, intravenous), aspirin, codeine, naproxen, Buscopan®, co-codamol, diamorphine, dihydrocodeine, ketamine, pethidine, Solpadeine® and tramadol. Non-pharmacological treatments included slings, splints, bandages and dressings.

Index of multiple deprivation (IMD) data was taken from the 2015 Ministry of Housing, Communities and Local Government (Ministry of Housing Communities and Local Government, 2015). IMD considers 7 domains; income, employment, education, skills and training, health and disability, crime, barriers to housing and services and the living environment. During this study 2019 data became available and was also extracted.

#### 4.2.1.4 Outcome of interest

The primary outcome measure was 'effective pain management', defined as the abolition or reduction of pain by ≥2 out of 10 on the numeric pain rating scale, Wong-Baker FACES® scale or face, legs, activity, crying and consolability (FLACC) scale. This measure was chosen due its ability to detect the minimum clinically significant difference in pain, as validated by a number of studies (Powell et al., 2001, Bulloch and Tenenbein, 2002, Bailey et al., 2010, Voepel-Lewis et al., 2011, Myrvik et al., 2013, Tsze et al., 2015).

This outcome measure has been used by a number of previous similar studies (Jennings et al., 2015, Lord et al., 2019, Siriwardena et al., 2019) with Bendall et al. (2011a) utilising a percentage reduction. The percentage reduction was considered as it would potentially reduce the effect of regression to the mean (Barnett et al., 2004) where those with an initial high pain score have a higher likelihood of achieving a greater reduction by chance than those with an initial moderate or low pain score. However, much of the validation work surrounding the minimum clinically significant difference in pain has been performed using a point reduction rather than a percentage reduction system, therefore for the purpose of this study the point reduction system was utilised.

A novel addition to this study was the inclusion of the 'abolition' criterion; this allowed children with an initial pain score of 1 out of 10, who achieve a reduction to 0 out of 10 to be classified as effective pain management. Other studies have excluded children with a low initial pain score, for example less than 3 (Jennings et al., 2015) or less than 4 (Lord et al., 2019) in an attempt to mitigate this problem. It was felt that the abolition criterion was beneficial as it increased the sample size and allowed a more accurate reflection of the population to be determined; pain score is fluid and can increase, stay the same or decrease. Including all lower pain scores allowed the observation of this fluidity, giving a more accurate reflection of true clinical practice than would have been achieved by excluding all children with a low initial pain score.

Some studies used the outcome measure 'analgesic administration' (Schauer et al., 2018, Browne et al., 2016b) to determine whether pain management was effective. Pain score reduction was a more desirable outcome measure because analgesic administration was considered an intermediate measure, a proxy for pain score reduction, and although children who receive analgesics are more likely to achieve a pain score reduction (Jennings et al., 2015), not all will.

#### 4.2.1.5 Data analysis

Descriptive statistics were displayed with means (standard deviation [SD]) and/or medians (interquartile ranges [IQR]) for continuous data and numbers (n) with percentage (%) for categorical data. Differences between included and excluded patient characteristics were determined using the t-test (means), binomial probability test (proportions) and Wilcoxon rank-sum test (medians). Univariable logistic regression analysis was performed showing odds ratios with 95% confidence intervals (CI) and p-values. Multivariable (or multiple) logistic regression analysis was shown with adjusted odds ratios, 95% CI and p-values. The independent variables used in the multivariable logistic regression analysis were child age, child sex, type of pain, analgesic administration, non-pharmacological treatment administration, paramedic crew, hospital travel time and index of multiple deprivation.

Katz (2011) stated that independent variables should be included that have been shown as confounders in prior research, theorised to be confounders or have a strong clinical relevance to the dependent variable and should not necessarily depend on association at univariable analysis. These variables were therefore chosen because of their relevance to the dependent variable and identification in previous research, specifically child sex, child age, type of pain and analgesic administration (Bendall et al., 2011a, Jennings et al., 2015, Lord et al., 2019).

One previous study (Jennings et al., 2015) performed multivariable logistic regression analysis to identify predictors of effective pain management and included initial pain score as an independent variable. While this was likely an attempt to adjust for regression to the mean, the results of the analysis may be erroneous due to the effect of mathematical coupling (Archie, 1981). When one variable (initial pain score) is used to calculated the dependent variable (final pain score minus initial pain score) *and* is also used as an independent variable, the results can be misleading due to the same variable being on both sides of the equation (Archie, 1981), potentially exaggerating or diminishing the effect size of the results. This cross-sectional study will account for mathematical coupling by not including initial pain score as an independent variable.

Continuous data were categorised as follows: child age (0-5, 6-11, 12-17 years), hospital travel time (<30 minutes, ≥30 minutes), child level of deprivation (index of multiple deprivation 1-3, 4-7, 8-10), clinician age (20-29, 30-39, 40-49, 50-59, 60-69, 70-79 years) and clinician experience (<5 years and ≥5 years).

The age categorisation was chosen from a mathematical and developmental level perspective, achieving an even split of years (n=6) in each group; 0-5 (pre-school group), 6-11 (mid-school group) and 12-17 (adolescent group).

The decision to categorise hospital travel time into <30 minutes and ≥30 minutes was informed by previously published research (Bendall et al., 2011a) and anecdotal evidence from clinical practice; most inner city commutes are less than 30 minutes to hospital whereas many rural commutes tend to be over 30 minutes.

Creating multiple IMD categories was preferable to dichotomisation as the latter leads to more information loss, reducing the statistical power to detect a relationship between the variable and outcome (Altman and Royston, 2006). The inclusion of IMD as an independent variable in this population and context has not previously been reported, therefore there was no prior evidence to inform this categorisation. It was felt that the creation of three categories, containing three (1-3), four (4-7) and three (8-10) indices was a pragmatic approach; using averages or the distribution curve to mark the cut points for groups would limit the comparability with future studies (as different populations are likely to have different distribution curves and averages), impeding future meta analyses (Altman and Royston, 2006).

The decision to dichotomise clinical experience into <5 years and ≥5 years was complex, as research was sparse and inconclusive. Rassafiani (2009) concluded that length of clinical experience was not an appropriate criterion for determining level of expertise, however one study defined novice clinicians as having ≤4 years of experience and holding a base grade position (Kuipers and Grice, 2009) and another study found that clinicians with less than 1 year of experience performed less well during clinical scenarios than the other three groups (1-2.5 years, 2.5-5 years and >5 years) (Byrne and Jones, 1997). The aim of this dichotomisation was not to

identify ‘experts’, but to separate the ‘novice’ less confident clinicians from the clinicians more comfortable and confident with their practice.

The variable ‘type of pain’ was dichotomised into ‘traumatic pain’ and ‘medical pain’. ‘Traumatic pain’ included alleged assault, head injury, limb injury, soft tissue injury and thermal injury, for example. ‘Medical pain’ included accidental overdose/poisoning, acute abdominal problem, back pain, chest pain and headache for example. Patients with traumatic *and* medical sources of pain were categorised as ‘traumatic pain’ due to traumatic pain being perceived as more urgent and receiving preferential treatment over medical pain (Bendall et al., 2011a, Jennings et al., 2015, Lord et al., 2019). For a comprehensive list of all clinical impression allocations see Supplementary File in Whitley et al. (2020b).

Where multiple clinicians were on scene, their demographics such as age, experience and sex were not merged or grouped. Instead, the ‘senior clinician’ on scene was identified, as it was likely this clinician would make the decisions regarding pain management. The ‘senior clinician’ was the highest-ranking clinician on scene; paramedic > technician > other (including trainee technician, emergency care assistant and urgent care assistant). Where more than one paramedic was on scene, the paramedic with the lowest PIN number was used (a sequential number assigned to clinicians when they join the East Midlands Ambulance Service NHS Trust). Generally, the lower the number, the more experience within the East Midlands Ambulance Service NHS Trust. This does not account for experience gained elsewhere. Determining the first paramedic on scene was considered, however there would be complications with this. The first paramedic on scene may not accurately represent the clinician who makes the majority of the decisions regarding pain management, as the first paramedic may choose to prioritise other conditions such as major haemorrhage, leaving pain management to the second paramedic. In addition to this, in the case of double paramedic crews, both paramedics would arrive on scene at the same time therefore it would be unclear which clinician was ‘attending’. Therefore, the use of PIN numbers, although not perfect, was the closest determinant of the ‘senior clinician’. This can be considered a type of information bias (Tripepi et al., 2010). The most important

type of information bias is misclassification bias, where an exposed/diseased participant is categorised as a non-exposed/non-diseased participant; fortunately this bias does not impact the dependent variable but does need to be considered as it will influence the independent variable and resultant multivariable logistic regression to a degree (Tripepi et al., 2010).

All available pain scores were extracted, including numeric and visual. Pain scores were not combined when both numeric and visual data were available, as their comparability is not well established. Instead, they were assessed separately, and it was determined that 'effective pain management' was achieved when at least one of the scores (numeric or visual) met the criteria (abolition or reduction of pain score by ≥2 out of 10).

Missing data within the independent variables were managed by categorising such cases as 'missing data'. Katz (2011) proposed a number of ways to deal with missing data within independent variables, including; 1) deleting cases with missing data, 2) creating dichotomous variables to represent the missing data, 3) increase efforts to obtain missing data, 4) reduce the number of included independent variables or 5) estimate the value of the missing variables. All of these solutions had the potential to create bias in different ways (except solution 3). Katz (2011) stated that deleting cases with missing data from independent variables is a common approach but creates a loss of power and introduces bias. Sterne et al. (2009) argued for multiple imputation to estimate the values of the missing data, stating that the type of missing data is an important consideration (discussed later in section *4.2.3 Discussion*). There was no way to obtain this missing data and I did not want to reduce the number of included variables, as they were all clinically relevant. This left two options, estimate the value of missing data or categorise the missing data separately. I opted for the latter due to the noted benefits; I did not have to make strong assumptions about the value of the missing data, as I would have with the former option, and I was able to assess the bias caused by the missing data.

Analyses were considered significant when $p<0.05$. Stata Statistical Version 15 (StataCorp, College Station, TX) was used for data analysis.

The decision to use Stata over other statistical packages such as SPSS, SAS or R was due to my supervisor, a Professor of Medical Statistics having a wealth of experience using Stata. Therefore, the opportunity to develop my statistical skills would have been diminished had I chosen a less familiar package. Stata was capable of performing all the analyses I required.

#### 4.2.1.5.1 Data cleaning

The data were received in the form of a Microsoft Office Excel spreadsheet, split into separate tabs for patient demographics, observations, treatments, clinician demographics and index of multiple deprivations scores. The first stage of data cleaning involved transforming from 'long' to 'wide' data. Where patients had multiple observations or treatments these were listed vertically, with one clinical record occupying numerous rows. These were transformed within Stata resulting in one clinical record per row, with multiple columns representing all of the observations and treatments.

Once the data was transformed from 'long' to 'wide', the separate datasets were linked together to form one dataset using the electronic patient report form number as the unique identifier. After all data were linked into one dataset, with each clinical record occupying one row, the exclusion criteria could be applied.

#### 4.2.1.6 Ethical considerations

Ethical approval was gained from the Health Research Authority following research ethics committee approval (18/NI/0120). The East Midlands Ambulance Service NHS Trust Clinical Audit and Research Unit also gave approval for data usage.

### 4.2.2 Results

#### 4.2.2.1 Initial data screening

During 1st October 2017 to the 30th September 2018 the East Midlands Ambulance Service NHS Trust received 818,340 calls. A vehicle was dispatched that arrived on

scene for 662,100 of these calls (the remainder being managed via telephone). This resulted in treatment on scene (n=195,523) or conveyance to further care (n=466,577). 517,190 electronic patient report forms (ePRF) were created during this period, giving an ePRF compliance rate of 78% (the remainder were either paper PRFs; not included in this study due to the manual data extraction being unfeasible, or a PRF was not completed for the incident, perhaps due to absconding patients or false calls). 41,494 of these electronic clinical records were of children (aged <18 years).

In order to comply with Caldicott principles and 'use the minimum necessary personal confidential data' (Caldicott, 2013), these 41,494 clinical records were screened by myself and another paramedic researcher to identify patients likely to be suffering acute pain. Our level of agreement and disagreement can be seen in *Table 5* (pg112).

In order to demonstrate that this level of agreement was not achieved by chance, the Cohen's Kappa statistic was performed in Stata version 15. The results of this analysis can be seen in *Table 6* (pg112).

Table 5 – Cross-sectional study: Initial data filter agreement and disagreement

| | | **Greg Whitley** | | **Total** |
|---|---|---|---|---|
| | | Suggestive of Acute Pain | Not Suggestive of Acute Pain | |
| **Research paramedic colleague** | Suggestive of Acute Pain | 516 | 21 | 537 |
| | Not Suggestive of Acute Pain | 45 | 739 | 784 |
| | **Total** | 561 | 760 | 1321 |

Table 6 – Cross-sectional study: Cohen's kappa statistic

| **Agreement** | **Expected Agreement** | **Kappa** | **Std. Error** | **Z** | **Prob>Z** |
|---|---|---|---|---|---|
| 95.00% | 51.41% | 0.8972 | 0.0275 | 32.63 | 0.0000 |

The Kappa statistic ranges from 0 (very poor agreement, likely caused by chance) to 1 (perfect agreement). With a Kappa rating of 0.8972 the agreement between myself and my research paramedic colleague was 'almost perfect' (Landis and Koch, 1977). This provided confidence in the clinical impressions chosen for full data extraction. All clinical impressions where disagreement occurred were included. This ensured potentially valuable cases were not missed from the analysis.

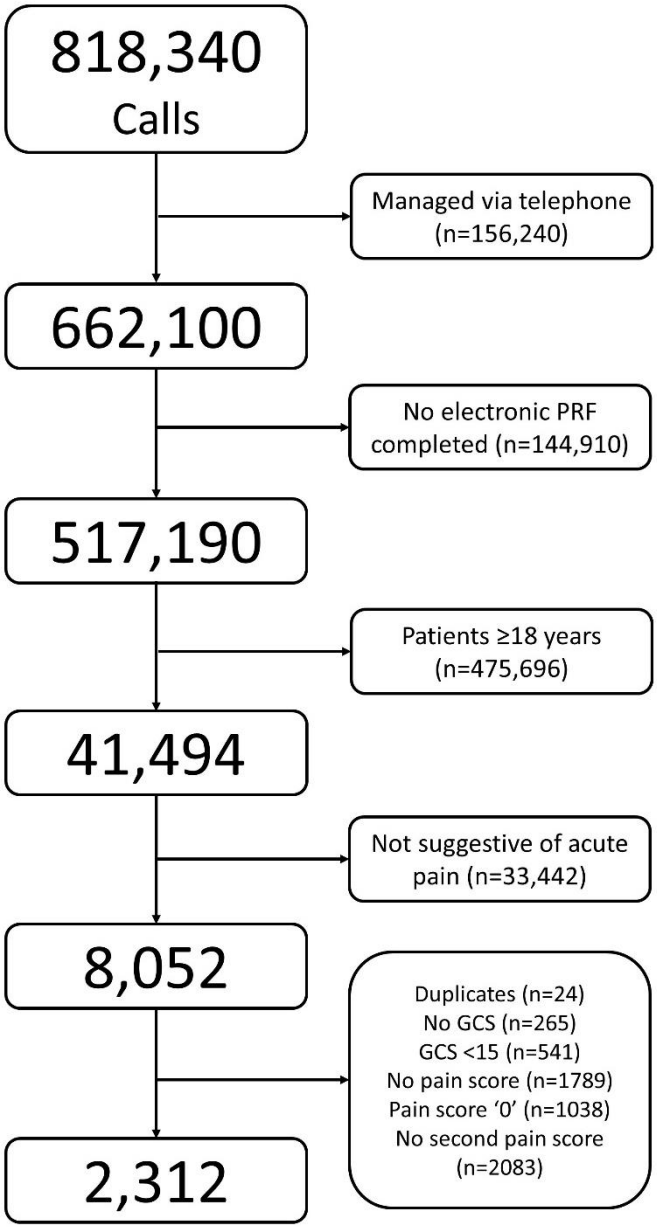
Full data extraction was requested once the screening of clinical impressions was complete. This resulted in 8052 clinical records being assessed for eligibility into the study.

Duplicate records (n=24) were initially removed leaving 8028 records. All patients with a GCS<15 at any time (n=541) were excluded. Also, patients with no documented GCS (n=265) were also excluded. This resulted in 7222 clinical records suitable for analysis.

I excluded all patients without a documented pain score (n=1789), with a documented pain score of zero (n=1038) or without two documented pain scores (n=2083). See Figure *7* (pg114) for the patient flow diagram.

A large group of children were excluded for no initial pain score or no second pain score (n=3872, 48%) (see Figure *7* pg114). This excluded group were significantly younger (median (IQR) 8 years (2-14) [p<0.0001]), closer to hospital (median travel time minutes (IQR) 17 (11-24) [p<0.0001]), suffered more traumatic pain (n=2801 (72%) [p<0.0001]), were attended by a paramedic more often (n=2815 (73%) [p=0.0046]), were from more deprived areas (median index of multiple deprivation (IQR) 4 (2-7) [p=0.0002]) and received fewer analgesics (n=1552 (40%) [p<0.0001]) than those included. See Appendix *9* for comparison of included and excluded data along with section *4.2.3.2.1 Selection bias* for further discussion.

Figure 7 – Cross-sectional study: Patient flow diagram




Calls – all calls including emergency (999) and non-emergency (111/GP referral), PRF – patient report form, GCS – Glasgow Coma Scale

4.2.2.2 Patient characteristics

For patient characteristics see *Table 7* (pg116). Index of multiple deprivation scores were available for 1585 (69%) children, with 670 (29%) having no home postcode documented and 57 (2%) home postcodes being unmatched/erroneous. Public location of incident was the likely cause for missing home postcode data. The low percentage of unmatched/erroneous postcode data suggests a low risk of bias. Hospital transport time was missing for 418 (18%) children, these were likely not conveyed and referred to another health care professional. Other missing data included senior clinician age (n=52) and senior clinician experience (n=37).

Non-pharmacological treatments were administered to 137 children and included dressings (n=57; 42%), splints (n=39; 28%) and slings (n=2; 1%) along with various other treatments such as patient positioning, cold compresses and eye irrigations for example (n=39; 28%).

Of those who achieved effective pain management (n=903), 191 (21%) achieved complete abolition of pain (of which n=9 were a reduction from 1 to 0) with the remaining 712 (79%) achieving a 2-point reduction.

Table 7 – Cross-sectional study: Patient and clinician characteristics

| Characteristic | Effective pain management (n = 903) | Not effective pain management (n = 1409) | Total (n = 2312) |
|---|---|---|---|
| Age y, median (IQR) | 12 (8-15) | 14 (9-16) | 13 (9-16) |
| Age y, mean (SD) | 11.2 (4.9) | 12.0 (4.8) | 11.7 (4.8) |
| Age, n (%) | | | |
| 0-5 y | 140 (15.5) | 189 (13.4) | 329 (14.2) |
| 6-11 y | 263 (29.1) | 322 (22.9) | 585 (25.3) |
| 12-17 y | 500 (55.4) | 898 (63.7) | 1398 (60.5) |
| Sex, n (%) | | | |
| Female | 383 (42.4) | 671 (47.6) | 1054 (45.6) |
| Male | 516 (57.1) | 733 (52.0) | 1249 (54.0) |
| Not documented | 4 (0.4) | 5 (0.4) | 9 (0.4) |
| Type of pain, n (%) | | | |
| Medical | 267 (29.6) | 509 (36.1) | 776 (33.6) |
| Trauma | 636 (70.4) | 900 (63.9) | 1536 (66.4) |
| Pain Score, median (IQR) | | | |
| Initial numeric | 8 (6-9) | 6 (4-7) | 7 (4-8) |
| Final numeric | 4 (2-6) | 6 (4-8) | 5 (3-7) |
| Difference numeric | 3 (2-5) | 0 (0-0) | 0 (0-2) |
| Initial visual | 6 (4-8) | 4 (2-6) | 4 (2-6) |
| Final visual | 2 (0-4) | 4 (2-6) | 2 (2-4) |
| Difference visual | 2 (2-4) | 0 (0-0) | 0 (0-2) |
| Hospital travel time (mins), median (IQR) | 22 (13-31) | 20 (13-28) | 20 (13-31) |
| Analgesic, n (%) | | | |
| Administered | 669 (74.1) | 794 (56.4) | 1463 (63.3) |
| Not administered | 234 (25.9) | 615 (43.7) | 849 (36.7) |
| Non-pharmacological treatment, n (%) | | | |
| Administered | 62 (6.9) | 75 (5.3) | 137 (5.9) |
| Not administered | 841 (93.1) | 1334 (94.7) | 2175 (94.1) |
| Index of multiple deprivation, median (IQR) | 5 (3-7) | 4 (2-7) | 4 (2-7) |
| Index of multiple deprivation, mean (SD) | 5.02 (2.83) | 4.58 (2.88) | 4.75 (2.87) |
| Paramedic crew, n (%) | | | |
| Paramedic | 669 (74.1) | 934 (66.3) | 1603 (69.3) |
| Non-paramedic | 234 (25.9) | 475 (33.7) | 709 (30.7) |
| Senior clinician age (y), median (IQR) | 44 (34-50) | 44 (34-50) | 44 (34-50) |
| Senior clinician experience (y), median (IQR) | 11 (3-16) | 10 (3-16) | 10 (3-16) |
| Senior clinician sex, n (%) | | | |
| Female | 307 (34.0) | 475 (33.7) | 782 (33.8) |
| Male | 525 (58.1) | 824 (58.5) | 1349 (58.4) |
| Not documented | 71 (7.9) | 110 (7.8) | 181 (7.8) |

y – year, IQR – interquartile range, SD – standard deviation, Numeric – numeric pain rating scale, Visual – Wong & Baker faces scale, Non-pharmacological treatment – slings, splints,

bandages and dressings, Senior clinician – highest rank clinician > lowest PIN number, Experience – total NHS (National Health Service, UK) employment, Index of multiple deprivation (2015) – calculated from home postcode (IMD is based on income, employment, education skills and training, health and disability, crime, barriers to housing and services and living environment [1 = Highest deprivation, 10 = Lowest deprivation]).

#### 4.2.2.3 Univariable logistic regression analysis

For the univariable logistic regression analysis see *Table 8* (pg118). Missing data has not been excluded from variables, but categorised as its own group within variables as 'missing data' (see section *4.2.1.5 Data analysis* for further discussion and justification).

#### 4.2.2.4 Multivariable logistic regression analysis

For the multivariable logistic regression analysis see *Table 9* (pg120). Missing data has not been excluded from variables, but categorised as its own group within variables as 'missing data' (see section *4.2.1.5 Data analysis* for further discussion and justification).

It was evident from *Table 9* (pg120) that children were significantly more likely to achieve effective pain management if they were younger, administered analgesics, attended by a paramedic or living in an area of low or medium deprivation.

Table 8 – Cross-sectional study: Univariable logistic regression analysis assessing the odds of achieving effective pain management (abolition or reduction of pain ≥2 out of 10)

| Predictor | Odds Ratio (95% CI) | p-value |
|---|---|---|
| Patient age, years | | |
| 0-5 | 1.33 (1.04-1.70) | 0.022 |
| 6-11 | 1.47 (1.21-1.78) | <0.000 |
| 12-17 (reference) | 1 | |
| Patient sex | | |
| Male | 1.23 (1.04-1.46) | 0.015 |
| Female (reference) | 1 | |
| Type of pain | | |
| Trauma | 1.35 (1.13-1.61) | 0.001 |
| Medical (reference) | 1 | |
| Analgesic | | |
| Administered | 2.21 (1.85-2.66) | <0.001 |
| Not administered (reference) | 1 | |
| Non-pharmacological treatment | | |
| Administered | 1.31 (0.93-1.86) | 0.126 |
| Not administered (reference) | 1 | |
| Index of multiple deprivation | | |
| Highest deprivation (reference) | 1 | |
| Medium deprivation | 1.41 (1.12-1.78) | 0.003 |
| Lowest deprivation | 1.35 (1.03-1.76) | 0.027 |
| Missing data | 1.18 (0.94-1.46) | 0.148 |
| Hospital travel time, minutes | | |
| <30 (reference) | 1 | |
| ≥30 | 1.03 (0.84-1.28) | 0.756 |
| Missing data | 0.92 (0.74-1.15) | 0.480 |
| Paramedic crew | | |
| Paramedic | 1.45 (1.21-1.75) | <0.001 |
| Non-paramedic (reference) | 1 | |
| Senior clinician age, years | | |
| 20-29 (reference) | 1 | |
| 30-39 | 1.09 (0.81-1.45) | 0.569 |
| 40-49 | 1.15 (0.88-1.49) | 0.304 |
| 50-59 | 1.06 (0.80-1.41) | 0.680 |
| 60-69 | 0.50 (0.28-0.91) | 0.022 |
| 70-79 | 0.55 (0.06-5.37) | 0.610 |
| Missing data | 0.95 (0.52-1.75) | 0.882 |
| Senior clinician sex | | |
| Male | 0.99 (0.82-1.18) | 0.877 |
| Female (reference) | 1 | |
| Senior clinician experience, years | | |
| <5 (reference) | 1 | |
| ≥5 | 1.06 (0.89-1.27) | 0.515 |
| Missing data | 0.99 (0.50-1.95) | 0.969 |

non-pharmacological treatment – slings, splints, bandages and dressings, index of multiple deprivation (2015) – highest deprivation (1-3), medium deprivation (4-7), lowest deprivation (8-10), senior clinician – highest rank clinician > lowest PIN number, experience – total NHS (National Health Service, UK) employment.

#### 4.2.2.5 Subgroup analysis

*Table 9* (pg120) showed that younger children were more likely to achieve effective pain management than older children. This conflicted with qualitative evidence synthesised in section *3.3.5 Qualitative synthesis* which found that younger children were more difficult to assess, cannulate and administer inhaled analgesics to. Therefore, I hypothesised that pain management strategies other than analgesics were associated with a higher chance of effective pain management for younger compared with older children. In an attempt to confirm this hypothesis, I restricted the multivariable logistic regression to include only children aged 0-5 years. See *Table 10* (pg121) for the subgroup analysis of children aged 0-5 years.

Table 9 – Cross-sectional study: Multivariable logistic regression analysis assessing the odds of achieving effective pain management (abolition or reduction of pain ≥2 out of 10)

| Predictor | Adjusted* Odds Ratio (95% CI) | p-value |
|---|---|---|
| Patient age, years | | |
| 0-5 | 1.53 (1.18-1.97) | 0.001 |
| 6-11 | 1.49 (1.21-1.82) | <0.001 |
| 12-17 (reference) | 1 | |
| Patient sex | | |
| Male | 1.17 (0.98-1.39) | 0.090 |
| Female (reference) | 1 | |
| Type of pain | | |
| Trauma | 1.18 (0.97-1.43) | 0.091 |
| Medical (reference) | 1 | |
| Senior clinician experience, years | | |
| <5 (reference) | 1 | |
| ≥5 | 0.97 (0.80-1.18) | 0.744 |
| Missing data | 1.42 (0.70-2.91) | 0.334 |
| Analgesic | | |
| Administered | 2.26 (1.87-2.73) | <0.001 |
| Not administered (reference) | 1 | |
| Non-pharmacological treatment | | |
| Administered | 1.08 (0.75-1.55) | 0.695 |
| Not administered (reference) | 1 | |
| Paramedic crew | | |
| Paramedic | 1.46 (1.19-1.79) | <0.001 |
| Non-paramedic (reference) | 1 | |
| Hospital travel time, minutes | | |
| <30 (reference) | 1 | |
| ≥30 | 1.00 (0.80-1.25) | 0.981 |
| Missing data | 1.00 (0.78-1.27) | 0.986 |
| Index of multiple deprivation | | |
| Highest deprivation (reference) | 1 | |
| Medium deprivation | 1.41 (1.11-1.79) | 0.005 |
| Lowest deprivation | 1.37 (1.04-1.80) | 0.027 |
| Missing data | 1.18 (0.94-1.48) | 0.158 |

Number of observations: 2,303.

non-pharmacological treatment – slings, splints, bandages and dressings, index of multiple deprivation (2015) – highest deprivation (1-3), medium deprivation (4-7), lowest deprivation (8-10), senior clinician – highest rank clinician > lowest PIN number, experience – total NHS (National Health Service, UK) employment.

*Adjusted for patient age, patient sex, type of pain, senior clinician experience, analgesic administration, non-pharmacological treatment administration, paramedic crew, hospital travel time and index of multiple deprivation.

Table 10 – Cross-sectional study: Subgroup analysis. Multivariable logistic regression of 0-5-year-old children assessing the odds of achieving effective pain management (abolition or reduction of pain >=2 out of 10)

| Predictor | Adjusted* Odds Ratio (95% CI) | p-value |
|---|---|---|
| Patient sex | | |
| Male | 1.08 (0.68-1.73) | 0.745 |
| Female (reference) | 1 | |
| Type of pain | | |
| Trauma | 1.89 (1.08-3.32) | 0.027 |
| Medical (reference) | 1 | |
| Senior clinician experience, years | | |
| <5 (reference) | 1 | |
| ≥5 | 1.37 (0.81-2.31) | 0.235 |
| Missing data | 3.83 (0.55-26.57) | 0.174 |
| Analgesic | | |
| Administered | 1.19 (0.75-1.89) | 0.468 |
| Not administered (reference) | 1 | |
| Non-pharmacological treatment | | |
| Administered | 0.94 (0.39-2.29) | 0.900 |
| Not administered (reference) | 1 | |
| Paramedic crew | | |
| Paramedic | 2.13 (1.21-3.76) | 0.009 |
| Non-paramedic (reference) | 1 | |
| Hospital travel time, minutes | | |
| <30 (reference) | 1 | |
| ≥30 | 1.01 (0.52-1.95) | 0.985 |
| Missing data | 0.94 (0.52-1.67) | 0.821 |
| Index of multiple deprivation | | |
| Highest deprivation (reference) | 1 | |
| Medium deprivation | 1.96 (1.05-3.66) | 0.033 |
| Lowest deprivation | 2.76 (1.25-6.06) | 0.012 |
| Missing data | 1.61 (0.88-2.95) | 0.121 |

Number of observations: 327.

non-pharmacological treatment – slings, splints, bandages and dressings, index of multiple deprivation (2015) – highest deprivation (1-3), medium deprivation (4-7), lowest deprivation (8-10), senior clinician – highest rank clinician > lowest PIN number, experience – total NHS (National Health Service, UK) employment.

*Adjusted for patient sex, type of pain, senior clinician experience, analgesic administration, non-pharmacological treatment administration, paramedic crew, hospital travel time and index of multiple deprivation.

*Table 10* (pg121) showed that the adjusted odds ratio (95% CI) for achieving effective pain management for children aged 0-5 years receiving analgesics and non-pharmacological treatments was 1.19 (0.75-1.89) and 0.94 (0.39-2.29), respectively. Therefore, for 0-5-year-old children, analgesic administration was not significantly associated with effective pain management. This contributed towards the above hypothesis (that pain management strategies other than analgesics were associated with a higher chance of effective pain relief for younger compared with older children). *Table 10* (pg121) did not show that non-pharmacological treatments were associated with effective pain management in this younger age group. This may be due to the difficulty in accounting for all non-pharmacological techniques due to lack of documentation or inability to screen records for non-pharmacological interventions documented within the written text.

The data collection period was October 2017 to September 2018 and the index of multiple deprivation data was taken from 2015. During this PhD, index of multiple deprivation data became available for 2019, therefore the updated data was requested and the multivariable logistic regression was performed again. The main findings of the analysis did not change. The results of this additional analysis can be found in Appendix *10*. Calculating weighted averages was considered and would have been possible for each case as the incident date was available, however due to time constraints I was unable to perform this analysis. It was felt that performing a 'before' and 'after' analysis of IMD scores was sufficient to demonstrate consistency in the IMD results. The technique of calculating weighted averages will be considered for future studies.

### 4.2.3 Discussion

For children suffering acute pain in the pre-hospital setting, predictors of effective pain management include patients who are younger (aged 0-5 and 6-11 years compared with older children aged 12-17 years), administered analgesics (compared to those who did not receive analgesics), attended by a paramedic (rather than a technician) or living in an area of low or medium deprivation (compared to those living in areas of high deprivation).

A number of the results confirm previous findings; Jennings et al. (2015) found that analgesic administration was a predictor of effective pain management in children, with an adjusted odds ratio (95% confidence interval) of 6.6 (5.9-7.3) when compared to those who did not receive analgesics.

Bendall et al. (2011a), Jennings et al. (2015) and Lord et al. (2019) found that younger children were more likely to achieve effective pain management than older children. Considering that analgesics do not predict effective pain management in younger children aged 0-5 years (see section *4.2.2.5 Subgroup analysis*), future prospective studies are needed to support the hypothesis that non-pharmacological treatments are associated with effective pain management in younger children. This was discussed further, in particular the emotional influence on the perception of pain in younger versus older children, in section *4.3.3.1 Explanation of predictors*.

Several findings did not confirm previously published data. Bendall et al. (2011a) identified child sex (male) as a predictor of effective pain management, although their definition of 'effective pain management' differed from the definition used in this study (pain score reduction ≥ 30% of initial pain score). Jennings et al. (2015) and Lord et al. (2019) also found that male children were significantly more likely than females to achieve effective pain management. *Table 9* (pg120) showed no statistically significant association (p=0.090) between child sex (male) and effective pain management, however the estimate of effect (0.98-1.39), in particular the lower confidence interval was close to the line of no effect, suggesting the 'true' odds ratio may be above 1. A meta-analysis was performed (see Figure *4* pg78) which showed a clear pooled estimate of effect in favour of male children being more likely to achieve effective pain management than female children, however the $I^2$ statistic of 60.5% may represent substantial heterogeneity (Higgins J.P.T & Green S Eds, 2011). The estimate of effect in this study was perhaps more conservative given the number of included independent variables (n=9). There is currently no evidence to explain why male children are more likely to achieve effective pain management than female children.

There was no significant difference (p=0.981) between children who face a shorter (<30 minutes) journey to hospital versus a longer journey (≥30 minutes). This

conflicted with data previously reported by Bendall et al. (2011a), which suggested that children closer to hospital were less likely to achieve effective pain management. A possible reason for this was perhaps that Bendall et al. (2011a) only included the distance to hospital variable in a univariable analysis, whereas the distance to hospital variable in this study was included in both univariable and multivariable analyses (although no significant association was found in either). Another explanation for the difference was perhaps cultural; the ambulance service and educational systems of the United States and United Kingdom are different, as one United States study found that clinicians have a culture of oligoanalgesia (being 'stingy' with analgesic administration) and fear attention from authority figures (Williams et al., 2012).

There was missing data for the following independent variables; index of multiple deprivation (n=727), hospital travel time (n=418), senior clinician age (n=52) and senior clinician experience (n=37). According to Sterne et al. (2009) there are three types of missing data; missing completely at random, missing at random and missing not at random. It was felt that the index of multiple deprivation data was missing completely at random because there was no perceived pattern or predictability to determine if a children would suffer a medical emergency at home or in a public place, as it was assumed that children without IMD data generated from a home postcode were attended to in a public place. It was also felt that missing senior clinician age and experience data were missing completely at random due to the low numbers and lack of clear reason for the missing data. The missing hospital travel time data was more complex, as some of the children may have been discharged on scene and referred to another health care professional (these would not be classed as 'missing data'), however as a clinician I am aware of practical mistakes that occur in clinical practice, and it is very easy to forget to press 'leave scene' and 'arrival at hospital' on the Terrafix screen in the cabin of the ambulance. This would result in these times not being recorded and ultimately not being sent to the electronic clinical record software resulting in missing data. I felt it was safer to document the lack of hospital transport times as 'missing data' than to exclude it from the analysis and assume all the exclusions were discharges on

scene. It could be argued that this data may not be missing at random, as a clinician's ability to remember to click 'leave scene' and 'at hospital' diminishes under pressure, particularly when a high acuity patient is on board where time is of the essence, therefore the missing distance to hospital data poses the greatest risk of bias to the study. Overall, the bias introduced to this study as a result of this missing data was considered minimal, as evident in *Table 9* (pg120) as none of the missing data categories were significantly associated with effective pain management. In addition to this, the main findings of the multivariable logistic regression analysis did not change when the analysis was performed with segregated missing data versus without segregated missing data (as discussed in section *5.3.1.1 Integrity within research*).

Analgesic administration was not selected as the primary outcome measure as this was deemed a proxy for effective pain management. The results of this study reinforced this decision as 848 children reported pain and received no analgesic, yet 233 (27%) of these still achieved effective pain reduction. Conversely, 1463 children received analgesics, however 794 (54%) of these did not achieve effective pain management. The reason for this phenomenon was likely complex and multifaceted, but a significant factor to consider was the method of outcome measurement. Measuring analgesic administration is relatively simple and binary, whereas measuring rates of effective pain management (abolition or reduction of pain by 2 or more out of 10) is much more challenging. These challenges relate to the validity of pain assessment tools, the appropriateness of their use and their ability to accurately reflect the patient's perceived pain experience; all discussed in section *4.2.3.2 Limitations*. This raises an important question: what is the gold standard outcome measure to ensure quality of care regarding pain management in children? Is it analgesic administration, pain score reduction or something else? At this time, pain score reduction appeared to be the gold standard outcome measure and is currently being utilised in a number of pioneering trials (Hartshorn et al., 2019, National Institute for Health Research, 2020), however the limitations of pain assessment tools must be acknowledged and pain assessment techniques should

continually be evaluated and improved where necessary through further research and development.

The floor and ceiling effect along with regression to the mean were also considered. Children who achieved a numeric pain score reduction from 1 to 0 were categorised as 'effective pain management' using the 'abolition of pain' criteria. Initial pain score could not be included as an independent variable in either logistic regression analysis to avoid mathematical coupling (Archie, 1981). A percentage reduction, as used in Bendall et al. (2011a) was considered for the outcome measure, however much of the validation work around the minimum clinically significant difference in pain has been performed using a point reduction (Powell et al., 2001, Bulloch and Tenenbein, 2002, Bailey et al., 2010, Voepel-Lewis et al., 2011, Myrvik et al., 2013, Tsze et al., 2015).

#### 4.2.3.1 Strengths

Some non-pharmacological treatments such as slings, splints, bandages and dressings were accounted for within this study; although their administration was not significantly associated with effective pain management. This data strengthened the evidence base as previous studies were unable to account for these techniques (Lord et al., 2016, Murphy et al., 2017). Patient deprivation level was also assessed as a predictor of effective pain management. To my knowledge, this is a novel predictor not previously reported in this population and context.

#### 4.2.3.2 Limitations

There are three main types of bias in health care research; selection bias, information bias and confounding (Law and Pascoe, 2013, Groenwold, 2013).

#### 4.2.3.2.1 Selection bias

Selection bias is caused early on in a study when the wrong subjects or people are included or when subjects who should have been included are not; when the right data is collected on the wrong people (Law and Pascoe, 2013).

The electronic patient report form (ePRF) compliance rate for the study period was high at 78%, therefore several paper PRFs were excluded due to the manual data extraction of these forms being unfeasible given the time restraints of this study. The exact number of excluded paper PRFs is unknown due to the mechanism of archiving; paper PRFs are stored as a visual image, therefore, to determine the number of eligible patients that have been excluded, a large amount of manual screening would be required. This was not possible given the resources and timeframe of the study.

In addition to excluding patients who had a paper PRF completed, patients were excluded where the dependent variable could not be calculated as either no pain score was documented (n=1789; 22%) or no second pain score was documented (n=2083; 26%). The characteristics of these excluded patients were significantly different to those of included patients, as highlighted in section *4.2.2.1 Initial data screening* and shown in Appendix *9*. This unavoidably introduced selection bias into the study, as the calculation of the dependent variable was essential. To minimise this selection bias in future, a study specific data collection tool (electronic or paper) that encourages the documentation of two pain scores rather than using routinely collected data should be utilised, or routine data collection software should be changed to mandate a second pain score when an initial pain score is entered.

#### 4.2.3.2.2 Information bias

Information bias is caused by errors in the measurement of collected information; when the wrong data is collected from the right people, for example instrument error or observer error (Law and Pascoe, 2013). The simplest way to minimise this

source of bias is to use reliable and valid tools to measure outcomes and ensure adequate training of staff to use the tools correctly (Law and Pascoe, 2013).

The validity of pain scoring tools for children is a concern, as none of the routinely used tools have been validated in the pre-hospital setting (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019b). This study assumes that the numeric pain rating scale, Wong and Baker FACES® scale and the FLACC scale are valid. It also assumes that these tools are used appropriately. This assumption limits the validity of this study as without non-participatory observation, as recently utilised by Sampson et al. (2019), there is no way of knowing whether staff use pain scoring tools appropriately and as validated. The results of the generic qualitative study (see section *4.3.2.2.5 Management*) showed that some clinicians use pain scales inappropriately and some do not use them at all, as discussed in section *4.3.3.2 Identification of barriers and facilitators*.

Defining 'effective pain management' as an objective measure (abolition or reduction of pain by ≥2 out of 10) may not be reflected in the patient's perceived experience. Although validation work had been undertaken (Powell et al., 2001, Bulloch and Tenenbein, 2002, Bailey et al., 2010, Voepel-Lewis et al., 2011, Myrvik et al., 2013, Tsze et al., 2015) it might be useful to consider subjective outcome measures in addition to objective measures in both clinical practice and future prospective research.

Determining the 'senior clinician' was challenging, as discussed at length in section *4.2.1.5 Data analysis* and while there was no ideal solution, I decided to assign the senior clinician based on rank initially followed by PIN number for cases with two paramedics on scene. This method of measurement of the 'senior clinician' may not accurately represent the clinician who made the decisions regarding pain management. To address this issue in future, a study specific data collection tool where the 'senior clinician' is identified on scene at the time of the incident could be utilised.

4.2.3.2.3 Confounding

Clinicians who were parents versus clinicians who were not *may* have influenced the rates of effective pain management; however, this data was not available for assessment. Future prospective research should consider this.

Confounding by indication was considered and explored (*4.4.2 Methods level*) as it was felt that paramedics were more likely to attend higher acuity patients reporting higher initial pain scores. *Table 12* (pg234) showed that paramedics attended children with a significantly higher mean initial visual pain score than children attended by technicians (p=0.0164). There was no significant difference between median initial visual pain score or mean/median initial numeric pain score. This difference may have influenced the analysis as the paramedic group may be more likely to show higher rates of effective pain management as the higher initial visual pain scores are more likely to achieve greater reductions by chance due to regress to the mean (Barnett et al., 2004).

4.2.3.2.4 Other limitations

The retrospective nature of this study meant that data could only be collected when clinicians documented their assessments and treatments in the appropriate sections of the clinical record, allowing electronic data extraction. Due to time constraints the 'free text' section of clinical records was not screened, therefore it was possible that some observations or treatments were missed.

EMAS clinicians could not report behavioural pain scores on the electronic PRF during the period of data extraction, except in the 'free text' section. EMAS follow the Joint Royal Colleges Ambulance Liaison Committee clinical practice guidelines (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019b) which advocate the use of FLACC (face, legs, activity, crying and consolability) as the choice behavioural pain assessment scale for pre-verbal children, therefore it was assumed that clinicians have used this scale where appropriate and reported it as a numeric pain score during documentation.

The influence of non-pharmacological pain management techniques such as distraction and staying close to relatives could not be assessed due to the difficulty of quantifying these approaches. However, the effects of other non-pharmacological treatments such as slings, splints, bandages and dressings were assessed.

Due to the lack of documentation, the impact of patient ethnicity on the dependent variable could not be determined. Data for clinician ethnicity was not available for extraction, therefore no ethnicity data was presented. This should be explored in future studies.

Type of incident location (home/public place/school) was not assessed within this study. This lack of social context placed limitations on the findings of this study and the integration section, particularly on the findings regarding deprivation (see *Table 14* pg235 and *Table 17* pg240). Whilst the meta-inference regarding deprivation (see *Table 17* pg240) focussed on the home environment and time spent on scene; aspects that are likely to be influenced by this limitation, the aspect regarding parental influence could apply in public places where parents are present or at schools when parents have been called, therefore the deprivation meta-inference may not be fully affected by this limitation. Further research would be useful to explore the phenomenon of deprivation and pre-hospital pain management in children.

Internal validity was deemed high due to the large number of potential confounders considered and the minimisation of selection bias by screening clinical records independently and in duplicate.

External validity was deemed high as some of the results match previously reported evidence (Jennings et al., 2015, Lord et al., 2019, Bendall et al., 2011a). The study population was diverse, encompassing a wide age range from urban and rural areas within a modern ambulance service.

#### 4.2.3.3 Implications for clinical practice

A large number of exclusions were made because no second pain score was documented (n=2083). Therefore, one recommendation for clinical practice was for organisations to encourage clinicians to document two pain scores when attending children likely to be suffering pain. This could be achieved by mandating a second pain score via the electronic software once an initial pain score has been entered. Turner et al. (2019) suggested new ways of measuring quality of care within ambulance services; one being mean pain score reduction. This will require the documentation of two pain scores, therefore audit and research will benefit from any organisational drive for pain score documentation compliance.

Further recommendations for clinical practice cannot be made at this stage as these predictors require explanation and the associated barriers and facilitators to the pain management process need further exploration. Further implications for clinical practice will be discussed in depth in the final chapter, see *Chapter 5 – Discussion and Conclusion*.

#### 4.2.3.4 Implications for future research

The identified predictors require explanation utilising a qualitative approach; one of the aims of the second phase of this mixed methods sequential explanatory study (see section *4.3 Generic Qualitative Study*). This integration of data will enrich the quantitative findings from this study by providing context from experience, culture and social norms. This will allow clinicians, policy makers and stakeholders to more comprehensively understand the reasons for the disparity in effective pain management.

Pain scoring tools for children should be validated within the pre-hospital setting and the appropriateness of their use should also be explored. Future research into predictive factors of effective pain management in children should consider patient and clinician ethnicity along with the clinicians' status as a parent.

### 4.2.4 Conclusion

Predictors of effective pain management in children were identified that match previously published data, including children who were younger, suffering traumatic pain and who were attended by a paramedic. A novel predictor was also identified; children living in an area of low or medium deprivation.

These observations require explanation to fully understand the underlying mechanisms. I aim to explain these findings in the next section, *4.3 Generic Qualitative Study*.

## 4.3 Generic Qualitative Study

### 4.3.1 Methods

#### 4.3.1.1 Study design and setting

A generic qualitative study (Caelli et al., 2003) was performed within one English ambulance service (East Midlands Ambulance Service NHS Trust [EMAS]). The justification for using a generic qualitative approach has previously been discussed (*2.3.4 Generic qualitative study*). EMAS was chosen due to the mix of clinician ranks, including paramedics and emergency medical technicians (EMTs). It was important to include both paramedics and EMTs within this qualitative study to help explain the 'paramedic crew' predictor identified in *Table 9* (pg120). In addition to this, it seemed logical to recruit participants from the same ambulance service from which the quantitative data was extracted. This was because the culture of the patients and relatives linked to the clinical records assessed in the cross-sectional study may be different to the culture of those in other areas of the UK (Galanti, 2000). Sociocultural differences may also be present in clinicians from different ambulance services, influencing the decision making process (Eisenberg, 1979). I felt that assessing patients and clinicians whose sociocultural norms interact due to their demographic of being in the same area (East Midlands, UK) would elicit a more accurate understanding of this complex phenomenon than assessing patients from one area and clinicians from another.

EMAS served a population of 4.8 million people over an area of 16,666 square kilometers across six counties covering both urban and rural areas (East Midlands Ambulance Service NHS Trust, 2017). Approximately 2,500 emergency calls were received per day and EMAS employed approximately 2,300 ambulance staff.

#### 4.3.1.2 Participants

##### 4.3.1.2.1 Inclusion criteria

- East Midlands Ambulance Service NHS Trust clinicians (paramedics/emergency medical technicians/emergency care practitioners [paramedics with enhanced primary care skills])
- Working on active front line duties during the last 12 months

It was important to include both paramedics and EMTs within the qualitative study. This was because the results of the cross-sectional study (see *Table 9* pg120) showed that children attended by a paramedic were significantly more likely to achieve effective pain management than those who were attended by an EMT. In order to understand this observation and explain why children attended by a paramedic were more likely to achieve effective pain management, experiences and perceptions from both paramedics and EMTs were required.

It was necessary that included clinicians were clinically active and had recent experience of managing pain in children. If for example, a clinician had experience of managing pain in a child from several years ago and had not been clinically active since, it could be argued that their experience was outdated and not reflective of the current level of care being provided to children. This was because organisational changes were likely to have occurred in that time resulting in changes to policy and practice.

#### 4.3.1.3 Sampling

Participants were selected purposively, specifically utilising maximum variation sampling, according to ambulance clinician characteristics (Green and Thorogood, 2018). Maximum variation sampling was used to ensure representativeness and diversity of findings by expanding the range of differences with a heterogeneous group of participants, rather than minimising the differences with a homogeneous group such as with snowball sampling for example (Palinkas et al., 2015). The benefit of maximum variation sampling is that it aims to capture the variability of experience, culture and social norms across a group of clinicians (Green and

Thorogood, 2018). Being non-exclusive in this sense allowed for a broader understanding; a necessity when aiming to delineate a complex clinical phenomenon such as pre-hospital child pain management.

The results of the cross-sectional study informed the sampling of the generic qualitative study (see section *4.4 Integration*), highlighting the need to include both paramedics and EMTs in the study.

An expression of interest was sent to all EMAS paramedics, EMTs and emergency care practitioners in the form of email, the service newsletter 'ENews' and the research newsletter 'EMAS AIR' (Actively Involved in Research). Data required from prospective participants for an expression of interest included:

- Name
- Contact telephone/email
- Clinical rank (paramedic/EMT/emergency care practitioner)
- Years of clinical experience
- Age
- Sex
- Clinically active in the last 12 months? (yes/no)

This information allowed the research team to purposively select an appropriate range of clinicians. Clinician rank data was required to ensure a mix of seniority, as *Table 9* (pg120) showed a significant difference in the rates of effective pain management between children attended by paramedics and EMTs. Clinician age, experience and sex were required to ensure a heterogenous sample, although these were not significant predictors of effective pain management (except for 60-69 year old clinicians at univariable analysis, which showed a negative association; see *Table 8* pg118). It was estimated that 10-20 participants would be required to achieve data saturation, based on sample sizes of similar studies (Williams et al., 2012, Murphy et al., 2014, Gunnvall et al., 2018, Holmström et al., 2019) and the literature on data saturation.

The concept of data saturation is contentious and complex but often freely stated in published papers (Green and Thorogood, 2018), perhaps without due diligence. Data saturation is considered essential to ensure the validity of one's findings (Fusch and Ness, 2015), requiring an open-ended approach (not setting an upper limit), with analysis occurring along-side the collection of data (Green and Thorogood, 2018). Data saturation is achieved when further coding is no longer feasible, there are enough data to replicate the study and when the ability to attain new information has been achieved (Fusch and Ness, 2015). Guest et al. (2006) stated that data saturation often occurs within the first 12 interviews, particularly when exploring a narrow research topic (Green and Thorogood, 2018). Hennink et al. (2016) investigated the concept of data saturation, concluding that nine interviews are needed to achieve 'code saturation' but 16-24 interviews are needed to achieve 'meaning saturation'. There is no 'one size fits all' in terms of data saturation and ultimately the number of interviews required to achieve data saturation depends on the individual study.

The number of participants was therefore dictated by the achievement of data saturation. I initially recruited three participants as pilot interviews, where major changes could occur to the interview schedule or technique. After completion and transcription, the data were deemed sufficiently 'rich' (Fusch and Ness, 2015). I then recruited nine more participants in an attempt to achieve 'thick' data (Fusch and Ness, 2015). During the process of analysis, fewer and fewer new codes were created as each transcript was incorporated. During the analysis of the last transcript no new themes were created, suggesting 'code saturation' had been achieved (Hennink et al., 2016). The number of participants included was twelve and I considered the data suitably rich and thick (Fusch and Ness, 2015) to address the objectives of this thesis (see section *1.4.2 Objectives*).

#### 4.3.1.4 Data collection

Participants were asked to sign a consent form before data collection began. Participants were assigned an anonymous 'Participant ID' for the purpose of the study and were referred to this code during the analysis and interpretation. The

'Participant ID' was a sequential number preceded by a 'P' if the participant was a paramedic or a 'T' if the participant was an emergency medical technician. It was necessary to illustrate these two different clinical ranks during the analysis and interpretation to help highlight any differences in experience or opinion, particularly for the predictor 'paramedic crew'.

Data collection aimed to address the following objectives:

- Explain identified predictors associated with effective pre-hospital pain management in children by ambulance services.
- Identify barriers and facilitators to the pre-hospital pain management process in children by ambulance services.
- Explore how pre-hospital pain management in children by ambulance services might be improved.

Data collection was achieved via the audio recording of in depth face-to-face semi-structured interviews (Green and Thorogood, 2018). Depth of understanding was required to satisfy the objectives of this thesis, therefore structured interviews would not have been suitable as they are in essence, verbally administered questionnaires akin to a survey design that allow no room for variation or follow up (Gill et al., 2008, Green and Thorogood, 2018). Unstructured/informal interviews generate significant depth by allowing complete freedom of discussion for a particular phenomenon, but are very time consuming and often take many hours to complete, potentially leading to tired, confused and disengaged participants and researchers (Gill et al., 2008, Green and Thorogood, 2018). It was felt that semi-structured interviews, lasting approximately one hour each, would provide the depth needed to understand the complex phenomenon of pre-hospital child pain management, whilst maintaining direction to address the specific objectives of this thesis (see section *1.4.2 Objectives*), without the participants or researcher becoming disengaged.

Group interviews were considered, such as focus groups, as they provide access to shared social meaning. Focus groups have been used within the context of pre-

hospital pain management in children to good effect (Murphy et al., 2014, Holmström et al., 2019), with other studies opting for semi-structured interviews (Williams et al., 2012, Gunnvall et al., 2018). Both techniques have benefits and drawbacks; as previously mentioned, group interviews allow the development of collective shared meaning, however this benefit is also its drawback as group interviews may not generate data about individuals, therefore marginal views may be missed (Green and Thorogood, 2018). Group interviews may be dominated by particularly vocal members resulting in the 'silencing' of marginal views; group interviews also produce less in-depth individual accounts (Green and Thorogood, 2018). It was felt that allowing participants to speak within an individual semi-structured interview, unhindered by more vocal members or members of perceived seniority, would elicit richer more in-depth data including marginal views that would have otherwise been unheard (Green and Thorogood, 2018).

Interviews were guided by an interview schedule, see *Appendix 11*. The interview structure and schedule were informed by several mechanisms, including the findings of the systematic mixed studies review, the cross-sectional study and wider reading of the literature. Firstly, the opening of the interview started with the participant discussing an incident they had attended regarding a child in pain. The use of vignettes can act as an ice breaker and facilitate the conversation (Barter and Renold, 1999). In this case, the participant provided the vignette from their own experience.

This vignette was then used to facilitate the second stage of the interview. This involved contrasting and comparing different scenarios, in an attempt to elicit explanation and reasoning as to why the participant felt there may have been a different outcome or different management of two scenarios. For example, if the participant used a traumatic injury vignette, the exact same case was proposed, same child age, same sex, however with a medical source of pain. The participant was then asked if they would expect any aspect of the scenario to change, and if so, explain why. This second phase was informed and guided by the results of the cross-sectional study (see *Table 9* pg120), with the focus being placed on explaining the significantly associated predictors (child age, type of pain, paramedic crew and

level of deprivation). Other proposed predictors were discussed including predictors I was unable to include in the multivariable logistic regression, for example the clinician's status as a parent.

The third phase of the interview aimed to identify barriers and facilitators to effective pain management. This was exploratory in nature, but prompts were available on the interview schedule informed by the results of the thematic synthesis from the systematic mixed studies review (see *Figure 5* pg81).

The final phase of the interview aimed to explore ways to improve pain management in children. This was entirely exploratory with no prompts. A heavy reliance was placed on the clinician's ability to provide insights into the changes they would like to see in the future. The interview ended with a chance for the participant to add any further comments they felt were necessary.

#### 4.3.1.5 Data analysis

Audio recordings were transcribed verbatim by myself. Transcription of recorded audio files to written text is an art form involving translation; variation in transcription ability among researchers is a concern as phrases and sentences can easily be misinterpreted by incorrect use of punctuation (Green and Thorogood, 2018, Davidson, 2009, Bucholtz, 2007). One benefit of verbatim transcription is that it creates a clear audit trail from interview to developed themes; however verbatim transcription is a highly technical and lengthy process and subject to errors, therefore the advantages and disadvantages should be carefully weighed (Halcomb and Davidson, 2006).

The decision to transcribe the audio recordings myself was two-fold. Firstly, transcription of audio recordings allows the researcher to become immersed in the data, facilitating the first step ('familiarising yourself with the data') of my chosen method of analysis, thematic analysis (Braun and Clarke, 2006). Secondly, transcription services were not free of cost, and there was no funding available for transcription services; if funding was available for transcription services I would

have ensured that I transcribed at least 50% myself in an attempt to satisfy the former reason.

After audio recordings were transcribed in full, I re-listened to the full interview whilst reading the transcript at the same time, adjusting grammar and typos accordingly. This 'spot-checking' of all the transcripts aimed to reduce errors during the transcription process (Poland, 1995, MacLean et al., 2004).

Thematic analysis (Braun and Clarke, 2006) was used to analyse the data. The decision to use thematic analysis over other types of analysis such as the Framework method was difficult and required some deliberation. The Framework method of analysis (Ritchie and Spencer, 1994, Gale et al., 2013) is considered a branch of thematic analysis and shares many of its features. It was originally developed in the late 1980s by Ritchie and Spencer to inform policy change (Gale et al., 2013). The Framework method applies a systematic structured approach, however this was considered a hindrance to a study aiming to satisfy multiple objectives that required more freedom within the analysis. The broader generic thematic analysis approach was deemed more accommodating for my thesis, considering the multiple objectives.

Respondent validation is the process of returning the findings of a study back to participants to check they agree, however this is a questionable method of providing validity (Green and Thorogood, 2018). A thorough analysis of qualitative data often involves navigating contradictions and conflicts between participants; neither participant is right or wrong, but the conflict itself provides useful insights. Unanimous agreement of the findings is unlikely to be achieved in these circumstances, and disagreement among participants regarding the findings would not necessarily mean the findings are incorrect. More importantly, respondent validation assumes there is a 'true' account of experience regarding the phenomenon of interest to be understood and agreed upon. It is unlikely that the participants would hold the same views as those generated from my analysis (Green and Thorogood, 2018). Considering the postpositivist lens and modified objectivist epistemological stance adopted for this thesis, as discussed in section *2.1.2 Philosophical paradigm*, respondent validation was discussed between myself

and my supervisory team and deemed unnecessary, as we may never know the truth, but our findings are probably true.

The analysis of data was both inductive and deductive. The initial thematic analysis explaining the predictors of effective pain management was performed using a largely deductive approach, utilising the interview schedule (see *Appendix 11*) as a framework. The second thematic analysis identifying barriers and facilitators was performed inductively and deductively; a number of different mid-range theories and models were used to frame this analysis, specifically comfort theory (Kolcaba, 1994), the biopsychosocial model of health (Engel, 1977) and competency frameworks stemming from Abdolmohammadi and Shanteau (1992). The physical and environmental aspects of Comfort Theory (Kolcaba, 1994) were combined with the psychological (emotional) and social aspects of Engel's (1977) biopsychosocial model along with the competencies of knowledge and experience identified by Abdolmohammadi and Shanteau (1992), with the addition of management and organisational factors to create a bespoke framework for the thematic analysis. The final thematic analysis exploring how pain management could be improved was performed entirely inductively and without any specific framework. Themes were generated organically and there were no specific prompts during the interview to guide participants.

From a reflexive stance, the role of the researcher within this study was considered. As a fellow clinician to the participants in this study, I was able to discuss clinical cases, scenarios and decision making in depth and from a level playing field. As a clinician, I shared the culture and prior understanding of the clinical participants (Odendahl and Shaw, 2001) enabling me to pursue more in depth details, as simpler concepts and terminology did not require explanation. As a clinician I was able to gain the participants' confidence with relative ease; a phenomenon that has previously been described (Aira et al., 2003). There was a slight concern that my status as a clinician may have created 'blind spots' (Aira et al., 2003) where seemingly simple concepts that are taken for granted may be overlooked. These 'blind spots' may be identified by non-clinical interviewers who have no preconceptions (Iversen et al., 2002, Coar and Sim, 2006). It was felt that the

rewards of gaining confidence and a deeper understanding outweighed the risk of not identifying some concepts due to preconceptions, therefore the decision to interview clinicians was not only justified but added strength to this study.

#### 4.3.1.6 Ethical consideration

Ethical approval was gained from the Health Research Authority following research ethics committee approval (18/NI/0120). Approval was also gained from the East Midlands Ambulance Service NHS Trust Clinical Audit and Research Unit.

### 4.3.2 Results

25 clinicians expressed an interest and 12 participants were included within this study, characteristics of which can be found in *Table 11* (pg143).

The results of this study aimed to satisfy three objectives (see section *1.4.2 Objectives*), to explain the predictors identified in *Table 9* (pg120), identify barriers and facilitators and explore ways to improve pain management in children suffering acute pain. The most effective way to illustrate the findings and demonstrate the achievement of these three objectives was to perform three separate thematic analyses.

#### 4.3.2.1 Explanation of predictors

All potential predictors were discussed at interview, however only the statistically significant predictors along with two non-significant predictors; type of pain and child sex, were included in this results section. Type of pain and child sex were included because their 95% confidence intervals (0.97-1.43 and 0.98-1.39, respectively) cross the line of no effect only by a small amount and they have both previously been identified as significant predictors (see *Table 2* pg75).

Table 11 – Generic qualitative study: Participant characteristics

| **Characteristic** | |
|---|---|
| Age, years | |
| Median, (IQR) | 43.5 (41.5, 45.75) |
| Mean, (SD) | 42.33 (6.02) |
| Minimum value | 30 |
| Maximum value | 49 |
| Sex | |
| Male, n (%) | 7 (58) |
| Female, n (%) | 5 (42) |
| Rank | |
| Paramedic, n (%) | 9 (75) |
| Technician, n (%) | 3 (25) |
| Experience, years | |
| Median, (IQR) | 12 (4.25, 15.5) |
| Mean, (SD) | 10.75 |
| Minimum value | 1 |
| Maximum value | 23 |
| Parental status | |
| Parent, n (%) | 7 (58) |
| Non-parent, n (%) | 5 (42) |

IQR – interquartile range, SD – standard deviation

4.3.2.1.1 Child age

Explaining why younger children were more likely to achieve effective pain management than older children was challenging, as many participants reiterated findings from the systematic mixed studies review thematic synthesis (see *Figure 5* pg81), stating that younger children are more difficult to assess, cannulate and administer inhaled analgesics (see section *4.3.2.2.5 Management*).

There were some interesting concepts that may shed light on this difficult explanation. The main themes arising from this explanation were that younger children express more emotion, they live more in the moment and are therefore easier to distract than their older counterpart who dwell on the consequences of illness or injury.

Many of the participants stated that younger children express more emotion:

*'whereas the younger, younger one you have to appreciate that they are still in those formative years, erm, and so need a little, probably a lot more, sympathy, erm in terms of the initial approach and management, as regards to the, the erm… the emotional, impact on the injury for them as opposed to the actual injury, and the fact that they are in pain and they've had this shock, is worse in a 2 to 3 year old than perhaps it is to a, somebody a bit older…'*

Participant P01

With some participants stating that relatively minor injuries are perceived as extremely painful in younger children:

'*I mean children fall over and they, have the tiniest graze on their knee and they, scream don't they for… 10, 15 minutes for a … Effectively a graze … You wouldn't get that with a 15-year-old.'*

Participant P03

Participants felt that younger children lived more in the moment than their older counterpart:

*'the younger ones very much live in the moment, I've either got pain or I haven't, there's nothing much in between the two so, I think, anything that you do for younger children tends to have a more immediate effect than say, the older age group'*

Participant P02

Participant P02 took this statement further by giving an example of their own children:

*'I've got two boys and they both broke their arms within four weeks of each other, we had a hell of a summer, and, the attitude from both of them was very different the five year old, it was very much in the moment, I've done this it's awful it's dreadful I'm screaming I'm crying, three or four weeks later when the arm's feeling better he's using the cast as a battering ram.'*

Participant P02

Due to younger children living more in the moment and being more emotional, it was found that younger children are easier to distract:

*'I think, yeah, I think the younger ones are more likely to get an instant… relief from it because they're an easier age group to distract…'*

Participant P02

This was verified by another participant stating that younger children are more likely to have a positive reaction to stickers, teddies and comfort:

*'I can imagine asking a 15, 16-year-old boy "here's a sticker for bravery" and stuff like that, he'd probably throw it back in my face or something like that [laughter], but I just, I just feel erm, it's, it's sort of, it's, it's something that the, the younger child knows as, as sort of a, a good, in a, in a good place you know, they know that, their, their, their favourite teddies, their comfort and stuff like that … so I find with the younger ones that's a lot more effective than I would say with the older ones.'*

Participant T01

Participants stated that older children think more long-term, and perhaps are more likely to dwell on the consequences of their illness/injury, concerned perhaps about an upcoming sports match:

*'Whereas, the older ones will still be thinking about, the thing that caused the pain in the first place, and thinking further ahead and worrying about, things…'*

Participant P02

With participants stating that older children have more comprehension of the injury making them more anxious:

*'the only difficulty is, with an older child because they do understand more, they're probably erm, more worried about the injury they've got… so they're probably more frantic about the injury'*

Participant P05

4.3.2.1.2 Analgesic administration

There was clear acknowledgement from all participants that analgesic administration should predict effective pain management. The two themes arising were that analgesics reduce physiological pain and psychological distress.

Participants felt that analgesics reduce physiological pain:

*'Oh yeah she was in agony, she was… she was not quite screaming but she was very vocal in a lot of pain she was very tearful there were tears running down her face, she didn't want anybody to touch it, erm, overriding our, I remember her saying "don't touch it don't touch it don't touch it", and it wasn't until the morphine had taken effect that she allowed us to even splint it'*

Participant P03

With participants stating that analgesics have the potential to completely remove pain:

*'when the morphine went in that was perfect because erm pain went from, from about 8 to a 0 I think it was, it was nothing left.'*

Participant T01

In addition to acknowledging the physiological effect of analgesics, participants were eager to mention the psychological effects and likened them to the placebo effect:

*'And also then you've got the, you're giving him something for the pain so you've got the psychological side that "I've had something for the pain" as well'*

Participant P06

With participants stating that children learn an association between taking medicine and feeling better:

*'And I suppose to, for, for a child of seven there is probably an association with the paracetamol that it would, it makes you better, so I don't know what kind of placebo effect there would be as well'*

Participant T03

4.3.2.1.3 Paramedic crew

Children attended by a paramedic were more likely to achieve effective pain management than those who were not (see *Table 9* pg120). The main themes arising included paramedics having a higher scope of practice, as they can administer morphine and technicians being less confident, having less scope of analgesics to administer therefore spending less time on scene. However other themes included the lack of perceived difference between paramedics and technicians and people skills being more important than rank.

Many of the participants stated that there should *not* be a difference in rates of effective pain management in children between paramedics and technicians:

'*everything else that I can do as a paramedic a technician can, can do as well*'

Participant P02

*'Erm, no, no difference at all, there's nothing that I did that was not outside the scope of practice for a technician. I had a trainee technician with me who led, and I allowed them to lead, just giving guidance where necessary because they'd never dealt with a burn before, but I allowed them to lead, and they, erm, were with this child because the pain relief was adequate there was no need for me to step in, they could manage it.'*

Participant P05

Other participants stated again that there should be no difference and that people skills were the most important factor:

*'it's not just as I say being a paramedic it's, it's anybody you know, if I was with another technician or even an ECA [emergency care assistant] it's, it's just that individual person's ability to be able to help control the situation and not get themselves erm, worked up'*

Participant T01

Some participants were able to explain why children attended by a paramedic were more likely to achieve effective pain management. Participants stated that paramedics have a wider scope of analgesics that included morphine sulphate:

*'The only difference I can see is the ability to give the Oramorph, the oral morphine'*

Participant P02

*'Erm, I think, obviously paramedics have got a little more in their arsenal when it comes to pain management'*

Participant T02

One participant (technician) discussed their confidence level, stating that they felt more comfortable with a paramedic on scene who had more experience and clinical knowledge:

*'I guess, having a paramedic there for the technician is a bit of peace of mind that the technician's got someone who's got a bit more experience and bit more sort of, erm, clinical knowledge'*

Participant T01

It was also clear that technicians spend less time on scene, in part due to less invasive interventions:

*'They would have probably left scene quicker … Because, the less skills that you have available, then, erm, if they'd been a technician crew they wouldn't have spent 5, 10 minutes cannulating giving pain relief and waiting'*

Participant P03

With some participants stating that paramedics are not always available and often the decision to 'load and go' is taken:

*'you can always request a paramedic and sometimes you, you know, if you're lucky to get a paramedic, great, if not then you know, there might not be no paramedics around, so perhaps we maybe rush it and go "right we'll just get, load and go", solve the problem.'*

Participant T01

There was also conflict between participants regarding the scope of analgesics available to technicians, with some stating that it was adequate:

*'the pain relief options that are currently available, erm and I think for the vast majority of patients we deal with they are sufficient for, for us as technicians'*

Participant T02

However, others felt the technician scope of analgesics was inadequate:

*'they're going to be restricted to, erm, Calpol really, you know, Entonox is a hand held delivery system, two broken wrists, he's not gonna be holding it … So they're gonna really struggle in that situation you know, they're gonna be looking for either backup or they're gonna try and manage with a very upset painful kiddy to A&E'*

Participant P06

*'I think, barriers as a technician, it does come down to scope of practice and I think we're limited in what we can do, erm, I think the pain relief sort of medication that we as technicians have got is, is not, for sort of immediate acute, yeah acute sort of pain it's not fit for purpose in a way, the only thing we've got to our, really to our, erm, disposal is, is Entonox and that's only for certain, obviously it's got cautions to and, and obviously erm, contraindications for so again we're limited on that as well, everything else just takes too long or you know, trying to get a child to swallow pills is even worse so you know, it's, it, it, yeah we're very, very limited in terms of that'*

Participant T01

4.3.2.1.4 Level of deprivation

Children from less deprived areas were more likely to achieve effective pain management than those from more deprived areas (see *Table 9* pg120). This predictor was novel, not previously identified in the literature in this context and population, therefore the explanation of this predictor was considered a high priority. Level of deprivation however was the hardest to explain due to many

contradicting experiences and perceptions. For example, some participants stated that parents from areas of high deprivation were more likely to administer analgesics to their child before ambulance arrival, yet others felt that parents from areas of low deprivation were more likely to administer analgesics early. Themes arising were that children from areas of high deprivation lived in unkempt environments (dirty, untidy and disorganised), had limited access to transport and their parents had limited analgesic stocks in the house. Children from areas of low deprivation had more demanding parents who sought help earlier and relied more on advice to treat their child. The final theme was that clinicians felt deprivation did not influence their clinical practice.

Many clinicians stated that a child's social background does not influence their clinical practice:

*'Erm, from an ambulance perspective I would say it shouldn't make any difference at all, that you would treat every child equally, regardless of their, regardless of their background.'*

Participant P03

*'I would hope the, the treatment wouldn't change, you know in terms of, if he was from an affluent area or non-affluent area it's still, it's still the child and it's still the same issues and stuff like that so I'd, I would hope there'd be no sort of change there just because of that'*

Participant T01

Some participants stated that more affluent families were likely to be more demanding:

*'So yeah, so, the, more affluent probably want better understanding from you what your intentions are to do, whereas those at the lower end are, for want of a better phrase, erm, sounds really crass but, aren't really fussed what you do as long as you take the pain away'*

Participant P06

*'So they'll [more affluent families] want us here yesterday, and they'll want that child treating, and they won't necessarily agree that we have the tools to treat them, and although they may want to start to treat them and they may want to be doing things like erm, breaking down "stranger danger" barriers and creating a relationship with that child, they just want that child in to see somebody they feel is as educated and knowledgeable as they are … ie a doctor, a consultant, a surgeon, somebody like that, opposed to a param-, an ambulance man'*

Participant P07

Participants felt that more affluent families seek help earlier, perhaps through their GP or non-emergency services such as 111:

*'more affluent areas tend to sort, we don't go to quite so many I think because they tend to sort their own children out, they're a little bit more capable of picking up the phone ringing the doctor earlier on getting children into the GP earlier, getting them down to hospital under their own steam, so we don't tend to go to quite so, as many, well-off families if you like, I think they tend to have, they're more articulate at being able to access the help earlier, if a child's medically unwell for example than perhaps a, a, another household is'*

Participant P02

*'The affluent have probably tried GPs … The out of hours services and things like that, whereas the others probably haven't considered it.'*

Participant P06

Participants stated that more affluent families were more reliant on help and advice to treat their child, with one participant stating that wealthier families do not feel comfortable making decisions regarding their child's health care or when to administer analgesics and that a sense of social responsibility has been removed:

*'in the two different areas I think that there is a, an area, well, the, the poorer, you get on with life, you get on and you do it, the wealthier the more affluent area, it's almost as though, a social responsibility towards our own health care, our own management of our health, has been removed and they no longer feel comfortable making decisions, how to look after their own children, how to look after themselves, when to give pain relief and, it's so much easier to be, to do it when you're told to do it by a doctor, a nurse, a paramedic, and it, it is absolutely, it's visible, erm, and it always amazes me.'*

Participant P04

With other participants stating that less affluent families were more likely to 'get on with it':

*'Erm socioeconomic type situations, environment, working class dads, working class families, suck it up, get on with it, expectations are different.'*

Participant P07

*'I'm from a, my background is from not being from a, from a quite poor area where I was born, and also a, an era whereby erm, parents used to say to you "crack on, get up, what's wrong with you" sort of thing, and I think that still, I think that still goes on, in the, more deprived Western areas, I think there's an element of, erm, parents that are hardened to it and, don't make as much out of things as what necessarily other people do…'*

Participant P09

Participants stated that the environment was often unkempt when attending families from an area of high deprivation:

*'I think it'd be like, you know, if you going to the really low end of things you know, you go into houses that are generally unkempt'*

Participant P06

With participants stating that it was easier to manage a child in a tidy, kempt home:

*'It definitely made a difference in terms of the hou-, the environment, erm, the environment for the male patient was clean and tidy erm, wealthy parents and I could, they had toys all laid out and it was nice and neat and clean whereas the female patient was in a house that was, barely enough room to walk let alone sit down anywhere, definitely a poorer family.'*

Participant P05

It was stated by participants that families from less affluent areas often had transport issues, stating they struggled to get to the GP or were concerned about how they would get back from hospital:

*'they [less affluent families] have more issues with transport to get that child to the doctor at the hospital which is why we tend to go'*

Participant P02

*'I think there's a fear, from experience, there's a fear of families who don't have cars and don't have money, about how they're going to get home, when they ring an ambulance, so I don't know whether that would affect them ringing an ambulance, because there's always that, "I don't know how I'm going to get home, I've got another child in bed, I've got no partner, no money, no taxi, no car, how, I can't come to the hospital, you know you can't take my child because… I've got no way home", and, and that's really, financially driven that isn't it.'*

Participant P03

The final theme arising that may help explain the disparity around level of deprivation was that many participants felt that children from less affluent families may not have received analgesics in the home due to the cost:

*'Erm, income you know, the lower end may not have any medications in the house to manage pain anyway so you, you're thinking "oh", you know, "for a few quid you could have got some Calpol, or some paracetamol in", whereas those that have got the cash have probably got that and may have already gone down that road anyway'*

Participant P06

*'Clearly Calpol is not free, it costs money and if you're on a budget where you can only just afford to buy food for your children and yourself, then Calpol can be, I don't know how much it is, 3, 4, 5 pound a bottle I assume … so, there's a possibility parents haven't adequately managed, pain for children and they may call an ambulance at a lower threshold … Because they haven't had the money to buy the analgesia, whereas maybe affluent, more affluent families always have Calpol in the cupboard'*

Participant P03

4.3.2.1.5 Type of pain

Although not statistically significant (see *Table 9* pg120), there may be a disparity between children suffering traumatic and medical pain; findings from previous research suggest that children suffering traumatic pain are more likely to achieve effective pain management than those suffering medical pain (see *Table 2* pg75). Participants stated that they expected a difference and provided explanations for this proposed disparity. The main themes arising were that traumatic injuries are visible, leading clinicians to presume pain which ultimately creates urgency, whereas medical sources of pain are more complex, creating a 'longer game' where symptoms have often been ongoing for a longer period of time and the assessment process takes longer.

Participants stated that traumatic injuries are visible, due to the presence of blood or deformity for example, whereas medical pain is not visible:

*'Yeah so physically seeing the injury, and the distress of the child, which is why I think we're probably better at trauma than medical because there's, if you see broken bones and bleeding bits and burns and scalds, it makes it really easy to go "I know this kid's in pain", whereas it might not be as easy to look at somebody that's a bit gripey with belly ache at 3-years-old to fully appreciate how much pain this kid's in'*

Participant P08

*'I think, with medical because you can't see it there isn't the shock factor as a clinician you don't walk up look at it and think "ouch".'*

Participant P03

Participants stated that because traumatic injuries are visible, there is a presumption of pain with trauma:

*'when there's an obvious injury, that everyone looks and goes "uhhh, that must hurt", but when you can't see it people just like, especially in children that can't communicate with you it's almost like "uh what's wrong?" sort of thing you know'*

Participant P09

*'I can see how, you know, someone's got a bone poking out, that you would automatically realise that that's very painful, erm and want to take that pain away, whereas if somebody's complaining of tummy ache it's subjective isn't it, erm, your tummy ache might not be as bad as my tummy ache, kind of thing.'*

Participant T03

Participants felt that because traumatic injuries are visible, coupled with the presumption of pain, it creates a sense of urgency to treat the pain:

*'Erm, the burn I think carries more, urgency, for me as, as an ambulance clinician, because it is an immediate, erm, it's a, it's a, it's a visible, pain, erm, as opposed to being more visceral'*

Participant P01

*'In trauma I would say so yeah, I would think that you definitely, that's probably up there, as soon as you see someone who's screaming with a, you know whatever traumatic injury, you want to take that pain away.'*

Participant T03

It was clear there were more challenges associated with medical pain, participants stated that medical pain is more complex:

*'medical is a bit more in depth because there's so many organs and things that it could be.'*

Participant P05

*'Yes, yeah, you know, generally there's a, a pretty straight forward erm, process to your trauma you know, him, riding bike, fell off … Cause and effect. Medical, "when did it start?", "how did it start?", "what were the preceding symptoms?" you know, it's, it could have been days, you know, so it's trying to pin point, you know trying to pin point a start you know, it's a n-, not necessarily an obvious start you know, "was it food poisoning?", "Was it not food poisoning?", "Was it", you know, "have they opened their bowels recently?" You know, and you've got to go down all that kind of process'*

Participant P06

Participants also stated that medical pain was a 'longer game'. Trauma is very much instant, cause and effect, whereas medical pain has often developed over a longer period, therefore there seems less urgency and because of the complexity it is more difficult to assess and manage:

*'they don't tend to be rolling around, screaming they've not got the upset of something suddenly happening to them quite so much with medical it's sort of crept up, erm… it's, it feels like a longer game to play if you like rather than a short one with a trauma, does that make sense?'*

Participant P02

*'Whereas if it's tummy ache you have to work out if it is tummy ache, and can they have Entonox because there's contraindications and, you know is it a bowel obstruction? Is something going on that would contraindicate my plan? It's more complex, I think getting to the bottom of what you can do is probably, and then there's the questions, kind of, potentially, the same as the paracetamol, how many hours? What's it been? What have they already had? But, I think I took a well child who had a, a traumatic injury… but with a poorly child that's got pain, that's probably been some kind of build-up there's probably more history to gain…'*

Participant P03

4.3.2.1.6 Child sex

Child sex was very difficult to explain because many participants expressed shock at the concept that male children have different outcomes to female children. The two themes arising were that there was no perceived difference between male and female children and the possible explanation; male children act tough.

Most participants felt there was no difference in the treatment of male versus female children:

*'I can't think I would necessarily treat a girl or a boy differently in pain its… the younger they are the more, the same they are, if that make sense?'*

Participant P02

*'I mean it's not something I, I've considered, I don't, I can't, I think historically there's not been any difference, you know, when you're looking at jobs across the sexes you know, I think the ages influences things but not necessarily the sex.'*

Participant P06

*'Erm, no not really erm, I don't think, no I don't think gender would, would play an issue, I think, i-if the same injury if it had been a female, the treatment would have been exactly the same, erm, we would have done exactly the same in terms of exposing, same, same erm analgesic you know, everything would have been the same I don't think there would have been a difference between, if it was male or female'*

Participant T01

The only form of explanation for the potential disparity was that participants stated male children act tough, boys are raised to be tough and not to cry:

*'Erm, perhaps in… school children, probably more so in, in males, erm, there might be an expectation to, erm, tough it out in front of their school mates as opposed to actually, [laughter] submitting and going yes, just, just, just give me something, p-probably thinking more senior school now, so you know, essentially, you, they're adults aren't they, n-near enough but, perhaps the, early teens they might be a little bit more, bravado, and erm, "no, no I'm alright I'm alright I can manage", that, that could be an element of, could be a barrier to us actually, doing what we're, what we're trying to do'*

Participant P01

*'but the sort of society attitudes of the girls are the princesses and the boys are the roughty toughtys, still, you know is, still going strong [laughter] in some areas of [Anonymised] and it's quite, difficult to get past that sometimes with parents that, yes the child's is in pain but, just because they're a girl doesn't mean to say they're experiencing the pain any more than a boy would in the same situation'*

Participant P02

4.3.2.2 Identification of barriers and facilitators

Participants were asked to identify barriers and facilitators that help or hinder the pain management process in the pre-hospital setting for children. Known barriers and facilitators identified from the systematic mixed studies review thematic synthesis (see *Figure 5* pg81) were used as prompts during this section of the interview. The following themes were developed; physical, emotional, social, knowledge and experience, management, environmental and organisational.

4.3.2.2.1 Physical

Participants discussed the physical bodily sensations that were experienced by the child. This primarily focussed on the visualisation of traumatic injuries specifically from the point of the child, explaining that it might heighten the child's experience of pain:

*'if they can see it erm, it's, it's not normal erm, they're gonna, they're gonna erm potentially exacerbate the, it's, they're gonna exacerbate their own erm, distress aren't they really, erm, if a, if a child can visually see that their ankle's pointing the other way, erm, it's, that's, that's not gonna be good for them, they're gonna feel, they're go-, they are gonna feel that pain quite a lot, especially when we start sort of manoeuvring and manipulating or whatever … Erm, if there's blood, obviously, erm, children resemble blood as bad so you know they, that sort of makes things worse, erm, so yeah I think erm, the, the visualisation of it'*

Participant T01

*'Yeah, yeah, they, they can see that something has changed on their body as opposed to something that's, inside the torso … That they can't, that they have no idea what, what's causing it. That, that could equally be as, as traumatic but, I think v-visualising something can be as bad if not worse…'*

Participant P01

This physical visualisation of trauma was considered a barrier due to its ability to exaggerate the child's perception of pain.

4.3.2.2.2 Emotional

Participants identified emotional influences from the child's and the clinician's perspective that were likely to impact the pain management process. Sub-themes identified here were: child fear/hysteria, child embarrassment, child shame, clinician empathy and clinician fear of treating children.

The child's level of fear or hysteria was considered a major barrier, as it was felt to exaggerate the child's perception of pain and promote catastrophising (defined as '*the tendency to exaggerate the threat value of pain and negatively evaluate one's ability to deal with pain*' Hirsh et al. (2008) pg806):

*'I think it's very difficult to distinguish what is fear and what is pain, and we could end up highly scoring a child for pain, because they're hysterical, and saying they're a 10 out of 10 pain and we could end up over-treating… because maybe we're treating fear'*

Participant P03

*'once we'd got the initial hysteria and anxiety controlled, that erm, allows to, to break down that, that cycle that, that erm inward cycle of, of, of pain.'*

Participant P04

*'And it was just [click] like flicking a switch, once he calmed down that was it, we got something into him and explained everything, he was fine but it's just trying to break down them initial barriers.'*

Participant P06

Participants also stated that children may be suffering from embarrassment, particularly of their own body, which can hinder the assessment of pain:

*'Erm, I think then they're starting to get more body conscious, erm so they might not want you to strip them down … he refused take any of his clothes off because he was embarrassed … Erm, and I guess that's not logical it's, but at that age you're probably not as logical as you are when you're, through the joys of adolescence erm, so yeah I think it gives you a whole different set of challenges when they're starting to get pre-pubescent and teenagery'*

Participant P08

One participant highlighted the possibility of boys feeling shame, because they feel they have let their dad down by not being tough:

*'I think little boys sometimes, are fearful that they let their dads down … By showing pain, or crying … Or wimping'*

Participant P07

It was felt that emotional factors from the clinician's perspective influenced the process, with participants stating that clinicians fear treating children:

*'I think people are scared of giving pain relief to children, erm, more advanced pain relief especially because of the effects it may have, and it's not something we do very often so it's quite a big thing to think about, and then gaining access to give further pain relief, Calpol is one that you know, people give to their own children and, but anything more than that is quite a, it's a barrier for the clinician I think.'*

Participant P05

*'I think, historically for ambulance staff, I think if you ask any, any ambulance member of staff what they dislike going to most it'll either be maternity or children, and it's because of the complexities of children … I've worked with a few people in the past that'll just go "oh my god it's a kid, can you deal with it?"'*

Participant P09

It was also apparent that the clinician's level of empathy was subject to fluctuation, depending on the type of shift, service demand and the status of their personal life:

*'**P:** Yeah I think it's times in life erm, and I guess that's around you as a person, what you're going through with life at the moment, how well you are, how, busy you are, the run of shifts you've had recently, the jobs you've had, whether you're happy, healthy.*

***I:** Do you think that could influence your assessment and management of children?*

***P:** Yeah erm, and again that's that kind of burn out you know if you get into the clinician burnout fatigue thing you're not gonna manage any job as well as you should be doing'*

Participant P08 (**P**=participant, **I**=interviewer)

*'So, middle of night, people are tired, that always seems to have, although it should never do, it always seems to have an effect on how people erm, approach people or some individuals approach people'*

Participant P09

4.3.2.2.3 Social

The social interactions between the child, the parents and the clinician seemed to play a pivotal role in the pain management process. Sub-themes emerging from the analysis included; importance of managing the parents, developing trust with the child, calm relaxed approach and teamwork with colleagues.

The importance of managing the parents was key to many participants, with some stating that it was as important to manage the parents as the child:

*'Because it's not just a case of managing the child is it, you're managing the parents as well, because quite often, they, they could exacerbate the situation, you know if they're really stressed or really distressed, that feeds into the child as well, erm, so you're trying to manage both the child and the parent at the same time, erm, and I think if you can calm both down, you know, "I'm not panicking, no need for you to panic" you know, then, that helps the situation'*

Participant T03

Effective management of the parents/relatives on scene was considered a facilitator. Some participants stated that parents can help the pain management process by remaining calm and relaxed on the outside, even if they're panicking on the inside, because the state of the parent is often reflected in the child:

*'And then you have other parents where, they're almost so, so laid back they're horizontal, "oh yeah they'll be fine", and the situation's a lot easier to cope with, they'll be more cooperative, they'll help with what's needed, they're quite pragmatic and very, you know, "sorry we've had to call you but we couldn't get them in the car" or "this has happened" or… you know. And you can see they're panicking underneath but they're keeping it calm for the child so that it does have a big, yeah, it does have a big influence on what, what's happening, in the attitude of the child, because that's how children learn isn't it, it's from parents and the reaction of the people around them, and that's how they learn to react to certain events.'*

Participant P02

However, some participants stated that parents can hinder the process by panicking, therefore calming panicked parents was deemed essential:

*'dad was vomiting, so dad had lifted the trou… erm, pulled the sock down and he'd seen this fracture and dad was vomiting and that terrified the child as much as the injury that the child had. I think if the parents are really stressed, then the child picks up on that stress, whereas I think calm parents help calm children.'*

Participant P03

*'if the parents are frantic and you can't get through to a parent there's no way you, the child's not gonna trust you either.'*

Participant P05

The interaction between the child and clinician was identified as very important, and the development of trust was described as essential by many of the participants:

*'Yeah so, gaining trust from a child is erm, quite difficult so, erm, she was not happy, she was cold, that was her biggest problem because she'd been put in a shower, erm, so getting anywhere near a child that is cold is quite difficult especially when they don't know you so, getting the burns dressings on as quick as possible so that she could then have something over the top of her skin, her favourite jumper, which then trusted us, she then trusted us and she was quite happy then, then to take pain relief, if we hadn't have done that first there was no way that she would have had anything from us, any observations.'*

Participant P05

*'The erm, the interaction with the child, I think gaining the trust erm, is a massive thing, it, once you've lost that with a child, sometimes it doesn't really matter what you do, the, the trust thing and once they get to trust you and once they feel easy and comfortable they become more compliant with information that you're gonna give 'em, they're more open to let you have a look at them, you know, the injury 'cause obviously their first thing is, is "this is gonna hurt if I let him touch it" … So the big softly softly approach first before anything else really.'*

Participant P09

Participants stated that a calm relaxed approach was essential to facilitate the pain management process, lowering the tension and stress of the situation and allowing a true assessment of the pain to take place:

*'if you try and go in all guns blazing and "right we need to do this and we need to do this" and there's some of them that, they get this tsunami of, of strangers coming in, interfering with them and trying to put things on them and, and that's upsetting itself as it is … So it's, it's being a bit softly, softly and coming in and… letting the child get used to you being there before anything happens, because it's already, they're already in a bad place anyway…'*

Participant P01

*'Like you say, it's a matter of calming them down isn't it initially and, trying to get the, because when you go in, that whole situation is quite heightened isn't it, but it's very different after about 10 minutes when you've built up a bit of a rapport and you've got them a little bit quieter and calmer you can probably get a, a truer sense of, of what's happening and how their feeling, as opposed to when you're going in and they're screaming and crying initially'*

Participant T03

Participants also felt that the relationship with their crewmate significantly influenced the process, with a preference for mixed sex crews:

*'my crewmate is my teammate, I'm assessing child, my crewmate is reassuring parents, I'm assessing child or getting things ready, erm, my crewmate is entertaining child'*

Participant P04

*'trying to get him settled down, which actually my crewmate did a better job than I did, erm, crewmate was being erm, female, so I think him being a young lad found that more comforting, erm, I wouldn't say, I use the word "mumsy" but she's got a child of her own so she's a lot more switched on, so she had that sort of empathy there'*

Participant P06

*'I think that crews should be mixed crews, as, as much as you can do, erm, for the reason that different patients respond better to different sexes'*

Participant T03

Participants also highlighted situations in which crewmates could hinder the pain management process:

*'certainly seen people hinder the process and that's just like going in and being very loud and erm, insensitive to the situation erm, only speaking to the parents and then expecting a child to agree to have all these assessments done, erm, not getting down to their level and not making them the forefront of what you're doing…'*

Participant P05

4.3.2.2.4 Knowledge and experience

Participants felt that knowledge and experience played an important role in the pre-hospital pain management process. The sub-themes identified were the child's prior experience of pain and the clinician's education and training, parental status, life experience and their low exposure rates to children.

The prior experience of the child was considered an important factor in the pain management process, stating that younger children have less experience of pain leading to a heightened experience:

*'I think with the younger kids you've got a very narrow gap of their perception of pain, an older child, same as adults you know, life experience up to that point has dealt them, so, various amounts of pain, so from their point of view they've got a, a better understanding of how bad that pain is, to a certain degree'*

Participant P06

It was also stated that children suffering long-term conditions are more likely to be willing and compliant with assessments and interventions:

*'The other thing is as well, children that are on long-term treatment are more resilient and will definitely allow you to do nearly anything that you ask them to do, so oncology patients they'll, kids, there's not many of them that'll say "oh I don't want a cannula", because they've had that many, they're quite used to it.'*

Participant P09

There were mixed and conflicting views on levels of education and training, with some participants stating that their training was inadequate and did not prepare them to manage pain in children:

*'I don't think there's enough training on pain management in children in general'*

Participant P06

*'We didn't have a lot of time… erm, in training school, and I think nothing prepares you for being out there on the road does it? Nothing, nothing prepares you for a screaming child, erm… particularly you know, when you've not been exposed to it very much erm, you know, and I suppose and also, particularly the trauma jobs you know nothing exposes you to, to seeing a child with a horrific injury erm, so no I don't think you're ever prepared for it really.'*

Participant T03

Other participants stated that their training and education taught them to fear children:

*'We're very much told, or taught at an early stage, that, you may, I'm sure you will have heard of this before but, babies and children compensate, compensate and then fall off a cliff, you know then they, they, when they no longer compensate, it's almost as though training college, you were taught to consider children as a ticking time bomb, that even a well child will suddenly become very unwell and I think we, we set ourselves up very much for a fall'*

Participant P04

Some participants however felt that their training was adequate:

*'It gave me the skills to assess children and get a rough idea what's going on if it's something acute'*

Participant T02

Some participants stated that education and training has improved significantly in recent years:

*'Yeah well the… It's a, it's quite a bit at the minute it's a 2 year degree, whereas previously it was a 12 week in house erm, learn the management and, and go and that's how it was until about 5 years ago with technicians as well until they've changed it and then they've all gone through the university route, so I think there's been a massive change in the last 5 years.'*

Participant P05

Other participants placed the onus on themselves stating that registered clinicians should actively seek continued professional development opportunities:

*'I think it's on erm, as an inherent responsibility as a clinician, when we sign to HCPC we say that, one of our standards is to maintain our, our knowledge, maintain our CPD, I don't think we get it to start off with, that doesn't mean to say that we don't look for it elsewhere, and there are some fantastic sites available'*

Participant P04

Some participants stated that their status as a parent helped improve the pain management process:

*'I think, yeah, I think so, I think when you've got your own children and they've been in a lot of pain, it does change your management slightly and it changes the urgency with which you want to do things it's very hard, erm … some of the things they've thrown at me over the years I probably wouldn't feel nearly as confident if I was sat here at this age without my own children, there'd be a huge gap in my knowledge '*

Participant P02

*'from my personal experience I feel more confident dealing with children erm, young children because I have some my, of my own and it's definitely empowered me to, be a bit more direct with my questioning, erm, and my erm, my management and my assessment.'*

Participant T02

Some participants however felt that being a parent was a hinderance and that clinicians might become too emotionally involved:

*'everybody that I speak to that's a parent they said "I couldn't imagine going to that, I wouldn't know…", because since having children they struggle to deal with other children, erm, that's something that I hear quite often'*

Participant P05

Yet there was conflict around this with other clinicians stating that they are able to detach themselves emotionally:

*'my youngest was, was really poorly … and I wondered how that was gonna react with me on the road if I saw a child in that similar condition and, funny enough actually erm, about two weeks after one episode at the hospital with my son it was, it was, which was quite distressing, we had a child very similar and all that sort of emotion went out the window and I just focussed on the job, so I didn't, I didn't treat it as a, I treated as a patient rather than a child, I just got on with it you know, this is what needed to be done, this is what I did and it wasn't until afterwards where I reflected on with my crewmate thinking "actually, I reacted to that a lot better than I thought I was gonna do"'*

Participant T01

Some participants stated that being a parent might make staff de-sensitised to illness and injury in children:

*'Erm, it could be a disadvantage in some respects because, the clinician might think "why have they rung an ambulance? I deal with this myself"'*

Participant T02

Life experience was considered a significant factor by many participants, with some stating that older staff with more life experience are likely to approach children more holistically:

*'Erm, I think life experience would, would play into that, erm your approach, your line of questioning… and based on my experience, erm I keep going back to it but I think the older staff member would look at things holistically a bit more'*

Participant T02

*'I do think there is something to be said for life experience erm… and being exposed to certain situations through, through life experience and, some, some young people have been exposed to lots of different things but I think, I think that exposure, in life, puts you in, a, an advantage I think'*

Participant T03

Participants felt that one of the barriers to effective pain management in children was the low exposure rates:

*'So you don't get the exposure, which doesn't build up your confidence base or your, your knowledge base … we learn by what we do you know and what we see, you know you can read your books, you can watch your webinars you know, "this is what a sick child looks like", unless you're sat there with it, and you hear them, you see them … That's when it sinks in'*

Participant P06

*'I just don't think we deal with, it, it, because, because kids aren't poorly, they're never poorly are they? How many times to we go to children? As opposed, you know, if you looked over a year and you said that you'd been to 1000 jobs, how many of them would be children? I bet very, very, handful … And normally it's, it's febrile stuff isn't it it's, erm infection type stuff it's … Temperature, it's pyrexia, it's never really pain it's seldom we go to children with pain, so therefore erm… are we competent in dealing with child pain? No.'*

Participant P09

It was also stated that the lack of exposure to children suffering pain increases the clinician's perception of fear:

*'we don't necessarily deal with a lot of children that have had a lot of poly-trauma, so there's that, lack of, knowledge, lack of experience, again the fear of doing the wrong thing…'*

Participant P02

4.3.2.2.5 Management

Participants felt that management, in terms of assessment and treatment, was a key consideration in the process of pre-hospital pain management in children. The sub-themes identified were challenging pain assessment, Entonox® difficulties, slow acting oral analgesics, difficult and painful cannulation, limited scope of analgesics and helpful non-pharmacological techniques.

There was a strong sense that pain assessment in children was challenging. Participants stated that pain assessment was difficult, particularly for younger children because they often struggle to locate the pain:

*'in, younger children, I can't remember what the age is now where pain pathways develop properly in children, but certainly in younger children they can't always locate pain very well…'*

Participant P02

Participants also stated that pain assessment tools were challenging to use, creating a barrier to the assessment process:

*'we've got the Wong & Baker FACES®, which come with a very long detailed explanation if you do it properly, and an explanation that is not suitable for a, certainly not suitable for a pre-school child, but it's complicated even at 7, 8, 9, the explanation is far too complicated'*

Participant P03

This resulted in many participants not using pain scales, often documenting a description instead:

*'I tend to just put a description on you know, child very unsettled, erm, looks miserable, withdrawn, screaming what, whatever the reaction is just to try and give a snapshot on the patient report form, what that child's like when I got there…'*

Participant P09

In addition to the complexity of pain assessment in children, with the challenging and often unused pain scales, there was a sense that pain scales were being used inappropriately, for example the Wong-Baker FACES® scale was reported as being used by participants as an objective measure of pain rather than for the subjective interpretation of the child. This was not necessarily through negligence, but rather

due to it being a pragmatic solution and perhaps the only feasible way of reporting a pain score:

*'If, if it's someone, if it's a child or sort of, who's sort of not verbalising quite as much then I'll do it off my perception I guess with the Wong scale … Erm, so if they're crying I'd work well they're 9, 10 up here aren't they … I'm then using my perception of it a little bit more than their perception, erm, it's sort of that, that sort of quite difficult age where you can't really get a definitive number so you're really yours, your, your opinion on it really'*

Participant T01

There were several barriers identified regarding the administration of pharmacological interventions. Participants stated that Entonox® was difficult to administer to children:

*'but Entonox®, the delivery systems, like, you have to stop a child crying, because they have to stop crying to actually take Entonox®, you can't cry and suck at the same time, so the child needs to be calmed, and calming a child who's in agony, and getting them to coordinate their breathing to suck, is like trying to talk a hyperventilation in the peak moment into, into breathing slowly isn't it … and I think it's, it's big and it's cumbersome and it's you know it's a big cylinder and it makes a noise and the mouth pieces are quite big, and the masks are quite scary, so the delivery system is not really tailored for children.'*

Participant P03

It was also noted by participants that oral analgesics are slow to act and when in the context of acute illness or injury, timeliness of interventions is important:

*'I'm always very aware with those sorts of jobs when a child's in a lot of pain like that, that the, paracetamol and the Nurofen® take some time to kick in, and when you've got children it's very hard to explain that they're gonna have to wait, for that pain relief to kick in, so there's nothing much that I can give a child…'*

Participant P02

*'I just think our pain relief management for children is not, not as easy for children as it is for, they're used to swallowing medicine aren't they? But it doesn't work quick enough in trauma.'*

Participant P03

Whilst intravenous morphine provides faster pain relief than oral analgesics, the process of cannulation was reported by participants as difficult and painful for children:

*'But certainly age would have done, because my consideration if they'd been 3, and they've got say puppy fat on the back of their hands still … The cannula's harder to go in, the ACFs [antecubital fossa] not a great place for a young child, because they, you stop them bending their arms, the choice of sites is, the choice of sites is more limited the veins that you can find are more limited, the child moving and, and not understanding to stay still because they're so young and their comprehension of staying still and not, they're more likely to fight you aren't they, the younger the child the more likely they are to pull away.'*

Participant P03

*'I thought cannulation would exacerbate her, her level of pain, her level of anxiety, so I went for a, an oral route rather than, than for vascular access.'*

Participant P04

There was also a consideration of what impact cannulation attempts would have on future encounters with health care professionals, as the child's experience of the event was considered important:

*'I think it's terrifying because we don't cannulate children that often … you don't want to keep repeating it because you know you're gonna hurt them and cause more fear and terror and, that sort of thing of erm, gonna make them phobic for the rest of their life sort of thing 'cause you've fumbled about'*

Participant P08

Participants stated that another barrier to effective pain management was the limited scope of analgesics that were available:

*'to my mind the paracetamol and the Nurofen® are at the bottom of the pain, ladder if you like for treatment, and then I've got Oramorph right at the top and there's not an awful lot in between the two to help manage the pain, but, and nothing that acts particularly quickly'*

Participant P02

*'or if there's some alternative some intermediate or, because we literally do go from ibuprofen, Calpol® to morphine, with zero in between'*

Participant P08

Most participants felt that non-pharmacological interventions were effective at managing pain in children, with some arguing that they are equal to analgesics:

*'things like distraction and using other bits of kit can help as much as giving the pain relief, I think we get very focussed on, what analgesics we've got to use without remembering that there's other things you can do to help pain management'*

Participant P02

*'I think all children have a level of pain management we can erm, address, non-pharmacologically.'*

Participant P04

4.3.2.2.6 Environmental

Participants discussed several environmental factors they felt influenced the pain management process. Sub-themes included light, noise and colour.

One participant discussed the use of lighting to help manage pain in children, stating that dim lights or different coloured lights would act as a method of distraction:

*'and the music was enough to erm, to soothe him, erm, and I liked it in the back of the ambulance so I put like the dim lights on or put the blue light on or, something that's a bit different to just to, a bit of distraction.'*

Participant T03

Participants stated that surrounding noise, coming from other people or from the ambulance/equipment inhibited their ability to effectively manage pain in children:

*'Straight off is erm, noise, distraction around, so I try and calm the situation'*

Participant P04

*'they just don't know what this big yellow thing does with all these noisy lights and this equipment and you two are just strangers and "who the hell are you?" and you've got all these big bulky pockets'*

Participant P08

Participants also discussed the colour of the ambulance and staff uniform, stating that it could be a barrier to effective pain management:

*'you know we're not friendly looking, big green uniform and a big yellow ambulance they're like "oh my god, I'm gonna be taken away in that, they're gonna take me away from my parents"'*

Participant P08

*'Reluctancy for the child to want you to do anything because of fear, so the jolly green giant walking through the door'*

Participant P09

4.3.2.2.7 Organisational

Several organisational factors were identified by participants. Sub-themes included service demand, policy, lack of paediatric equipment, limited service education and training and distance to hospital.

One participant identified service demand as a potential barrier, stating that if he was on scene requesting backup to transport a child to hospital, the length of time waiting was variable and unknown, which influences the pain management process on scene:

*'Erm, and not very often is there, when I attended a patient now, erm, is there a vehicle available in a short period of time, to take them to hospital, very often … the demand outstre-, erm outstrips the, the resources, so therefore I have to think about how I'm going to manage them in the meantime'*

Participant P07

Participants described how organisational policy influenced their management of children on scene, some stated that policy was restrictive:

*'with the, the child, child under two policy for example, erm, clinicians are very quick to just go "well they're gonna go to hospital anyway because policy says they need to go to see a Doctor"'*

Participant T01

Other participants acknowledged that policy was in place to help both clinicians and patients:

*'but with the aid of such things as Pathfinder [clinical decision aid], erm, that does make things, it gives you the guidelines and the framework to make, to make good decisions and minimise erm, disagreements between clinicians, I'd say, because we're all here to, we all do this job, we all understand that that's, you know, we have those, those frameworks in place to, to help us and to help the patient'*

Participant T02

Some participants described a lack of paediatric equipment as a barrier to effective pain management:

*'A lot of the kit that we've got, things like the traction splints and things are all set up, for adults, there's no paediatric versions of some of the stuff that we carry…'*

Participant P02

*'We don't have paediatric mouth pieces for Entonox®, the alternative is we put a mask over their face and we help deliver it, and that's not, that's not nice either is it.'*

Participant P03

Participants stated that organisational education and training was not sufficient, with paediatrics rarely being covered:

*'Erm, we don't, I'm trying to think I'm honestly trying to think the last time we had any sort of child training … and I can't remember when it last was…'*

Participant P02

*'If you look like at our 'Stat and Mand' [statutory and mandatory training] we don't do anything on paediatrics, unless it's cardiac arrest, that's what we focus on'*

Participant P08

Distance to hospital was also considered a factor that influenced the pain management process, however there was disagreement on this with some participants stating that children closer to hospital are less likely to receive analgesics:

*'When you first qualified, if you've got a 5 minute journey to hospital and you're not sure how to deal with something, you scoop them and take them to hospital, and you almost make that somebody else's problem, because they're more experienced they could put the cannula in easier they could choose the pain relief, you're a bit nervous about your options with children.'*

Participant P03

One participant stated that closer to hospital, children are likely to still receive oral paracetamol and perhaps Entonox® but would be very unlikely to receive morphine for example:

*'Yeah, I think children who are closer to hospital erm, they'll, I think that, the, the simple erm, oral an-, oral paracetamol, erm, that can go down, because we can get that down easily, maybe ramp up quickly to, to an Entonox® so they are getting analgesia, great, but if they needed anything else, if they needed to go to that next level the, the top level of analgesia, not a chance are they getting it, not at 5 minutes out, we'll get them to hospital every time.'*

Participant P04

Participants stated that if they were further away from hospital, they felt more obliged to manage the pain, stating that they wouldn't be doing their job otherwise:

*'yeah if you're further away and, and there's still pain evident, you have to, you have to do something, because that's, that's our job [laughter] if we don't, if we don't try and address the pain we're not really doing our job, erm, which is problematic, I think.'*

Participant P01

Other participants stated that it didn't matter how far away the hospital was, if the treatment of pain was necessary, it would be implemented regardless of distance:

*'whether you're 20 miles away or 2 miles away, I wouldn't, I wouldn't withhold pain just because I was close to hospital … patient comes first rather than distances, times, protocols, whatever, the presentation of the patient is what is important and making them comfortable, the distance isn't a factor, is not a factor to me.'*

Participant P09

4.3.2.3 Exploration of improvements

Participants were asked to discuss improvements they would like to see that they felt would improve the process of pain management in children. The three major themes of improvement included the management of pain, organisational factors and educational improvements.

4.3.2.3.1 Management

Management was a key area of improvement identified by participants and consisted of the following sub-themes; non-pharmacological improvements including lollipops and cartoon videos, pharmacological improvements including analgesic lollipops, the intranasal and intramuscular route, non-opiate analgesics, Penthrox® and intravenous numbing cream and scope to improve pain assessment tools.

Participants stated that the use of cartoon videos could help improve the pain management process, stating that ambulances have small screens that could be utilised or tablets/mobile phones could be used:

*'in every ambulance we have, we have little VDU [video display unit] screens, little video screens, why can't we have some fun cartoons, I mean, there's a concern that the erm, the crews maybe sat in the back at hospital watching Peppa Pig … Exactly, but, either those or, or tablets or something that we can erm, entertain, I know a lot of crews, a lot of parents now take their children's Kindles or other tablets in with videos while they're sat waiting in A&E waiting rooms, if you go into any one in the country you will see parents who've given up their mobile phones with videos'*

Participant P04

There was also a strong sense that intranasal analgesics would help the pain management process, with participants stating that the method of administration is much kinder to children with the onset of analgesia being much faster than with oral analgesics for example:

*'the method of administration [intranasal] is much kinder for a child, the quick squirt up a nostril, is, is universally acceptable isn't it, to all children ages … It's not painful … its onset is really quick isn't it … And that's what you want with a young child isn't it, you want them out of pain quickly.'*

Participant P03

Participants stated that Penthrox® could improve pain management in children as the delivery system is less cumbersome and less challenging than Entonox® with less sucking power required to inhale the analgesic:

*'it [Penthrox®] is easier, it's less scary than using erm a big blue gas cylinder in a big bag and a great big unwieldy pipe [Entonox®], which is really, really difficult for adults to even hold and manipulate and it will hurt your gums and your teeth if you twist it wrong and it, and that plastic thing smacks you in the mouth, you know, so maybe something like that, erm an appropriate size, erm, erm anaesthetist, erm anaesthetic gas it's a really good way of doing it'*

Participant P07

There were also suggestions that a topical numbing cream would be helpful to reduce the pain caused by intravenous cannulation, even though it might not have time to work during the pre-hospital phase of care, it would be useful for the continuation of care within hospital:

*'if the potential is for that child to be cannulated, if we get to hospital and they're still in pain for whatever reason i.e. they won't accept the medicine or we can't give it or whatever, at least if we could have got the Emla cream on then when they get to hospital the chances of them being cannulated is gonna be a lot quicker than them applying it and waiting half an hour for it to work, so would that be a better patient experience? Yeah. Would that be quicker pain relief? Yeah … Patient treatment would be a lot better … And more prompt, less suffering'*

Participant P09

One participant was concerned about giving opiate-based analgesics in the pre-hospital phase of treatment because the hospital was then more reluctant to give further opiate-based analgesics on arrival. The use of non-opiate analgesics was discussed, with one participant stating that it would be useful:

*'if I've got something that was non-opiate based, that I could use that would be, that, that wouldn't all, certainly they could give the diamorphine with it, that would be the best solution, for me.'*

Participant P02

With a further participant stating that ketamine could be a non-opiate-based solution:

*'Ketamine's a buzz thing isn't it at the minute, erm in pre-hospital care, and the fact that the side ef-, the long-term side effects of it is quite short, and that it's given by erm somebody who's gonna be very experienced, a very experienced erm paramedic or physician, that it's some, that it, it, it would be a good thing to be, erm to be considered'*

Participant P07

One participant suggested intramuscular injections as a potential solution; providing staff with more confidence around intramuscular injections may improve pain management:

*'Or give us more confidence to do IM [intramuscular] injections if that's appropriate erm, just so that we fully understand the administration of morphine at smaller doses IM'*

Participant P08

Participants stated that lollipops could help improve pain management by creating a positive connection between the clinician and child:

*'but lollipops in younger kids are always a favourite, aren't they, so, w-whether we actually need to be in the business of, of having some on the vehicle I don't know, e-even if it's a way of, of, of making that connection'*

Participant P01

Lollipops containing active analgesics such as fentanyl were also suggested:

*'**I**: What kind of lollipops?*

***P**: Is it fentanyl?*

***I**: Yeah*

***P**: Is it I think*

***I**: So lollipops with an active drug?*

***P**: Yeah active drug in 'em yeah yeah … But obviously it's an unbalanced [sigh] you know, the absorption rate's gonna be slightly different, one lollipop doesn't suit all'*

Participant P06 (**I**=interviewer, **P**=participant)

There were clear calls from participants for improved pain assessment techniques, with some stating that current tools are outdated and that technology could be better utilised:

*'Wong-Baker, I've mentioned numerous times through this interview, I don't think that's always the, the best, version, it, it's, it's, there's a lot of evidence for it but there are a lot of new versions, there are a lot of bright pretty coloured pictures, we have erm, erm electronic devices, erm, phones, we have erm, the Getac [electronic tablet], we can bring up, there's a lot of different versions, with touch technology, so the, the child can, can, and audio, so child can point and, engage more, a little bit more fun perhaps, a little bit more attractive than a black and white, erm, [inaudible] face smiley'*

Participant P04

*'but ultimately how we score the pain, I haven't got an answer for it but I think we need a different system…'*

Participant P06

4.3.2.3.2 Education

Two sub-themes were generated within the education theme; enhanced training and peer-to-peer debrief/dialogue.

Participants stated that more education and training around managing children in pain would be beneficial, with one participant stating that fractures are more difficult to manage in children compared to adults:

*'possibly even more training and knowledge around things like straightening limbs or splinting… I don't know, would be beneficial as well, I think there's still quite a reluctance to, to move children too much, and to be fair a lot of the fractures are, are different in children where, things are bent rather than being, because of the sort of greenstick type of effect it's, harder to know whether you can straighten or not, or what to do.'*

Participant P02

With other participants stating clinicians need regular training to increase confidence levels:

*'But I also think we should be doing a lot more workshops on paediatrics in general, just to give people more confidence… can almost make it rolling CPD.'*

Participant P08

Some participants felt that education and training could be in the form of peer-to-peer discussions, particularly between mentors and mentees:

*'when I say education I, I, I think it should be around about the peer group discussions … Erm, about keeping up-to-date erm, and knowledge, erm mentor-mentee discussions on things what went well and things what didn't go so well, because I think as a mentor, erm, I don't mind discussing things what didn't go so well, and it doesn't make me less of a mentor in fact I think it makes the mentee feel more comfortable to talk to me about things what they worry about and things that don't go so well, if they realise that I'm not infallible myself.'*

Participant P07

*'when I do my operational shifts it's nice that because I've possibly been quite lucky that I've had opportunity to do more and learn more and you can then pass that down the chain little bit, some people aren't quite doing things correctly, you can just tweak their practice a little bit, erm just discuss a few things'*

Participant P08

4.3.2.3.3 Organisation

Participants felt that several organisational improvements could be made, including the following sub-themes; more paramedics, crew mix (rank, experience, sex), regular crewmate, paediatric equipment, look less scary, public interaction and electronic clinical records.

Participants stated that crew mix was an important consideration, particularly the skill of the crew because having a paramedic on scene to deal with more complex cases and administer more potent analgesics was perceived as beneficial. Therefore, having more paramedics within the organisation was considered a method in which pain management could be improved:

*'a lot of these sort of big jobs we are having to at the moment be called, call, erm, have to call a paramedic in, erm, so potentially, erm, maybe mixing, having more para-tech crews'*

Participant T01

There were further discussions around the crew mix, many participants stated that male and female crew members might approach children differently, with male clinicals being more objective and focussed on the clinical objectives and female clinicians more subjective perhaps offering comfort and soothing in the initial phase of the assessment, therefore having a mix of male and female crew members may be beneficial:

*'Whereas erm, the male erm, clinicians tend to go down assessment and management, at different routes, at different times, so, men tend to assess and manage and then try and soothe and comfort whereas female try and do the other, you know, spend more time on the comforting and soothing.'*

Participant P04

There was a sense that more experienced clinicians are more confident in their practice and often take a more holistic approach to manging the child compared to less experienced clinicians who are perhaps more protocol driven:

*'And I think, when you first start you probably don't have the confidence to take your time to assess, to try and solve the situation yourself, but I think that's important that we do take time and we make the children feel comfortable and that we relieve the pain, because now, with experience I know that we can get to hospital and that child might still have to wait another hour in the corridor.'*

Participant P03

The final discussion around crew mix was around having a regular crewmate. It was felt by participants that having a regular crewmate made a significant difference to more complex or higher acuity cases, because when clinicians work with each other for the first time, they are unsure of each other's expectations and often have to invest more time and energy in managing each other; whereas when regular crewmates work together they know each other's expectations, they have experience of working together and their collaboration to achieve tasks is more seamless:

*'Human factors is huge, a huge issue erm, sometimes erm… erm some people you see might have a technician attending and a paramedic as the lead on the vehicle erm and they might very much work as a cohesive unit if they know each other well, but if they don't know each other very well, there might be a little bit of awkwardness'*

Participant P02

Participants stated that the lack of paediatric equipment was a hinderance to effective pain management and it was suggested that more child friendly equipment such as smaller Entonox® mouth pieces or paediatric splints could improve pain management:

*'they say "oh put it in a splint this that the other", they're not the, the prettiest looking things, they look pretty medical and pretty scary'*

Participant P06

Considering that medical equipment looks '*pretty scary'*, to further that sentiment participants stated that staff uniform and the ambulance also looked scary, with one participant likening staff uniform to the jolly green giant and others stating the

inside of the ambulance looked very clinical. It was proposed by participants that the ambulance could be made to look less scary:

*'so let's make it a bit more inviting, let's make the, the inside of the ambulance look a little less, clinical, somehow, the, the touch of a button or, or there's some pretty pictures erm, printed on the inside of the, the windows, that are normally covered by the blinds, but, I don't know let, let's just make ourselves look less scary to children.'*

Participant P04

Whilst other participants stated that the appearance of staff is not cuddly or friendly and we could do more, akin to paediatric nurses and perhaps wear tabards:

*'there's not fluffy teddy bear or a paediatric shirt in sight, whereas we know paed nurses generally are a bit fluffier with teddy bears or tabards or something that made them cuddlier, whereas we're just not [laughter] … I'd love to see ambulance staff with teddy bear [laughter] teddy bear tabards.'*

Participant P08

Participants discussed public interaction as a method to improve pain management and reduce fear and anxiety of children when an ambulance is required. Some participants stated that they make a habit of waving cheerfully to children from the ambulance as they drive past on the street, stating that if that child needs an ambulance in the future, the last paramedic they saw was waving happily at them. Participants stated that public expectations were not always realistic, with many members of public believing all ambulance staff wearing green are paramedics and that if they call an ambulance one will arrive immediately. It was proposed that more school visits could perhaps address this problem:

*'Erm, so maybe, maybe this is where from a completely different aspect, we should be going more into schools and nurseries so that people aren't afraid of us, so that we take away, erm and I've done a couple of school visits to get kids on the back of an ambulance so that they're not frightened of it, "so this is what this does, sit on the bed" or, you know "it goes up it goes down, it does this" erm, we can play with the kit a little bit, we can stick all the things on you, it doesn't hurt, erm, so then some of the child's fears gone away'*

Participant P08

There was also a discussion around electronic clinical records as participants felt they facilitated pain assessment, as the Wong and Baker FACES® scale could be easily shown on the screen and the child could interact and touch the screen:

*'I think it's better now we've got the Getacs I think, erm, I, I feel more confident getting a better idea of this, of that particular child's pain, now.'*

Participant T02

4.3.3 Discussion

Objectives 3, 4 and 5 of this thesis (see section *1.4.2 Objectives*) have been addressed; possible explanations for the majority of the identified predictors from *Table 9* (pg120) have been provided (see section *4.3.2.1 Explanation of predictors*), barriers and facilitators have been identified (see section *4.3.2.2 Identification of barriers and facilitators*) and ways to improve pain management in children in the ambulance service have been explored (see section *4.3.2.3 Exploration of improvements*). These results will now be discussed in more depth and in the context of what is already known.

#### 4.3.3.1 Explanation of predictors

A thematic map was created to illustrate the themes and interactions between sub-themes, see *Figure 8* (pg200).

The qualitative explanations were integrated with the quantitative data to provide a more comprehensive understanding (discussed in section *4.4 Integration*). To avoid duplication of discussion, the primary discussion of these explanations (and subsequent meta-inferences) was performed in the discussion chapter (see section *5.2.1 Meta-inferences*).

##### 4.3.3.1.1 Child age

Younger children were more likely to achieve effective pain management than older children (see *Table 9* pg120) which was likely due to younger expressing more emotion, being easier to distract and living in the moment, whereas older children think more long-term (see section *4.3.2.1.1 Child age*). A hypothesis was generated stating that the emotional impact on the perception of pain was greater in younger children than in older children. This hypothesis was developed from the findings of this thesis and from McGrath (1994), who stated that the perception of pain in younger children was more likely to be adversely affected by emotions during treatments, medical tests, hospitalisation and separation from family than older children (who were more likely to dwell on future consequences of their illness/injury). See *Figure 9* (pg201) for an illustration of this hypothesis.

Figure 8 – Qualitative study: Thematic map of explanations

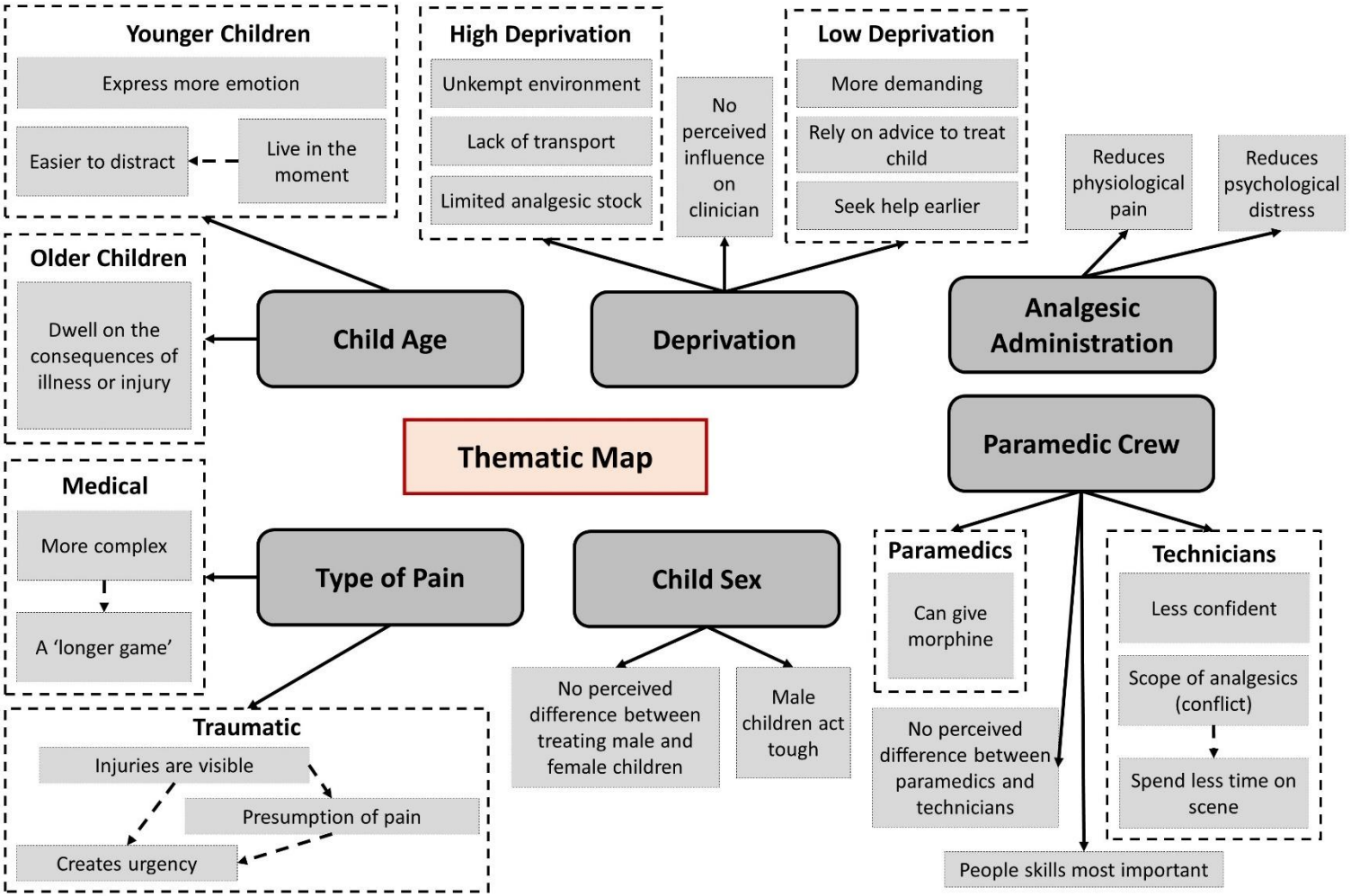


Figure 9 – Qualitative study: Emotional impact on the perception of pain in younger versus older children

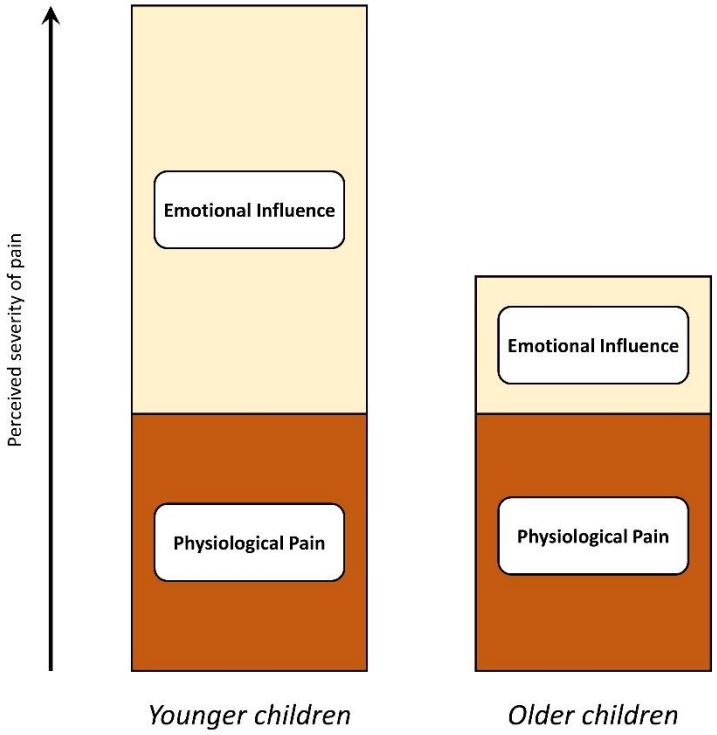



*Figure 9* (pg201) shows that that the opportunity for pain reduction is greater in younger children by addressing their emotional needs (reducing fear and anxiety) using non-pharmacological techniques such as distraction and comfort. This offers a clear explanation as to why younger children were more likely to achieve effective pain management, as found in *Table 9* (pg120). Considering this hypothesised greater emotional influence, it could be argued that the initial reported pain score might be higher for younger children than for older children, this was assessed in the integration section (see section *4.4.2 Methods level*). In summary, it was found that younger children (0-5 years) did report significantly higher mean visual pain scores than older children (12-17 years) (p=0.0245), see *Table 16* (pg237). However, the reverse was evident for numeric pain scores; younger children suffered significantly less initial numeric pain than older children (p=<0.0001), see *Table 16* (pg237).

The problem with comparing initial pain scores of younger and older children is the differences in scales used, as evident with the different scores between the numeric pain rating scale and visual scale (Wong & Baker FACES® scale). This however does not excuse oligoanalgesia (failure to provide analgesics) or mitigate the need to administer pharmacological interventions, which are still necessary to reduce to amount of physiological pain a child is suffering from.

Whilst assessing the effectiveness of distraction techniques for reducing pain during venepuncture in children, Vessey et al. (1994) noted age as a significant covariate, stating that younger children reported perceiving greater intensities of pain and demonstrated more active observable behavioural distress than older children. This finding reinforced the above hypothesis, illustrated in *Figure 9* (pg201). Further to this, a recent systematic review found that non-pharmacological techniques such as distraction, hypnosis, combined cognitive behavioural therapy, and breathing interventions are effective at reducing procedural pain and distress in children (Birnie et al., 2018), however the authors stated that the evidence focussed on children aged 12 years and younger, therefore the applicability of these findings to adolescents is uncertain.

4.3.3.1.2 Analgesic administration

Children were more likely to achieve effective pain management when administered analgesics (see *Table 9* pg120) due to their perceived physiological and psychological effects (see section *4.3.2.1.2 Analgesic administration*). An important consideration here was the psychological effect on the child. Clinicians may not administer analgesics to a child because of the delayed onset time, as oral analgesics were perceived to have a slow mechanism of action (see section *4.3.2.1.2 Analgesic administration*), however, given the potential for psychological effects, akin to the placebo effect, analgesic administration should always be considered when indicated, even if the onset of effect is considered slow, particularly for older children. Weimer et al. (2013) found that the placebo response rates appeared to be higher in children and adolescents than in adults, supporting the argument that analgesics have positive psychological effects. It is

unclear whether there is a difference in placebo response rate between younger and older children. Analgesics did not predict effective pain management for younger children (see *Table 10* pg121). This was perhaps because younger children do not understand or comprehend the positive effects of analgesics, therefore the psychological effect is hampered, minimising any placebo effect. Further research is required to support this theory.

4.3.3.1.3 Paramedic crew

Children were more likely to achieve effective pain management when attended by a paramedic versus a technician (see *Table 9* pg120) however the explanation for this was not conclusive. Paramedics have a wider scope of practice and are able to administer morphine, however cannulation is difficult and painful (see section *4.3.2.1.3 Paramedic crew*). Technicians were also considered less confident and spent less time on scene. Given the delayed onset time of oral analgesics, if technicians spent less time on scene, the analgesics were less likely to have taken effect before arrival at hospital. These factors explain to some extent the disparity, however it was felt more was at play, particularly given the conflict within this qualitative data. It was deemed necessary to revisit the cross-sectional study (see section *4.2 Cross-sectional Study*) and conduct further analyses on the quantitative data in an attempt to elicit new insights to help explain this observed phenomenon. A subgroup analysis was performed, see *Table 12* (pg234) along with subsequent discussion in section *4.4 Integration* and *5.2.1 Meta-inferences*. Considering the data from this qualitative study and data arising from the integration (following a thread), the reason why children attended by paramedics were more likely to achieve effective pain management was probably multifaceted, in that paramedics were older and therefore had more life experience, they had more clinical experience and they attended children with slightly higher visual pain scores meaning they were more likely to achieve a greater pain reduction due to regression to the mean (Barnett et al., 2004). In addition to this, paramedics have more scope of practice and can administer morphine and participants felt that

paramedics were more confident and spent more time on scene. It was felt that all these factors combined offered an adequate explanation for this disparity.

4.3.3.1.4 Level of deprivation

The disparity between level of deprivation was challenging to explain, in part because of the conflicting experiences but also because many clinicians felt there were no differences between groups in terms of the clinician's management. It was found that parents from less deprived areas were perhaps more demanding, therefore clinicians may feel more inclined to administer analgesics or provide more non-pharmacological interventions. Cookson et al. (2016) found that individuals with fewer resources tend to have poorer health and subsequently need more health care. This isn't to say that less affluent patients are more demanding during clinical consultations however, just that the poorer state of health necessitates more health care.

Participants also stated that the home environment of families from areas of high deprivation were unkempt (dirty, untidy and disorganised), making the management of the child more difficult. Living conditions influence health over the life course (Cookson et al., 2016) along with the environment in which medical consultations occur; enhanced environments (increased space, light and greater comfort) improve patient-clinician communication, reduce patient anxiety and improve the satisfaction of patients and clinicians (Rice et al., 2008). It is likely that unkempt home environments make for more challenging child assessment and management and promote early extrication from scene into the ambulance; this may be reflected in different on scene times between cases of high and low deprivation, however clinicians may continue their assessment and management in the vehicle outside the property on scene before officially 'leaving scene', therefore there may be no difference in time on scene. It was hypothesised that clinicians would spend less time on scene in high deprivation areas, opting for earlier removal of the child from perhaps more unkempt, cluttered environments. This 'thread' was followed back to the quantitative data and the difference in time on scene between attendances to children who lived in areas of high versus low deprivation

was explored (see integration section *4.4.2 Methods level*). It was found that clinicians spent significantly more time on scene when attending children in areas of low deprivation (see Table *14* pg235).

It was not clear how 'lack of transport' influenced the rates of effective pain management in children. Syed et al. (2013) found that transportation barriers lead to delayed care, missed appointments and missed or delayed medication use, particularly for those with lower incomes; all of which can lead to poor management of chronic conditions and poor health outcomes. The influence that 'lack of transport' played in the acute management of pain in children is unclear and perhaps was mentioned by participants in the wider context of health care. Some participants mentioned that parents might be concerned about how they would return home from hospital without transport such as a car, particularly from areas of high deprivation where money for a taxi might be limited and where public transport routes are limited; this might influence the decision to travel to hospital in the first instance.

Participants felt that parents in areas of high deprivation had limited analgesic stocks, perhaps leading to reduced analgesic administration rates prior to ambulance arrival. If analgesics are not administered early and children must wait until ambulance arrival, oral analgesics take time to act, therefore there may be little observed effect whilst the child is in the care of the ambulance clinician.

Participants also felt that families of low deprivation sought help earlier; Cookson et al. (2016) found that more affluent patients tend to seek help earlier. Participants also stated that families in areas of low deprivation relied more on advice to treat children. When calculating the outcome measure for the cross-sectional study, the pain scores used were those obtained during the clinician assessment. This does not accommodate any change in pain score prior to ambulance arrival. If for example a child suffered a burn injury and it was clear to the parents the child was in severe pain, after they have called the ambulance service they may have administered paracetamol solution. By the time the ambulance arrived on scene the analgesic may have started to take effect, therefore clinicians were perhaps more likely to observe a pain score reduction. However, if the analgesic was

administered a long time prior to ambulance arrival, the pain would have reduced, and the clinician might not observe any pain reduction.

Participants stated that parents from less deprived areas rely on advice to treat their child, therefore there may have been a more noticeable change in pain score with the ambulance crew for children of low deprivation because the parents have waited for advice to administer analgesics, either from the ambulance control or from the clinician. The only clear explanation for this predictor was that families from low deprivation areas are more demanding and live in cleaner, tidier environments, potentially allowing for longer more comprehensive assessments with more time for administered interventions to take effect.

Participants felt that families from areas of low deprivation may be more demanding. This could result in a higher administration rate of analgesics or non-pharmacological interventions. Again, this was tested within the quantitative data and discussed in the integration section (see section *4.4.2 Methods level*). It was found that more children from areas of low deprivation were administered analgesics than those from areas of high deprivation, however the difference was not statistically significant (see Table *15* pg236).

4.3.3.1.5 Child sex

Male children may be more likely to achieve effective pain management than female children. Although this predictor was not statistically significant (see *Table 9* pg120), it has previously been identified as a predictor by other authors (see *Table 2* pg75). The views and experiences of the participants seemed to validate the non-significant finding, as most participants did not believe a disparity existed. There was an explanation offered for the existence of the disparity; 'boys act tough', conforming to familial, cultural and societal norms (McGrath, 1994). However, Endendijk et al. (2016) found no major differences in the way parents raise boys and girls in a recent meta-analysis. Further, there is uncertainty regarding how this explains any difference in rates of effective pain management. Perhaps boys more readily agree to interventions being effective, or perhaps state the pain has

improved by itself, therefore no interventions are necessary. Physiological differences between male and female children, for example hormonal differences and the susceptibility of different sexes to different painful conditions (such as testicular torsion and endometriosis, for example) may offer insight to this disparity (McGrath, 1994). Further research is required to explore the disparity between male and female children.

#### 4.3.3.1.6 Type of pain

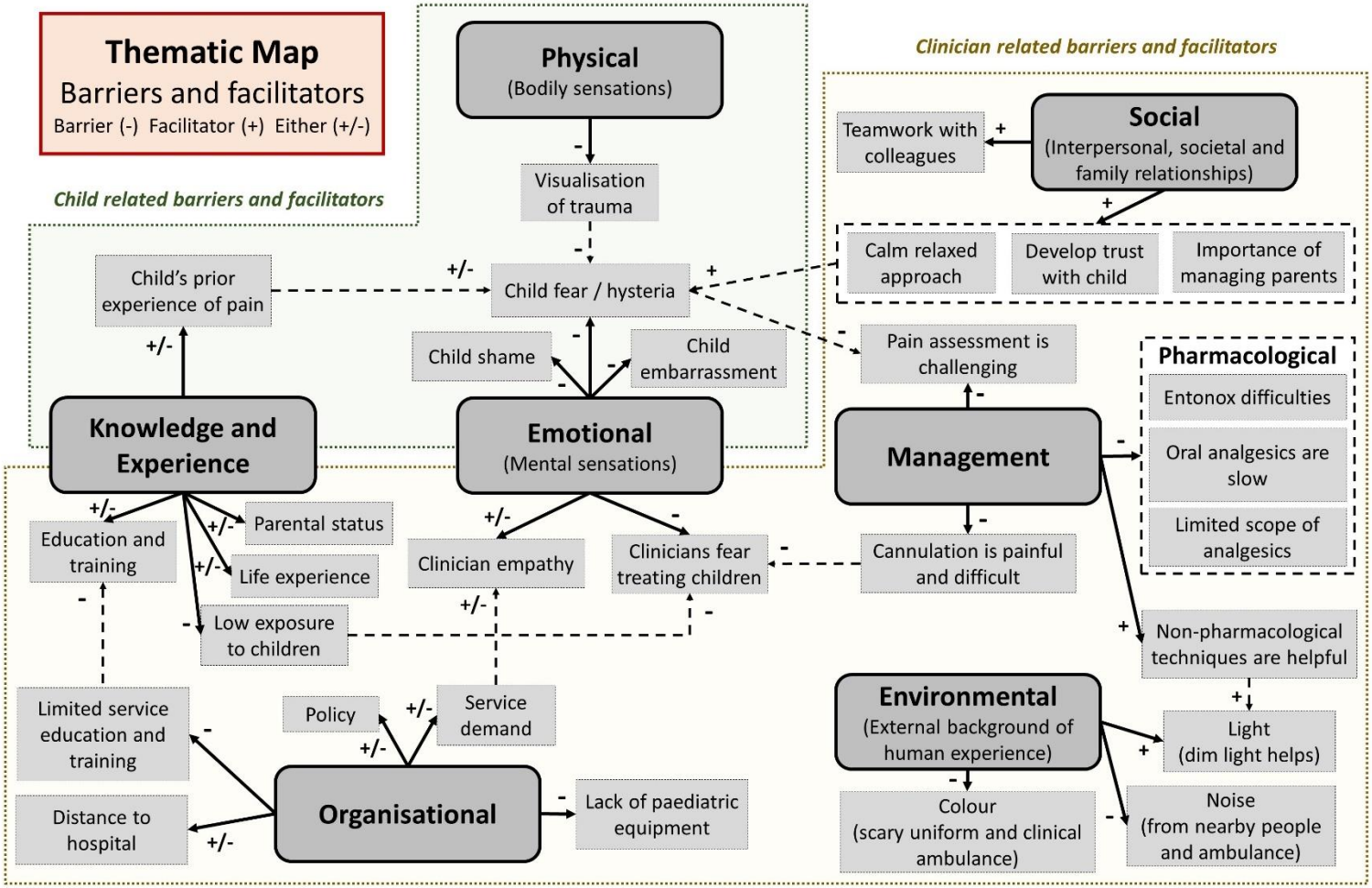
Although traumatic pain was not found to be a significant predictor of effective pain management (see *Table 9* pg120), participants felt there was a clear disparity, with medical and traumatic sources of pain being approached differently with clear explanations being provided. These included traumatic injuries being visible, therefore a presumption of pain was present creating urgency, whereas medical pain was not visible, more complex and a 'longer game', meaning the onset was over a longer period of time, creating less urgency and the clinical assessment was much longer. Considering traumatic pain has been identified as a predictor in previous studies (see *Table 2* pg75), there seemed strong evidence for the disparity. The estimate of effect in this study (see *Table 9* pg120) was perhaps more conservative due to the number of independent variables included in the analysis.

To illustrate the interaction between observation (see *Table 9* pg120) and explanation (*4.3.2.1 Explanation of predictors*), a joint display was created. See *Table 17* (pg240) for the joint display. These meta-inferences were discussed further in section *5.2.1 Meta-inferences*.

### 4.3.3.2 Identification of barriers and facilitators

A thematic map was created to illustrate the themes and complex interactions between sub-themes, see *Figure 10* (pg208).

Figure 10 – Qualitative study: Thematic map of barriers and facilitators



Identified barriers and facilitators centred around the following themes; physical, emotional, social and environmental influences, knowledge and experience, management and organisational factors. Many of these barriers and facilitators have previously been identified.

Most of the barriers associated with the theme 'management' have been identified previously. Murphy et al. (2014) acknowledged the limited scope of analgesics available to ambulance clinicians; the strength of analgesics available to ambulance clinicians jumps from mild (paracetamol, ibuprofen) to strong (morphine) with little in the middle. A number of papers found pain assessment a key barrier due to its challenging nature (Murphy et al., 2014, Williams et al., 2012, Gunnvall et al., 2018) with Holmström et al. (2019) stating that pain assessment tools are often unused, with participants instead opting to use a 'clinical glance' and vitals to inform their interpretation of pain severity in the child.

This strengthens the finding regarding pain assessment tools not always being utilised and that clinical judgement is often used (see section *4.3.2.2.5 Management*). There was also agreement in the literature that cannulation is painful and difficult in children (Williams et al., 2012, Holmström et al., 2019).

The clinician's emotion of feeling fearful has previously been identified (Murphy et al., 2014, Williams et al., 2012, Holmström et al., 2019) and is exacerbated by the low rates of exposure to children, with Murphy et al. (2014) stating *'we're not doing five of them a day'* pg495 and Gunnvall et al. (2018) stating *'pre-verbal children were seldom encountered in the prehospital setting, resulting in lack of practice'* pg42. The child's fear and anxiety levels have also previously been identified as a barrier (Gunnvall et al., 2018, Holmström et al., 2019).

Methods to address this fear and anxiety have been proposed. Similar to the findings in section *4.3.2.2.3 Social*, a calm relaxed approach has been identified as helpful (Gunnvall et al., 2018), along with managing the parents effectively (Williams et al., 2012, Gunnvall et al., 2018) and developing trust with the child (Gunnvall et al., 2018, Holmström et al., 2019). An additional social factor that was deemed helpful was effective teamwork with colleagues, to include ambulance

service and in-hospital colleagues. This facilitator has also been identified previously (Murphy et al., 2014, Williams et al., 2012, Gunnvall et al., 2018).

Organisational barriers such as distance to hospital and policy have previously been identified, with Murphy et al. (2014) and Williams et al. (2012) finding that distance to hospital often influences clinician's decision making, opting for early transport over treatment when closer to hospital and Gunnvall et al. (2018) finding that guidelines were restrictive: *'as for education and guidelines, of course we're not allowed to give sufficiently high doses'* pg42.

The education and training of clinicians was found to be a major barrier within this study (see section *4.3.2.2.4 Knowledge and experience*). This was also reflected in previous research, with many studies finding the education and training inadequate (Murphy et al., 2014, Williams et al., 2012, Gunnvall et al., 2018).

A number of barriers and facilitators identified in this study were considered novel, specifically; visual trauma (the child's reaction to seeing blood or deformity), child shame, child embarrassment, clinician empathy, the child's prior experience of pain, the clinician's parental status and life experience, limited 'in service' education and training, service demand and lack of paediatric equipment along with all of the identified environmental factors (light, noise and colour).

#### 4.3.3.2.1 Physical

Kolcaba's Comfort Theory (1994) facilitated the development of the 'physical' theme, with visual trauma being identified as a barrier to effective pain management. Although the child's perception wasn't assessed, it was felt the clinician's perception and experiences provided valuable insights into the child's experience; clinicians attend children with and without traumatic injury and are well placed to compare these children. When children can see a physical abnormality, such as blood or a deformed limb, they become more anxious and fearful (see *Figure 10* pg208). This fear and anxiety may exacerbate the perception of pain (Choinière et al., 1989, Yildizeli Topcu et al., 2019, Hirsh et al., 2008), creating a vicious cycle. It is important to break the cycle. Breaking the visual path

is key and can be achieved by either covering the injury with a dressing for example or distracting the child. There is evidence in the literature that pain arising from trauma is treated more readily than that arising from medical pain (Murphy et al., 2014), which is backed by *Table 9* (pg120) and explained in section *4.3.2.1.5 Type of pain*, however there doesn't appear to be evidence of the child's visualisation of trauma as a barrier. This appears to be a novel barrier not previously identified through rigorous research methods in this context.

4.3.3.2.2 Emotional

Child shame was identified as a barrier to the pre-hospital pain management process (see section *4.3.2.2.2 Emotional*). This has not previously been identified. Shame experienced by children, particularly adolescent children is prevalent in sport psychology, where adolescent athletes have a fear of failure and subsequently a fear of shame and embarrassment (Gustafsson et al., 2017). Shame typically leads individuals to hide, deny or escape interpersonal interaction (Tangney, 1999). This may explain why shame was identified as a barrier, as children may be less likely to interact fully with the clinician and perhaps less likely to truthfully report pain.

The participant quotation supporting the 'child shame' theme; boys feeling they may have let their dads down by being injured or showing pain, was emotive and powerful. From a reflexive stance, as a father of two young boys I have personal experience of this phenomenon of shame. My seven-year-old son would rather hide his minor injuries from me or pretend he hasn't injured himself, when in fact I can see on his face he is in pain.

Embarrassment is again relevant to sport psychology as mentioned above where adolescents fear failure. There is debate about the causes of embarrassment, for example some argue that it is caused by public exposure, perhaps where social interactions go awry or it could be caused by negative self-evaluation, akin to a mild form of shame (Tangney, 1999). There seems to be consensus on the function of embarrassment; it is considered a method of appeasement, diffusing negative

social evaluation and any prospect of retaliation (Tangney, 1999). Children are perhaps embarrassed when an injury occurs among peers to prevent negative social evaluation. They may also be embarrassed during assessment as they are the centre of attention, akin to being sung 'happy birthday' to.

The clinician's level of empathy was identified as an influencing factor to the pain management process. It could be a barrier when empathy levels are low or a facilitator when empathy is high. Patients attended by clinicians with high levels of empathy are significantly more likely to have reduced severity and duration of illness (Rakel et al., 2009). Further, patients treated by clinicians with high levels of empathy are more likely to retain information and comply with self-administration of medication (Flickinger et al., 2016). Retaining empathy can be difficult; the findings of this study highlighted a number of factors that can influence the clinician's level of empathy, including health status, run of shifts, job types, how busy the clinician has been and the time of day or night. These can lead to fatigue and ultimately burnout. There is increased awareness of the mental health needs of ambulance service clinicians, evident by the increasing number of doctoral studies being undertaken on the topic of staff wellbeing in the field of paramedicine (Paramedic PhD, 2020).

#### 4.3.3.2.3 Knowledge and experience

The child's prior experience of pain was identified as an influencing factor. It was felt by participants that children who have experienced painful illnesses, injuries or procedures in the past may tolerate pain better and are perhaps more willing to endure painful procedures such as cannulation. It was hypothesised that the pain threshold (time taken for the stimulus to be perceived and reported as painful) and tolerance (time from threshold to withdrawal from stimulus) (Schmitz et al., 2013) would be greater in children with previous experience of painful illness or injury. The evidence base however suggests otherwise. Duarte et al. (2000) found that children suffering recurrent abdominal pain had a lower pain threshold than children with recurrent or chronic disease with no pain. Tsao et al. (2012) found no difference in pain intensity or tolerance when comparing children suffering chronic

pain to controls ('healthy' children). Tsao et al. (2012) did however find that children suffering chronic pain were significantly more likely to complete a 1-minute fixed cold compressor trial than controls, suggesting perhaps a higher psychological tolerance and are perhaps better mentally prepared.

There was a strong sense that clinicians who were parents, or who had frequent contact with children within their family such as with nieces and nephews, felt more confident when dealing with children. This is particularly important within the ambulance service as the exposure to children is relatively low, therefore confidence is difficult to build based purely on professional exposure. Other health care professionals working in paediatric specialities, such as paediatric nurses, may not experience the same dichotomy between clinicians who are and are not parents. The evidence on this phenomenon was sparse and further research is required.

Clinicians with more life experience were deemed more confident when dealing with children within the ambulance service. Interestingly, the univariable analysis (see *Table 8* pg118) showed that children attended by clinicians aged between 60-69 were significantly less likely to achieve effective pain management than those attended by clinicians aged 20-29 years (p=0.022). This provides a small amount of evidence to refute this theory, however clinician age was not included in the multivariable logistic regression due to it being deemed less clinically relevant than the included variables, therefore further research is required to assess this phenomenon in more depth. The evidence is limited and out of context, however it appears that younger clinicians provide better treatment than older clinicians; Tsugawa et al. (2017) found that the adjusted 30 day mortality rate was higher for patients treated by older clinicians (12.1%) than younger clinicians (10.8%). This study however only included adults aged ≥65 years and therefore excluded children. Patients preferred not to be seen by very young or very old doctors (general practitioners), with an average preferred age of 42 years (McKinstry and Yang, 1994).

4.3.3.2.4 Organisational

As previously mentioned, limited education and training has been identified as a barrier to effective pre-hospital pain management in children. However, limited post-qualification 'in service' mandatory training regarding pain management in children has not previously been identified. This has been identified as a novel barrier; addressing this could help improve rates of effective pain management. The challenge of addressing this barrier comes from a pragmatic perspective. The 'in service' mandatory training occurs over a limited time period, within the East Midlands Ambulance Service NHS Trust this is currently one day per year, therefore it is likely that higher priority training and higher acuity conditions will dominate, such as cardiac arrest updates for example.

Service demand and lack of paediatric equipment were identified as organisational barriers to effective pain management. Again, these have not previously been identified. Calls to ambulance services are triaged, so that patients with life threatening conditions are prioritised. Within England, ambulance services use the Ambulance Response Programme (NHS England, 2017). Calls are categorised as either category 1 – life threatening, category 2 – emergency, category 3 – urgent and category 4 – less urgent. When demand for the ambulance service increases, calls for patients who are not suffering life threatening illness or injury often wait longer for an ambulance. This applies to many children suffering pain, as most cases are not life threatening, therefore during periods of high demand it is likely that children will suffer pain for longer than they otherwise would have under normal circumstances. A lack of paediatric equipment was identified by numerous participants, it was felt that more specialist paediatric equipment would help children experience less fear and anxiety.

4.3.3.2.5 Environmental

Environmental factors such as light, noise and colour were identified as influencing factors. The findings of this study suggest that dim light and coloured light (blue) could help. The dim light could perhaps promote relaxation and minimisation of fear and anxiety, addressing pain as illustrated in *Figure 9* (pg201). The coloured

light could perhaps work as a distraction tool. The physiological impact of light on pain is not clear. One study showed that supplementary bright light and even low light was effective at reducing pain intensity in adults suffering nonspecific back pain (Leichtfried et al., 2014). Another study in rats has shown green light to be a promising mechanism to promote antinociception (Ibrahim et al., 2017). The optimum brightness and colour of light to promote effective pain management is currently unknown and requires more research.

The ambient noise from the environment (house or public place) from family or friends arguing or perhaps being anxious or fearful along with noise from the ambulance and equipment was identified as a potential barrier to effective pain management in children. Quite simply, it was recommended that removal of the child from the noisy environment or removal of the noisy stimulus from the environment was beneficial. Noise however may not be the issue as audio-analgesia; the use of sound to suppress pain, has been described extensively (Kryter, 2013, Morosko and Simmons, 1966), with white noise being used to sooth new-born babies for example (Karakoç and Türker, 2014). However, there is less evidence exploring the potential negative effective of noise from crowding of anxious family and friends for example, or noise from unfamiliar equipment and vehicles. It would be useful to explore this further.

Concerns were raised by participants about the colours viewed by children; ambulance staff uniform is all green, with one participant calling staff *'jolly green giants'*. Ambulances are also bright yellow and very clean and clinical in inside. It was suggested that staff could wear brightly coloured tabards, or the ambulances could be made more fun inside with pictures of cartoons perhaps on the inside of the ambulance window blinds. The East Midlands Ambulance Service NHS Trust was the first UK ambulance service to develop dementia friendly ambulances, which included a picture of a poppy field inside the blind (Emergency Live, 2019). Something similar perhaps could be implemented for children.

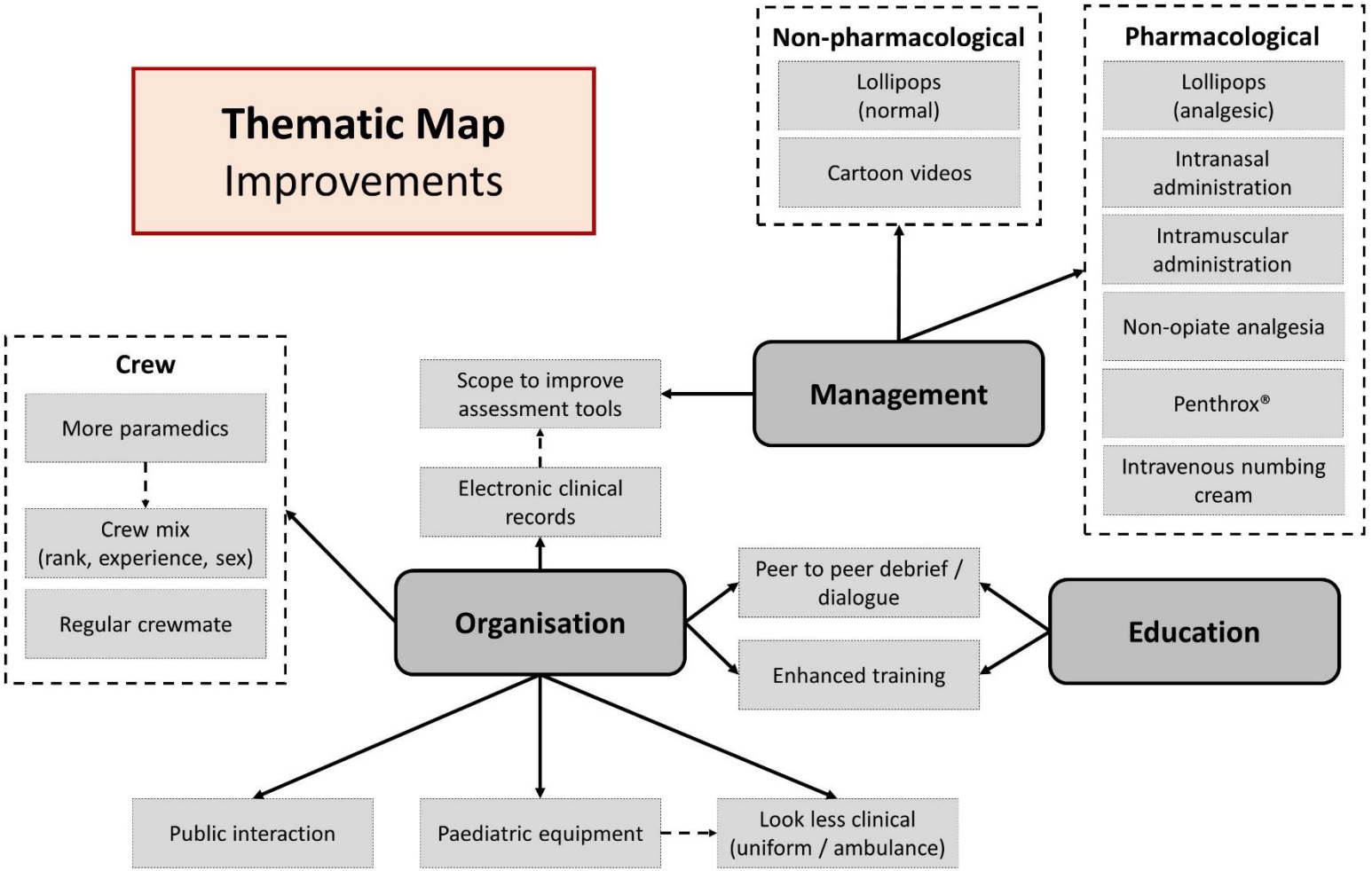
#### 4.3.3.3 Exploration of improvements

A thematic map was created to illustrate the themes and interactions between sub-themes, see *Figure 11* (pg217).

Participants proposed several improvements they felt would help increase the rates of effective pre-hospital pain management for children. These improvements fell within three categories; management, education and organisation. Some of these proposed improvements have already been identified in previous studies. The need for intranasal analgesics was identified by Williams et al. (2012), Murphy et al. (2014) and Holmström et al. (2019). This method of administration has been implemented into a number of ambulance services, evaluated and deemed effective (Murphy et al., 2017, Lord et al., 2019).

The need for enhanced education and training for ambulance service clinicians has previously been identified (Williams et al., 2012, Murphy et al., 2014, Gunnvall et al., 2018) along with the need for enhanced pain assessment (Murphy et al., 2014, Gunnvall et al., 2018). Whilst participants did not specifically discuss improved policy or guidelines as a method to improve pain management in this study, it was identified as a barrier, and has been previously identified by Murphy et al. (2014) and Gunnvall et al. (2018).

Figure 11 – Qualitative study: Thematic map of improvements



#### 4.3.3.3.1 Management

The intramuscular (IM) route of analgesic administration was proposed by participants as a method of improvement. Ambulance service clinicians routinely utilise the intramuscular route for the administration of a number of drugs, including morphine sulphate (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019a). One participant stated that more confidence around IM injections, particularly the dosing for children, may be helpful. Whilst the difficulty of cannulation would be avoided, the pain of injection would still exist. There is a line of argument for preference of IM morphine versus intravenous (IV) morphine in children. In adults, IV morphine is more effective and has a faster onset time than IM morphine for adult patients suffering moderate postoperative pain (Tveita et al., 2008). There was a similar finding for children with post-operative pain, as greater pain score reductions were achieved with IV morphine versus IM morphine (Hendrickson et al., 1990). A recent review concluded that morphine is better administered IV versus IM, whereas drugs such as adrenaline and some antibiotics are better administered IM versus IV (Jin et al., 2015). Current evidence suggests IV morphine is preferential to IM morphine, however this disregards the difficulty of pre-hospital cannulation in children by clinicians who have little exposure to children. Further pre-hospital research would be ideal to address this uncertainty.

Lollipops were suggested as a potential intervention to improve rates of effective pain management in children. Oral transmucosal fentanyl citrate (fentanyl lollipop) first achieved regulatory approval under the brand name Oralet® in 1993 in the United States for use in adults and children (Stanley, 2014). A new formula, marketed as Actiq®, was approved by the United States Food and Drug Administration for use in children in 1997 (Ault, 1997).

Some of the limitations of the Actiq® fentanyl lollipop include its sugar content (potential to cause dental cavities and complications with diabetes) and slow dissolution time, with peak plasma concentrations reached between 20-40 minutes (Electronic Medicines Compendium, 2019a). This has prompted the development

of faster acting methods of administration, such as the nasal and sublingual route (Stanley, 2014).

Fentanyl lollipops have been trialled in children for bone marrow aspiration and lumbar puncture and deemed effective and safe, with itching and vomiting identified as common side-effects (Schechter et al., 1995). Transmucosal fentanyl medications have been deemed more effective than oral morphine for breakthrough cancer pain (Zeppetella et al., 2014). Currently within the United Kingdom buccal administration of fentanyl via lozenge is only licenced for 16 and 17 year old children for breakthrough cancer pain (National Institute for Health and Care Excellence, 2020a).

Non-analgesic lollipops were discussed as they may serve as a method of distraction or the interaction of sugar and pain may come into play; Shann (2007) stated that newborn distress caused by heel prick, immunisation or venepuncture can be substantially reduced by administering sucrose two minutes before the procedure, followed by a cuddle plus breastfeeding or pacifier during the procedure. The effectiveness of sugar for treating newborn pain was further confirmed with a recent systematic review (Stevens et al., 2016). Oral glucose was effective at reducing distress in infants up to the age of 12 months (Thyr et al., 2007) however the effectiveness of sugar at reducing pain in older children is less clear. Miller et al. (1994) concluded that intraoral sucrose may be effective at reducing pain in pre-pubescent children. Pepino and Mennella (2005) found that sucrose was effective at increasing pain threshold and tolerance in children aged 5-10 years.

The combination of an active analgesic agent (fentanyl) coupled with the sugar (sucrose) of a lollipop is therefore an appealing intervention. In the acute setting, emergency department studies showed that fentanyl lollipops were effective in children at reducing pain (Lind et al., 1991, Mahar et al., 2007) and two battlefield studies (Wedmore et al., 2012, Kotwal et al., 2004) concluded that oral transmucosal fentanyl citrate provided rapid non-invasive analgesia that was safe and effective to injured army casualties. Further research is required to determine the safety and efficacy of oral transmucosal fentanyl citrate in the pre-hospital civilian setting.

Participants discussed the use of video cartoons to distract the child and stated that many ambulances have small visual display units that perhaps could have videos playing whilst in the ambulance. Preston and Bray (2015) surveyed 26 ambulance clinicians on the types of distraction they used when attending children; 92% (n=24) stated they did use distraction, with the following methods being utilised: verbal (n=10), balloon glove (n=10), child's own toy (n=10), pen torch (n=7), vomit bowl (n=5), lights inside the ambulance (n=4) and tickle (n=2). Whilst the use of video distraction wasn't evident in this survey, it was clear that the use of any distraction techniques occurs frequently, as 92% of surveyed staff stated they routinely use distraction. The use of non-immersive virtual reality helps create a more positive experience for children undergoing needle-related procedural pain and distress (Nilsson et al., 2009) and the use of video gaming helps to reduce procedural pain scores for children suffering acute burn injuries (Das et al., 2005). Therefore, it stands to reason that the use of video cartoons during ambulance encounters should help reduce pain, fear and anxiety. Further research is required to explore this hypothesis.

Penthrox® (methoxyflurane) was specifically discussed by several participants as a potential intervention to improve pain management. Participants explained that Penthrox® is longer lasting and easier to inhale than Entonox® making it more appealing. A recent systematic review found that Penthrox® appeared safe and effective (Hartshorn and Middleton, 2019). Australian ambulance services have been using Penthrox® to treat pain in children for many years (Babl et al., 2006). Penthrox® however is not currently licenced for children within the United Kingdom (Electronic Medicines Compendium, 2019b) and is currently under investigation within a randomised controlled trial (Hartshorn et al., 2019) with a view to amend the licence if deemed safe and effective. Penthrox® may have the potential to replace Entonox® as the pre-hospital inhaled analgesic of choice.

Topical numbing creams to reduce the pain of intravenous cannulation were identified as a potential method to improve pain management in children. Topical creams are effective at reducing pain in children during needle insertion (Lander et al., 2006). The concern for pre-hospital use is the timeliness. When a child is

suffering acute illness or injury, rapid interventions are necessary to reduce suffering and facilitate extrication and transport to hospital. Eutectic Mixture of Local Anesthetics (Emla) cream should be applied for a minimum of one hour for children (Electronic Medicines Compendium, 2017), therefore such creams may only be useful for instances of prolonged on scene or long journey times. Consideration should be given to onward care; it would be useful for the hospital to be able to cannulate the child after arrival if further analgesics or other drugs are required.

The use of non-opiate analgesics was discussed by participants. Within the UK the strongest analgesic that most paramedics can administer is morphine sulphate (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019a). Morphine has a number of undesirable side-effects such as nausea and vomiting along with cardiovascular compromise (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019a). Ketamine has been proposed as an alternative and within the UK a randomised controlled trial has recently been funded (PACKMaN trial) to compare intravenous ketamine and morphine for injured adults suffering severe pain in the pre-hospital setting (National Institute for Health Research, 2020). Intranasal ketamine has been deemed safe and effective in children in the emergency department when compared to intranasal fentanyl but had more minor side effects; bad taste, dizziness and sleepiness (Reynolds et al., 2017). It is likely intranasal ketamine for children in the pre-hospital setting would be useful, particularly for those suffering cardiovascular compromise where opiates would be contraindicated. Further research to determine the safety and effectiveness of intranasal ketamine or other non-opiate analgesics for children in the pre-hospital setting is needed.

The introduction of electronic clinical records within the East Midlands Ambulance Service NHS Trust was deemed to have a positive impact on the ability of clinicians to assess pain in children, because the child can select the suitable Wong and Baker face from the tablet screen. It was also suggested that other types of pain scales could be developed that are more interactive. Electronic clinical records increase legibility and improve the quality of clinical record documentation (Porter et al.,

2020). Ambulance services who have not implemented electronic clinical records should consider doing so, and those who have implemented electronic records are well placed to accommodate future electronic pain assessment tools.

Participants stated that improved, more pragmatic pain assessment tools for children might help improve the pain management process. There are a significant number of pain assessment tools currently available, including the numeric pain rating scale, visual analogue scale, adjective response scale, Wong and Baker FACES® scale and the face, legs, activity, crying and consolability (FLACC) scale (Breivik et al., 2008, Whitley, 2018). EVENDOL® is currently the only pain assessment tool for children that has been validated in the pre-hospital setting (Beltramini et al., 2019). EVENDOL® is an objective tool, similar to FLACC, that measures verbal and facial expression, movements, postures and interaction with the environment. Participants discussed the development of a pain assessment tool that was more interactive, with colour and perhaps sound. Given the availability of electronic clinical records, it would be timely to develop a more sophisticated tool for children to interact with. The International Children's Palliative Care Network (2020) have developed an app for children to help locate their pain and describe the quality and intensity, all from a smart phone or tablet. This requires the child to interact with the screen, using different illustrations and colours. Further developmental research should be undertaken to explore a pragmatic, interactive method of pain assessment for children utilising electronic clinical records.

#### 4.3.3.3.2 Organisation

The multivariable logistic regression analysis showed that children attended by paramedics were significantly more likely to achieve effective pain management (see *Table 9* pg120). It was also suggested by participants that more paramedics within the ambulance service, creating a higher skilled crew mix, might be beneficial. One participant stated that some ambulance services are more proactive in training new paramedics than others; therefore, a potential

improvement at the organisational level would be to train and recruit more paramedics.

Crew mix was also discussed in terms of sex and experience, as children may prefer one sex over the other. One male participant made it very clear that for a particular child his female colleague was essential to managing the case as the child did not react well to him. The practicality of encouraging a male/female mix on vehicles would have to be determined within organisations as many would likely prioritise clinical rank over sex.

Having a regular crewmate was considered important by participants, with many stating that it makes difficult cases easier to manage as clinicians can focus on the patient rather than managing their crewmate at the same time. Vyvyan (2018) found that having a regular crewmate enhanced the psychological coping strategies of critical care paramedics when dealing with life threatening events.

The combination of having a crew of clinicians who work together regularly, who are of opposite sex and contain at least one paramedic could improve rates of effective pain management in children suffering acute pain. This theory should be investigated with further research.

One participant referenced clinicians as 'jolly green giants', another proposed tabards to reduce fear and anxiety for children suffering pain. Fear and anxiety are important emotions to consider in the perception of acute pain (McNeil et al., 2018) as they are likely to increase the perception of pain (Choinière et al., 1989, Yildizeli Topcu et al., 2019, Hirsh et al., 2008) which in turn increases fear and anxiety, creating a vicious cycle (Andreasen et al., 1972, Choinière et al., 1989). Reducing the fear and anxiety experienced by children during an ambulance call-out is likely to reduce their perceived level of pain by disrupting this cycle. Paediatric nursing staff have altered their clothing to improve the experience of children for many years with brightly coloured uniforms preferred by children (Festini et al., 2009, Wocial et al., 2010, Albert et al., 2008, Albert et al., 2013) which reduce anxiety (Pakseresht et al., 2019, Roohafza et al., 2009) and increase positive emotions for example feeling calm, relaxed or happy (Albert et al., 2013). There is

currently no evidence regarding the use of brightly coloured paediatric tabards for use in ambulance services to reduce fear and anxiety suffered by children.

Brightly coloured paediatric tabards worn by ambulance clinicians when attending a child during a medical emergency may help reduce levels of fear and anxiety, reducing perceived pain (see *Figure 9* pg201) and improving child satisfaction. This theory should be explored with further research.

The physical appearance inside of ambulances was discussed in the previous section (*4.3.3.2 Identification of barriers and facilitators*) along with the creation of the first dementia friendly ambulances within the United Kingdom, specifically how the inside of the window blind was illustrated with a poppy field. There is also scope for modifications to make ambulances more child friendly. A large number of paediatric ambulance services exist, many of which have tailored the design, colour and equipment to suit children. Examples of such ambulances include those from the United Kingdom (St John Ambulance, 2020, North West and North Wales Paediatric Transport Service, 2020), Canada (Jim Pattison Children's Hospital Foundation Trust, 2016) and United States (Baptist, 2020). These are specialist ambulances designed specifically for children. The question remains, what modifications are *acceptable* for generic 'standard' ambulances that could perhaps make children feel more at ease? This could be explored and implemented through consensus methods such as a Delphi approach initially, followed by a service improvement plan, implementation and periodic evaluation.

Considering the lack of paediatric equipment identified in section *4.3.2.2.7 Organisational*, it was felt that the introduction of such equipment, including smaller Entonox® mouth pieces and paediatric splints, would help address this barrier. This may help the emergency event feel less scary for the child. Deficits in paediatric equipment for ambulance services have previously been identified, such as paediatric blood pressure cuffs (Al-Anazi, 2012), face masks and pulse oximeters (Gaffney and Johnson, 2001). Roberts et al. (2005) reviewed emergency equipment used by UK ambulance services for paediatric patients and concluded that several deficits were identified, including for paediatric pulse oximetry and lower limb traction splints; a more recent review is not currently available therefore UK

ambulance services may have introduced more paediatric equipment during the last fifteen years.

Public engagement was discussed as a method to improve pain management in children, reducing the level of fear and anxiety by minimising 'fear of the unknown'. Public engagement was discussed at varying levels, from simply waving and smiling at children as clinicians drive past them in public, to attending schools to allow children to become familiar with the inside of an ambulance and ask questions. The majority of public engagement from ambulance services focuses on cardiac arrest, and teaching cardiopulmonary resuscitation (CPR) (Owen and McGeorge, 2016) for example. The UK Government plans to introduce compulsory CPR training in schools from 2020 (Department for Education, 2019), however other countries have been training school children in CPR for a significant time, for example Sweden have been training children since 1989 (Strömsöe et al., 2010). In terms of public engagement to reduce the stress and anxiety suffered by children, Lerwick (2016) proposed a framework in which child health care induced anxiety could be reduced, including *agenda*; letting the patient and family know what to expect during their encounter. Increased public engagement at schools could facilitate this agenda criterion by informing children what to expect if they should ever need an ambulance.

#### 4.3.3.3.3 Education

Peer-to-peer discussions between mentors and mentees, or simply between colleagues, perhaps between more experienced and less experienced members of staff could improve pre-hospital pain management in children. One participant described how older more experienced clinicians might know that a certain technique works well but may not understand how it works and younger less experienced clinicians might understand the technical aspects but are not sure which techniques work well. It was proposed that peer to peer discussions would help bridge the gap between experience and knowledge. Pronovost and Hudson (2012) stated that health care could learn from the nuclear industry by

implementing peer-to-peer assessments to facilitate horizontal learning through a voluntary, non-punitive approach.

#### 4.3.3.4 Strengths

Qualitative research explores aspects of phenomena that quantitative methods cannot (Green and Thorogood, 2018). For example, with quantitative research clinical practice can be observed and associations can be determined (see *Table 9* pg120), but this does not elicit any explanation; qualitative research is needed to elicit deeper understanding and explanation. This improves the overall understanding of a phenomenon, such that it can be addressed. For example, it was observed that younger children were more likely to achieve effective pain management than older children (see *Table 9* pg120). Instead of concluding that older children should be treated more aggressively to address the disparity, qualitative research provided an explanation for this observation; younger children express more emotion, are easier to distract and live more in the moment than their older counterpart. This explanation informed a hypothesis; the impact of emotion on the perception of pain is greater in younger children than for older children (see *Figure 9* pg201). Therefore, the disparity in rates of effective pain management is likely due to the difficulty clinicians encounter when differentiating between fear/anxiety and pain (Williams et al., 2012). If the amalgamation of fear/anxiety and pain is typically greater in younger than in older children, then younger children are likely to score higher on initial pain assessment and more likely to achieve effective pain reduction, as simpler techniques such as distraction may have a greater impact. Without qualitative methods, this level of understanding would not have been achieved.

Quantitative research deals with numerical data and stems from an objective, reductionist paradigm whereas qualitative research deals with nonnumerical information and stems from a more subjective paradigm inexplicably tied with human senses (Leung, 2015). Subjectivity and human influence are considered an undesirable bias in quantitative research, yet in qualitative research they are to be encouraged and considered essential (Leung, 2015). A strength of this research was

the human influence introduced to the research by myself, the researcher. As a clinical academic, I aim to bridge the gap between clinical practice and health care research and as discussed in section *4.3.1.5 Data analysis* my role as a clinical academic was viewed as a strength within this study.

Qualitative research can have elements of conceptual generalisability and transferability (Green and Thorogood, 2018). For example, the concept that high deprivation environments are generally more unkempt, leading to a reduced ability to assess and manage patients effectively is perhaps transferable to other settings and populations, such as primary care.

#### 4.3.3.5 Limitations

Due to the qualitative nature of this study, the results are not considered generalisable to other populations or contexts, however there is an element of conceptual generalisability and transferability (Green and Thorogood, 2018), as discussed above in section *4.3.3.4 Strengths*.

This study aimed to explain identified predictors of effective pain management. Due to the subjective nature of qualitative research, the explanations provided may not be fully conclusive and there may be alternative explanations not identified in this study. This reflects the philosophical stance of postpositivism adopted for this thesis (see section *2.1.2 Philosophical paradigm*), as we may never know the truth, but our findings are 'probably true' (Denzin and Lincoln, 1994).

Interviews provide access to what people *say*, not what people *do* (Green and Thorogood, 2018). There may be inconsistencies between the two. Nonparticipant observation could be a method to address this problem, as performed with a recent multiple case study design assessing pain management in UK emergency departments (Sampson et al., 2019); it was found that pain scoring may not accurately reflect patient experience and staff often documented pain scores themselves rather than asking the patient.

Participants offered possible explanations regarding the deprivation predictor identified in *Table 9* (pg120). Due to the limitation within the quantitative data (type of incident location was not assessed), participants may have provided experiences and perceptions associated with their previous attendances at home locations only. Therefore, the explanations offered regarding deprivation, in particular home environment and on scene time, may only be applicable to incidents occurring at home locations and may be less applicable to incidents occurring in public places or at school. Further research would be useful to explore this in greater detail.

Children and parents were not included in the qualitative study as it was considered beyond the scope of this PhD. Experiences of children and parents are highly important to fully understanding the process of pre-hospital pain management in children and it is likely such research will take place at the post-doctoral stage, perhaps using techniques such as 'draw, write and tell' (Pope et al., 2019).

#### 4.3.3.6 Implications for clinical practice

Implications for clinical practice could not accurately be made at the level of this individual generic qualitative study. They were made later within *Chapter 5 – Discussion and Conclusion* where the synthesis of data arising from *Chapter 3 – Systematic Mixed Studies Review* was combined with the meta-inferences developed in *Chapter 4 – Mixed Methods Sequential Explanatory Study* along with the identified barriers, facilitators and proposed methods of improvement, whilst also considering the surrounding literature. This allowed the production of sound implications for clinical practice, as described in section *5.4 Implications for Policy, Practice and Research*.

#### 4.3.3.7 Implications for future research

Future research should explore the perspectives of children and parents, utilising maximum variation sampling to ensure participants are recruited from areas of high

and low deprivation. This will help provide a more comprehensive understanding of the pre-hospital pain management process.

Brightly coloured paediatric tabards worn by ambulance staff should be investigated to determine their safety, practicality and effectiveness at reducing fear and anxiety experience by children during emergency call outs.

Fentanyl lollipops and non-opioid analgesics such as ketamine should be explored to determine their safety and efficacy.

Variations in crew mix, including mixed sex, rank and working with regular crewmates should be explored to determine the effect on both children and staff, particularly the staff working dynamic.

#### 4.3.4 Conclusion

In summary, novel explanations for predictors of effective pain management have been provided, barriers and facilitators have been identified; some of which have previously been identified, others are novel and potential methods for improvement have been identified.

The explanations of predictors were discussed further in section *4.4 Integration* to produce meta-inferences. These meta-inferences will be discussed along with the identified barriers and facilitators, the proposed improvements and surrounding literature regarding the context and methodology to provide a clear plan for clinical practice improvements and further research; see *Chapter 5 – Discussion and Conclusion*.

## 4.4 Integration

Integration is considered essential to the definition of mixed methods research (O'Cathain et al., 2010, Creswell, 2014). Without integration, the study would be considered multi-methods; an amalgamation of quantitative and qualitative studies interpreting and reporting their results separately.

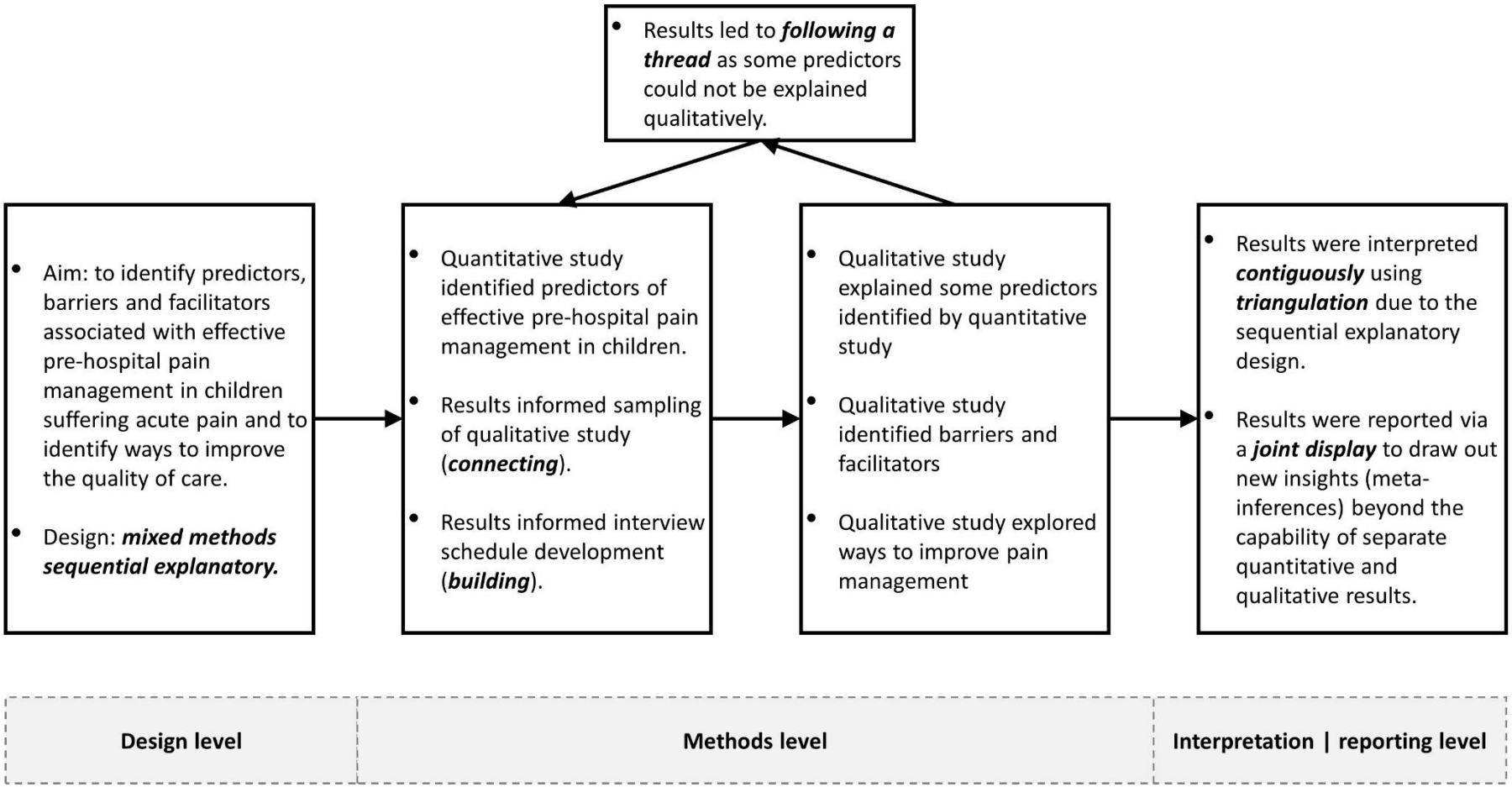
Integration can occur at different levels of a study: at the design, methods and interpretation and reporting level (Fetters et al., 2013). O'Cathain et al. (2010) described three techniques of interpretation; triangulation protocol, akin to the weaving and contiguous approach described by Fetters et al. (2013), following a thread and using a mixed methods matrix.

See *Figure 12* (pg231) for an illustration showing how integration has been achieved within this thesis.

### 4.4.1 Design level

At the design level, a sequential explanatory approach was adopted to address the aim of this research. The reason a sequential explanatory approach was chosen over the sequential exploratory and convergent approach has previously been discussed (see section *2.3.2 Mixed methods sequential explanatory approach*). The sequential explanatory design (Creswell, 2014, Fetters et al., 2013) is inherently structured to generate integration, since the second study (qualitative) aims to explain the findings of the first (quantitative). The studies were performed in sequence and not in parallel as the results of the initial quantitative study informed the development of the final qualitative study, as discussed in the next section (see section *4.4.2 Methods level*).

Figure 12 – Illustration of integration



4.4.2 Methods level

As discussed in section *4.3.1.3 Sampling*, the choice of participants for the qualitative study was informed by the results of the quantitative study. Fetters et al. (2013) described one method of integration as 'linking', with 'connecting' being a type of 'linking' where the sampling is informed by the initial study. 'Connecting' was evident within this mixed methods sequential explanatory study, as evidenced by the following two points:

1. Children attended by paramedics were significantly more likely to achieve effective pain management than those attended by non-paramedics (emergency medical technicians) (see *Table 9* pg120). This resulted in the essential recruitment of paramedics *and* technicians in the qualitative study to help explain this disparity. This created a more balanced view, with experiences and perceptions explored from both sides.
2. Clinician experience was hypothesised to be a predictor of effective pain management in children, based on anecdotal experience. This was found not to be significant in the subsequent quantitative analysis (see *Table 9* pg120). However, maximum variation sampling was still adopted in the qualitative study, to achieve a balance of views from clinicians with different levels of experience and to identify potential discordance between these perspectives; the qualitative findings suggest that clinical experience plays a fundamental role in the process of pain management, conflicting with the previous quantitative findings. Considering the qualitative results, although clinical experience was not identified as a main theme (see *4.3.2.2 Identification of barriers and facilitators*), parental status and life experience were considered to be important.

Another method of 'linking' according to Fetters et al. (2013) is 'building', which occurs when the results of one study inform the data collection approach of the other. 'Building' is evident within this mixed methods sequential explanatory study via the interview schedule (see Appendix *11*). Statistically significant predictors (see *Table 9* pg120) were included for further exploration in the interview schedule,

constituting ‘building’; moreover, they were highlighted in bold and constituted a focal point within the first phase of the interview, where a conscious effort was made to gain an in-depth explanation of these highlighted predictors. Predictors that were not identified as statistically significant were still included and discussed for the same reason as mentioned above; for the possibility of identifying discordance between the quantitative and qualitative findings.

The final method of integration used at the methods level was ‘following a thread’ (O’Cathain et al., 2010). Considering the significant association between paramedic crew and effective pain management, it was deemed necessary to explore the differences between the ‘paramedic’ and the ‘non-paramedic’ group. This was highlighted during the qualitative phase of this study (see section *4.3.2 Results*); many participants were unable to offer an explanation as to why children attended by a paramedic were more likely to achieve effective pain management than those who were not. It was therefore necessary to investigate further and identify any differences in age, sex or experience between the two groups of clinicians which might have provided plausible explanations for this finding.

Confounding by indication was also explored. It was possible that crews with at least one paramedic were more likely to be sent to higher acuity patients, because they were deemed to require a more senior clinician, and these children may therefore have reported a higher initial pain score than those attended by non-paramedic crews. This could have confounded the analysis because higher initial pain scores are more likely to demonstrate regression to the mean (Barnett et al., 2004), potentially giving a greater pain reduction than those reporting moderate or mild pain initially. See Table *12* (pg234) for the comparison.

Table 12 – Integration: Comparison of senior clinician characteristics between the paramedic and non-paramedic group.

| Characteristic | Paramedic crew (n=1603) | Non-paramedic crew (n=709) | p value* |
|---|---|---|---|
| Senior clinician experience, y | | | |
| Mean (SD) | 12.5 (8.7) | 7.0 (7.5) | <0.0001 |
| Median (IQR) | 11 (5, 18) | 3 (2, 9) | <0.0001 |
| Senior clinician sex, proportion | | | |
| Male, (%) | 927 (57.8) | 422 (59.5) | 0.4468 |
| Female, (%) | 567 (35.4) | 215 (30.3) | 0.0180 |
| Not Known, (%) | 109 (6.8) | 72 (10.2) | 0.0056 |
| Senior clinician age, y | | | |
| Mean (SD) | 43.6 (10.1) | 40.7 (10.8) | <0.0001 |
| Median (IQR) | 44 (37, 51) | 41 (31, 49) | <0.0001 |
| Initial numeric pain score | | | |
| Median (IQR) | 7 (5, 8) | 7 (4, 8) | 0.5782 |
| Mean (SD) | 6.2 (2.7) | 6.1 (2.7) | 0.4116 |
| Initial visual pain score | | | |
| Median (IQR) | 4 (2, 6) | 4 (2, 6) | 0.1099 |
| Mean (SD) | 4.6 (2.8) | 4.3 (2.7) | 0.0164 |

y – year, IQR – interquartile range, SD – standard deviation

*t-test (means); binomial probability test (proportions as percentage); Wilcoxon rank-sum test (medians)

*Table 12* (pg234) shows that the 'paramedic crew' senior clinicians were significantly more experienced, included a higher percentage of female clinicians, were older and attended children with a higher initial mean visual pain score than the 'non-paramedic crew' senior clinicians, indicating a degree of confounding by indication which was discussed in section *4.2.3.2.3 Confounding*.

It was also found in the qualitative study that technicians may spend less time on scene (see *Figure 8* pg200). This was investigated in the quantitative data, see *Table 13* (pg235).

Table 13 – Integration: 'On scene' time versus paramedic crew

| | Paramedic crew (n=1306) | Non-paramedic crew (n=586) | All (n=1892) | p-value* (Paramedic vs Non-paramedic) |
|---|---|---|---|---|
| On scene time, mins | | | | |
| Mean (SD) | 34.63 (18.61) | 30.93 (17.71) | 33.49 (18.41) | 0.0001 |
| Median (IQR) | 31 (22-44) | 28 (20-37) | 28 (22-42) | <0.0001 |

*t-test for means, Wilcoxon Rank Sum test for medians

*Table 13* (pg235) shows that when a child is attended by a paramedic, the crew spend significantly longer on scene than when a child is attended by a technician, substantiating the qualitative finding that technicians were perceived to spend less time on scene (see *Figure 8* pg200).

I 'followed a thread' to explore several theories, therefore generating and answering several questions simultaneously; one of the benefits of mixed methods research. For example, I theorised that clinicians may spend less time on scene with children who lived in areas of high deprivation due to the environment possibly being unkempt. I was able to compare the on-scene time for clinicians attending children living in areas of high and low deprivation to assess for any difference.

Table 14 – Integration: 'On scene' time versus index of multiple deprivation

| | Index of multiple deprivation | | | | | p-value* (High vs Low) |
|---|---|---|---|---|---|---|
| | High (n=553) | Med (n=468) | Low (n=287) | Missing (n=584) | All (n=1892) | |
| On scene time, mins | | | | | | |
| Mean (SD) | 31.65 (17.13) | 34.09 (21.05) | 37.35 (20.32) | 32.84 (15.89) | 33.49 (18.41) | <0.0001 |
| Median (IQR) | 26 (20-38) | 28 (22-42) | 33 (24-46) | 31 (22-39) | 28 (22-42) | <0.0001 |

*t-test for means, Wilcoxon Rank Sum test for medians
High – IMD 1-3, Med – IMD 4-7, Low – IMD 8-10

*Table 14* (pg235) shows that ambulance crews spend significantly less time on scene when attending children in areas of higher deprivation. This substantiated the explanation identified from the thematic analysis (see *Figure 8* pg200) that participants perceived that some environments in areas of high deprivation were more unkempt. Possibly due to a dirtier and untidier environment, ambulance crews may have opted for early extrication to the ambulance and therefore an earlier departure to hospital. This may decrease the likelihood of the child receiving analgesics or non-pharmacological interventions, reducing their chances of achieving effective pain management. Alternatively, the rates of analgesic administration could be similar, but the opportunity for the analgesic to take effect may be reduced, reducing the chances of observing a positive clinical effect (abolition or reduction of pain score by 2 or more out of 10). I assessed the rates of analgesic administration between the levels of deprivation, to address the aforementioned hypothesis and to investigate the finding that some participants perceived parents from areas of low deprivation as more demanding (see *Figure 8* pg200). It was felt that if parents were more demanding, the rates of analgesic administration may be higher, see *Table 15* (pg236).

Table 15 – Integration: Rates of analgesic administration versus index of multiple deprivation

| | **Index of multiple deprivation** | | | | | **p-value* (High vs Low)** |
|---|---|---|---|---|---|---|
| | **High (n=656)** | **Med (n=580)** | **Low (n=349)** | **Missing (n=727)** | **All (n=2312)** | |
| Analgesic administered, n | | | | | | |
| Yes (%) | 397 (60.5) | 382 (65.9) | 229 (65.6) | 455 (62.6) | 1463 (63.3) | 0.1124 |
| No (%) | 259 (39.5) | 198 (34.1) | 120 (34.4) | 272 (37.4) | 849 (36.7) | |

*test of proportions

High – IMD 1-3, Med – IMD 4-7, Low – IMD 8-10

*Table 15* (pg236) shows that children living in areas of high deprivation were administered lower rates of pain medication (60.5%) than those in areas of low deprivation (65.6%), however this difference was not statistically significant (p=0.1124). This may mean that parents from areas of low deprivation are more demanding, however there are likely to be other explanations that require exploration, such as unconscious clinician bias for example.

The final integrative analysis within the methods level to take place was to examine initial pain scores in younger compared with older children. Younger children were significantly more likely to achieve effective pain management than older children (see *Table 9* pg120), which was explained by younger children being more emotional, easier to distract and living more in the moment than older children (see *Figure 8* pg200). It was hypothesised that the emotional impact on the perceived level of pain was higher in younger children than for older children (see section *4.3.3.1.1 Child age*) and therefore it was felt that the initial pain score reported by younger children may be higher than that of older children. This additional analysis was performed to assess this theory, see *Table 16* (pg237).

Table 16 – Integration: Initial pain score versus child age

| | **Child age, years** | | | | **p-value* (0-5 vs 12-17)** |
|---|---|---|---|---|---|
| | **0-5 (n=63)** | **6-11 (n=366)** | **12-17 (n=1328)** | **All (n=1757)** | |
| Initial pain score, numeric | | | | | |
| Mean (SD) | 3.30 (3.42) | 5.67 (2.99) | 6.41 (2.46) | 6.14 (2.69) | <0.0001 |
| Median (IQR) | 2 (0-6) | 6 (4-8) | 7 (5-8) | 7 (4-8) | <0.0001 |
| | **Child age, years** | | | | **p-value* (0-5 vs 12-17)** |
| | **0-5 (n=312)** | **6-11 (n=421)** | **12-17 (n=573)** | **All (n=1306)** | |
| Initial pain score, visual | | | | | |
| Mean (SD) | 4.76 (2.91) | 4.62 (2.76) | 4.32 (2.70) | 4.52 (2.78) | 0.0245 |
| Median (IQR) | 4 (2-8) | 4 (2-6) | 4 (2-6) | 4 (2-6) | 0.1052 |

*t-test for means, Wilcoxon Rank Sum test for medians

*Table 16* (pg237) shows that younger children reported a significantly higher mean initial visual pain score than older children (p=0.0245). Conversely, younger children reported a significantly lower initial numeric pain score than older children (p<0.0001).

This integration led to a much deeper understanding of this complex phenomenon, discussed further in section *5.2.1.1 Meta-inferences developed from this thesis*.

### 4.4.3 Interpretation and reporting level

The integration achieved at the interpretation and reporting level is often best illustrated through the use of a joint display (Guetterman et al., 2015, Fetters et al., 2013). Such displays show the main results from the quantitative and qualitative study, allowing a comparison of findings *across* studies.

Due to the sequential nature of this study, findings from both studies were combined to create 'meta-inferences' using triangulation techniques (O'Cathain et al., 2010) where the data agreed, expanded or contradicted each other. The data were considered in agreement when a clear explanation was provided for the predictor (for example child age) and in contradiction when the explanation argued against the predictor (for example type of pain).

There is a line of argument that quantitative and qualitative finding are not capable of confirming or refuting each other as they seek to answer different aspects of a phenomenon (Sandelowski et al., 2006). Complementarity was assessed during the meta-integration of the systematic mixed studies review (*3.3.6 Meta-integration*) rather than confirmation/refutation. This was due to the nature of incorporating individual findings from separate studies; the findings did not address the same aspect of the target phenomenon. However, with the mixed methods sequential explanatory design of this study, it was felt that the integration allowed the findings to address the same aspect of the target phenomenon, providing explanation and therefore some of the findings were able to confirm or refute each other. See *Table 17* (pg240) for the joint display of the mixed methods findings.

Fundamental to the process of making meta-inferences is having a comprehensive understanding of the participants and context of the research. Without first understanding the participants and the social and cultural context of their behaviours and experiences, the credibility of the meta-inferences drawn will be compromised, even if the methodological approach is robust (Teddlie and Tashakkori, 2009). Making meta-inferences is an art as much as it is about science; it involves elements of creativity, intuition and meaning making and requires the ability to compartmentalise aspects of a phenomenon, understand them and then reconstruct the parts to create a whole (gestalt) for a full understanding that is considered more than or beyond the sum of its parts (Teddlie and Tashakkori, 2009).

A number of steps have been proposed by Teddlie and Tashakkori (2009) when developing meta-inferences; 1) keep the research purpose and question at the forefront of the development process, 2) make tentative interpretations (inferences) about each part of the results, which answer some or all of the research question and 3) examine the interpretations to see if they can be combined, compared, contrasted and explain any differences between them. These three steps were considered when developing the meta-inferences shown in *Table 17* (pg240) and they were generated using an iterative process of discussion between myself and my supervisory team.

Table 17 – Integration: Joint display showing relationship between quantitative and qualitative findings

| **Quantitative findings** (see *Table 9* pg120) | | **Qualitative findings** (*4.3.2.1 Explanation of predictors*) | **Meta-inference** |
|---|---|---|---|
| Predictors of effective pain management* | AOR** (95% CI) | Themes | |
| Younger (0-5 years) versus older children (12-17 years) | 1.53 (1.18–1.97) | • Younger children express more emotion<br>• Younger children are easier to distract<br>• Younger children live in the moment<br>• Older children dwell on the consequences of illness of injury | Younger children achieve more effective pain management than older children. This was perceived to be because younger children express more emotion, therefore are easier to distract and they live more in the moment than their older counterpart. |
| Children administered analgesics versus no analgesics | 2.26 (1.87–2.73) | • Analgesic administration reduces physiological pain<br>• Analgesic administration reduces psychological distress | Children administered analgesics achieve more effective pain management than those who are not. This was perceived to be because analgesics reduce physiological pain and psychological distress. |
| Children attended by a paramedic versus non-paramedic (EMT) | 1.46 (1.19–1.79) | • Paramedics can administer morphine<br>• Technicians are less confident<br>• Technicians spend less time on scene<br>• Technician scope of analgesics (conflict)<br>• People skills most important<br>• No perceived difference between paramedics and technicians | Children attended by paramedics achieve more effective pain management than those attended by EMTs. This was perceived to be because paramedics are older, more experienced, more confident, have a greater scope of practice and spend more time on scene than EMTs. |

| **Quantitative findings** (see *Table 9* pg120) | | **Qualitative findings** (*4.3.2.1 Explanation of predictors*) | **Meta-inference** |
|---|---|---|---|
| Predictors of effective pain management* | AOR** (95% CI) | Themes | |
| Children living in an area of low (IMD 8-10) versus high (IMD 1-3) deprivation | 1.37 (1.04–1.80) | • High – limited analgesic stock<br>• High – lack of transport<br>• High – unkempt environment<br>• Low – more demanding<br>• Low – rely on advice to treat child<br>• Low – seek help earlier<br>• No perceived influence on clinician | Children living in areas of low deprivation achieve more effective pain management than those in areas of high deprivation. This was perceived to be because the kempt environment facilitates assessment and management, clinicians spend more time on scene and their parents were perceived as more demanding. |
| Male versus female children*** | 1.17 (0.98–1.39) | • Male children act tough<br>• No perceived difference between treating male and female children | There was no statistical difference in rates of effective pain management between male and female children. This was supported by the interviews where most participants stated they expected no difference. This finding conflicts with previous research and therefore requires further investigation. |

| **Quantitative findings** (see *Table 9* pg120) | | **Qualitative findings** (*4.3.2.1 Explanation of predictors*) | **Meta-inference** |
|---|---|---|---|
| Predictors of effective pain management* | AOR** (95% CI) | Themes | |
| Children suffering traumatic versus medical pain*** | 1.18 (0.97–1.43) | • Traumatic injuries are visible<br>• There is a presumption of pain in trauma<br>• Trauma creates urgency<br>• Medical pain is more complex<br>• Medical pain is a 'longer game' | There was no statistical difference in rates of effective pain management between children suffering traumatic and medical pain. The qualitative findings along with previous research conflicted with this lack of statistical difference, therefore further research is required. |

AOR – adjusted odds ratio, CI – confidence interval, IMD – index of multiple deprivation, EMT – emergency medical technician

*Defined as the abolition or reduction of pain by ≥2 out of 10. **Adjusted for patient age, patient sex, type of pain, senior clinician experience, analgesic administration, non-pharmacological treatment administration, paramedic crew, hospital travel time and index of multiple deprivation. ***Not significant however other studies have found these predictors significant.

#### 4.4.3.1 Quality assessment of meta-inferences

When considering quality assessment of mixed methods studies as a whole, the good reporting of a mixed methods study (GRAMMS) criteria has been proposed as a reporting guideline (O'Cathain et al., 2008). Criterion 6 from the GRAMMS guideline *'Describe any insights gained from mixing or integrating methods'* (O'Cathain et al. (2008) pg 97) seeks to ensure any meta-inferences generated from mixed methods research are adequately described in published outputs.

There are several considerations when attempting to assess the quality of meta-inferences derived from a mixed methods study. It could be argued that meta-inferences generated from mixed methods studies are weak, given the challenges of integrating findings from two diverse study types (Teddlie and Tashakkori, 2009). In addition to this, some may argue that there is inconsistency between standards for assessing inferences of quantitative and qualitative studies, making meta-inference assessment of mixed methods studies impossible (Teddlie and Tashakkori, 2009). Given these challenges, Teddlie and Tashakkori (2009) have provided an integrative framework for assessing inference quality. This was later incorporated into a broader more encompassing 'quality framework for mixed methods research' discussed by O'Cathain (2010).

The integrative framework for assessing inference quality is divided into two sections: 'design quality' (assessing: 1. design suitability, 2. design fidelity, 3. within-design consistency and 4. analytic adequacy) and 'interpretive rigor' (assessing: 5. interpretive consistency, 6. theoretical consistency, 7. interpretive agreement, 8. interpretive distinctness, 9. integrative efficacy and 10. integrative correspondence) (Teddlie and Tashakkori, 2009). The quality of meta-inferences rests on the quality of the initial inferences generated from both quantitative and qualitative studies. The process of evaluation for inference quality (Teddlie and Tashakkori, 2009) requires satisfaction of criteria 1-8 and 10 for both sets of inferences, followed by satisfaction of criteria 9 and 10 for meta-inferences in order to ensure the reporting of good quality meta-inferences. See *Table 18* (pg244) for the quality assessment of meta-inferences.

Table 18 – Integration: Quality assessment of meta-inferences

| Aspect of quality | Research criterion | Example | Criterion met? |
|---|---|---|---|
| Design quality<br><br>(*the degree to which the researcher has selected and implemented the most appropriate procedures for answering the research questions*) | 1. Design suitability (appropriateness) | The method of study was suitable and appropriate to answer the research question, for example the cross-sectional study design was adopted over other methods such as cohort study and randomised controlled trial due to the observational need to assess children at one point in time, as discussed in section *2.3.3 Cross-sectional study*. The overall mixed methods sequential explanatory design was justified in section *2.3.2 Mixed methods sequential explanatory approach*. | Yes |
| | 2. Design fidelity (adequacy) | The components of the design were implemented adequately, for example the use of semi-structured interviews to elicit in-depth detail without leading to disengaged and exhausted participants or researchers (see section *4.3.1.4 Data collection*) were well justified and ensured the process was adequate to achieve the level of understanding required to address the research question. | Yes |
| | 3. Within-design consistency | The design components, such as sampling and data collection were considered a good fit. For example, the sampling of paramedics and EMTs for the qualitative study matched well with the decision to perform individual semi-structured interviews as this avoided 'silencing' of minority views or intimidation by senior ranks, as discussed in section *4.3.1.4 Data collection*. | Yes |
| | 4. Analytic adequacy | The analysis was considered adequate, for example a multivariable logistic regression was used to determine the predictors of effective pain management rather than a univariable analysis as discussed in section *4.2.1.5 Data analysis*. Further, no a priori themes were used to guide the final section of the qualitative interviews, encouraging new methods of improvement to be uncovered, as discussed in section *4.3.1.4 Data collection*. | Yes |

| Aspect of quality | Research criterion | Example | Criterion met? |
|---|---|---|---|
| Interpretive rigor<br><br>(*the degree to which credible interpretations have been made based on the obtained results*) | 5. Interpretive consistency | Interpretive consistency is evident within this study, for example the themes and sub-themes generated within the qualitative study were supported by numerous quotations, presented within section *4.3.2 Results*, demonstrating transparency and a clear audit trail from raw data to interpretations. | Yes |
| | 6. Theoretical consistency | The inferences were consistent with current theory and the state of knowledge in the field, for example many of the barriers and facilitators along with identified improvements had already been identified, including the need for intranasal analgesics as discussed in section *4.3.3.3 Exploration of improvements*. | Yes |
| | 7. Interpretive agreement | Interpretive agreement was evident as other scholars have, given the same findings, agreed on the conclusions I have made. For example, the conclusions generated from this study have been discussed extensively between myself and three supervisors with a consensus on conclusions achieved. Further, the cross-sectional study has been published in a peer-reviewed journal (Whitley et al., 2020b) where blinded peer review has been successfully undertaken, adding to the number of scholars who agree with my conclusions. | Yes |
| | 8. Interpretive distinctiveness | Each inference was more credible than other plausible conclusions that might be made using the same findings. For example, whilst explaining the child sex predictor within the qualitative study, two explanations were offered; no difference and male children act tough (*4.3.2.1.6 Child sex*). The former finding was used to generate the conclusion and meta-inference as it was more plausible; the view was represented by the majority of participants and it adequately explained the 'no difference' finding from the quantitative study. However, alternative interpretations are valid and coupled with previous findings of statistically significant differences between male and female children (see *Table 2* pg75), warrant further research. | Yes |

| Aspect of quality | Research criterion | Example | Criterion met? |
|---|---|---|---|
| Interpretive rigor<br><br>(*the degree to which credible interpretations have been made based on the obtained results*) | 9. Integrative efficacy | The inferences generated within each strand (quantitative and qualitative study) were effectively integrated into a theoretically consistent meta-inference. For example, there was clear agreement between the 'child age' predictor and the explanation offered generating a simple but seamless meta-inference that was well placed within the literature, as discussed in section *5.2.1.1 Meta-inferences developed from this thesis*. Another example included the 'paramedic crew' predictor; the qualitative inferences were unable to adequately explain the quantitative inference, therefore I 'followed the thread' (O'Cathain et al., 2010) back to the quantitative data to elicit further understanding that was more theoretically consistent (see section *4.4.2 Methods level*) and well placed within the literature (*5.2.1.1 Meta-inferences developed from this thesis*). | Yes |
| | 10. Interpretive correspondence | The meta-inferences generated from this study satisfy the initial purpose for utilising a mixed methods approach. One of the reasons for using a mixed methods approach was to create a deeper understanding of this highly complex phenomenon and delineate some of the barriers to effective pain management in children, as discussed in section *4.1 Introduction*. To my knowledge, explanations for predictors of effective pain management in children in the ambulance service have not previously been provided, therefore this new knowledge will extend the body of evidence and provide a much needed deeper understanding, as discussed in *Chapter 5 – Discussion and Conclusion*. | Yes |

Adapted from Teddlie and Tashakkori (2009) pg 301-302

Inferences should meet criteria 1-8 and 10 for progression to meta-inference development and meta-inferences should meet criteria 9-10 for reporting of findings (Teddlie and Tashakkori, 2009).

*Table 18* (pg244) shows that the meta-inferences generated from this study were of good quality (Teddlie and Tashakkori, 2009). These meta-inferences were discussed further along with their transferability in section *5.2.1 Meta-inferences*.

# Chapter 5 – Discussion and Conclusion

## 5.1 Overview

Previous research concluded that pre-hospital pain management in children was poor (Samuel et al., 2015, Murphy et al., 2016, Lord et al., 2016, Whitley and Bath-Hextall, 2017). Oligoanalgesia was prevalent in children suffering pain in the pre-hospital setting (Whitley and Bath-Hextall, 2017, Lord et al., 2016, Lerner et al., 2014, Watkins, 2006, Browne et al., 2016a). Several barriers had been identified to the pain management process for children, including a lack of education, training and exposure of clinicians to children, coupled with difficulty in assessing and treating pain (Murphy et al., 2014, Williams et al., 2012). Pain (see section *1.2.2 Pain*), children (see section *1.2.3 Children*) and the unpredictable ambulance service setting (see section *1.2.1 Ambulance service*) create a highly complex intersection.

The combination of oligoanalgesia, barriers to the pain management process and the highly complex nature of this phenomenon produce significant challenges when attempting to improve the quality of care for this patient group. A deeper understanding of the complexities involved in this process was required in order to provide evidence to improve the quality of care.

The aim of this thesis was to build on these previous findings and further examine why pain management in children in the pre-hospital setting was poor. To help create a deeper understanding of this complex phenomenon, a mixed methods approach was taken to develop unique insights, identify previously unrecognised barriers and delineate the perceived barriers (see section *2.3.2 Mixed methods sequential explanatory approach*).

The objectives of this thesis were to review the existing evidence regarding predictors, barriers and facilitators; identify predictors of effective pain management in children; explain any identified predictors; identify barriers and facilitators and explore ways to improve pain management in children.

*Chapter 3 – Systematic Mixed Studies Review* investigated the evidence base and found eight studies that identified predictors of effective pain management and five studies that identified barriers and facilitators (Whitley et al., 2020a). These studies were synthesised and integrated within a meta-integration (see *Table 4* pg88) to produce recommendations for clinical practice and further research. These recommendations were to explore ways to facilitate analgesic administration and to address the culture of managing traumatic pain more readily than medical pain. Considering the conflict between the predictor 'child age' and the lack of evidence to explain the 'child sex' predictor, further research was deemed necessary; the proposed mixed methods study was therefore justified and initiated.

*Chapter 4 – Mixed Methods Sequential Explanatory Study* investigated the predictors of effective pain management in children in the pre-hospital setting and aimed to explain these predictors using qualitative methods, whilst also exploring barriers and facilitators and ways to improve pain management. This study made several novel findings:

1. Level of deprivation influenced the likelihood of children achieving effective pain management (Whitley et al., 2020b). This predictor has not previously been identified in this context and setting. This study aimed to explain this disparity, amongst others, and the inferences generated from the quantitative (see section *4.2 Cross-sectional Study*) and qualitative study (see section *4.3 Generic Qualitative Study*) were integrated into meta-inferences (see section *4.4 Integration*) and discussed in the next section: *5.2.1.1 Meta-inferences developed from this thesis*.
2. Several barriers were identified that have not previously been identified in this patient population and context, including child related (visualisation of trauma, shame, embarrassment and prior experience of pain) and clinician related (empathy, parental status, life experience, limited 'in service' training, service demand, lack of paediatric equipment and environmental factors including light, noise and colour) barriers.

The combination of the known and newly identified predictors, barriers and facilitators coupled with the participants' perception of how they felt pain management could be improved allowed the production of a driver diagram (ACT Academy, 2020) (see Figure *14* pg287) which provided recommendations for clinical practice improvement, discussed further in section *5.4 Implications for Policy, Practice and Research*.

This thesis produced several findings all related to the same phenomenon of interest. These findings were in the form of meta-inferences (generated from the findings of the cross-sectional study and the initial explanatory phase of the generic qualitative study), barriers and facilitators and proposed methods of improvement. The identified barriers and facilitators were discussed extensively with regard to their relationship with existing literature in section *4.3.3.2 Identification of barriers and facilitators*. The identified methods of improvement were also discussed in section *4.3.3.3 Exploration of improvements* and further discussed in section *5.4.2 Practice*. Although the predictors of effective pain management were discussed in section *4.2.3 Discussion*, and the proposed explanations for these predictors were discussed briefly in section *4.3.3.1 Explanation of predictors*, the meta-inferences generated (see *Table 17* pg240) were not discussed. Therefore, this chapter discusses the meta-inferences generated from this thesis along with their transferability, the overall philosophical considerations, the perceived contribution to theory, a reflexive section discussing how the research and researcher were shaped over the course of this PhD along with a section discussing the impact of patient and public involvement.

The main contributions of this thesis are listed below, and the strengths and limitations of this thesis (see section *5.3 Strengths and Limitations*) and the recommendations for policy, practice and research (see section *5.4 Implications for Policy, Practice and Research*) are discussed later in this chapter.

### 5.1.1 Main contributions of this thesis

The main contributions of this thesis are highlighted below:

1. Comprehensively and concisely synthesised the existing literature on predictors, barriers and facilitators to effective pre-hospital pain management in children (Whitley et al., 2020a).
2. Identified a novel predictor of effective pre-hospital pain management in children: level of deprivation (Whitley et al., 2020b).
3. Offered possible explanations to previously observed phenomena, including the newly identified level of deprivation predictor (see sections *4.3.2.1 Explanation of predictors*, *4.3.3.1 Explanation of predictors* and *5.2.1.1 Meta-inferences developed from this thesis*).
4. Identified novel barriers and facilitators to effective pre-hospital pain management in children (see section *4.3.3.2 Identification of barriers and facilitators* and *Figure 10* pg208).
5. Provided a clear plan to improve pre-hospital pain management in children (see section *5.4.2 Practice* and driver diagram *Figure 14* pg287).
6. Provided clear recommendations for policy (see section *5.4.1 Policy*) and future research (see section *5.4.3 Research*).
7. Proposed a novel theoretical model for pre-hospital pain management in children (see section *5.2.3 Contribution to theory* and *Figure 13* pg270).

## 5.2 Discussion

### 5.2.1 Meta-inferences

Meta-inference was defined as *'a conclusion generated by integrating the inferences obtained from the qualitative and quantitative strands of a mixed methods* study' (Adapted from Teddlie and Tashakkori (2009) pg338). Inferences generated from the cross-sectional and generic qualitative study have been discussed in their respective chapters (see sections *4.2.3 Discussion* and *4.3.3.1 Explanation of predictors*). The aim of this section was to discuss the meta-inferences generated from the integration of the inferences produced by the cross-sectional study and the initial explanatory part of the qualitative study. These meta-inferences were identified within the integration chapter (see section *4.4.3 Interpretation and reporting level*), see *Table 17* (pg240).

#### 5.2.1.1 Meta-inferences developed from this thesis

##### 5.2.1.1.1 Child age

*Younger children achieve more effective pain management than older children. This was perceived to be because younger children express more emotion, therefore are easier to distract and they live more in the moment than their older counterpart.*

This meta-inference may imply that ambulance service clinicians struggle to differentiate between pain and a child's display of emotion. Initial mean visual pain scores documented for younger children were significantly higher than for older children (see *Table 16* pg237). Ambulance clinicians report finding it challenging to differentiate between the physiologic pain a child may be suffering and their display of emotion, such as fear and anxiety caused by the stress of the situation (Williams et al., 2012). This difference in pain score may be due to the increased emotional state (McGrath, 1994).

Fear and anxiety are both important emotions to consider in the perception and assessment of acute pain (McNeil et al., 2018); they may increase the perception of pain (Choinière et al., 1989, Yildizeli Topcu et al., 2019, Hirsh et al., 2008, McGrath, 1994) which could increase fear and anxiety, creating a vicious cycle (Andreasen et al., 1972, Choinière et al., 1989, McGrath, 1994). Reducing fear and anxiety experienced by children during attendances by ambulance clinicians may reduce their perceived level of physiological pain by disrupting this positive feedback loop. Arguably, this may be easier to achieve in younger children given their initial heightened emotional state, due to the greater scope for reduction and perhaps because younger children were perceived to live more in the moment (see *Figure 8* pg200). McGrath (1994) stated that younger children are often affected adversely by heightened emotions due to treatments, medical tests, admission to hospital and separation from family, whereas older children are more distressed by the implications of their illness/injury on their potential for a normal, healthy life (supporting this meta-inference). Distraction techniques are likely to reduce the heightened emotional state in younger children and therefore may contribute to the observed reduction in pain. Distraction techniques are rarely documented in the pre-hospital setting (Pilbery et al., 2019) hence it is difficult to test this theory. Prospective research could explore this with a comprehensive data collection approach to capture different types of non-pharmacological intervention.

One of the findings of this thesis was that analgesic administration was not a predictor of effective pain management for younger children (0-5 years) (see *Table 10* pg121), with an adjusted odds ratio (95% confidence interval) of 1.19 (0.75-1.89). Non-pharmacological techniques might predict effective pain management in younger children (0-5 years); a more comprehensive dataset including a wide range of non-pharmacological techniques would be required to assess this hypothesis.

The observed disparity in rates of effective pain management between younger and older children may be due to the inability of the clinician to accurately assess pain. A pain assessment tool with the capability to identify and account for emotional distress may be useful and could provide a more meaningful baseline for

comparison between the ages. Such a tool would require development and validation.

Fisher et al. (2017) identified several (n=7) scales that assessed pain anxiety, pain catastrophizing and fear of pain in children suffering chronic pain. These scales could be adapted and developed to assess children suffering acute pain in the pre-hospital setting. The Faces Anxiety Scale (McKinley et al., 2003) was developed as an anxiety self-report tool for intensive care patients and could be adapted and combined with the Wong and Baker FACES® scale to assess both pain and anxiety in children.

It could be argued that separating and assessing emotional distress and physiologic pain is not necessary, because the reduction of both is considered a desirable outcome and efforts should be focussed on accurate documentation and facilitation of non-pharmacological interventions rather than distinguishing between pain and emotion. This was highlighted during the patient and public involvement within this research, as discussed in section *5.2.5 Patient and public involvement*.

*Conclusion:*

Non-pharmacological interventions may predict effective pain management in younger children (0-5 years) in the pre-hospital setting. Further research involving comprehensive clinical data (including all non-pharmacological interventions), parents and children would be useful to explore this further.

5.2.1.1.2 Analgesic administration

*Children administered analgesics achieve more effective pain management than those who are not. This was perceived to be because analgesics reduce physiological pain and psychological distress.*

The pharmacological impact of analgesic administration for children suffering pain is well established and its benefit was an expected finding in this thesis. However, the perceived psychological benefit of administering analgesics was interesting. This was discussed in section *4.3.3.1.2 Analgesic administration* and likened to the placebo effect, particularly due to the participant statement *'so you've got the psychological side that 'I've had something for the pain' as well'*. Although likened to the placebo effect, this cannot accurately be described as a placebo effect, or 'placebo analgesia' (Benedetti, 2007) as this would require the absence of analgesic administration. A better description would be the psychosocial component of treatment (Colloca et al., 2004). Colloca et al. (2004) stated that treatments in general have specific and non-specific effects. For example, a specific effect would be the pharmacological action of an analgesic and a non-specific effect would be the psychosocial effect, or the psychological impact of receiving treatment.

Colloca et al. (2004) explored overt versus covert administration of analgesics to patients suffering from Parkinson's disease and found that those who were administered analgesics overtly achieved more effective pain management; reduction of pain was quicker, but their pain relapsed quicker once analgesic treatment was stopped. This psychosocial effect may influence the pre-hospital child pain management process, although it would be difficult to demonstrate this since covert analgesic administration in children would be challenging (and arguably unethical) (National Institute for Health and Care Excellence, 2020b, Guidry-Grimes et al., 2020).

One of the barriers of effective pain management identified in previous research and in the systematic review in *Chapter 3 – Systematic Mixed Studies Review* was that oral analgesics take a long time to act, compared to the inhaled or intravenous route for example. Whilst this is true (Ritter et al., 2019, Whitley and Bath-Hextall, 2017), there may be psychosocial effects in addition to specific pharmacological effects of taking these 'slow acting' analgesics.

The relationship between clinicians who perceive oral analgesics to have a slow onset and the subsequent rate at which they administer oral analgesics is unclear. It would be useful to explore this because not administering analgesics due to their

perceived slow onset would likely reduce the chances of achieving effective pain management, both from a lack of specific pharmacological action *and* a lack of psychosocial effects.

*Conclusion:*

It was strongly recommended that methods to facilitate pre-hospital analgesic administration in children should be sought, as this would promote the psychosocial benefit of administering analgesics. Such methods should consider the route of administration, prioritising routes with faster onset times. This was discussed further in section *5.4 Implications for Policy, Practice and Research*.

5.2.1.1.3 Clinician rank

*Children attended by paramedics achieve more effective pain management than those attended by EMTs. This was perceived to be because paramedics are older, more experienced, more confident, have a greater scope of practice and spend more time on scene than EMTs.*

The association between older more experienced clinical staff providing more effective pain management and a higher quality of care should not be assumed. There is evidence to the contrary; older more experienced clinicians may be at risk of providing a lower quality of care as they may have less factual knowledge and are less likely to adhere to appropriate standards of care (Choudhry et al., 2005). As discussed in section *4.3.3.2.3 Knowledge and experience*, Tsugawa et al. (2017) found that in hospital patients ≥65 years of age suffered a higher mortality rate when treated by older doctors. Interestingly, at univariable analysis, children attended by clinicians aged 60-69 years were less likely to achieve effective pain management than those attended by 20-29 year old clinicians (see *Table 8* pg118). The difference in age between paramedics and EMTs identified in *Table 12* (pg234)

is a potential reason for the observed disparity, however further research is needed to fully understand this association.

Clinician confidence in communicating with patients is considered important, however the impact of confidence on patient outcomes is unclear (Hecimovich and Volet, 2009). Clinicians who are more confident may be more likely to interact directly with the child and take a holistic approach, creating a stronger clinician-patient relationship. McCaffery (2002) discussed the benefit of a strong clinician-patient relationship; giving a few minutes of undivided attention to the patient discussing their pain may be the most effective non-pharmacological treatment for pain. Therefore, increased clinician confidence may strengthen the clinician-patient relationship through more direct patient interaction, providing a beneficial psychosocial effect.

The enhanced scope of practice and extended length of on-scene time are both likely to be associated with rates of effective pain management. Intravenous morphine sulphate is more effective and faster at reducing pain in children in the pre-hospital setting than paracetamol tablets and suspension, and oral morphine is more effective at reducing pain than paracetamol tablets (Whitley and Bath-Hextall, 2017). The extended on-scene time, identified in *Table 13* (pg235), allowed more time for administered analgesics to take effect and for those effects to be measured, therefore the observed disparity could partly be explained by this time difference. When considering the whole patient journey, it was difficult to say with any confidence how this difference in on-scene time may impact on the quality of care. It would be useful to explore linked data between the pre-hospital and emergency department phase of care to assess overall quality of care, including pain management and patient satisfaction.

*Conclusion:*

It was recommended that ambulance services prioritise staff training and maximise the number of highly trained clinicians. Increased numbers of paramedics may increase the rates of effective pain management in children. This association was

clear from *Table 9* (pg120) and was reinforced during the qualitative study and integration techniques. This was discussed further in section *5.4 Implications for Policy, Practice and Research*.

5.2.1.1.4 Deprivation

*Children living in areas of low deprivation achieve more effective pain management than those in areas of high deprivation. This was perceived to be because the kempt environment facilitates assessment and management, clinicians spend more time on scene and their parents were perceived as more demanding.*

It was perceived by participants during the qualitative study that homes of less-affluent families were less welcoming and unkempt, which resulted in more challenging assessment and management of the child. As discussed in section *4.3.3.1.4 Level of deprivation*, medical consultations in enhanced environments (increased light, space and greater comfort) improve the communication between the patient and clinician, reducing patient anxiety and improving the satisfaction of both patients and clinicians (Rice et al., 2008). To corroborate this finding, it was found that clinicians spent significantly more time on scene when attending children who lived in less deprived areas (see *Table 14* pg235). The association between less welcoming, unkempt environments and early extrication was unclear; this was because other explanations may be present for reduced on-scene time, such as unconscious bias among clinicians (Blair et al., 2011) or ethnic minority differences where cultural or language barriers may precipitate (Flores, 2006).

It was perceived by some of the participants that more affluent parents were more demanding; this was partly substantiated from the quantitative data, as there was a small difference in the rate of analgesic administration between areas of low (65.6%) and high (60.5%) deprivation, however this difference was not statistically significant (p=0.1124) (see *Table 15* pg236).

Ezenwa and Huguet (2013) reviewed the evidence regarding sociodemographic disparities (age, gender, ethnicity, health-insurance and residential region) in child pain management. It was found that most studies did not find statistically significant disparities in care, and of those that did, it was unclear whether they were clinically meaningful. One study was found reporting on the impact of residential region (Yen et al., 2003); disparity was found in rates of opioid and analgesic administration between geographic location, however it was unclear whether these areas represented different levels of deprivation. Ezenwa and Huguet (2013) suggested that future studies exploring sociodemographic disparities in child pain management assess whether the disparities are clinically meaningful. The clinically meaningful outcome measure used for the cross-sectional study within this thesis (*4.2.1.4 Outcome of interest*) allowed the identification of disparity regarding level of deprivation to also be deemed clinically meaningful.

*Conclusion:*

No strong recommendations could be made at this time regarding this meta-inference.

The predictor of deprivation identified in this thesis was novel in this population and context, and this potential explanation for the observed disparity was also novel. It would be useful to perform further research, ensuring the assessment of deprivation data, to strengthen this finding. The possible explanations provided for the disparity identified in *Table 9* (pg120) included home environment (kempt versus unkempt), which may have influenced the on-scene time of clinicians and parental demand may have influenced rates of analgesic administration. Due to the conflicting data arising from the qualitative research (see section *4.3.2.1.4 Level of deprivation*), the subsequent lack of confidence around these explanations and the limitations identified in sections *4.2.3.2 Limitations* and *4.3.3.5 Limitations*, further research is required before recommendations for improvement can be made (see section *5.4 Implications for Policy, Practice and Research*).

5.2.1.1.5 Child sex

*There was no statistical difference in rates of effective pain management between male and female children. This was supported by the interviews where most participants stated they expected no difference. This finding conflicts with previous research and therefore requires further investigation.*

Although male sex was not a statistically significant predictor of effective pain management within the cross-sectional study (see *Table 9* pg120), it has been identified as significant in previous research (see *Table 2* pg75) and when the odds ratios and 95% confidence intervals (CI) were pooled within a meta-analysis, the combined odds ratio (95% CI) was statistically significant: 1.21 (1.04-1.40) (see Figure *4* pg78). This analysis was subject to significant heterogeneity according to the $I^2$ value of 60.5% (Higgins J.P.T & Green S Eds, 2011). Fletcher (2007) described using a random effects model in the presence of significant heterogeneity in order to give a more conservative estimate. This was performed (see Figure *4* pg78), however a narrative synthesis was still the most appropriate method of synthesis due to the small number of studies included (n=3) and the difference in outcome measure used between the studies (see *Table 2* pg75).

The narrative synthesis within the systematic mixed studies review concluded that child sex (male) was a predictor of effective pain management (see section *3.3.4.1 Predictive factors*). Despite the congruence found between the non-significant result of the cross-sectional study (see *Table 9* pg120) and the 'no difference' perspective of the majority of ambulance clinicians (see *Figure 8* pg200), it was important to discuss the overall finding of the mixed methods systematic review (child sex (male) does predict effective pain management) and the minority perspective of the qualitative analysis that found 'male children act tough' (see *Figure 8* pg200).

Accepting the theory that male children are more likely to achieve effective pain management in the pre-hospital setting, the proposed explanation that 'male

children act tough' was explored in more depth within the literature. McGrath (1994) stated that male children may be encouraged to suppress verbal pain complaints and develop active coping mechanisms to conform to familial, cultural and societal expectations. Fivush et al. (2000) strengthened this argument by exploring the sex difference in parent-child narratives of past emotional (sadness, happiness, anger and fear) experiences in 40-45-month-old children. It was found that mothers talked more, used more emotion words and talked more about the emotional aspects of the experience than fathers (Fivush et al., 2000). Girls talked more about the emotional aspect of their experiences than boys, and girls used more emotion words when talking about scary events. Both mothers and fathers used more emotional words when discussing sad events when talking to their daughters than their sons. It appeared overall that the conversation was more emotional for parent-daughter than for parent-son groups. This study strengthened the 'male children act tough' finding because if male children were less likely to discuss emotions with their parents, and parents were less likely to discuss emotions with their sons, it was likely that male children would attempt to hide emotional behaviour associated with pain.

Moon and Unruh (2013) discussed the influence of child and adolescent sex and gender on pain and concluded that female children appear to seek more social support and may be more susceptible to catastrophising, and male children were more likely to engage in distraction techniques. Moon and Unruh (2013) stressed that further research is needed in this area as many studies show no difference and others contradict each other.

*Conclusion:*

No strong recommendations could be made regarding this meta-inference at this time, as the disparity was not fully understood. It is likely that research involving male and female children who have experienced acute pain and presented to the ambulance service may help to shed light on this highly complex and elusive meta-inference.

5.2.1.1.6 Type of pain

*There was no statistical difference in rates of effective pain management between children suffering traumatic and medical pain. The qualitative findings along with previous research conflicted with this lack of statistical difference, therefore further research is required.*

Similar to the child sex meta-inference discussed above (see section *5.2.1.1.5 Child sex*), type of pain was not deemed a statistically significant predictor of effective pain management (see *Table 9* pg120), however previous research showed that it was a significant predictor (see *Table 2* pg75). The qualitative findings (see *Figure 8* pg200) strongly agreed with the previous evidence; participants perceived that children suffering traumatic pain were more likely to achieve effective pain management than those suffering medical pain. Participants felt this was because traumatic injuries are visible, there was a presumption of pain and an overall heightened level of urgency to treat trauma (see *Figure 8* pg200).

An important question regarding this 'type of pain' meta-inference was how acceptable the disparity was. Was the disparity a by-product of good clinical practice? Participants stated that medical pain was 'more complex' and a 'longer game' (see *Figure 8* pg200) therefore the administration of analgesics to children suffering medical pain was arguably a more judicious process. For example Entonox® was contraindicated for patients suffering abdominal pain where intestinal obstruction is suspected (Joint Royal Colleges Ambulance Liaison Committee. Association of Ambulance Chief Executives, 2019a) as nitrous oxide gas diffuses into the bowel, increasing the pressure of air filled spaces (Akca et al., 2004, Reinelt et al., 2001), increasing pain. This judicious approach for medical pain in the form of extensive history taking and examination was necessary to avoid complications due to potential misdiagnosis, whereas an injured limb such as a fracture or burn requires significantly less information prior to pain treatment. Therefore, it may not be appropriate to correct this disparity, particularly from a pharmacological perspective.

There was an argument for the correction of any non-pharmacological disparity between trauma and medical pain, as techniques such as distraction and patient positioning could be implemented early in medical pain with limited history taking with little risk to the patient.

An additional consideration was the emotional impact on the child from visualising the traumatic injury. Participants believed that a child seeing a visually apparent injury made the situation worse, as identified in section *4.3.2.2.1 Physical*. This may create a heightened state of fear and anxiety, adding to the perception of pain (Choinière et al., 1989, Yildizeli Topcu et al., 2019, Hirsh et al., 2008, McGrath, 1994). This perceived pain may be reduced when the site of injury is covered, with a plaster or bandage for example. With medical pain there is generally no visual stimulus to remove, therefore the perception of pain cannot be reduced by removing visual stimuli. The disparity between traumatic and medical pain may therefore in part be due to the physical visualisation of the traumatic injury, which can be easily rectified (by covering with a bandage or dressing for example) when compared to medical pain, which may not have any visual influence, particularly for abdominal pain for example (unless there is distension or bruising).

Considering the need for judicious administration of analgesics for medical causes of pain and the potential impact of the visualisation of pain by the child for traumatic injuries, rectification of this disparity may not be possible; clinicians should ensure that where appropriate, non-pharmacological techniques are implemented for both medical and traumatic causes of pain in a timely fashion.

*Conclusion:*

Non-pharmacological interventions should be encouraged early with children suffering acute pain, caused from either traumatic injury or medical illness.

Given the increased complexity of medical causes of pain and the increased due diligence required prior to analgesic administration, early non-pharmacological interventions were a logical recommendation for children suffering medical pain.

Future research should explore prospective approaches with custom data collection enabling the capture of specific non-pharmacological intervention data (such as rubbing/vibration, patient positioning, comfort, reassurance, distraction, lighting etc.).

#### 5.2.1.2 Transferability of meta-inferences

Only meta-inferences that are well conceived and credible should have their transferability considered (Teddlie and Tashakkori, 2009). The meta-inferences discussed in section *5.2.1.1 Meta-inferences developed from this thesis* were subject to a quality assessment that examined the design quality of the studies informing them and their interpretive rigor, see *Table 18* (pg244) for the results. It was deemed that the meta-inferences generated were good quality, therefore their transferability could be considered.

Tashakkori and Teddlie (2010) stated that meta-inferences can be made at the basic level, which aim to answer the research question, and at the more abstract level, which aim to explain why events, behaviours or relationships occur. Considering these different levels, it was argued that meta-inferences from mixed methods research may be transferable at different levels, namely the ecological (other settings similar to the one being studied), population (other people; individuals/groups), temporal (other times; future) and theoretical (Teddlie and Tashakkori, 2009). The transferability of meta-inferences from mixed methods research is enabled, in part, due to the advantages of performing mixed methods research; larger more representative samples are included in the quantitative strand, with more in-depth rich understandings being derived from the qualitative strand (Teddlie and Tashakkori, 2009). In other words, the power of numbers are combined with the power of stories (Pluye and Hong, 2014).

##### 5.2.1.2.1 Ecological transferability

The meta-inferences discussed above were considered transferable to other settings, including other ambulance services both within the UK and internationally.

As discussed in section *1.2.1.1 International perspective* there are differences in ambulance services internationally, some provide nurse-led care, some provide physician-led care, some ambulance services are amalgamated with the fire service. Despite these differences, the results informing the systematic mixed studies review were considered generalisable due to studies being incorporated from a variety of countries, including Sweden (nurse-led care) (Gunnvall et al., 2018, Holmström et al., 2019), the United States (emergency medical technician/paramedic led care) (Williams et al., 2012), Ireland, Australia, Denmark and the United Kingdom (all paramedic-led care) (Murphy et al., 2014, Jennings et al., 2015, Lord et al., 2019, Whitley et al., 2020b). Many of the findings of the mixed methods sequential explanatory study in this thesis reflected previous findings identified and synthesised by the systematic mixed studies review, providing external validity to the findings of this thesis.

These meta-inferences were not deemed transferable to in-hospital settings due to the vast differences, including staffing levels, resource availability and clinical environment (Palmer and Babl, 2013). However, they could be considered transferable to the primary care setting, especially considering the growing mobility of the paramedic profession into primary care (Eaton et al., 2020).

5.2.1.2.2 Population transferability

The transferability of these meta-inferences to other populations was difficult to establish due to their dyad structure; they concerned two populations, children suffering acute pain and pre-hospital clinicians. Whilst the process of pre-hospital child pain management consists more of a triad structure (child, clinician and parents; see *Figure 13* pg270), for the purpose of discussing the transferability of the meta-inferences developing in this thesis, I will refer to their dyad structure as the parent element was not explored in any great detail (parents were not interviewed, nor were their details captured in the cross-sectional study).

The aim of this research was to be inclusive of all children aged under 18 years, as discussed in section *1.2.3.1 Age*, particularly due to the systematic exclusion of 16

and 17 year old patients from clinical research. Therefore, these meta-inferences should be deemed transferable across the age span from birth to 17 years for those suffering acute pain in the pre-hospital setting.

The meta-inferences might be deemed transferable where only one component of the dyad is altered. The findings may be transferable, to some extent, to children suffering chronic pain in the pre-hospital setting. This includes the same clinician group but a different patient group. Similarly, the findings may be transferable to other clinicians who are exposed to children suffering acute pain, such as in primary or urgent care. Caution must be exercised when transferring these findings, as acute and chronic pain are very different processes, as discussed in section *1.2.2 Pain* and the difference in scope of practice between primary/urgent care practitioners and pre-hospital clinicians must be considered.

5.2.1.2.3 Temporal transferability

The degree to which these meta-inferences will be transferable and applicable in the future is uncertain. This research was performed over a three-year period and included research papers into the systematic review from 2006, therefore these findings are representative of a 15-year time period (approximately). This should provide some assurance that the findings will be relevant in the near future.

Considering the rapid evolution of the paramedic profession (*1.2.1 Ambulance service*) there is uncertainty regarding the transferability of these meta-inferences in the long-term, as the education and training of paramedics enhances it is likely that knowledge and confidence will grow, addressing some the barriers to effective pain management identified in this thesis (see *Figure 10* pg208).

5.2.1.2.4 Theoretical/conceptual transferability

Theoretical/conceptual transferability relates to the degree to which findings are transferable to other theoretical constructs. For example, if effective pain management had been defined differently, like a subjective outcome measure for

children/parents to score their satisfaction, would the meta-inferences still stand? Unfortunately, these meta-inferences were not tested between theoretical constructs, however this will be considered for future research, as Teddlie and Tashakkori (2009) state that this process can provide a 'more general and meaningful meta-inference' (pg262).

### 5.2.2 Philosophical considerations

The analysis and interpretation of the findings of this thesis were framed within the postpositivist paradigm, which was considered to adopt the ontological stance of critical realism and the epistemological stance of modified objectivism. This was discussed is section *2.1.2 Philosophical paradigm*.

Congruence from paradigm through to methodology, methods, analysis and interpretation was evident in this thesis. Critical realism argues that reality exists, but is only imperfectly apprehensible due to flawed human intellect and the complexity of nature; modified objectivism follows from this and argues that repeated findings are probably true and that external fit with existing knowledge is important (Guba and Lincoln, 1994). Given this overarching philosophical framework, the methodology section (see section *2.3 Methodology*) discussed how the mixed methods sequential explanatory approach, supported by a systematic mixed studies review, was the most appropriate method.

The methods and analysis chosen complemented the philosophical underpinnings and were discussed in the following sections; *3.2 Methods*, *4.2.1 Methods* and *4.3.1 Methods*. For example, the variables chosen for the multivariable logistic regression were chosen, in part, because some were previously identified from existing literature (*4.2.1.5 Data analysis*). This ensured a good fit with pre-existing knowledge, as the findings could easily be compared with previous studies (see *Table 2* pg75), and where appropriate within a meta-analysis to determine cumulative findings and heterogeneity (see Figure *4* pg78). The concept that repeated findings are probably true was also evident within the analysis of the qualitative data (see section *4.3.3 Discussion*). Many of the findings from the

qualitative study were previously identified, providing external validity, strengthening the findings of this thesis.

The conservative interpretation of data complemented the philosophical underpinnings of this thesis. It was important to highlight that the explanations provided in section *4.3.2.1 Explanation of predictors* were the perceptions of the participating clinicians, and not necessarily definitive explanations (as this thesis was not performed under a positivist paradigm where generalisable laws are sought (Lincoln and Guba, 1985, Tashakkori and Teddlie, 2010)). Critical realism argues that reality is apprehensible, but only imperfectly, with modified objectivism arguing that finding are *probably* true. The conservative conclusions described in section *4.3.3.1 Explanation of predictors*, in particular that *possible* explanations have been provided, with the limitation that other explanations may exist being described in section *4.3.3.5 Limitations*, complemented the philosophical assumptions of this thesis.

### 5.2.3 Contribution to theory

In section *1.2.4 Pre-hospital pain management in children* a model was developed to illustrate the complexity of pre-hospital pain management in children (see Figure *1* pg18). This model was based primarily on clinical experience and expert opinion. As this thesis has unfolded, the findings of the systematic mixed studies review along with the findings of the mixed methods sequential explanatory study have informed the revision of this model. Specifically, the relevance of organisational factors such as service demand, policy, equipment and training along with the influence of parents on scene, both identified in *Figure 10* pg208. Engel's (1977) biopsychosocial model of health was used to frame the model. Biological influences on the child's perception of pain included the mechanistic process of pain, involving the activation of nociceptors (Melzack and Wall, 1965) and physical influences such as visualising traumatic abnormality, as identified in *Figure 10* (pg208). The psychological influences on the child's perception of pain included fear, anxiety, shame and embarrassment; on the clinician included fear, anxiety and empathy; and on the parents included fear and anxiety (as identified in *Figure 10*

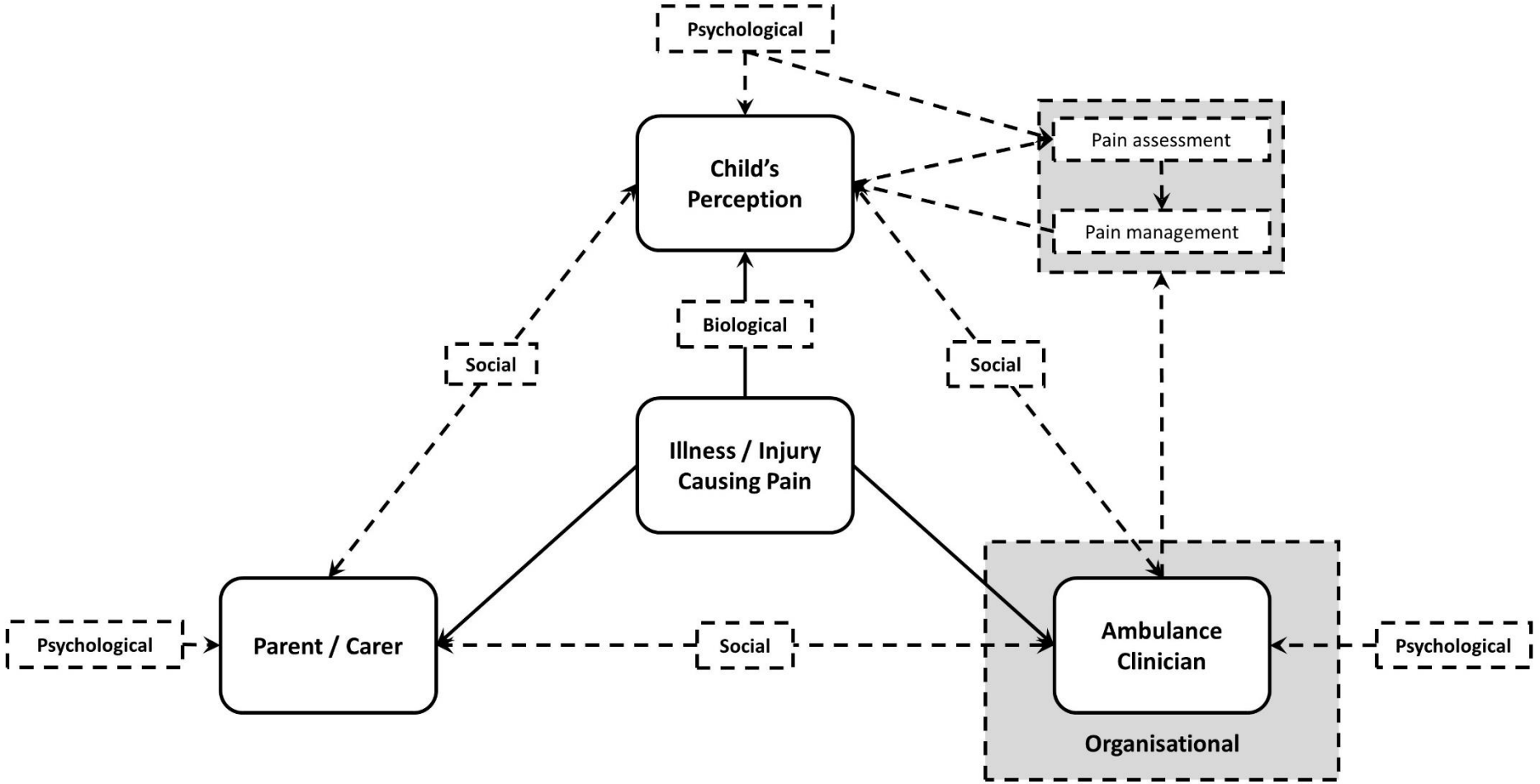
pg208). The social influences between all three parties were also covered by Engel's model; the social interaction between clinician and child covered factors such as level of deprivation (one of the meta-inferences developed from this thesis) along with broader social factors such as communication, culture, and beliefs that influence the social interactions between all parties (see section *1.2.2.3 Culture of pain*).

Currently, a theoretical model for pre-hospital acute pain management in children does not exist. Young (2005) developed a model for conceptualizing and studying paediatric procedural pain (for example cannulation, immunisation, dental care or minor accident and emergency procedures such as wound care), illustrating a pathway from pre-procedure to post-procedure, highlighting individual factors that influence the process, such as individual, ethnic, cultural and societal factors. Whilst procedural pain is included in the context of pre-hospital child pain management, specifically cannulation and wound care, it does not incorporate other sources of pain such as traumatic injury or medical illness, nor does it account for the 'unplanned' element of pain or the unpredictable environment, therefore a more relevant model was needed.

The social communication model of pain (Craig, 2009) has also been proposed which illustrated the process of acute pain in children from physical trauma to personal experience of pain, to pain expression, to pain assessment, to pain management highlighting intrapersonal and interpersonal influences. This model however does not highlight the importance of organisational factors such as service demand and the impact this can have on effective pain management in the context of the ambulance service. This reinforced the need for a specific model relevant to pre-hospital care.

A novel theoretical model of pre-hospital child pain management was developed, see *Figure 13* (pg270).

Figure 13 – Theoretical model of pre-hospital acute pain management in children



The theoretical model of pre-hospital acute pain management in children shown in *Figure 13* (pg270) has four pillars; the illness or injury causing the pain, which was deemed central to the whole process (see discussion of the meta-inference regarding type of pain in section *5.2.1.1.6 Type of pain*), which directly influences the other three pillars; the child's perception, the parent/carer and the ambulance clinician.

The influence of the ambulance clinician on the whole process is subject to organisational factors, identified in *Figure 10* (pg208), such as service demand, guidance and policy, availability of paediatric equipment, distance to hospital and 'in-service' training and education. The ambulance clinician also has influencing factors that affect their ability to assess and manage the child's pain, identified in *Figure 10* (pg208) such as difficulty using pain scoring tools and difficulty cannulating and challenges with pharmacological interventions, all highlighted in this thesis. Finally, the ambulance clinician is subject to their psychological state and emotions, such as their own fear, anxiety and level of empathy (*Figure 10*).

The child's perception of pain is influenced by the illness/injury and their psychological state (as identified in *Figure 8* pg200 and *Figure 10* pg208) and their subsequent management of pain is influenced by biological factors such as their age and sex, disparities identified in this thesis as meta-inferences (*5.2.1.1 Meta-inferences developed from this thesis*).

The parent/carer influences the child's perception of pain through social interaction, highlighted by Hadjistavropoulos et al. (2011) with their communications model of pain; this model explained the importance of the social interplay between child and parent (Goubert and Simons, 2013) and the subsequent importance of empathy (Goubert et al., 2005). McGrath (1994) stated that parents (and siblings) shape the knowledge, coping mechanisms and expression of the child's pain through learnt behaviours and language. Culture and beliefs are also likely to play a part here, as discussed in section *1.2.2.3 Culture of pain*, the acceptability and normality of pain likely influence the child's perception and expression of pain (Clemente, 2013). The emotional interplay between parent

and child, promoting or minimising catastrophising (as discussed in section *4.3.2.2.2 Emotional*), will likely influence the process.

### 5.2.4 Reflexivity

My role within this research was considered briefly in section *4.3.1.5 Data analysis*; an essential consideration for qualitative research. It was concluded that my position as a clinical academic was more a strength than a limitation to the study. That sentiment was carried through to this thesis in a broader sense.

Clinical academics are well placed to identify problems and gaps in practice and have the enthusiasm to seek the answers through research (Trusson et al., 2019, Trueland, 2015). During this PhD I have maintained my clinical competencies by undertaking frontline shifts, one week per month, for the three-year period. This allowed for regular periods of 'grounding', where focus was maintained on the problem so that the research did not become too theoretical.

Being a father of two small boys (aged seven and three) provided insight into the problem of pre-hospital child pain management that would perhaps not be available to someone who did not have their own children. Hackett (2017) discussed parents as researchers, both as collaborators (assisting with interviewing their own children) and as researchers (interviewing other adults and children) and found that participants who perceived researchers as parents have unique opportunities to build rapport with adults and connect with children. Having first-hand daily experience of my own children provided a high level of background knowledge and experience. This was perceived as an advantage, as it allowed the qualitative interviews to reach a deeper level of exploration, because basic level knowledge was assumed and did not require clarification or explanation (*4.3.3.4 Strengths*). This could also be considered a limitation, as I may have missed more basic insights that I take for granted. Broadly, I feel that the thesis as a whole has been well-grounded as a result of my clinician and parent status; this should help provide more focussed and pragmatic recommendations for clinical practice

(discussed in section *5.4 Implications for Policy, Practice and Research*) than perhaps would have been achieved from a more theoretical approach.

From an academic development perspective, I have learnt to be more sceptical of my findings. During the qualitative study, when interpreting the explanations of predictors, I readily treated the explanations provided by participants as firm, definitive explanations. After further consideration, re-evaluation of my postpositivist lens and iterative interpretation of the findings of this thesis, I have realised that the explanations provided were 'possible explanations'. These possible explanations were perceptions of the research participants, and therefore there are likely to be other viable explanations. This uncertainty has been difficult to accept. As a clinical academic I prefer clear answers that are black or white, rather than shades of grey.

Richard Feynman said:

*'I think it's much more interesting, to live not knowing, than to have answers that might be wrong.'*

(British Broadcasting Corporation, 1981)

With this statement in mind, it makes uncertainty a little more acceptable and better prepares me for a future career as a clinical academic, as it is better to be under-confident than over-confident in my research findings.

### 5.2.5 Patient and public involvement

Patient and public involvement (PPI) in health care research helps to improve the quality and relevance of research and essentially is the involvement of patients and/or the public in the design, conduct and dissemination of research (Health Research Authority, 2020, Staniszewska et al., 2017). PPI is increasingly becoming an integral component of health care research and is often a mandatory aspect of

research funding bids in the field of health and social care research (Boivin et al., 2018).

The University of Lincoln School of Health and Social Care has a dedicated PPI group called the HAPPI (Healthier Aging Patient and Public Involvement) group. During the inception of this research project, a face-to-face meeting with members of HAPPI was arranged primarily to discuss my research. This took place on University of Lincoln premises on the 28th February 2017. There were four members of the HAPPI group present, reimbursement for time and refreshments were provided, funded by the University of Lincoln. Prior to the meeting I had generated and circulated a plain English summary of the proposed research project.

I wanted to know from the HAPPI group whether the research question made sense. There was a clear acknowledgement from all members that the question did make sense. I then wanted to know whether they thought it was an important problem. One member explained that her daughter had suffered a dislocated kneecap and that without appropriate pain relief her transport to hospital would have been much more uncomfortable. Another member raised a question about the pain threshold of different patients and how that could be incorporated into the assessment of pain. This was an excellent point and was taken on board. All members of the group agreed it was an important problem.

All members of the group agreed that it would be useful to know the results of this study and all agreed that the methods made sense. When asked which outcome was important, pain reduction was mentioned however fear was also raised. A reduction in fear from the patient or even from the parents would be useful.

Other issues were raised such as alcohol and drug consumption and learning difficulties, both of which are potential barriers to effective pain management.

The involvement of patients and the public early in the research process provided useful insights into the research project. The identification of fear reduction as a useful outcome measure at this early stage was a trend witnessed throughout this thesis. The relevance of fear reduction was identified within the systematic mixed studies review during thematic synthesis (see *Figure 5* pg81) as paramedics found it

difficult to distinguish between fear/anxiety and pain. It was then later highlighted during the explanation of the 'child age' predictor (see section *4.3.2.1.1 Child age*) and the identification of child fear/anxiety as a barrier to effective pain management (see section *4.3.2.2.2 Emotional*). It was hypothesised that the emotional influence on the perception of pain was greater in younger children than for older children (see *Figure 9* pg201). The theme of 'child fear/anxiety' continued through to the recommendations for practice (see section *5.4.2 Practice*) and the development of the driver diagram (see *Figure 14* pg287) as 'reduce child fear and anxiety' was proposed as a primary driver.

The congruence from PPI involvement to the final recommendations of this thesis demonstrated the impact of early PPI involvement. Concordance between early PPI input and final research findings helped to ensure the recommendations were well grounded.

## 5.3 Strengths and Limitations

### 5.3.1 Strengths

The strengths of the individual quantitative and qualitative study, along with the systematic mixed studies review have previously been discussed, see sections *4.2.3.1 Strengths*, *4.3.3.4 Strengths* and *3.4.1 Strengths*, respectively. The purpose of this section was to discuss the broader strengths of this thesis overall.

The inherent benefits of using mixed methods within this thesis provided overall strength, as mixed methods research aims to create depth and breadth of understanding (Johnson et al., 2007) which is considered more than the sum of its parts (Teddlie and Tashakkori, 2009). The integration of statistical analysis with a rich understanding of experience and culture provides a better understanding of the phenomenon of interest (Creswell, 2014) than performing separate quantitative and qualitative studies in isolation. This allows for a deeper understanding of complex clinical problems. It was felt that this deeper understanding was achieved during this thesis through the integration, as discussed in section *4.4 Integration*.

Performing mixed methods research provides the opportunity to address confirmatory and exploratory questions at the same time (Teddlie and Tashakkori, 2009). This is a major strength as it allows many more questions to be answered within the same study, simultaneously generating and verifying theories. This would not be achievable by performing separate studies, as further studies would have to be developed to verify any generated theories, taking a significant amount of time. One of the limitations of mixed methods research is the time taken to perform the overall study (Hansen et al., 2016). It could be argued that generating and verifying theory within a mixed methods study saves a significant amount of time overall. When attempting to understand complex clinical problems, if individual studies are adopted, it is likely that further studies would need to be developed to verify the theories generated from the initial study; this takes a long time overall. It is unclear which approach takes the longest time overall, however it does argue against the limitation that mixed methods studies take a long time to perform (as the enhanced, deeper understanding is a reasonable trade-off and it may take just as long to reach the same depth of understanding with a 'single

study' approach). Within this thesis, theory was generated via the cross-sectional study (see section *4.2 Cross-sectional Study*) as predictors of effective pain management were identified. Verification was then sought via the generic qualitative study (see section *4.3 Generic Qualitative Study*), in the form of explanation. Theory was also generated via the generic qualitative study (see section *4.3 Generic Qualitative Study*) as explanations were offered; verification was then sought through integrative methods (see section *4.4 Integration*), primarily by 'following a thread' (O'Cathain et al., 2010) back to the quantitative data. Punch (2013) argued that quantitative research can be used for theory generation *and* verification, and that qualitative research can be used for theory verification *and* generation, justifying the dual approach of theory generation and verification used in this thesis.

Teddlie and Tashakkori (2009) argued that the inferences generated from mixed methods research (meta-inferences) are stronger and more accurate than the inferences generated from individual studies. Combining observation with lived experience through techniques such as triangulation and complementarity create strong inferences (Greene et al., 1989). Corroboration between two different types of data make the findings more difficult to refute. For example, if a single qualitative study identified that ambulance clinicians found it difficult to cannulate children in pain to administer strong analgesics, it could be argued that the study was not representative of the wider profession and only represented the views of a small number of participants and was highly subjective. However, if quantitative data was integrated with this finding using triangulation, which showed low rates of cannulation and analgesic administration among large numbers of children who ultimately suffered more severe pain without intervention, the data would complement each other and create strong meta-inferences that would be more difficult to refute than the individual inferences generated from each study (see Figure *6* pg99).

Mixed methods research also provides the opportunity to identify conflict or disagreement between data. This is not a failure of the research but rather an interesting component of mixed methods research that should be encouraged

(O'Cathain et al., 2010) as it may lead to other important research questions. The identification of disagreement between data may lead to a re-examination of the underlying assumptions and conceptual framework (Teddlie and Tashakkori, 2009). This not only helps to create a deeper understanding of the phenomenon being investigated but helps create a more accurate understanding. For example, there was some disagreement surrounding child sex as the systematic mixed studies review concluded that male children were more likely to achieve effective pain management (Whitley et al., 2020a), but most ambulance clinicians felt that there should not be a difference between the sexes (discussed in section *5.2.1.1.5 Child sex*). This helped to provide a deeper understanding of this phenomenon, which ultimately warranted further investigation.

Other strengths of this thesis include its potential ability to increase the overall confidence in cumulative evidence within the systematic mixed studies review. The qualitative study may address the methodological limitations and limited adequacy of data informing the main findings, as identified in the GRADE CERQual analysis (see *Appendix 7* and *Appendix 8*).

One of the aims of undertaking a PhD thesis is to create an original and substantial contribution to the evidence base. The cross-sectional study (Whitley et al., 2020b) was considered original for three reasons; firstly, predictors of effective pain management in children suffering acute pain in the pre-hospital setting had not previously been identified within the United Kingdom before; secondly, level of deprivation had not previously been identified as a predictor of effective pain management and thirdly, the cross-sectional study acted as the initial study in a mixed methods approach; a method that has not previously been used before to identify and explain predictors of effective pain management in children in the pre-hospital setting. The publication of the cross-sectional study, along with the systematic mixed studies review (Whitley et al., 2020a), in high-quality peer-reviewed journals acknowledges the original contribution of this thesis to the evidence base.

Another strength of this thesis was its integrity, as discussed in the next section *5.3.1.1 Integrity within research*.

5.3.1.1 Integrity within research

Integrity in research is a growing concern, particularly with the recent rise of predatory journals (Grudniewicz et al., 2019). A definition of such journals has recently been developed which I feel is pertinent to quote in full:

> *'Predatory journals and publishers are entities that prioritize self-interest at the expense of scholarship and are characterized by false or misleading information, deviation from best editorial and publication practices, a lack of transparency, and/or the use of aggressive and indiscriminate solicitation practices.'*
>
> Grudniewicz et al. (2019) pg211

In a society growing more dependent on scientific findings to address challenges (Munafo et al., 2018), particularly in the field of pre-hospital emergency medicine, integrity is of fundamental importance and should represent a core principle within all academics. There is a concern however that transparency can also be used against researchers, where critics engage in unbalanced argument, therefore distinguishing scrutiny from harassment is important (Lewandowsky and Bishop, 2016).

The reason I mention integrity within research is because I found an error in my research after it had been published. During the coding of my cross-sectional study data, when using the operator greater than '>' within Stata, I was unaware that this included missing data fields. For example, when coding the index of multiple deprivation category, the latter category (8-10) was coded using the command '> 7'. This included all patients with an IMD of 8, 9 and 10 but also all patients with missing data, coded as '.'. Therefore, missing data had been included in some of my categorised variables, specifically senior clinician age (n=52), senior clinician experience (n=37), hospital travel time (n=418) and index of multiple deprivation (n=727) within the univariable and multivariable analyses.

After discussion with my supervisor Professor Law, I decided the best method to correct this oversight was to segregate the missing data within each variable and re-run the analysis. The alternative method was to delete the missing data and re-run the analyses. I chose to keep the missing data within the analysis because I was interested to see if the missing data were significantly associated with achieving effective pain management (they were not) and because it was a valid method of dealing with missing data (Katz, 2011).

After correcting this error, I wrote to the editor of the American Journal of Emergency Medicine explaining the oversight, illustrating the updated analysis (which fortunately showed very little change to the results and no changes to the findings of the study) and offering, if deemed necessary, to submit a corrigendum. This resulted in a request to correct the current proof, with an updated version of the paper subsequently published. I have presented the updated analysis within this thesis, including the segregated missing data (see *Table 9* pg120).

I feel my attention to detail enabled me to identify this error in the first place. My integrity as an early career researcher, honesty and transparency drove me to flag this error as soon as it was identified to a) my supervisors and b) the editor of the published paper. I believe these qualities will provide immeasurable benefit to my future career in research. Further, if I had chosen not to disclose the error, my research would be no different to many of the papers published by predatory journals, many of which forgo the rigorous process of quality assessment that is gained through publishing with established journals.

### 5.3.2 Limitations

The limitations of the individual quantitative and qualitative study, along with the systematic mixed studies review have previously been discussed, see sections *4.2.3.2 Limitations*, *4.3.3.5 Limitations* and *3.4.2 Limitations*, respectively. The purpose of this section was to discuss the broader limitations of this thesis overall.

One of the theoretical limitations of this research was the incompatibility thesis, which argues that the integration of quantitative and qualitative methods is

impossible due to the incompatibility of the underlying paradigms of each method (Teddlie and Tashakkori, 2009). This was discussed in section *2.1.5 Philosophy in mixed methods research*. Teddlie and Tashakkori (2009) argued that the incompatibility thesis has largely been discredited, in part by researchers demonstrating integration within their research projects. Within this thesis, the integration achieved was discussed in section *4.4 Integration*; this argues against the incompatibility thesis as integration has clearly been demonstrated.

One of the limitations of mixed methods research is its questionable ability to maintain rigor, highlighted by the uncertainty regarding the quality of meta-inferences generated, which was discussed in section *4.4.3.1 Quality assessment of meta-inferences*. Morse (2010) stated that to maintain rigor in mixed methods research, the methodological principles of the quantitative and qualitative aspects should be kept separate, until the point of interface. This was illustrated well in the quality assessment of meta-inferences suggested by Teddlie and Tashakkori (2009) (see *Table 18* pg244) as the first four criteria addressed design quality and should be assessed for individual study inferences. Therefore, to maintain rigor and produce good quality meta-inferences, the individual studies must be of good quality and should select the most appropriate procedures and methods to answer the research question (Teddlie and Tashakkori, 2009). The quality of the individual studies in this thesis was deemed good and the overall quality of the meta-inferences was deemed good, see section *4.4.3.1 Quality assessment of meta-inferences*.

The choice of outcome measure, described in section *1.3 Research Question*, could be perceived as a limitation to this PhD thesis due to the inherent difficulty of accurately assessing pain in children, identified by previous research (see *Figure 5* pg81) and from this thesis (see *Figure 10* pg208). It was also found that some clinicians opted to ignore pain scoring tools and use their own judgement (see section *4.3.2.2.5 Management*). This had implications for the validity or the cross-sectional study, as clinicians may not have used pain scales appropriately. This was acknowledged, see section *4.2.3.2 Limitations* and Whitley et al. (2020b). Unfortunately, due to the complex nature of pain and its highly subjective

manifestation (see section *1.2.2 Pain*), using pain score assessment as the outcome measure to determine quality of care presents limitations around the validity of data. Ideally, pain would be measurable, through a biomarker perhaps, or other objective means such as electromyography or electroencephalogram/functional magnetic resonance imaging scan (Eccleston et al., 2020), to remove the patient and clinician subjectivity. Unfortunately, such assessments are not easily utilised in the pre-hospital setting, nor pragmatic, therefore the measurement of pain scores through internationally recognised scales, whilst not perfect and not without limitation, is the most acceptable outcome measure at this time. The justification for not using 'analgesic administration' as the outcome measure has previously been discussed (*4.2.1.4 Outcome of interest*).

A major limitation of this PhD was that it lacked the perspective of the child. It was beyond the scope of this PhD thesis to explore this perspective. The experiences of children (and parents) are an invaluable component of pre-hospital child pain research and therefore the child voice will be explored during post-doctoral research projects and recommended as an area of research for other academics.

The transferability of findings from this thesis to other populations and contexts has been discussed in section *5.2.1.2 Transferability of meta-inferences*. It was concluded that the findings may be transferable to some populations and contexts. Due to the complex nature of the meta-inferences generated from this thesis, as the child and pre-hospital clinician aspects were integrated, it was not possible to separate the meta-inferences and apply them to specific contexts or populations, therefore the limited transferability of the findings was considered a limitation of this thesis.

## 5.4 Implications for Policy, Practice and Research

As a clinical academic, the conception of this research project was founded in 'real-world' experience of the complexity and challenges experienced when dealing with children in pain. One of the aims of this research was eventually to impact clinical practice by improving the quality of care children receive by ambulance services. This section highlighted the specific recommendations of this thesis in terms of policy, practice and research.

Eccleston et al. (2020) recently published a comprehensive paper highlighting the suboptimal treatment of pain in children and provided four transformative goals to address the issue. These included:

1. **Make pain matter**
    - Investment in a strong research base for paediatric pain was needed in the field of social science. Knowledge translation was poor, health care professionals were insufficiently trained and there was inequality in access to pain management.

The findings of this thesis resonate with this first goal highlighted by Eccleston et al. (2020), particularly that health care professionals were insufficiently trained (see *Figure 10* pg208) and the inequality in access to pain management identified (see *Table 9* pg120 and *Table 15* pg236), particularly the difference in level of deprivation. The findings of this thesis will contribute to the research base, however further research is required, as discussed in section *5.4.3 Research*, therefore further investment is required to fund this necessary and important research.

2. **Make pain understood**
    - Further understanding of the mechanics of pain was required as gaps exist. It was recommended that the biopsychosocial model (Engel, 1977) be used as a framework to develop a broader understanding of pain mechanisms.

This thesis contributed to this second goal as the biopsychosocial model of health (Engel, 1977) was used as a framework within this thesis. In particular, the barriers and facilitators identified in *Figure 10* (pg208) and the development of a theoretical model of pre-hospital child pain management (see *Figure 13* pg270) contributed to the broader understanding of influencing factors.

3. **Make pain visible**
    - A call for optimised pain assessment tools was made. It was concluded that pain should be assessed in every child and there was scope to improve current pain assessment tools. It was also highlighted that outcomes should be measured that are important to patients, and not necessarily clinicians or researchers.

This thesis highlighted the need for more pragmatic pain assessment tools for children in the pre-hospital setting, as the qualitative research highlighted many challenges, including clinicians opting not to use the tools or using them inappropriately (see section *4.3.2.2.5 Management*). The need for more pragmatic pain assessment tools was discussed later in section *5.4.2.12 Facilitate pain assessment*.

4. **Make pain better**
    - This final transformative goal put forward by Eccleston et al. (2020) aimed to improve the treatment of pain, incorporating psychological, pharmacological and physical interventions. There was a call for

more clinical trials in children to determine the most effective interventions, as research in this field was lacking.

It was beyond the scope of this thesis to perform interventional research, however recommendations for clinical practice and further research were made which included several pharmacological and non-pharmacological interventions; these are discussed later in this section. In addition to addressing the mechanistic cause of pain (nociception) with analgesics, McGrath (1994) stated that attempts to effectively manage a patient's pain will be inadequate without due consideration to the psychological and environmental factors that modulate pain. Given the findings of this thesis and the high relevance of emotions, familial, societal, cultural and environmental factors, a holistic pain management approach adopting the biopsychosocial model of health is recommended.

### 5.4.1 Policy

The recommendations for policy makers, including individual ambulance services and clinical guideline developers, align closely to some of the policy recommendations put forward by Eccleston et al. (2020). These included:

- National level initiatives that encourage the measurement of pain; essentially, strengthening the audit of pain assessment in children. Considering mean pain reduction has been identified as a key quality measure of ambulance service performance (Turner et al., 2019) and within the cross-sectional study in this thesis, 1789 patients (out of 8052 patients with a clinical impression suggestive of acute pain) had no pain score documented, and 2083 had no second pain score (see Figure *7* pg114), initiatives to encourage the measurement and documentation of pain are strongly recommended.
- Implement knowledge mobilisation strategies to minimise the gap between evidence and clinical practice. Morris et al. (2011) found that it takes on average 17 years to translate research findings into routine clinical practice. However, there are complexities around this average

figure that require unpacking, such as how to define the start and end points. Nevertheless, strategies to facilitate early adoption of best evidence-based practice should benefit patients.

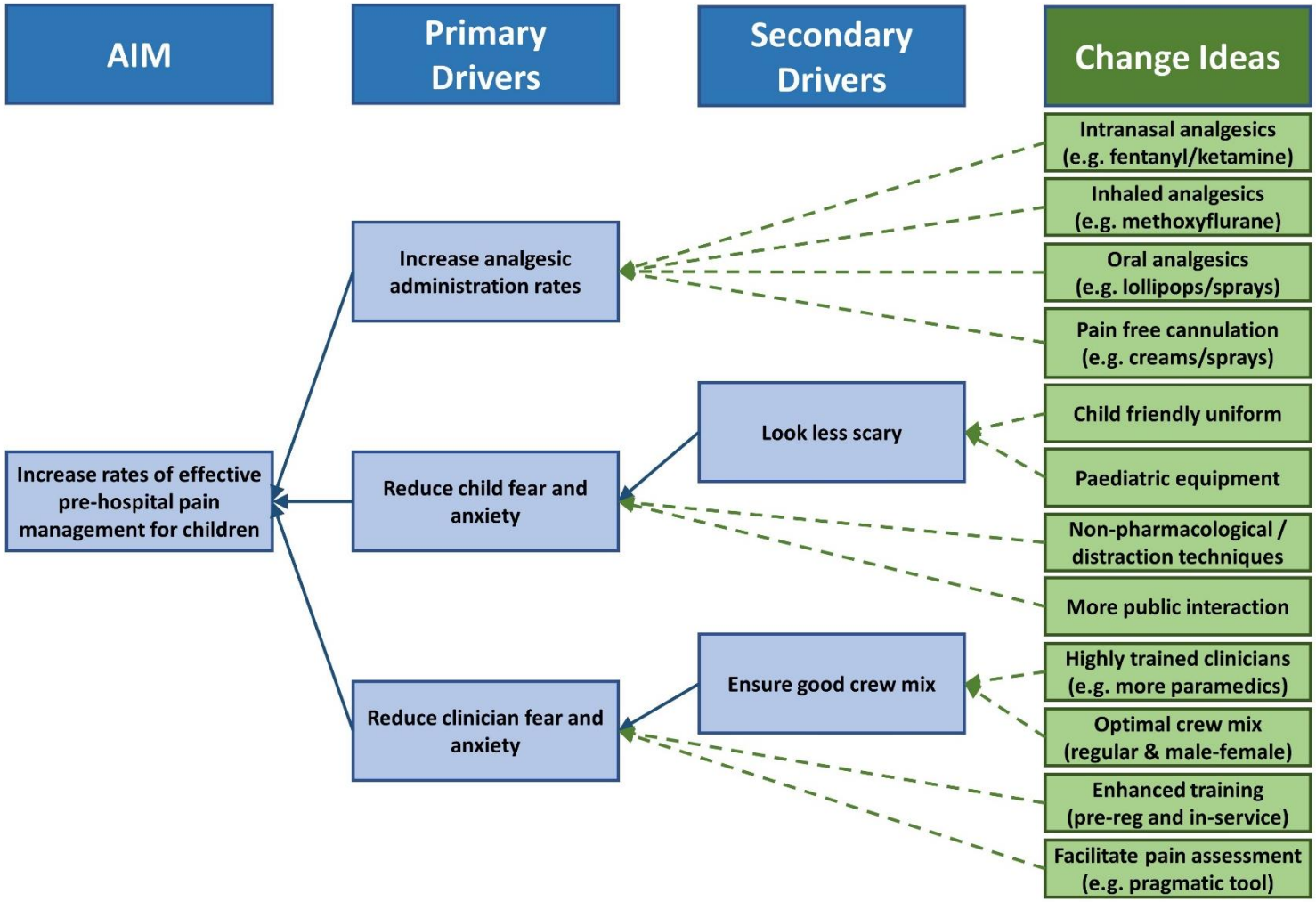
- Introduce institutional commitment initiatives regarding the treatment of child pain and documentation of interventions. This might require amendments to patient clinical record documentation to facilitate the capture of such data; for example, having clear 'tick box' criteria or checklists for a range of non-pharmacological interventions such as distraction, comfort, reassurance and staying close to parents.

### 5.4.2 Practice

Several improvements were suggested by participants that could potentially increase rates of effective pain management in children (see *Figure 11* pg217). These, combined with the other main findings of this thesis, along with the wider literature, resulted in the development of a driver diagram. This driver diagram (Reed et al., 2014, ACT Academy, 2020) was created to illustrate the recommendations for clinical practice in a simple structure to facilitate implementation using the plan, do, study, act (PDSA) cycle. See *Figure 14* (pg287) for the driver diagram.

*Figure 14* (pg287) shows the overall aim of the improvement plan: '*increase rates of effective pre-hospital pain management in children'*. This aim should be realised by achieving the primary and secondary drivers, which in turn should be achieved by appropriately investigating and implementing the '*change ideas*'.

Figure 14 – Recommendations for clinical practice: Driver diagram



It should be stressed, that each of these change ideas should be assessed according to the needs of individual ambulance services and explored accordingly. Where evidence is insufficient to determine the safety or efficacy/effectiveness of certain interventions, further empirical research should be performed prior to implementation (or at least a robust programme of clinical evaluation). Each of these 'change ideas' were discussed separately below.

#### 5.4.2.1 Intranasal analgesics

Intranasal analgesics were identified within this thesis as a potential method to overcome the barriers of administering medicines to children suffering acute pain. These barriers included difficult and painful cannulation, difficulty administering Entonox® and the slow onset of oral analgesics (see *Figure 10* pg208). These barriers have been identified in previous research (Williams et al., 2012, Holmström et al., 2019, Murphy et al., 2014).

It has been demonstrated that the introduction of intranasal analgesics improves the rates of effective pain management in children suffering acute pain in the pre-hospital setting (Murphy et al., 2017, Lord et al., 2019). O'Donnell et al. (2013) explored the effect of introducing a mucosal atomisation device (for intranasal administration) for the administration of fentanyl on the rate of fentanyl administration. Although 38% of children received fentanyl after the device was implemented compared with 30% before, the difference was not statistically significant (odds ratio 1.75, 95% confidence interval 0.86-3.66). The introduction of intranasal analgesics such as fentanyl may increase the likelihood of children achieving effective pain management and may increase the rates of analgesic administration.

A recent rapid evidence review concluded that no interventional studies have been conducted investigating the use of intranasal analgesics for children in the pre-hospital setting (Whitley and Pilbery, 2019). Although observational data seem promising (Murphy et al., 2017, Lord et al., 2019), rigorous interventional research

would be ideal to explore the efficacy and safety of intranasal analgesics for children in the pre-hospital setting prior to widespread clinical implementation.

5.4.2.2 Inhaled analgesics

This thesis identified Entonox® administration as a barrier to the pain management process in children (see *Figure 10* pg208) as it was deemed noisy, big, cumbersome and difficult to inhale, especially when children were crying. Penthrox® (methoxyflurane) was proposed as an alternative (see *Figure 11* pg217) as it is not contained in a pressurised cylinder like Entonox® and therefore does not require deep suction to activate the valve and inhale the drug. Further, methoxyflurane administered via the Penthrox® inhaler is light weight and easier to hold as it is not connected to tubing.

Methoxyflurane has been used in Australia to treat children suffering acute pain in the pre-hospital setting since at least 2006 (Babl et al., 2006). An observational comparative study found that methoxyflurane was an effective analgesic, however intravenous morphine and intranasal fentanyl were significantly more effective (Bendall et al., 2011a). Methoxyflurane is not currently licenced for UK use in children (Electronic Medicines Compendium, 2019b). A randomised controlled trial is in progress within the UK to determine the safety and efficacy of methoxyflurane for use in children aged 6-17 years suffering acute traumatic pain in the emergency department setting (Hartshorn et al., 2019). The results of this trial will likely inform any considerations to change the licencing of methoxyflurane to include administration to children. If the UK licencing does change to allow administration to children, economic evaluation may be required to implement methoxyflurane into ambulance services that do not currently provide this analgesic. As methoxyflurane administration via a Penthrox® inhaler does not require advanced skills such as intravenous cannulation, there may be cost saving from a staff perspective, as clinicians with lower scopes of practice may be able to manage severe child pain without requiring backup from clinicians with extended scopes of practice.

Within the UK, the results of the MAGPIE trial (Hartshorn et al., 2019) are required along with a change to the licencing for methoxyflurane administration to be considered for implementation. Internationally, if methoxyflurane is licenced for administration to children then it may be considered for implementation, however the strength of empirical evidence regarding the safety and efficacy of methoxyflurane in children is poor (Grindlay and Babl, 2009, Hartshorn et al., 2019), hence the need for high quality randomised controlled trials.

#### 5.4.2.3 Oral analgesics

One of the potential improvements identified from this thesis was analgesic lollipops. The combination of the sugar from the lollipop and the analgesic agent was discussed extensively in section *4.3.3.3.1 Management*.

Roberston and Costa-Scorse (2009) performed a literature review and a survey of advanced paramedics to determine their perspectives of current pain management practices and the potential inclusion of oral transmucosal pain relief. However, the study was only published as a conference abstract with no full text paper available. It was found that oral transmucosal analgesics were effective at reducing pain and anxiety and no clinically significant respiratory depression was noted. A systematic review would be useful to confirm the findings of this conference abstract.

Actiq® (Electronic Medicines Compendium, 2019a) is a potential candidate for analgesic administration, however its benefits over the intranasal route are unclear. Roberston and Costa-Scorse (2009) suggested that the oral lollipop would overcome the intranasal barrier of a blocked/runny nose, and perhaps nasal trauma, however the incidence of these barriers is unknown. Where intranasal analgesic administration is not available, Actiq® fentanyl lollipops maybe an effective solution, however the efficacy and safety in children is not well established and it is not currently recommended for children under 16 years of age (Electronic Medicines Compendium, 2019a), therefore interventional research is recommended prior to clinical practice implementation.

5.4.2.4 Pain free cannulation

Intravenous numbing cream was suggested as a method to overcome the barrier 'cannulation is painful', identified in *Figure 10* (pg208). This was discussed in section *4.3.3.3.1 Management* and it was concluded that timeliness was a significant consideration. In the pre-hospital environment when children suffer acute pain from medical illness or traumatic injury, rapid analgesia is required. Therefore, topical creams to reduce the pain of peripheral intravenous cannulation would be of little benefit for the immediate care of the child, due the time needed for the cream to take effect.

Needle-free jet injections have been used for approximately 75 years, yet have never been considered a mainstream treatment option in health care (Barolet and Benohanian, 2018). Such devices can be spring-loaded or gas-powered and major concerns have been around infection, pain during injection, perforation of the skin and bruising (Barolet and Benohanian, 2018). Therefore, disposable devices would be ideal to eliminate the cross-infection risk between patients and consideration for the driving pressure and space between the device and skin should be explored to minimise bruising and perforation.

The J-Tip™ needle-free injection system (J-Tip, 2020) is a single use device that delivers lidocaine to the procedural site via gas compression. This allows anaesthesia to take place rapidly, in one to two minutes (J-Tip, 2017). Jet injected lidocaine via the J-Tip™ delivery system is more effective at reducing pain than cooling spray (Lunoe et al., 2015) or numbing creams (Spanos et al., 2008, Jimenez et al., 2006) for children undergoing peripheral venous cannulation, although Stoltz and Manworren (2017) found that Emla cream provided superior anaesthesia when compared to the J-Tip. Stoltz and Manworren (2017) continued to state that where a waiting time of 60-90 minutes was not feasible, the J-Tip was a suitable alternative. The J-Tip™ delivery system was also deemed more cost effective than other types of anaesthesia including creams and patches (Pershad et al., 2008).

Given the existing evidence regarding the effectiveness of needle-free jet injection of lidocaine in children for peripheral venous cannulation, such interventions could be implemented and evaluated to determine the rates of analgesic administration

and rates of effective pain management. For the purpose of pain relief, where the intranasal route of analgesic administration is available, there may not be any need for an anaesthetic agent to facilitate cannulation in the pre-hospital setting. In the absence of intranasal analgesics, needle-free jet injection of lidocaine may be considered.

5.4.2.5 Child friendly uniform

The use of child friendly uniform, perhaps in the form of a brightly coloured tabard was suggested by participants as a potential improvement method, see *Figure 11* (pg217). This was discussed in section *4.3.3.3.2 Organisation* and it was concluded that a child friendly tabard could act as a non-pharmacological intervention to distract children, reduce fear and anxiety and therefore potentially reduce the perceived severity of pain. Evidence from the field of nursing, discussed in section *4.3.3.3.2 Organisation*, demonstrated a clear benefit for children that may be transferable into the pre-hospital setting.

Implementing a child friendly tabard into an ambulance service would be relatively straight forward. To meet infection, prevention and control requirements the tabard would have to be laminated and easy to clean after each use. It would have to be brightly coloured to sufficiently attract the attention of children to facilitate its distraction function. It would have to be friendly in nature, perhaps of cartoon characters, animals or shapes and not overly complicated. It would have to be easy to equip and remove, minimising the time delay to reach the child. It would have to be functional, not restrict mobility, moving and handling and not inhibit the clinician from performing their primary role of assessment and treatment.

Evaluating the effectiveness of tabards would be challenging as the choice of outcome measure(s) would require careful consideration. Rates of effective pain management could be assessed, or patient/parent satisfaction, or fear/anxiety levels, or a combination of these.

5.4.2.6 Paediatric equipment

A lack of paediatric equipment was identified as a barrier to the pain management process in children, see *Figure 10* (pg208), and it was suggested that more paediatric equipment could be a method of improvement, see *Figure 11* (pg217). This was discussed in section *4.3.3.3.2 Organisation* and it was concluded that an updated review of equipment status was required to better inform this potential change idea. Therefore, a survey of ambulance service equipment should be undertaken before this change idea is pursued.

The practicality of equipping ambulances with more paediatric equipment should be considered. Considering the low exposure rate of ambulance clinicians to children; approximately 9% (see section *1.2.1 Ambulance service*), the equipment may not be used enough to warrant purchase. Interventions and equipment used in health care should demonstrate value for money; this is of particular importance when using taxpayers' money (Department of Health, 2015). Therefore, judicious consideration of the most appropriate equipment needed should take place; this might involve key stake holders such as patients and relatives along with clinicians to determine the most important equipment. This could be incorporated with further research to explore the experience of the child, as discussed in section *5.4.3 Research*.

5.4.2.7 Non-pharmacological/distraction techniques

Non-pharmacological interventions such as distraction techniques were identified as a method to improve the pain management process in children, see *Figure 11* (pg217). This was discussed in section *4.3.3.3.1 Management* and it was concluded that further research was needed to determine the effectiveness of video distraction techniques.

The potential to incorporate video distraction into routine clinical practice exists, as mentioned by one participant in section *4.3.2.3.3 Organisation*, ambulances within the UK often have visual display units which could be used to show video content. Approximately half of ambulance services within the UK have electronic clinical

records (Porter et al., 2020), therefore video content could be stored on the electronic devices. This would allow usage at the scene of the incident, rather than waiting for the child to board the ambulance.

5.4.2.8 More public interaction

School visits were proposed by participants as a method to improve the experience of children. This was discussed in section *4.3.3.3.2 Organisation* and it was concluded that more public engagement, perhaps through school visits, may reduce fear and anxiety experienced by children as they would know what to expect during emergency call outs. When a child requires attendance from an ambulance for the first time, they may be more anxious and fearful from not knowing what to expect. However, the opposite could be argued; if a child has a painful experience with a health care professional, they may be more reluctant and more anxious at the next encounter (Jurko et al., 2016). This emphasises the need for a positive first encounter; a friendly exploration of the ambulance and equipment under non-emergency circumstances could help minimise potential anxiety and fear when the child subsequently needs an ambulance under emergency conditions.

The extent to which ambulance services currently participate in public engagement is not well understood, also the benefit of such involvement is perhaps even less understood. Having worked in the UK ambulance service for over 10 years, I have not personally been involved in delivering public engagement sessions to schools at any time, but I am aware of others that have. Further research is recommended to understand the scope for improvement and understand the potential benefits to be gained from increased public engagement in schools.

5.4.2.9 Highly trained clinicians

Multivariable logistic regression analysis found that children attended by paramedics were significantly more likely to achieve effective pain management than those attended to by emergency medical technicians (EMTs) (see *Table 9* pg120). Possible explanations were provided for this by interviewing paramedics

and EMTs (see section *4.3.2.1.3 Paramedic crew*). It was concluded that paramedics were older, more experienced, more confident, had a greater scope of practice and spent more time on scene than EMTs (see section *5.2.1.1.3 Clinician rank*).

Given the findings of this thesis, it was recommended that ambulance services prioritise the training of their clinical workforce, encouraging progression to higher ranks with enhanced training and skills; this may improve confidence and scope of practice. It is likely that increased numbers of highly trained staff will help increase the rates of effective pain management in children.

5.4.2.10 Optimal crew mix

During the identification of barriers and facilitators (see *Figure 10* pg208) and the exploration of improvements (see *Figure 11* pg217) it was found that working with a regular crewmate facilitated the management of complex cases, such as child pain management cases. It was also found that having both sexes within the crew (male *and* female) may provide benefits, as the child may react more favourably to a particular sex clinician.

At univariable analysis, senior clinician sex was not deemed a significant predictor of effective pain management (see *Table 8* pg118). This may have been due to the presence of both sexes on scene; it may be more informative to assess whether children attended by all female crews were more likely to achieve effective pain management than all male crews. Waseem and Ryan (2005) studied 200 children (70% male) aged 8 to 13 years attending a paediatric emergency department for laceration repair. They found that 79% of children who needed a suture in the emergency department would prefer to be treated by a female doctor (whereas 60% of parents preferred a male doctor). Interestingly, the children did not seem to care about experience of the doctor, opting for their preferred sex instead of the 'best' physician.

Where possible, ambulance service scheduling departments should aim to mix male and female members of staff when working on double crewed ambulances, and

ideally make them regular crewmates so that they develop confidence with each other and produce seamless clinical care and collaboration on scene. Although the benefits of female clinician presence on scene during cases of acute child pain have not been proven in this thesis or elsewhere, there are no apparent risks or drawbacks.

5.4.2.11 Enhanced training

The findings of this thesis along with previous research have concluded that ambulance service clinicians feel that their education and training has not prepared them to effectively manage acute pain in children. Within the United Kingdom, the Health and Care Professions Council (2018), who is the body for paramedic professional registration, have upgraded their entry level requirement to the register. From the 1st September 2021 all *new* paramedics must have a Bachelor's degree to gain registration (Health and Care Professions Council, 2018). This is in-line with other health care professionals such as doctors and nurses. It is likely that upscaling entry level education will increase knowledge and confidence; it would be useful to explore the impact of this with future research.

Training was also discussed in the context of ambulance service 'in-house' training. Ambulance services within the United Kingdom undertake statutory and mandatory training that is compulsory for clinicians to attend (London Ambulance Service NHS Trust, 2016, Yorkshire Ambulance Service NHS Trust, 2019, North West Ambulance Service NHS Trust, 2020). This training is often undertaken once per year. There is scope to increase the volume of training offered to clinicians per year; this would allow for additional training to cover more complex cases, such as acute child pain management. This may help increase rates of effective pre-hospital pain management in children.

In addition to formal education and 'in-service' training, continual professional development (CPD) provides an opportunity for enhanced training. Podcasts were suggested as a source of education in the generic qualitative study in this thesis (see section *4.3.3.3 Exploration of improvements*). The Royal College of Nursing

stated that CPD was vitally important for nursing staff and it contributed to improved patient outcomes and increased public confidence (Royal College of Nursing, 2018). However, Eustace (2001) argued that the association between CPD activities and patient outcomes was not clear, and further research was required. Griscti and Jacono (2006) reviewed the evidence on continuing education in nursing and concluded that it was difficult to determine whether nurses implemented what they had learnt into practice. Khomeiran et al. (2006) found that theoretical knowledge was one of the six main factors that influenced competence development and highlighted the benefit of continuing development that is tailored to real needs in practice.

Although the association between CPD and patient outcomes is not clear, the potential benefit of improving clinical competence makes CPD a recommended route of education.

#### 5.4.2.12 Facilitate pain assessment

The findings of this thesis (see *Figure 10* pg208) and previous research (Whitley et al., 2020a) highlight the difficulty of pre-hospital pain management in children, particularly younger children. During the qualitative study, participants suggested the development of a simpler, more pragmatic pain assessment tool (see section *4.3.3.3 Exploration of improvements*).

Two options for future research exist; 1) modify or create a new pain assessment tool for pre-hospital use in children to measure pain score and/or 2) determine the most appropriate outcome measure that is deemed important to children and their parents. It was suggested with the patient and public involvement within this thesis (see section *5.2.5 Patient and public involvement*) that fear reduction would be a useful outcome. Further research with children and parents may reveal that during the pre-hospital ambulance service encounter, pain score is not important. Pain scores are useful for clinicians and researchers as they are able to determine the effectiveness of interventions.

Important outcomes in child acute pain, according to McGrath et al. (2008), include '*pain intensity, global judgment of satisfaction with treatment, symptoms and adverse events, physical recovery, emotional response, and economic factors*' (pg 774). Therefore, pain scores only constitute one (pain intensity) out of six important outcomes here. Global satisfaction with treatment could easily be incorporated into pre-hospital child pain assessment with a simple, binary 'yes/no' question. The emotional response related to feelings such as fear, anxiety, depression, unhappiness, distress or dysphoria. Emotional scales could be incorporated into pre-hospital child pain assessment, as discussed in section *5.2.1.1.1 Child age* with the use of the Faces Anxiety Scale (McKinley et al., 2003). It would be useful to compare the outcome measures deemed important by children and parents who have experience of suffering acute pain in the pre-hospital setting to those identified by McGrath et al. (2008) and perhaps create a hierarchy of outcome priorities.

### 5.4.3 Research

Future research should focus on several key areas:

1. **Experience of the child.** The experience of the child suffering acute pain in the pre-hospital setting should be explored, as child voice data was clearly lacking from the evidence base. This would help to:
    a. Inform important outcome measures and further barriers and facilitators.
    b. Explore the disparity in child age; the hypothesis that younger children express more emotion and that younger children may respond better to non-pharmacological interventions.
    c. Explore the disparity in child sex by comparing experiences of male and female children regarding episodes of acute pain managed by the ambulance service.
    d. Explore the disparity in deprivation by comparing the experiences of children and parents from areas of high and low deprivation during ambulance call-outs for acute pain.

e. Explore the disparity in medical and trauma causes of pain and test the hypothesis that early non-pharmacological interventions could be a method of improvement.

2. **Determine the appropriate use of pain scales.** Observational research should be undertaken to assess the appropriate use of pain scales by pre-hospital clinicians when assessing pain in children. Similar research was performed in the emergency department setting (Sampson et al., 2019) and therefore could be used to guide a similar study in the pre-hospital setting.

3. **Validate pain scales.** Currently, EVENDOL (Beltramini et al., 2019) is the only child pain assessment scale validated in the pre-hospital setting. The Wong & Baker FACES® scale has been validated in the emergency department setting (Garra et al., 2010), however it would be useful to confirm its validity in the pre-hospital setting, along with the numeric pain rating scale and the FLACC scale. In addition to this, it would be useful to determine the most important outcome measure for patients and parents, as discussed by Eccleston et al. (2020), as there may be a more important measure than pain scores, such as fear/anxiety reduction or improved comfort for example.

4. **Clinician and patient ethnicity.** Data were unavailable for child and clinician ethnicity, therefore ethnicity could not be included in the multivariable logistic regression analysis. Yen et al. (2003) found no significant difference between racial and ethnic groups of children attending emergency departments for isolated long bone fracture. The influence of child ethnicity should be explored from the pre-hospital perspective. Future research identifying predictors of effective pain management in children in the pre-hospital setting should consider including ethnicity data, where available.

5. **Clinician parent status.** Clinicians who are parents versus clinicians who are not *may* be more or less likely to manage children suffering acute pain effectively. Future research identifying predictors of effective pain management should include clinician parent status, where available.

6. **Crew mix.** The following crew mixes should be tested for their association with effective pre-hospital pain management in children:
    a. Male-female crews (versus all male and all female).
    b. Regular crew mates (versus crew mates who work together infrequently, on relief shift patterns for example).

7. **Intervention development, evaluation and investigation.** Several applied recommendations have been made, see section *5.4.2 Practice*. Many of these recommendations require development and evaluation as a minimum, some may require rigorous research methods to determine efficacy, safety and satisfaction from clinicians and children. Specific interventions that require further research include:
    a. **Intranasal analgesics:** fentanyl and ketamine
    b. **Inhaled analgesics:** methoxyflurane
    c. **Oral analgesics:** analgesic lollipops
    d. **Non-pharmacological / distraction techniques:** video cartoons in ambulances or on electronic patient report form tablets, child friendly tabards.

## 5.5 Conclusion

Pre-hospital pain management in children is extremely complex with biological, psychological and social factors to consider along with the interactions between the child, clinician and parent triad. Pain management may be improved by increasing rates of analgesic administration and reducing the fear and anxiety experienced by children and clinicians. Investment in future research and intervention development is imperative; as Eccleston et al. (2020) stated, we need to *make pain matter*. Only then can we improve the quality of care we provide to children suffering acute pain in the pre-hospital setting.

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# Appendices

Appendix 1 – Systematic mixed studies review: Search strategy

| | Database | | | | | |
|---|---|---|---|---|---|---|
| | **MEDLINE** | **CINAHL complete** | **PsycINFO** | **EMBASE** | **Scopus** | **Web of Science Core Collection** |
| S1 | Infant* OR Child* OR Pediatric* OR Paediatric* OR Adolescen* OR (MH 'Pediatrics') OR (MH 'Adolescent') | Infant* OR Child* OR Pediatric* OR Paediatric* OR Adolescen* OR (MH 'Pediatrics') OR (MH 'Adolsecence') | Infant* OR Child* OR Pediatric* OR Paediatric* OR Adolescen* OR DE 'Pediatrics' | Infant* OR Child* OR Pediatric* OR Paediatric* OR Adolescen* OR Pediatrics/ OR adolescent/ OR child/ | TITLE-ABS-KEY ( ( infant* OR child* OR pediatric* OR paediatric* OR adolescen* ) AND ( ambulance* OR 'Emergency Medical Service*' OR prehospital OR pre-hospital OR 'Out of hospital' OR paramedic* ) AND ( pain OR analgesi* ) ) | TS=((Infant* OR Child* OR Pediatric* OR Paediatric* OR Adolescen*) AND (Ambulance* OR 'Emergency Medical Service*' OR Prehospital OR Pre-hospital OR 'Out of hospital' OR Paramedic*) AND (Pain OR Analgesi*) ) |
| S2 | Ambulance* OR 'Emergency Medical Service*' OR Prehospital OR Pre-hospital OR 'Out of hospital' OR Paramedic* OR (MH 'Emergency Medical Services') OR (MH 'Ambulances') | Ambulance* OR 'Emergency Medical Service*' OR Prehospital OR Pre-hospital OR 'Out of hospital' OR Paramedic* OR (MH 'Emergency Medical Services') OR (MH 'Ambulances') | Ambulance* OR 'Emergency Medical Service*' OR Prehospital OR Pre-hospital OR 'Out of hospital' OR Paramedic* OR DE 'Emergency Services' | Ambulance* OR 'Emergency Medical Service*' OR Prehospital OR Pre-hospital OR 'Out of hospital' OR Paramedic* OR ambulance/ | | |
| S3 | Pain OR Analgesi* OR (MH 'Acute Pain') OR (MH 'Pain Management') | Pain OR Analgesi* OR (MH 'Pain') OR (MH 'Pain Management') | Pain OR Analgesi* OR DE 'Pain' | Pain OR Analgesi* OR Pain/ OR analgesia/ | | |
| S4 | S1 AND S2 AND S3 | S1 AND S2 AND S3 | S1 AND S2 AND S3 | S1 AND S2 AND S3 | | |

Appendix 2 – Systematic mixed studies review: Worked search MEDLINE

EBSCOhost

Tuesday, June 30, 2020 6:43:29 AM

| # | Query | Limiters/Expanders | Last Run Via | Results |
|---|---|---|---|---|
| S4 | S1 AND S2 AND S3 | Expanders - Apply equivalent subjects<br>Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Basic Search<br>Database - MEDLINE | 1,022 |
| S3 | Pain OR Analgesi* OR (MH "Acute Pain") OR (MH "Pain Management") | Expanders - Apply equivalent subjects<br>Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Basic Search<br>Database - MEDLINE | 833,050 |
| S2 | Ambulance* OR "Emergency Medical Service*" OR Prehospital OR Pre-hospital OR "Out of hospital" OR Paramedic* OR (MH "Emergency Medical Services") OR (MH "Ambulances") | Expanders - Apply equivalent subjects<br>Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Basic Search<br>Database - MEDLINE | 82,284 |
| S1 | Infant* OR Child* OR Pediatric* OR Paediatric* OR Adolescen* OR (MH "Pediatrics") OR (MH "Adolescent") | Expanders - Apply equivalent subjects<br>Search modes - Boolean/Phrase | Interface - EBSCOhost Research Databases<br>Search Screen - Basic Search<br>Database - MEDLINE | 4,441,697 |

Appendix 3 – Systematic mixed studies review: Data extraction form

| **Study ID:** | **Report ID :** | Date form completed: |
|---|---|---|
| First author: | Year of study: | Data extractor: |
| Citation: | | |

## 1. General Information

| Publication type Journal Article ☐ Abstract ☐ Other (specify e.g. book chapter)_____ | |
|---|---|
| Country of study: | |
| Funding source of study: | Potential conflict of interest from funding? Y / N / unclear |

## 2. Study Eligibility

| **Study Characteristics** | | | **Page/ Para/ Figure #** |
|---|---|---|---|
| **Type of study** | ☐ Interventional Study<br>☐ Cohort Study<br>☐ Case Control Study<br>☐ Cross-sectional Study<br>☐ Survey | ☐ Qualitative Study<br>☐ Multi-Methods | |
| | ☐ Other design (specify): | *Does the study design meet the criteria for inclusion?*<br>Yes ☐ No ☐ →**Exclude** Unclear ☐ | |
| **Participants** | Describe the participants included: | | |
| | Are participants either children >18 years, patient relatives or Ambulance / EMS clinicians? | Yes ☐ No ☐<br>Unclear ☐<br>Details: | |
| | *Do the participants meet the criteria for inclusion?* | Yes ☐ No ☐ →**Exclude**<br>Unclear ☐ | |

| | | | |
|---|---|---|---|
| **Phenomena of Interest** | Does the study identify predictors, barriers or facilitators associated with effective or ineffective management of acute pain in children within ambulance / EMS services? | Yes ☐ No ☐<br>Unclear ☐<br>Details: | |
| | *Does the phenomena of interest meet the criteria for inclusion?* | Yes ☐ No ☐ →**Exclude**<br>Unclear ☐ | |
| **Context** | *Is the context of the study within any international ambulance or EMS service?* | Yes ☐ No ☐ →**Exclude** Unclear ☐ | |

**Summary of Assessment for Inclusion**

| | |
|---|---|
| **Include in review** ☐ | **Exclude from review** ☐ |
| Independently assessed, and then compared? Yes ☐ No ☐ | Differences resolved Yes ☐ No ☐ |
| Request further details? Yes ☐ No ☐ | Contact details of authors: |
| **Notes:** | |

DO NOT PROCEED IF PAPER EXCLUDED FROM REVIEW

## 3. Study details

| **Methods** | **Descriptions as stated in the report/paper** | **Page/ Para/ Figure #** |
|---|---|---|
| Study Type | | |
| Method of Participant Recruitment | | |
| Date range of participant recruitment | | |
| Sample size calculation:<br>What assumptions were made?<br>Were these assumptions appropriate? | <br><br>*(Yes/No/Unclear)* | |
| Inclusion/exclusion criteria for participation in study | | |

| | | |
|---|---|---|
| Representativeness of sample: Are participants in the study likely to be representative of the target population? | | |
| Statistical methods used and appropriateness of these methods | | |

## 4. Results

| **Population Characteristics** | **Descriptions as stated in the report/paper** | **Page/ Para/ Figure #** |
|---|---|---|
| Number of participants | | |
| Setting (Urban / Rural) | | |
| Age (Range / Mean / Median) | | |
| Gender | | |
| Race / Ethnicity | | |
| Baseline Source of Pain (medical / trauma) | | |
| Baseline Pain Severity | | |
| Clinical Experience of participants | | |

| **Outcomes of Significance** | **Include information for each group (i.e. intervention and controls) under study** | **Page/ Para/ Figure #** |
|---|---|---|
| • Identified Predictive Barriers (including | | |

| | | |
|---|---|---|
| OR/RR/P-values as appropriate) | | |
| • Identified Predictive Facilitators (including OR/RR/P-values as appropriate) | | |
| • Identified Barriers | | |
| • Identified facilitators | | |
| • Key Themes Arising and Supporting Statements | | |

## 5. Recommendations

| **Recommendations** | **Include information for each group (i.e. intervention and controls) under study** | **Page/ Para/ Figure #** |
|---|---|---|
| • For Future Research | | |
| • For Clinical Practice | | |

## 6. Conclusions

| **Conclusions** | **Include information for each group (i.e. intervention and controls) under study** | **Page/ Para/ Figure #** |
|---|---|---|
| • Main Conclusions of the study authors | | |

## 7. Other relevant information

| | |
|---|---|
| Potential for author conflict *ie. evidence that author or data collectors would benefit if results favoured the intervention under study or the control* | |

| | |
|---|---|
| Could the inclusion of this study potentially bias the generalisability of the review? Equity pointer: Remember to consider whether disadvantaged populations may have been excluded from the study. | |
| Additional notes by review authors | |
| Correspondence required for further study information (from whom, what and when) | |

Appendix 4 – Systematic mixed studies review: Quality/risk of bias assessments

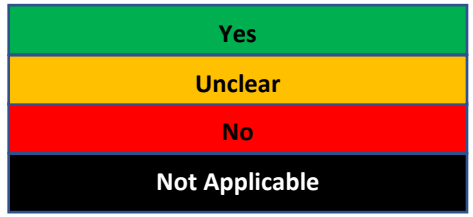
Cross-sectional study assessment:

| Question | Study | | | | | |
|---|---|---|---|---|---|---|
| | Bendall et al. (2011a) | Jennings et al. (2015) | Karlsen et al. (2014) | Lord et al. (2019) | Murphy et al. (2017) | Whitley et al. (2020b) |
| *1. Were the aims/objectives of the study clear?* | | | | | | |
| *2. Was the study design appropriate for the stated aim(s)?* | | | | | | |
| *3. Was the sample size justified?* | | | | | | |
| *4. Was the target/reference population clearly defined? (Is it clear who the research was about?)* | | | | | | |
| *5. Was the sample frame taken from an appropriate population base so that it closely represented the target/reference population under investigation?* | | | | | | |
| *6. Was the selection process likely to select subjects/participants that were representative of the target/reference population under investigation?* | | | | | | |
| *8. Were the risk factor and outcome variables measured appropriate to the aims of the study?* | | | | | | |
| *9. Were the risk factor and outcome variables measured correctly using instruments/measurements that had been trialled, piloted or published previously?* | | | | | | |
| *10. Is it clear what was used to determined statistical significance and/or precision estimates? (eg, p values, CIs)* | | | | | | |

| Question | Study | | | | | |
|---|---|---|---|---|---|---|
| | Bendall et al. (2011a) | Jennings et al. (2015) | Karlsen et al. (2014) | Lord et al. (2019) | Murphy et al. (2017) | Whitley et al. (2020b) |
| *11. Were the methods (including statistical methods) sufficiently described to enable them to be repeated?* | | | | | | |
| *12. Were the basic data adequately described?* | | | | | | |
| *15. Were the results internally consistent?* | | | | | | |
| *16. Were the results for the analyses described in the methods, presented?* | | | | | | |
| *17. Were the authors' discussions and conclusions justified by the results?* | | | | | | |
| *18. Were the limitations of the study discussed?* | | | | | | |
| *19. Were there any funding sources or conflicts of interest that may affect the authors' interpretation of the results?* | | | | | | |
| *20. Was ethical approval or consent of participants attained?* | | | | | | |

AXIS tool used (Downes et al., 2016)

Key:

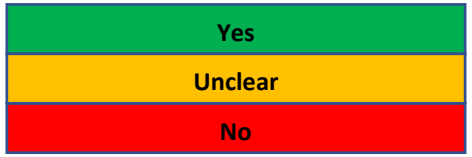


Case Series Study Assessment:

| Question | Study | |
|---|---|---|
| | Babl et al. (2006) | Johansson et al. (2013) |
| *1. Were there clear criteria for inclusion in the case series?* | | |
| *2. Was the condition measured in a standard, reliable way for all participants included in the case series?* | | |
| *3. Were valid methods used for identification of the condition for all participants included in the case series?* | | |
| *4. Did the case series have consecutive inclusion of participants?* | | |
| *5. Did the case series have complete inclusion of participants?* | | |
| *6. Was there clear reporting of the demographics of the participants in the study?* | | |
| *7. Was there clear reporting of clinical information of the participants?* | | |
| *8. Were the outcomes or follow up results of cases clearly reported?* | | |
| *9. Was there clear reporting of the presenting site(s)/clinic(s) demographic information?* | | |
| *10. Was statistical analysis appropriate?* | | |

Joanna Briggs Institute tool used (Moola et al., 2017)

Key:



Qualitative Study Assessment:

| Question | Study | | | | |
|---|---|---|---|---|---|
| | Jepsen et al. (2019) | Holmström et al. (2019) | Gunnvall et al. (2018) | Murphy et al. (2014) | Williams et al. (2012) |
| *1. Was there a clear statement of the aims of the research?* | | | | | |
| *2. Is a qualitative methodology appropriate?* | | | | | |
| *3. Was the research design appropriate to address the aims of the research?* | | | | | |
| *4. Was the recruitment strategy appropriate to the aims of the research?* | | | | | |
| *5. Was the data collected in a way that addressed the research issue?* | | | | | |
| *6. Has the relationship between researcher and participants been adequately considered?* | | | | | |
| *7. Have ethical issues been taken into consideration?* | | | | | |
| *8. Was the data analysis sufficiently rigorous?* | | | | | |
| *9. Is there a clear statement of findings?* | | | | | |

Qualitative CASP tool used (Critical Appraisal Skills Programme, 2013)

Key:

| |
|---|
| **Yes** |
| **Unclear** |
| **No** |

Appendix 5 – Systematic mixed studies review: Thematic synthesis

| Quotes [source] | Initial Themes | Descriptive Themes | Analytical Themes |
|---|---|---|---|
| 'I had a sick 15-year old and one of the issues I had, he was given IV morphine after a musculoskeletal injury, but he came in the ambulance with his coach, it was a football match, and I had a lot of questions in my head about consent, you know? I suppose I erred on the side of doing the best for him I could or what I thought was the best for him at the time…' [Murphy et al. (2014) pg496] | Concern about consent when administering analgesics | Education and training is considered poor by the majority of clinicians | **Internal Influences on the Clinician** |
| 'As for education and guidelines, of course we're not allowed to give sufficiently high doses, even according to paediatric experts. The first thing they do at the receiving unit where we drop the child off is to supplement our pain treatment and that doesn't feel at all satisfactory.' [Gunnvall et al. (2018) pg42] | Restrictive clinical guidelines inhibit effective pain management | | |
| 'I think from the training point of view, its two or three days in the paediatric A&E, in comparison to over two weeks in an adult A&E, with much more actual interaction with the staff and obviously clinical practice in terms of interventions…' [Murphy et al. (2014) pg495] | Lack of exposure to children during education and training | | |
| 'When you are on placements, they are so precious about the children, you are not allowed near them for fear that you would upset them or make it worse…' [Murphy et al. (2014) pg495] | | | |
| 'Not much pediatric education in paramedic or EMT programs at any level of prehospital training . . . I don't think there's a lot of emphasis on pediatrics per se. In class we had I think five or six sessions on pediatrics and that's going through the whole gamut of everything that has to deal with pediatrics . . .. Pain management wasn't really covered that much at all.' [Williams et al. (2012) pg523] | | | |
| '[We] are not allowed to touch [pediatric patients] when you're in paramedic school so when you get out of paramedic school you're in a trend.' [Williams et al. (2012) pg523] | | | |
| 'I don't know if you have all been involved in some of the elearning that PHECC have been doing and it's excellent…' [Murphy et al. (2014) pg495] | e-learning is beneficial | | |
| 'eLearning …they're economical for their service provider, it wouldn't cost them money, and they're easy to do for people, you can do them in your own time, and for people who don't necessarily like attending formal courses and exams, there's less pressure, it's a route that's working well in other areas that I think might be of benefit...' [Murphy et al. (2014) pg495] | | | |
| 'I just felt if I missed the IV now, I'm after wasting five minutes missing an IV and that's five minutes closer to the hospital, so, having used intranasal midazolam a number of times, it's super, getting it out and drawing it up and giving it…you wouldn't even have your line and Tegaderm out by the time you have the intranasal midazolam given…' [Murphy et al. (2014) pg496] | Preference to defer analgesic administration until hospital arrival | Clinicians fear treating children in pain | |
| 'I'm not going to stay on scene for an extra ten minutes to insert a line and give morphine if the hospital is only 5 minutes down the road…' [Murphy et al. (2014) pg496] | | | |
| 'When we went through class we were always told to look for reasons to not give medication and there's never a great reason to give morphine . . .. I don't think we covered too much about it in class at all. I just remember the overall generalization of medications: always look for reasons not to give it.' [Williams et al. (2012) pg523] | | | |
| 'I deferred when close to the hospital because I think there's more of a comfort level in the hospital. They deal with it more. I think they're better. They have the ability to assess pain better than we do. They do drug dosages, which isn't that big of a deal but it's just something that they're more comfortable with . . . .' [Williams et al. (2012) pg524] | | | |

| | | | |
|---|---|---|---|
| 'I mean all of the controlled substance charts are 100% QA'd, which I'm sure Dr. [agency medical director] reads as well . . . I know that our ALS chief reads it. So maybe that's a part of it as far as deferring . . . 'Am I really comfortable doing this, and if I'm not and I screw up am I gonna lose my job? Am I gonna lose my card? Am I gonna get kicked back down to a basic level?'' [Williams et al. (2012) pg524] | | | |
| 'I'm stingy with all my drugs.' [Williams et al. (2012) pg524] | | | |
| 'I am indifferent to distance from the hospital in terms of whether to give it or not. If it's indicated, might as well get it to them sooner than later.' [Williams et al. (2012) pg524] | | | |
| 'If I'm two minutes away from the hospital, it's gonna take me longer to stop, start the IV, put the person on the monitor, put the pulse oximetry on cuz you gotta check for that respiratory effort, and then actually administer the medicine versus driving two and a half or three minutes and havin' the hospital do it.' [Williams et al. (2012) pg524] | | | |
| 'Morphine is risky if you don't know a child's gonna have an allergic reaction to it.' [Williams et al. (2012) pg523] | Concern for adverse effect when using strong analgesics | | |
| ' . . .you know if you give an adult too much morphine for example and you make them hypotensive and you depress their respiratory rate and effort, you can fix that pretty quickly in an adult, but the repercussions of doing that in a little kid? The risk is higher.' [Williams et al. (2012) pg523] | | | |
| 'It can happen and then you overdose them based on that guesstimate [of the patient's weight] for some [expletive] little pain problem? No, it's not gonna fly. But if it's something serious, like a femur fracture . . .then at least the ends justify the means. I can't justify it for some [expletive].' [Williams et al. (2012) pg523] | | | |
| 'You do not have the same routine to take care of children, you do not meet children seven days a week, like adults ... but children are not like little adults anyway, they are something else that requires extra supervision of the doses .. and other things and that is a stress factor.. ' [Holmström et al. (2019) pg24] | | | |
| 'When we went through class we were always told to look for reasons to not give medication and there's never a great reason to give morphine . . .. I don't think we covered too much about it in class at all. I just remember the overall generalization of medications: always look for reasons not to give it.' [Williams et al. (2012) pg523] | | | |
| 'A child with a deformed arm is more likely to get significant analgesia than a child in severe abdominal pain, let's say, and appendicitis…' [Murphy et al. (2014) pg496] | Decision making; trauma is treated more readily than medical pain | Prior clinical experience influences pain management | |
| 'People won't even consider paracetamol or ibuprofen for tummy pain…' [Murphy et al. (2014) pg496] | | | |
| '…We have a lot of barriers to IV access in younger children. The older ones wouldn't be a major problem but certainly younger children, which again certainly affects your mind set in relation to using the likes of morphine…' [Murphy et al. (2014) pg496] | Lack of confidence with IV analgesics | | |
| 'I find it really hard to judge when is the right time, when is someone bad enough to warrant inflicting more pain with a cannula, and then the possibility that you might stick it into them two or three times before you would get anywhere, I would say, and with 90% of kids, I would really have no cannula…' [Murphy et al. (2014) pg496] | | | |
| '... Nowadays we don't always have to hurt the child by inserting a PVC ... since we have the intranasal technique. And then it could be so anyway, that I have to insert this ... It hurts and can be messy ... They are chubby at a certain age ... it is often difficult to find the vessels...' [Holmström et al. (2019) pg26] | | | |

| | | | |
|---|---|---|---|
| 'I think it's more of a familiarity and comfort issue. It's just not done often enough so that people are comfortable with it and will go ahead and utilize it . . .. People are just generally speaking afraid of kids because of a lack of familiarity and particularly pain management runs high on that list because it's one of the things we do least often.' [Williams et al. (2012) pg523] | | | |
| 'I'm not that keen on treating pain in a child … because children incapable of communicating make me feel insecure, I don't know what effect my treatment is having. Is it bad, is it good, what information am I getting?' [Gunnvall et al. (2018) pg42] | Lack of prior clinical experience | | |
| 'When it comes to a paediatric emergency or an obstetric emergency, and it's just the exposure, we're not doing five of them a day, so I think we have to try and make up for that deficit somehow again be it in placements, be it in simulation…' [Murphy et al. (2014) pg495] | | | |
| ...'I must really try to gather my thoughts and have a mental preparation for how I should work directly in a place when arriving ..I have to show that this sort of thing is what I do every day; I am competent and it will be all right, I will take care of you.' [Holmström et al. (2019) pg25] | | | |
| 'When it comes to children, we don't take histories, we don't actually have any hands-on experience and so our experience is very low. I think we are even at the stage whereby I think routinely we don't strip a child, we don't get them down to their nappy, we don't do that…' [Murphy et al. (2014) pg496] | | | |
| 'I knew he was in pain because of his presentation. He was screaming with any movement or palpation to the area. He was tachycardic too. His vital signs coincided with his presentation and his discomfort. I looked for elevated heart rate, elevated blood pressures.' [Williams et al. (2012) pg523] | Prior experience of managing pain is helpful | | |
| 'I can say I have to prepare myself during a trip to a severely ill child... because first of all, I have a noticeably higher rate of stress ... depending on the nature of the alarm, of course ...if it's a prior one and a bad case with a child involved, so to speak, then it is stressful' [Holmström et al. (2019)pg25] | Raised clinician anxiety results in increased cautiousness | | |
| 'Makes you a little more anxious when you're dealing with a child. I feel that when our anxiety level is raised we're gonna be a little more hesitant about doing things that we should. A little more cautious I should say. Maybe it hinders our ability to assess the patient appropriately.' [Williams et al. (2012) pg524] | | | |
| 'I have had a couple of appendicitis', I was at the GP's, and you go in there and the child is obviously in distress, in a lot of abdominal pain, and you're saying (to the GP), 'Are you going to give him something for the pain?' And he's like, 'No, you can't give him anything for the pain, it will only mask the symptoms when they get up to the hospital.' So where do you go with that?' [Murphy et al. (2014) pg496] | Discordance between HCPs is challenging | Colleagues influence the pain management process | **External Influences on the Clinician** |
| 'It's very hard to turn around and say to parents, 'I know the GP has said not to give analgesia but the ambulance driver is now saying, Oh I'm going to give them analgesia'… those are becoming issues as well...' [Murphy et al. (2014) pg496] | | | |
| 'It's something that could be in the back of your mind as well, the interaction you are having with the emergency department staff when you get there, and you know that if this, if you are going to do something it's actually going to cause a difficulty even though it's within your scope. It may be something that contributes to your decision of whether or not to do it...' [Murphy et al. (2014) pg496] | | | |
| 'I think I may be more inclined to call for help from specialised units and the helicopter and such, as compared to when it's an adult.' 'Seek assistance from the resources at hand. We have good resources, we have specialised units and units with doctors in them and doctors on the phone.' [Gunnvall et al. (2018) pg42] | Collaboration between HCPs can be helpful | | |
| 'On the best of days, we are two ambulances when there is a child involved ... then we are four people, which makes an opportunity to designate one person to take care of hysterical parents ... ' [Holmström et al. (2019) pg25] | | | |
| 'Oh no, this child is reacting strongly against me somehow, you know. My voice or whatever, they can get scared. Then it might be better for the colleague to step in, much better.' [Gunnvall et al. (2018) pg42] | | | |

| | | | |
|---|---|---|---|
| ‘Calling medical control at certain places around here and getting orders for pain control is an almost impossible task . . .. I have never successfully argued for a pain control order out of [hospital]. I have never successfully argued for a pain control order out of [hospital] for kids.’ [Williams et al. (2012) pg523] | Clinical support is not beneficial | | |
| ‘I think I may be more inclined to call for help from specialised units and the helicopter and such, as compared to when it’s an adult.’ ‘Seek assistance from the resources at hand. We have good resources, we have specialised units and units with doctors in them and doctors on the phone.’ [Gunnvall et al. (2018) pg42] | Clinical support is beneficial | | |
| ‘I feel that pediatric medical control doctors are more willing to work with you . . . having medical control doctors that are willing to chat with you on the phone definitely helps as far as increasing the usage of pain medication in the field.’ [Williams et al. (2012) pg523] | | | |
| ‘When we got there [to the ED] I told them I gave 10 mg morphine and they flipped out. ‘You gave 10 mg morphine?! Why’d you give 10 mg morphine?!’ The doctor was cool with it. It was the nurses who were all flippin’ out . . .. So that’s another thing to keep in the back of my head. Am I gonna get yelled at by the hospital staff whether it’s warranted or not?’ [Williams et al. (2012) pg523] | Negative judgement of colleagues hinders analgesic use | | |
| ‘You know, we are not on a level footing, in terms of professionalism… Sometimes it’s a mind-set in a particular department...’ [Murphy et al. (2014) pg496] | | | |
| ‘Depending on your boss of the year, some of them are in support of it, while some of them could care less. Our last boss used to brag about how we had the least narcotics administrations out of all the area paramedics.’ [Williams et al. (2012) pg523] | Positive judgement of colleagues encourages analgesic use | | |
| ‘ . . .he [paramedic mentor] is very liberal with his pain meds . . . some of the paramedics that I’ve been trying to emulate are more liberal with their pain meds and I think that’s what pushed me in that direction.’ [Williams et al. (2012) pg523] | Confident mentors encourage analgesic administration | | |
| ‘Well, I think that when we have children as patients, we often have several patients; even if we don’t treat the adults, they play a big part in our handling of this instance of care.’ [Gunnvall et al. (2018) pg42] | Parents help the pain management process | Relatives on scene influence the pain management process | |
| ‘Talk to the parent first, take that detour, and try to keep the parent calm because how the parents are is reflected so much in the children, it’s reflected a whole lot in the child.’ [Gunnvall et al. (2018) pg42] | | | |
| ‘ . . .carry a Broselow tape and whip it out on every kid because I will admit that I struggle when it comes to judging a kid’s weight . . .. If the parent knows and they’re pretty reliable based on a well-baby checkup then I defer to the parent.’ [Williams et al. (2012) pg523] | | | |
| ‘I have to establish contact so I can get close to the child; you have to learn to meet at their level. First of all, I learned to kneel or on the floor so that we reach the same eye level. I've learned to ask questions so that the child understands me. Also, I’ve learned to meet the child and show that I'm a kind person and not a threat. How I do it depends a bit on what kind of child I have in front of me. If I have a child who does not even want to look at me, I may start with talking to Mom and Dad. ‘ [Holmström et al. (2019) pg25] | | | |
| ‘He measured my bloodoxygen (saturation)… Then he explained that it was really good, and then my son easily cooperated with the assessment…’ [Jepsen et al. (2019) pg5] | | | |
| ‘I would say it’s 50% of the time they’re helping, 50% of the time impeding, because you get the parents that are very supportive of what you’re doing and they just kind of stand back and then you have the other parents that are in your face . . ..’ [Williams et al. (2012) pg523] | | | |
| ‘I would say it’s 50% of the time they’re helping, 50% of the time impeding, because you get the parents that are very supportive of what you’re doing and they just kind of stand back and then you have the other parents that are in your face . . ..’ [Williams et al. (2012) pg523] | Parents hinder the pain management process | | |

| | | | |
|---|---|---|---|
| ‘On the best of days, we are two ambulances when there is a child involved ... then we are four people, which makes an opportunity to designate one person to take care of hysterical parents ... ‘ [Holmström et al. (2019) pg25] | | | |
| ‘I’ve never had a parent get in the way as far as tellin’ us how to treat, but I think maybe when they’re upset because their child’s hurt it does hinder our ability to take care of the patient in the way we’re supposed to.’ [Williams et al. (2012) pg523] | | | |
| ‘It’s very important to alleviate children’s pain. Especially thinking about their future healthcare, since they’ll remember the second we get there until the second it no longer hurts. If we can make the pain disappear right away, then we’ve come a long way, then we’re the heroes of the day.’ [Gunnvall et al. (2018) pg41] | Pain relief is important for the holistic care of the child | Child experience of event is important | **Child Factors** |
| ‘And I view this taking care of a child’s pain, that it’s not only a matter of taking care of the child but the whole situation around it, because it’s the child’s lifeworld I’m taking care of.’ [Gunnvall et al. (2018) pg42] | | | |
| ‘Its purpose is to lessen pain and to make things better for the patient and that’s why we’re here—to make the patient better.’ [Williams et al. (2012) pg523] | | | |
| ‘Yes, I agree, but spontaneously, I would say that the primary focus is always the child. Parents will be secondary ... So, parents fall a little bit away. You get some kind of tunnel vision if there are few nurses in a place. It's the child and nothing else just then... until the child is stable ... then you can take care of the parents.’ [Holmström et al. (2019) pg25] | Child’s experience more important than parent’s experience | | |
| ‘… I usually prefer to do as much as possible in their home. Like we said before, then you can involve parents, colleagues, other relatives. And you can also involve the room, toys and such ….’ [Gunnvall et al. (2018) pg41] | Preference to treat at home in the child’s own environment | | |
| ‘But everything I’m going to do I explain first, and then, well, see the reaction. I want the child to participate, at least to have the sense of being in on it and making decisions.’ [Gunnvall et al. (2018) pg42] | Preference to involve the child in the clinical decision making | | |
| ‘You know, I have to build up a relationship. Even if things happen quickly sometimes, I just must get the child to feel some kind of trust towards me, or it will be impossible for me to do anything at all. If not, I’ll get nowhere in caring for the child, I won’t even be able to alleviate the child's pain.’ [Gunnvall et al. (2018) pg41] | Developing trust between clinician and child is important | | |
| ...’I must really try to gather my thoughts and have a mental preparation for how I should work directly in a place when arriving ..I have to show that this sort of thing is what I do every day; I am competent and it will be all right, I will take care of you.’ [Holmström et al. (2019) pg25] | | | |
| ‘I have to establish contact so I can get close to the child; you have to learn to meet at their level. First of all, I learned to kneel or on the floor so that we reach the same eye level. I've learned to ask questions so that the child understands me. Also, I’ve learned to meet the child and show that I'm a kind person and not a threat. How I do it depends a bit on what kind of child I have in front of me. If I have a child who does not even want to look at me, I may start with talking to Mom and Dad. ‘ [Holmström et al. (2019) pg25] | | | |
| ‘… They played at the same time as they were assessing and giving him the treatment…’ [Jepsen et al. (2019) pg5] | | | |
| ‘I know my ambulance. I feel good, I like it there. I think I can convey this to the child: you’ll like it here too.’ [Gunnvall et al. (2018) pg41] | | | |
| ‘I find it really hard to judge when is the right time, when is someone bad enough to warrant inflicting more pain with a cannula, and then the possibility that you might stick it into them two or three times before you would get anywhere, I would say, and with 90% of kids, I would really have no cannula…’ [Murphy et al. (2014) pg496] | Risk versus benefit of IV access | | |
| ‘IVs are something we definitely don’t like to do in kids. We cause them more pain starting IVs a lot of times . . .. Really don’t like to do it . . .. That might be part of our decision as to whether or not we give pain management.’ [Williams et al. (2012) pg523] | | | |

| | | | |
|---|---|---|---|
| '... Nowadays we don't always have to hurt the child by inserting a PVC ... since we have the intranasal technique. And then it could be so anyway, that I have to insert this ... It hurts and can be messy ... They are chubby at a certain age ... it is often difficult to find the vessels...' [Holmström et al. (2019) pg26] | | | |
| '…We have a lot of barriers to IV access in younger children. The older ones wouldn't be a major problem but certainly younger children, which again certainly affects your mind set in relation to using the likes of morphine…' [Murphy et al. (2014) pg496] | | | |
| 'Not only did it relieve some of his pain, but it relieved some of his anxiety. Calmed him down a little bit more. It was easier to deal with him so it does have its benefits.' [Williams et al. (2012) pg523] | Analgesia improves child anxiety and compliance | Analgesic are helpful but administration is challenging | |
| '... Nowadays we don't always have to hurt the child by inserting a PVC ... since we have the intranasal technique. And then it could be so anyway, that I have to insert this ... It hurts and can be messy ... They are chubby at a certain age ... it is often difficult to find the vessels...' [Holmström et al. (2019) pg26] | IV access is difficult, especially in younger children | | |
| 'If I've got a distressed toddler with a deformed upper limb...pain score of 10/10 (indicating severe pain). This child, like most, won't tolerate oral medication, is even less likely to cooperate with the administration of inhaled nitrous oxide. Securing vascular access is often technically challenging in children, for most APs, even for those experienced in cannulation, so even attempting the procedure will add to the child's anxiety and fear. So there's nothing we currently have that'll work, from a practical perspective. Clearly the intranasal route, if available, would prove ideal in this scenario.' [Murphy et al. (2014) pg497] | | | |
| '…We have a lot of barriers to IV access in younger children. The older ones wouldn't be a major problem but certainly younger children, which again certainly affects your mind set in relation to using the likes of morphine…' [Murphy et al. (2014) pg496] | | | |
| 'If you have a child that is vomiting and that you can't get a line on, you're kind of snookered as well because it eliminates everything you can do really, which is where your intranasal drug would come in fantastic...' [Murphy et al. (2014) pg496] | Intranasal drugs may be beneficial when IV access is difficult | | |
| 'If I've got a distressed toddler with a deformed upper limb...pain score of 10/10 (indicating severe pain). This child, like most, won't tolerate oral medication, is even less likely to cooperate with the administration of inhaled nitrous oxide. Securing vascular access is often technically challenging in children, for most APs, even for those experienced in cannulation, so even attempting the procedure will add to the child's anxiety and fear. So there's nothing we currently have that'll work, from a practical perspective. Clearly the intranasal route, if available, would prove ideal in this scenario.' [Murphy et al. (2014) pg497] | | | |
| '... Nowadays we don't always have to hurt the child by inserting a PVC ... since we have the intranasal technique. And then it could be so anyway, that I have to insert this ... It hurts and can be messy ... They are chubby at a certain age ... it is often difficult to find the vessels...' [Holmström et al. (2019) pg26] | | | |
| 'I just felt if I missed the IV now, I'm after wasting five minutes missing an IV and that's five minutes closer to the hospital, so, having used intranasal midazolam a number of times, it's super, getting it out and drawing it up and giving it…you wouldn't even have your line and Tegaderm out by the time you have the intranasal midazolam given…' [Murphy et al. (2014) pg496] | | | |
| ' . . .carry a Broselow tape and whip it out on every kid because I will admit that I struggle when it comes to judging a kid's weight . . .. If the parent knows and they're pretty reliable based on a well-baby checkup then I defer to the parent.' [Williams et al. (2012) pg523] | Difficulty determining child's weight | | |
| 'I think that it is very effective (nitrous oxide) but I think you are limited by the fact that the patient is self-administering and has to understand kind of your instructions and so, you're kind of knocking out the younger paediatric age group straight away…' [Murphy et al. (2014) pg496] | Inhaled analgesics are difficult to administer to younger children | | |
| '…Your younger patients are effectively ruled out with the Entonox…' [Murphy et al. (2014) pg496] | | | |

| | | | |
|---|---|---|---|
| ‘I am fully aware that a four-month-old baby will most likely not understand my reasoning, but maybe it can hear my voice and understand when I touch it.’ [Gunnvall et al. (2018) pg41] | Younger children are more difficult to assess | Assessment of children is challenging | |
| ‘How are you going to assess pain in children who cannot communicate, who are too small // Yeah, well, these preverbal children, it’s very, very hard to communicate.’ [Gunnvall et al. (2018) pg42] | | | |
| ‘We don’t actually perform assessments on very young children, so like say at the age of 3 and below, where almost you might as well take them out of the pain relief category because it’s nearly impossible to assess it…’ [Murphy et al. (2014) pg495] | | | |
| ‘We’re probably less equipped at the younger age and it’s really just a general, your general impression…’ [Murphy et al. (2014) pg496] | | | |
| ‘Until they’re actually at a stage where they can comprehend what you’re saying or they can get to the stage where, they can understand the Wong–Baker chart, it’s a bit hit-and-miss…’ [Murphy et al. (2014) pg496] | | | |
| ‘I think you hear how the little child screams and so on. You can recognise the type of scream. Whilst it gets more difficult, I think, when you get to teenagers and some older children. There can be a lot of difficult assessments with teenagers’ [Holmström et al. (2019) pg26] | Older children are more difficult to assess | | |
| ‘Are you screaming because you’re in pain? Are you screaming because you’re sad? Are you screaming because you’re afraid? Are you screaming because … well, I don’t know.’ [Gunnvall et al. (2018) pg41] | Assessment of pain is very difficult in children | | |
| ‘When you don’t know why they are screaming, I think it’s hard…’ [Jepsen et al. (2019) pg5] | | | |
| ‘When it comes to children, we don’t take histories, we don’t actually have any hands-on experience and so our experience is very low. I think we are even at the stage whereby I think routinely we don’t strip a child, we don’t get them down to their nappy, we don’t do that…’ [Murphy et al. (2014) pg496] | | | |
| ‘…I don’t think it has taken the importance or it hasn’t got to the same level of relevance as say, adult pain relief has, where that’s a taken and it’s a given that there will be pain relief given as early as possible…’ [Murphy et al. (2014) pg494] | Difference between treating adults and children is challenging | | |
| ‘It’s something I would look up just because it’s not something that I do as often as other protocols. I would definitely need to look them [pediatric protocols] up more so than for adults . . ..’ [Williams et al. (2012) pg523] | | | |
| ‘People aren’t used to it and haven’t gotten into the mind set that pain relief is an integral part of paediatric treatment…’ [Murphy et al. (2014) pg494] | | | |
| ‘You do not have the same routine to take care of children, you do not meet children seven days a week, like adults ... but children are not like little adults anyway, they are something else that requires extra supervision of the doses .. and other things and that is a stress factor.. ‘ [Holmström et al. (2019)] | | | |
| ‘Well, their play, in so far as … or, rather, kids’ curiosity. All kids are curious. And that’s also very important when, like, you see these tired, drooping, pain … if you see the slightest sign of curiosity in their eyes, then you know, well, it’s not like … OK, the kid is sick, but not taking it so super seriously … A lot of times you get that feeling.’ [Gunnvall et al. (2018) pg42] | Physiological signs are helpful in identifying pain | | |
| ‘I knew he was in pain because of his presentation. He was screaming with any movement or palpation to the area. He was tachycardic too. His vital signs coincided with his presentation and his discomfort. I looked for elevated heart rate, elevated blood pressures.’ [Williams et al. (2012) pg523] | | | |

Appendix 6 – Systematic mixed studies review: GRADE assessment

| Identified predictor | Quality assessment | | | | | Summary of findings | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Design | Quality | Consistency | Directness | Other modifying factors* | Number of patients | Effect<br>AORs (95% CI)<br>[patient group (comparator)] | Quality** | Importance |
| Child gender (male) | Observational and other studies | No serious limitations | No important inconsistency | Some uncertainty about directness (people and outcome measure) | Sparse data | 3312 | 1.42 (1.19–1.71)<br>[males (compared to females)] | **Very Low** | Important |
| | | | | | | 15,016 | 1.1 (1.0-1.3)<br>[males (compared to females)] | | |
| | | | | | | 9833 | 1.27 (1.09-1.49)<br>[males (compared to females)] | | |
| | | | | | | 2312 | 1.17 (0.98-1.39)<br>[males (compared to females)] | | |

| Identified predictor | Quality assessment | | | | | Summary of findings | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Design | Quality | Consistency | Directness | Other modifying factors* | Number of patients | Effect<br>AORs (95% CI)<br>[patient group (comparator)] | Quality** | Importance |
| Child age (younger) | Observational and other studies | No serious limitation | No important inconsistency | Some uncertainty about directness (people and outcome measure) | Sparse data | 3312 | 1.33 (1.00–1.75)<br>[5-9 years (compared to 10-15)] | **Very Low** | Important |
| | | | | | | 15,016 | 0.7 (0.6-0.95)<br>[5-9 years (compared to 0-4)] | | |
| | | | | | | 15,016 | 0.5 (0.4-0.6)<br>[10-14 years (compared to 0-4)] | | |
| | | | | | | 9833 | 0.93 (0.41-2.10)<br>[3-6 years (compared to <3 years)] | | |
| | | | | | | 9833 | 0.60 (0.28-1.32)<br>[7-9 years (compared to <3 years)] | | |
| | | | | | | 9833 | 0.49 (0.23-1.06)<br>[>9 years (compared to <3 years)] | | |
| | | | | | | 2312 | 1.53 (1.18-1.97)<br>[0-5 years (compared to 12-17 years)] | | |
| | | | | | | 2312 | 1.49 (1.21-1.82)<br>[6-11 years (compared to 12-17 years)] | | |

| Identified predictor | Quality assessment | | | | | Summary of findings | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Design | Quality | Consistency | Directness | Other modifying factors* | Number of patients | Effect<br>AORs (95% CI)<br>[patient group (comparator)] | Quality** | Importance |
| Type of pain (trauma) | Observational and other studies | No serious limitation | No important inconsistency | Some uncertainty about directness (people and outcome measure) | Sparse data | 3312 | 0.69 (0.50-0.96)<br>[Abdominal Pain/Problems (compared to trauma)] | **Very Low** | Important |
| | | | | | | 15,016 | 1.7 (1.5-1.9)<br>[Musculoskeletal (compared to medical)] | | |
| | | | | | | 15,016 | 1.6 (1.1-2.5)<br>[Burns (compared to medical)] | | |
| | | | | | | 15,016 | 1.4 (1.1-1.9)<br>[Trauma (Other) (compared to medical)] | | |
| | | | | | | 9833 | 0.45 (0.14-1.41)<br>[Poisoning (compared to musculoskeletal)] | | |
| | | | | | | 9833 | 0.22 (0.08-0.60)<br>[Cardiac (compared to musculoskeletal)] | | |
| | | | | | | 2312 | 1.18 (0.97-1.43)<br>[Trauma (compared to medical)] | | |

| Identified predictor | Quality assessment | | | | | Summary of findings | | | |
|---|---|---|---|---|---|---|---|---|---|
| | Design | Quality | Consistency | Directness | Other modifying factors* | Number of patients | Effect<br>AORs (95% CI)<br>[patient group (comparator)] | Quality** | Importance |
| Analgesic administration | Observational and other studies | No serious limitation | No important inconsistency | Some uncertainty about directness (people and outcome measure) | None | 15,016 | 6.6 (5.9-7.3)<br>[Any analgesic (compared to no analgesic)] | **Low** | Important |
| | | | | | | 2312 | 2.26 (1.87-2.73)<br>[Analgesic administered (compared to no analgesic)] | | |
| | | | | | | 268 | Four studies demonstrated an association between analgesic administration and effective pain management | | |

AOR – Adjusted Odds Ratios

*Imprecise or sparse data, a strong or very strong association, high risk of reporting bias, evidence of a dose-response gradient, effect of plausible residual confounding.

**__High__ = Further research is very unlikely to change our confidence in the estimate of effect. **Moderate** = Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate. **Low** = Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate. **Very low** = Any estimate of effect is very uncertain.

Appendix 7 – Systematic mixed studies review: GRADE CERQual evidence profile

| Summary of Review Finding | Studies contributing to the review finding | Methodological Limitations | Coherence | Adequacy | Relevance | CERQual assessment of confidence in the evidence | Explanation of CERQual assessment |
|---|---|---|---|---|---|---|---|
| 1. The ability of pre-hospital clinicians to effectively manage pain in children is influenced by internal factors such as fear, prior clinical experiences and education and training. | (Holmström et al., 2019, Williams et al., 2012, Murphy et al., 2014, Gunnvall et al., 2018) | Minor concerns regarding methodological limitations that may reduce confidence in the review finding. (Two studies with no concern, one study with minor concern [insufficient rigorous data analysis] and one study with moderate concern [unclear justification for recruitment strategy, little reflexivity and insufficient rigorous data analysis]) | No or very minor concerns about coherence | No or very minor concerns about adequacy | Minor concerns regarding relevance that may reduce confidence in the review finding. (All three studies represent three different sub-groups of EMS staff [paramedics, advanced paramedics and pre-hospital emergency nurses]) | Moderate | Minor concerns regarding methodological limitations and relevance |

| Summary of Review Finding | Studies contributing to the review finding | Methodological Limitations | Coherence | Adequacy | Relevance | CERQual assessment of confidence in the evidence | Explanation of CERQual assessment |
|---|---|---|---|---|---|---|---|
| 2. The ability of pre-hospital clinicians to effectively manage pain in children is influenced by external factors such as colleagues and relative on scene. | (Jepsen et al., 2019, Holmström et al., 2019, Williams et al., 2012, Murphy et al., 2014, Gunnvall et al., 2018) | Minor concerns regarding methodological limitations that may reduce confidence in the review finding. (Three studies with no concern, one study with minor concern [insufficient rigorous data analysis] and one study with moderate concern [unclear justification for recruitment strategy, no reflexivity and insufficient rigorous data analysis]) | No or very minor concerns about coherence | Moderate concerns about adequacy of data: all five studies offered limited thin data, particularly around the influence of relatives on scene. | Minor concerns regarding relevance that may reduce confidence in the review finding. (All three studies represent three different sub-groups of EMS staff [paramedics, advanced paramedics and pre-hospital emergency nurses]) | Low | Moderate concerns about adequacy of data and minor concerns about methodological limitations and relevance |

| Summary of Review Finding | Studies contributing to the review finding | Methodological Limitations | Coherence | Adequacy | Relevance | CERQual assessment of confidence in the evidence | Explanation of CERQual assessment |
|---|---|---|---|---|---|---|---|
| 3. The ability of pre-hospital clinicians to effectively manage pain in children is influenced by child factors such as challenging pain assessment and analgesic administration and the perceived importance of the child's experience. | (Jepsen et al., 2019, Holmström et al., 2019, Williams et al., 2012, Murphy et al., 2014, Gunnvall et al., 2018) | Minor concerns regarding methodological limitations that may reduce confidence in the review finding. (Three studies with no concern, one study with minor concern [insufficient rigorous data analysis] and one study with moderate concern [unclear justification for recruitment strategy, no reflexivity and insufficient rigorous data analysis]) | No or very minor concerns about coherence | Minor concern about adequacy of data: Three studies offered limited data towards the 'importance of the child's experience' theme | Minor concerns regarding relevance that may reduce confidence in the review finding. (Four studies represent three different sub-groups of EMS staff [paramedics, advanced paramedics and pre-hospital emergency nurses]) | Moderate | Minor concerns about methodological limitations, adequacy of data and relevance |

Appendix 8 – Systematic mixed studies review: GRADE CERQual summary of qualitative findings

| Objective: To identify, appraise and synthesise qualitative research evidence on the barriers and facilitators to effective pain management in children by ambulance services<br>Perspective: Experiences and attitudes of clinicians, patients and relatives in any country | | | |
|---|---|---|---|
| Summary of review finding | Studies contributing to the review finding | CERQual assessment of confidence in the evidence | Explanation of CERQual assessment |
| 1. The ability of pre-hospital clinicians to effectively manage pain in children is influenced by internal factors such as fear, prior clinical experiences and education and training. | (Holmström et al., 2019, Williams et al., 2012, Murphy et al., 2014, Gunnvall et al., 2018) | Moderate | Minor concerns regarding methodological limitations and relevance |
| 2. The ability of pre-hospital clinicians to effectively manage pain in children is influenced by external factors such as colleagues and relative on scene. | (Holmström et al., 2019, Jepsen et al., 2019, Williams et al., 2012, Murphy et al., 2014, Gunnvall et al., 2018) | Low | Moderate concerns about adequacy of data and minor concerns about methodological limitations and relevance |
| 3. The ability of pre-hospital clinicians to effectively manage pain in children is influenced by child factors such as challenging pain assessment and analgesic administration and the perceived importance of the child's experience. | (Holmström et al., 2019, Jepsen et al., 2019, Williams et al., 2012, Murphy et al., 2014, Gunnvall et al., 2018) | Moderate | Minor concerns about methodological limitations, adequacy of data and relevance |

Appendix 9 – Cross-sectional study: Comparison of included and excluded data

| Characteristic | Included (n = 2312) | Excluded (without initial or second pain score) (n = 3872) | p-value* |
|---|---|---|---|
| Age y, median (IQR) | 13 (9-16) | 8 (2-14) | <0.0001 |
| Age y, mean (SD) | 11.7 (4.8) | 8.3 (5.9) | <0.0001 |
| Age, n (%) | | | |
| 0-5 y | 329 (14.2) | 1541 (39.8) | <0.0001 |
| 6-11 y | 585 (25.3) | 904 (23.3) | 0.0818 |
| 12-17 y | 1398 (60.5) | 1427 (36.8) | <0.0001 |
| Sex, n (%) | | | |
| Female | 1054 (45.6) | 1686 (43.5) | 0.1173 |
| Male | 1249 (54.0) | 2175 (56.2) | 0.0999 |
| Type of pain, n (%) | | | |
| Medical | 776 (33.6) | 1071 (27.7) | <0.0001 |
| Trauma | 1536 (66.4) | 2801 (72.3) | <0.0001 |
| Hospital travel time (mins), median (IQR) | 20 (13-31) | 17 (11-24) | <0.0001 |
| Analgesic, n (%) | | | |
| Administered | 1463 (63.3) | 1552 (40.1) | <0.0001 |
| Not administered | 849 (36.7) | 2320 (59.9) | <0.0001 |
| Non-pharmacological treatment, n (%) | | | |
| Administered | 137 (5.9) | 191 (4.9) | 0.0919 |
| Not administered | 2175 (94.1) | 3681 (95.1) | 0.0919 |
| Index of multiple deprivation, median (IQR) | 4 (2-7) | 4 (2-7) | 0.0002 |
| Index of multiple deprivation, mean (SD) | 4.75 (2.87) | 4.44 (2.92) | <0.0001 |
| Paramedic crew, n (%) | | | |
| Paramedic | 1603 (69.3) | 2815 (72.7) | 0.0046 |
| Non-paramedic | 709 (30.7) | 1057 (27.3) | 0.0046 |
| Senior clinician age (y), median (IQR) | 44 (34-50) | 44 (35-51) | 0.0568 |
| Senior clinician experience (y), median (IQR) | 10 (3-16) | 11 (3-17) | 0.0004 |
| Senior clinician sex, n (%) | | | |
| Female | 782 (33.8) | 1325 (34.2) | 0.7502 |
| Male | 1349 (58.4) | 2297 (59.3) | 0.4505 |

*t-test (means); binomial probability test (proportions); Wilcoxon rank-sum test (medians)

y – year, IQR – interquartile range, SD – standard deviation

Appendix 10 – Cross-sectional study: Updated multivariable logistic regression analysis with 2019 index of multiple deprivation data

| Predictor | Adjusted* Odds Ratio (95% CI) | Significance (p-value) |
|---|---|---|
| Patient age, y | | |
| 0-5 | 1.52 (1.18-1.97) | 0.001 |
| 6-11 | 1.49 (1.21-1.82) | <0.001 |
| 12-17 (reference) | 1 | |
| Patient sex | | |
| Male | 1.17 (0.98-1.40) | 0.082 |
| Female (reference) | 1 | |
| Type of pain | | |
| Trauma | 1.18 (0.97-1.43) | 0.095 |
| Medical (reference) | 1 | |
| Senior Clinician Experience | | |
| <5 years (reference) | 1 | |
| ≥5 years | 0.97 (0.80-1.17) | 0.738 |
| Missing data | 1.44 (0.71-2.95) | 0.315 |
| Analgesic administration | | |
| Administered | 2.26 (1.87-2.73) | <0.001 |
| Not administered (reference) | 1 | |
| Treatment Administered | | |
| Administered | 1.08 (0.75-1.56) | 0.680 |
| Not administered (reference) | 1 | |
| Paramedic crew | | |
| Paramedic | 1.46 (1.19-1.79) | <0.001 |
| Non-paramedic (reference) | 1 | |
| Hospital travel time | | |
| <30 minutes (reference) | 1 | |
| ≥30 minutes | 1.00 (0.80-1.24) | 0.974 |
| Missing data | 0.99 (0.78-1.26) | 0.936 |
| Index of multiple deprivation | | |
| Highest deprivation (reference) | 1 (ref) | |
| Medium deprivation | 1.53 (1.20-1.95) | 0.001 |
| Lowest deprivation | 1.39 (1.06-1.82) | 0.017 |
| Missing data | 1.23 (0.98-1.54) | 0.076 |

Number of observations: 2,303.

y – years, non-pharmacological treatment administration – slings, splints, bandages and dressings, index of multiple deprivation (2019) – highest deprivation (1-3), medium deprivation (4-7), lowest deprivation (8-10), senior clinician – highest rank clinician > lowest PIN number, experience – total NHS (National Health Service, UK) employment.

*Adjusted for patient age, patient sex, type of pain, senior clinician experience, analgesic administration, non-pharmacological treatment administration, paramedic crew, hospital travel time and index of multiple deprivation.

Appendix 11 – Qualitative study: Interview schedule

**Interview Schedule**

**Date:** **Participant ID Number:**

**Pre-Interview:** PIS & Privacy Notice Read? ☐ | Questions? ☐ | Consent Form ☐

1. Can you tell me about a time you have managed acute pain in a child under 18 years?
    a. What made the process more difficult? Or easier?

2. Can you think of any groups of children that might receive more effective or less effective pain management?

| | | | | |
|---|---|---|---|---|
| **Child Age** ☐ | **Paramedic Crew** ☐ | **Analgesia Administration** ☐ | **Deprivation** ☐ | Child Sex ☐ |
| Child Ethnicity ☐ | Trauma / Medical ☐ | Distance to Hospital ☐ | Treatment Administration ☐ | Clinician Experience ☐ |
| Clinician Sex ☐ | Clinician Age ☐ | Clinician Ethnicity ☐ | Clinician Status as Parent ☐ | Other |

Other:

3. What are the barriers and facilitators to managing pain effectively in children?

| | | | |
|---|---|---|---|
| Fear ☐ | Education & Training ☐ | Experience / Exposure ☐ | Colleagues ☐ |
| Relatives ☐ | Assessment ☐ | Management ☐ | Experience of the Child ☐ |

Other:

4. How could pain management for children be improved in the future?

5. Any Questions?

6. Comments: