Abstract of dissertation entitled

“Applying Eutectic Mixture of Local Analgesia Cream Prior to Transrectal Prostate Biopsy to Reduce Procedural Pain”

Submitted by

Yeung Lam

For the degree of Master of Nursing

at The University of Hong Kong

in July 2016

Prostate cancer is the 3rd most common cancer in males in Hong Kong. A transrectal ultrasound guided prostate biopsy (TRUS-Bx) is a diagnostic test for patients with are suspected prostate cancer, but it is considered invasive. Although the annual incidence rate of prostate cancer in Hong Kong has reached 1600 cases in 2012, the need to relieve pain during prostate biopsy is often underrated in public hospitals. In particular, there is no pain relief measure for TRUS-Bx in my local setting, a urology clinic in a public hospital. Around 300 patients have TRUS-Bx at the target setting every year. Pain control is the main concern of patients during the biopsy procedure. Recent studies have found that application of Eutectic Mixture of Local Analgesia (EMLA) cream to the rectum prior to TRUS-Bx can be effective in relieving
the pain involved in TRUS-Bx. However, no systematic review or evidence-based guidelines are available on using EMLA cream for pain relief in Hong Kong, including my urology clinic. Therefore, this dissertation is intended to review the best current evidence on applying EMLA cream prior to TRUS-Bx for pain relief, to develop an evidence-based practice guideline, to determine the feasibility and transferability in the local setting, and to devise an implementation plan.

After searching four electronic databases: PubMed, CINAHL, OvidSP and the Cochrane Library, five randomized controlled studies targeting the use of EMLA cream in patients undergoing TRUS-Bx were identified. The methodological quality of the studies was appraised using the Scottish Intercollegiate Guidelines Network grading system. All five identified studies supported the use of EMLA cream in reducing procedural pain during TRUS-Bx. One study was rated 1++, three were rated 1+ and one was rated 1-. The use of EMLA cream should be feasible and transferable to the local setting. The estimated set-up cost was HKD$3113 while the annual running cost was HKD$34837.5.

An evidence-based guideline was established for the local setting. Subsequently, we will seek approval and communicate with different stakeholders within 5 months. Then a 3-month pilot test will be conducted on 20 patients. Finally, a 6-month evaluation plan of 80 patients will be conducted with evaluation of pain scores after
ultrasound probe insertion and after TRUS-Bx. A decrease in the pain scores 1.5 after ultrasound-guided probe insertion and prostate biopsy would be regarded as successful result.
Applying Eutectic Mixture of Local Analgesia Cream Prior to Transrectal Prostate Biopsy to Reduce Procedural Pain

By

Yeung Lam

B.Nurs. H.K.U.

A thesis submitted in partial fulfillment of the requirement for the Degree of Master of Nursing at the University of Hong Kong

July 2016
Declaration

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

Signed..............................................................................................................

Yeung Lam
Acknowledgements

I would like to express my sincere gratitude to my dissertation supervisors Dr. Daniel Fong and Dr. Polly Chan for their guidance and enlightenment. This dissertation could not have been completed without their generous support.

In addition, I would like to convey my heartfelt appreciation to Dr. Janet Wong for offering help in the journey of writing a dissertation.

Moreover, I would like to deeply thank my family and colleagues for their continuous support and patience with me.
# TABLE OF CONTENTS

Declaration .............................................................................................................................. v

Acknowledgements .............................................................................................................. vi

Table of Contents ................................................................................................................ vii

List of Appendices ................................................................................................................ viii

Abbreviations ...................................................................................................................... ix

Chapter 1 Introduction ........................................................................................................ 1
  1.1 BACKGROUND ............................................................................................................ 1
  1.2 AFFIRMING THE NEEDS ......................................................................................... 3
  1.3 OBJECTIVES AND SIGNIFICANCE .......................................................................... 5

Chapter 2 Critical Appraisal ................................................................................................. 8
  2.1 SEARCH AND APPRAISAL STRATEGIES ............................................................. 8
  2.2 RESULTS .................................................................................................................. 10
  2.3 SUMMARY AND SYNTHESIS ................................................................................ 13

Chapter 3 Implementation Potential and Clinical Guideline ............................................. 18
  3.1 TRANSFERABILITY ................................................................................................. 18
  3.2 FEASIBILITY ........................................................................................................... 21
  3.3 COST-BENEFIT RATIO ......................................................................................... 21
  3.4 EVIDENCE-BASED PRACTICE GUIDELINES .................................................... 26

Chapter 4 Implementation Plan ........................................................................................... 28
  4.1 COMMUNICATION PLAN ....................................................................................... 28
  4.2 PILOT STUDY PLAN ............................................................................................. 32
  4.3 EVALUATION PLAN ............................................................................................... 34
  4.4 BASIS FOR IMPLEMENTATION ............................................................................ 38
Lists of Appendices

Appendix A: Prisma Flow Diagram & Database Search Strategy and Results .............40

Appendix B: Bibliographic citation of selected studies.............................................42

Appendix C: Table of Evidence................................................................................43

Appendix D: Quality Assessment of Studies .............................................................46

Appendix E: Appendix E: SIGN grading system 1999 – 2012....................................49

Appendix F: Set up Costs of Conducting the Innovation...........................................50

Appendix G: Running Costs of Conducting the Innovation per year............................51

Appendix H: EBP Guideline on applying EMLA cream prior to TRUS-Bx..................52

Appendix I: The Estimated Timeframe for Implementation Plan..................................59

Appendix J: Perceived score Pain using VAS (0-10) ..................................................60

Appendix K: Staff Evaluation Form ...........................................................................61

Appendix L: Patient Satisfaction Questionnaire.........................................................62
### Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Full Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>DRE</td>
<td>Digital rectal examination</td>
</tr>
<tr>
<td>DOM</td>
<td>Department operation Manager</td>
</tr>
<tr>
<td>EBP</td>
<td>Evidence-based practice</td>
</tr>
<tr>
<td>EMLA cream</td>
<td>Eutectic Mixture of Local Analgesia (2.5% lidocaine and 2.5% prilocaine)</td>
</tr>
<tr>
<td>IANS</td>
<td>Institute of Advanced Nursing Studies</td>
</tr>
<tr>
<td>PPNB</td>
<td>Periprostatic nerve block</td>
</tr>
<tr>
<td>PSA</td>
<td>Prostate-specific antigen</td>
</tr>
<tr>
<td>RCTs</td>
<td>Randomized controlled trials</td>
</tr>
<tr>
<td>SIGN</td>
<td>Scottish Intercollegiate Guideline Network</td>
</tr>
<tr>
<td>TOE</td>
<td>Table of evidence</td>
</tr>
<tr>
<td>TRUS-Bx</td>
<td>Transrectal ultrasound guided prostate biopsy</td>
</tr>
<tr>
<td>TRUS</td>
<td>Transrectal ultrasound</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
</tr>
<tr>
<td>WM</td>
<td>Ward Manager</td>
</tr>
</tbody>
</table>
CHAPTER 1 INTRODUCTION

1.1 BACKGROUND

Transrectal ultrasound guided prostate biopsy (TRUS-Bx) is a diagnostic test for patients with suspected prostate cancer. During the biopsy procedure, an ultrasound probe is inserted into the rectum and a biopsy needle is inserted into the prostate gland through the rectal wall to obtain prostate tissue for pathologic analysis.

Despite the importance of early detection of prostate cancer, patients consider the pain during TRUS-Bx procedure an unpleasant experience. A periprostatic nerve block (PPNB) injection is currently the standard means of pain control. However, it is not commonly used in Hong Kong. Pain control for TRUS-Bx is neglected by many urologists and nurses in Hong Kong. In recent studies, alternative pain control methods such as application of Eutectic mixture of local analgesia (EMLA) cream to the rectum prior to TRUS-Bx was found effective in relieving the pain from TRUS-Bx. Moreover, it can provide better pain control when combined with a PPNB than that from a PPNB alone.

Prostate cancer is the 3rd most common cancer in males in Hong Kong (Hong Kong Cancer Registry, 2014). The incidence rate of prostate cancer in Hong Kong was around 1600 cases in 2012. Worldwide, more than 1.10 million cases of prostate cancer...
cancer were recorded in 2012, accounting for around 15 per cent of all new cancer cases in men (World Cancer Research Fund International, 2014).

TRUS-Bx was the standard diagnostic method recommended by the European Association of Urology (EAU) in 2015 for diagnosis of prostate cancer. During TRUS-Bx, an ultrasound probe is inserted into the rectum. Sound waves emitted by the probe and transmit graphics that help clinicians guide biopsy needles through the rectal wall to the prostate gland. In Hong Kong, 12 prostate tissue samples are removed for pathologic analysis.

The majority of patients perceive TRUS-Bx as a physically and psychologically traumatic experience (Nazir, 2014). In one study, discomfort was reported in 65% to 90% patients and significant pain was reported in 30% patients (Clements, 2005). Pain is defined as “an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage” (International Association for the Study of Pain, 2014). Pain during a prostate biopsy is believed due to two factors, the ultrasound probe insertion and the biopsy of the prostate (Nazir, 2014). Pain from ultrasound probe insertion is induced by mechanical stretching of an unrelaxed anal sphincter and direct contact with the ultrasound transducer. Biopsy pain is due to needle insertion into the rectal wall and prostate.

According to World Population Ageing 2009 published by the United Nations, at
least half of the Hong Kong population will be 55 years old or above by 2050. Since the risks of prostate cancer increase with age, the number of patients undergoing TRUS-Bx will increase substantially in Hong Kong.

1.2 AFFIRMING THE NEEDS

My local setting is a urology clinic in a public hospital. We perform around 300 TRUS-Bx every year. In my clinic, there is no pain control method for TRUS-Bx. Nurses have a relatively weak role in pain control for TRUS-Bx. Although TRUS-Bx is becoming increasingly common, the use of analgesics is uncommon in Hong Kong.

Some urologists do not consider the pain from a TRUS-Bx an important issue because the procedure is short, and they consider the rectum an insensate structure (Nazir, 2014). However, according to a qualitative study by Medd et al. in 2005, “many men experience pain, discomfort and anxiety during a prostate needle biopsy and most would be willing to participate in trials of interventions to make it less unpleasant”. In fact, patients in my local setting often ask whether there are pain relief measures for TRUS-Bx and they are quite worried about the pain induced by the biopsy procedure. Although no study in Hong Kong has investigated pain during TRUS-Bx, one foreign study found that 24% patients experienced moderate to extreme pain when between 4 and 8 biopsies were performed (Crundwel, Cooke &
Wallace, 1999). More biopsies are taken nowadays to obtain more precise histopathologic results. In my local setting, at least 12 biopsies are taken, so it can be predicted that patients will experience more pain than previous years. It is not uncommon for patients to cancel TRUS-Bx appointments. One of the main reasons is fear of pain.

The lack of pain control measures in current practice for TRUS-Bx in my setting indicates a need to innovate measures for pain control. There are various efficient pain control methods, such as general anesthesia, intravenous propofol and PPNB. However, intravenous propofol and general anesthesia are time-consuming and impractical because of the need for an operating theater-like set-up and therefore, have not been applied in public hospitals in Hong Kong. PPNB was recommended for prostate biopsies by the EAU in 2015. However, it has little effect in reducing the pain associated with ultrasound probe insertion and manipulation, which is regarded as a major source of discomfort during the procedure by some patients (McCabe et al., 2007). Moreover, the pain caused by needle puncture during anesthetic infiltration is comparable to or even worse than that of needle insertion for the prostate biopsy (Ingber, et al., 2010). In view of the invasiveness and suboptimal pain control of PPNB, studies have been done to find alternatives. Some studies suggested that application of EMLA cream to the perianal and intrarectal areas alone has an effect in pain
control in TRUS+Bx (Kandirali, et al., 2009; Raber, et al., 2005; Galosi, et al., 2005).

Some studies even suggested combining PPNB with application of EMLA cream to the rectum to obtain a comprehensive pain control in TRUS-Bx (Dong, et al., 2010; Giannarini, et al., 2008). EMLA cream is a eutectic mixture of local analgesia (EMLA). It is a combination of 2.5% lidocaine and 2.5% prilocaine and is a topical analgesic agent that does not include protective material. It has a 10% absorption rate and a low incidence of systemic side effects. It has shown reliable safety and non-irritant properties (Basar, et al., 2004). Topical application of EMLA cream is a desirable alternative and a non-invasive technique because it can be administered easily before the introduction of an ultrasound probe and it does not require a needle puncture (Kandirali, et al., 2009).

EMLA cream application prior to TRUS-Bx is a safe and easy method (Cormio, et al., 2011). Nurses can provide pain relief method for patients with TRUS-Bx via EMLA cream application. Despite the effectiveness of EMLA cream application, an evidence-based guideline is needed to support the innovation in my local setting. A translational study is needed to develop this innovation of application of EMLA cream.

1.3 OBJECTIVES AND SIGNIFICANCE

The objectives of this study are listed below:
1) To perform a systematic search of relevant literature related to the use of EMLA cream in pain control for patients with TRUS+Bx.

2) To perform quality assessments of the studies.

3) To determine the feasibility and transferability of EMLA cream application to the target patients.

4) To develop an evidence-based guideline on the use of EMLA cream as a pain control measure for TRUS-Bx.

5) To develop a pilot study and evaluation plan for implementation of EMLA cream application.

TRUS-Bx is perceived as a physically and psychologically traumatic experience by the majority of patients (Nazir, 2014). In 1999, Crundwell et al. noted that some patients refused to undergo the procedure due to significant pain. In an earlier study, 90% of patients reported discomfort and 30% reported significant pain when undergoing TRUS-Bx without any analgesics (Collins et al., 1993). Irani et al. in 1997 stated that approximately 19% of patients were not willing to undergo a repeat procedure without any pain management. This may lead to delayed diagnosis or undetected prostate cancer. Moreover, pain during a prostate biopsy has an important bearing on a patient’s well-being and compliance (Nazir, 2014).

Reducing pain by using EMLA cream also helps reduce stress experienced by the
nursing staff. During TRUS-Bx, patients may involuntarily withdraw from the pain. Nurses need to advise and help patients remain motionless throughout the procedure and provide psychological support. Although a hospital has used EMLA cream in combination with PPNB, there is no guideline to indicate the time and dosage for EMLA application. Experience with EMLA cream application in the hospital cannot directly apply to the local setting. Conducting a systematic review and setting up an evidence-based guideline will help clear up confusion and give guidance on daily practice.

For the health care system, reducing pain during TRUS-Bx can prevent suspension of procedures when patients experience a high degree of discomfort and increase their willingness to return for future biopsies when necessary (Chopra et al., 2008). Risks of a false negative pathology result or a delayed diagnosis of prostate cancer can be avoided. Early detection is the key in treatment of prostate cancer. Most prostate cancer patients can enjoy a 15-year (or longer) survival if the disease is detected early. Application of EMLA cream helps reduce their unwillingness to have a biopsy due to pain, and thereby reducing their risk of disease progression if it is detected early. Treating advanced prostate cancer is much more expensive than treating it in the early stage (Cancer Research UK, 2014). Money can be saved if it is detected and treated early.
CHAPTER 2 CRITICAL APPRAISAL

2.1 SEARCH AND APPRAISAL STRATEGIES

A search for relevant studies was done through electronic databases including PubMed (from 1990 to 2016), CINAHL (from 2001 to 2016), OvidSP (from 1990 to 2016) and Cochrane Library. Reference lists of relevant articles were also searched for suitable trials. The keywords ‘eutectic mixture of local anesthetics’, ‘EMLA’, ‘lidocaine and prilocaine’, ‘prostate biopsy’ and ‘pain’ were typed in into each electronic database. Interrelated keywords were searched using OR to include all possible findings, and “AND” is to generate more specific findings. Results obtained were screened by title and abstract. Exclusion criteria were also applied to narrow down the number of articles, for example, full text available. A manual search of references from the selected studies was also performed to explore more potential studies.

Articles were included if they (1) were published from the year 2000 onwards to ensure the acquired information was up-to-date and accurate, (2) used randomized controlled trials (RCT) and clinical trials as research methods to validate empirical evidence, (3) were written in English or Chinese, and (4) used EMLA cream application alone compared with a placebo or no EMLA cream.

Since the target of this review was to evaluate the effectiveness of EMLA cream in pain control during TRUS-Bx, but not to compare the effect of EMLA cream with
other pain control methods, only studies related to EMLA cream application versus placebo or no EMLA cream were included.

Articles meeting the following criteria were excluded from the critical appraisal if they (1) studied EMLA cream application compared with other pain control methods or (2) were written in languages other than English and Chinese.

2.2 RESULTS

2.2.1 Data Extraction

There were 17 papers retrieved from the four electronic bibliographic databases related to EMLA cream application for TRUS-Bx pain control. By narrowing down the search results according to the inclusion and exclusion criteria, five eligible papers were identified (Basar, et al., 2005; Giannarini, et al., 2009; Kandirali et al., 2009; Raber., 2005; Galosi, et al., 2005). No additional eligible studies were found among the references of the identified studies. The details of the search history are presented with a PRISMA flow diagram in a table of the search strategy in Appendix A.

Overall, a total of 5 papers, with studies conducted from 2005 to 2016, were selected and reviewed. They are listed in Appendix B.

The results from the 5 identified studies are summarized in a table of evidence (TOE) in Appendix C. Data such as the study type, patient characteristics, description
of the intervention and comparison groups, outcome measures and results are included in the TOE for easy comparison of studies.

2.2.2 Appraisal Strategies

Since all identified studies in this review were RCTs, the quality of the studies was assessed using the checklist of the Scottish Intercollegiate Guideline Network (SIGN). The SIGN checklist was used to grade the level of evidence and rate the studies’ internal validity and overall quality. The results are summarized in Appendix D. The following section provides a comprehensive analysis.

2.2.3 Summary of the appraisal results

Characteristics of studies:

All five studies were written in English and were conducted using an RCT design. All were single-center studies. The years of publication ranged from 2005 to 2009. None of the studies mentioned conflicts of interest in their studies (Basar, et al., 2005; Giannarini et al, 2009; Kandiralia, et al., 2009; Raber, et al., 2005; Galosi, et al., 2005).

Three studies were conducted in Italy (Giannarini et al, 2009; Raber, et al., 2005; Galosi, et al., 2005), and two in Turkey (Basar, et al., 2005; Kandiralia, et al., 2009).

In four studies, EMLA was applied as the intervention and compared with either a placebo or control (Basar, et al., 2005; Kandiralia, et al., 2009; Raber, et al., 2005; Galosi, et al., 2005). In one study, application of EMLA cream was compared with a
control and EMLA cream combined with PPNB was compared with a placebo combined with PPNB (Giannarini et al, 2009).

Sample sizes ranged from 74-280 and sample sizes in each group ranged from 20-70. In two studies, written informed consent was obtained from the subjects (Kandiralia, et al. 2009, Giannarini et al, 2009); the other 3 studies did not mention consent (Basar, et al., 2005; Raber, et al., 2005; Galosi, et al., 2005).

Methodology and Outcome Measures:

All five papers were RCTs, but the randomization was mentioned in only two. Both Giannarini et al. (2009) and Raber, et al. (2005) used computer programs for randomization.

Allocation concealment was not mentioned in any of the studies. With this method, researchers are unaware of the treatment group before subjects enter the study to prevent overestimation of the intervention effect (Melnyk & Fineout-Overholt, 2011).

Double blinding of patients and investigators was not mentioned in four RCTs (Basar, et al., 2005; Giannarini et al, 2009; Kandiralia, et al., 2009; Raber, et al., 2005). Only Galosi et al. (2005) mentioned single blinding of patients.

There were no differences in patient baseline data (prostatic specific antigen [PSA] level, age, prostate volume) among comparison groups in any of the five papers.
Dropout rates were reported in only one paper, 10% in the placebo group, 7.6% in the control group (Galosi, et al., 2005).

Outcome Measurements

The pain score was the targeted outcome in the five studies. A 10-point visual analogue scale (VAS) was used in all five studies as the outcome measurement tool. VAS for pain score is a unidimensional measure of pain intensity. It is consisted of one horizontal or vertical line with varying time points and descriptor anchors. It has good reliability and validity for pain (Hawker, et al., 2011). The pain score was assessed after TRUS-Bx in all five studies and after ultrasound probe insertion in three studies (Giannarini et al., 2009; Kandiralia et al., 2009; Raber et al., 2005).

The statistical analysis was conducted among using SPSS software. In four of the five studies (Giannarini et al, 2009; Raber, et al., 2005; Basar, et al., 2005; Kandiralia, et al.) significant difference between groups were reported. Galosi et al. (2005) did not mention significance. Details are listed in Appendix C.

Three studies included sample size calculations to determine statistical power (Giannarini et al, 2009; Galosi, et al.; Kandiralia, et al.)

Levels of Evidence:

A level of evidence was assigned to each of the studies according to the criteria listed in Appendix D. One study was rated 1++ (Raber, et al., 2005), three studies
were rated 1+ (Baser, et al., 2005; Giannarini et al., 2009; Kandiralia, et al., 2009), and one study was rated 1- (Galosi, et al, 2005).

2.3 SUMMARY AND SYNTHESIS

2.3.1 Summary of Study Results

In all studies, the effectiveness of EMLA cream application prior to TRUS-Bx in reducing procedure pain was evaluated. In four studies, the effectiveness of this intervention was confirmed with statistically significant reductions in VAS pain scores (Basar, et al., 2005; Kandiralia, et al., 2009; Raber, et al., 2005; Giannarini et al, 2009). The other study showed a numeric reduction in the pain score, but did not provide data of the p-value (Galosi, et al., 2005).

Patient Characteristics

Patient characteristics were similar in the five studies. In three studies the mean ages ranged from 63.1-64.75 years (Basar, et al., 2005; Giannarini et al, 2009; Kandiralia, et al., 2009), while in one study, the median age was 66.8 years (Raber, et al., 2005). Galosi et al (2005) did not mention the age of the patient. Recruitment criteria were similar in all studies as follows: male patients with elevated PSA levels with or without abnormal results on digital rectal examinations (DRE), or male patients with normal PSA values but with prostate nodules on DRE. With similar patient characteristics, the results of the five studies are comparable.
Intervention and Comparison

EMLA cream application prior to TRUS-Bx was the common intervention in the five studies. The effectiveness of EMLA cream application compared with no analgesics or placebo was examined in all studies (Giannarini et al, 2009; Basar, et al., 2005; Kandiralia, et al., 2009; Raber, et al., 2005; Galosi, et al., 2005). Giannarini et al (2009) also compared the effectiveness of EMLA cream combined with PPNB versus PPNB alone. A placebo gel was used in four studies, a lubricant gel in three and an ultrasound gel in one (Basar, et al., 2005; Kandiralia, et al., 2009; Raber, et al., 2005; Galosi, et al., 2005).

In four studies, 5ml EMLA cream was applied to both the perianal and intrarectal areas 30 minutes prior to TRUS-Bx. In the remaining study, 1ml EMLA cream was applied to the prostate 15 minutes prior to the procedure (Basar, et al., 2005).

Raber et al. (2005) also compared the effectiveness of EMLA cream in pain control between younger man (under 67 years) and older man during TRUS-Bx.

Outcome Measures:

The pain score on a VAS during the TRUS-Bx procedure was the common outcome measure in the five studies. In two studies, the pain score was examined only after the TRUS-Bx procedure (Basar, et al., 2005; Galosi, et al., 2005). In the other three
studies, pain score were assessed after both the probe insertion and TRUS-Bx procedure (Giannarini et al, 2009; Kandiralia, et al., 2009; Raber, et al., 2005).

EMLA cream significantly reduced the pain induced by probe insertion in the three studies where this was assessed. In all studies, pain scores were examined after TRUS-Bx and it was concluded biopsy pain could be reduced with the application of EMLA cream. Raber et al (2005) even stated that EMLA cream was more effective in younger men (under 67 years), could reduce their discomfort and pain during the entire TRUS biopsy procedure, and also resulted in no complications.

Overall, the results obtained from the five studies consistently showed that EMLA cream application was effective in reducing pain in patients having TRUS-Bx.

2.3.2 Synthesis

All five studies supported the use of EMLA cream in reducing the pain level of patients having TRUS-Bx. By extracting and summarizing data from these studies, an evidence-based practice (EBP) guideline could be synthesized.

Target group: From the five studies, all patients with TRUS-Bx had reduction of procedural pain with the use of EMLA cream.

Dosage: Dosages of EMLA cream of 1ml or 5ml were both effective in reducing pain during TRUS-Bx. In four of the five studies, 5ml was used, with only one study using 1ml. Since the VAS pain score for 5 ml was comparatively lower than for 1ml
(1.27-2.67 vs 2.91), and since more studies used 5 ml in their intervention, 5 ml seemed to be the better option when implementing the innovation.

**Site, time and method of application:** EMLA cream was applied to the prostate 15 minutes prior to the procedure in only one study (Basar, et al., 2005). In the other studies, EMLA cream was applied to the perianal and intrarectal areas. Application to the perianal area aimed to reduce probe insertion pain, while application to the intrarectal area helped to reduce biopsy pain, so application to both areas should be more effective in pain control. EMLA cream was applied 30 minutes prior to TRUS-Bx in four studies. Experience with genital mucosa biopsy indicates EMLA cream should be applied at least 15-30 minutes prior to the biopsy (Wright, 2001). This allows enough time to reach a maximum analgesic effect.

In two studies, syringes were used to instill EMLA cream into the perianal and intrarectal areas (Giannarini, et al., 2009; Raber, et al., 2005). Massage of EMLA cream into these areas using fingers was suggested by Giannarini et al. (2009).

**Outcome measuring tool:** The VAS pain score was commonly used in the five studies. It is a valid and easy to use measuring tool.

**2.3.3 Implications for Practice**

Overall, application of EMLA cream 30 minutes prior to TRUS-Bx could reduce pain among patients. Pain scores were significantly lower after ultrasound probe insertion.
and prostate biopsy in patients with EMLA cream application in all five studies. It is effective in pain control when used alone or can be added to PPNB. It is an innovation for pain control in TRUS-Bx in the local setting. An EBP guideline for effective pain management of TRUS-Bx should be formulated to facilitate translation of knowledge into practice.
CHAPTER 3 IMPLEMENTATION POTENTIAL AND CLINICAL GUIDELINE

The previous chapter described the need for pain control during TRUS-Bx and critically appraised the effectiveness of applying EMLA cream in reducing pain during this procedure. In this chapter, the implementation potential of the innovation will be assessed. The transferability, feasibility and cost-benefit ratio will be considered before adopting the innovation. An EBP guideline will be established after this assessment.

3.1 TRANSFERABILITY

3.1.1 Target Setting

The target setting is a local urology clinic in a public hospital in Hong Kong. Patients who need to undergo TRUS-Bx will be admitted as day cases. The procedure is done by urologists in the clinic. The target setting is similar to those in the identified studies. Therefore, the innovation can fit into the target setting.

Nurses in the target setting are responsible for providing information on TRUS-Bx to patients before the procedure. This includes procedure time, number of biopsies to be taken, any use of analgesics, discharge time and possible complications.

3.1.2 Target Audience

The target audience comprises patients who need to have TRUS-Bx. In the target
setting, these are male patients who have PSA levels greater than or equal to 4ng/ml with or without abnormal DRE results, a suspected malignancy on the TRUS with or without abnormal DRE results, or an abnormal DRE finding (Basar, et al., 2005; Raber, et al., 2005; Galosi, et al., 2005; Kandiralia, et al., 2009 & Giannarini et al., 2009). The ages of patients in the identified studies ranged from 46-87 years and in the target setting around 48-86 years.

The target audiences in the local setting share the same characteristics as patients in the identified studies.

3.1.3 Philosophy of Care

The Hospital Authority is a “people-first” organization committed to providing patient-centered care. It means to not only provide the best possible services to patients, but also to understand patients’ needs with a caring heart. The philosophy of care of the innovation is to reduce procedural pain for patients during TRUS-Bx, which meets the Hospital Authority’s values. Moreover, one of the missions in my local setting is to provide high quality of service. Satisfying the need for pain control helps to improve the quality of service provided to patients.

3.1.4 Patients Who Will Benefit

According to records in my local setting, around 300 patients had TRUS-Bx in 2014-2015. Since prostate cancer is closely associated with aging and the aging
population is increasing in Hong Kong, more and more patients will need TRUS-Bx and will benefit from the innovation.

3.1.5 Duration for Implementation and Evaluation

After approval of the innovation, a committee consisting of the nursing, pharmacy and medical disciplines will be formed. The innovation can be divided into 3 stages, preparation, implementation and evaluation. The preparation stage will take around 2 months. Guidelines for the innovation will be set up by the committee in one month. Another month will be needed to train related staff on application of EMLA cream, data collection and the logistics of ordering EMLA cream.

A pilot program will be run during the implementation stage. The pilot program will last for one month and 20 patients will be recruited into the program.

The evaluation stage will commence after the pilot program has been completed. Guidelines will be refined after evaluation. Evaluation and guideline revision will take one month.

Implementation of the whole innovation will take four months.

Since the target setting and population are similar to those in the identified studies and the philosophy of care behind the innovation is consistent with the target setting, the innovation is transferrable to my local setting.
3.2 FEASIBILITY

3.2.1 Administrative Support

As mentioned above, my local setting is a clinic under the Hospital Authority. In recent years, the Hospital Authority has highly supported the development of EBP. One of the objectives of the Institute of Advanced Nursing Studies (IANS), which is a training organization run by the Hospital Authority, is to “promote evidence-based practice to excel the quality of care”. As long as the innovation is beneficial to patients, the administrative level will support it.

My target hospital has put many resources into EBP training, including an annual training course by the IANS or an overseas training center. Staff are welcomed to apply for the training and sponsorship is provided. In addition, there is a team which helps in the development of EBP clinical pathways. Staff can get help from them if they want to set up an EBP clinical pathway.

With a good organizational climate, the supervisor of the target setting and administrative level will have a positive and supportive attitude towards the implementation of the innovation.

3.2.2 Nurses’ Autonomy

Applying EMLA cream is a noninvasive therapy for pain reduction in patients having TRUS-Bx. With the support of the division chief in the local setting, nurses
have the autonomy to initiate the noninvasive therapy for patients. When there are undesirable effects from an innovation, such as allergies, nurses have the freedom to terminate it.

3.2.3 Interference with Current Function

As no pain reduction method has been used before the implementation of the innovation, extra time will be required for nurses to carry out the therapy. Nurses will need to explain the procedure to patients and get their consent to apply EMLA cream. Moreover, application of EMLA cream to patients also requires time. The manpower in the target setting is tight, and there are only four nurses. It is expected the innovation will increase staff workload. At the present time, nurses have one hour to prepare patients for TRUS-Bx. The preparation time will be longer in conducting the innovation. This may cause mild interference with current function.

Special work arrangements will be required for staff to attend a training course on EMLA cream application and services in the target setting may need to be reschedule.

3.2.4 Consensus

The implementation of the innovation is a change in current practice. To reduce obstacles in implementing the innovation, consensus from different stakeholders is
Resistance may arise from nursing staff due to the increased workload and hesitancy to learn new skills. The staff are unfamiliar with the new skill. They may fear applying it and have negative feelings about it.

Some senior urologists are used to the old practice of not providing pain control measures for patients with TRUS-Bx. They may not feel there is a need to conduct the innovation.

In order to conduct the innovation smoothly, consensus must be achieved from the nursing and medical staff.

3.2.5 Availability of Skills, Equipment and Evaluation Tools

Skills: EMLA cream application is not difficult, but nursing staff have not done it before. There are no education pamphlets or videos that can be used as references and a training course is required.

Equipment: The required equipment for the innovation includes EMLA cream, a 5 ml syringe for instillation of the cream and education pamphlets. EMLA cream can be obtained from pharmacy. The 5ml syringe and education pamphlets can be prepared in the target setting. The preparation of equipment is not difficult and will not affect implementation of the innovation.

Evaluation Tools: Pain scores will be assessed after probe insertion and after
prostate biopsy. VAS pain score assessment will be used to measure the pain level.

The assessment tool will be prepared in the local setting.

### 3.3 COST-BENEFIT RATIO

#### 3.3.1 Potential Benefits of the Proposed Innovation

With the innovation, patients could become less agitated during the TRUS-Bx procedure. They can remain calm and maintain the desired position. This ensures safety in a prostate biopsy. The biopsy gun will not slip to the nontargeted areas, such as the urethra or outside the prostate, which would increase the risks of complication such as bleeding. A more accurate pathology result can be obtained which helps in making an accurate diagnosis.

For patients, the TRUS-Bx procedure will be less painful and they may be more willing to have a repeat biopsy if needed.

Moreover, the innovation could also relieve the workload and stress of nursing staff in calming patients. Nursing staff could also have a higher level of job satisfaction by exercising autonomy in providing better pain control measures for patients.

#### 3.3.2 Potential Risks of the Proposed Innovation

There were no reported complications from application of EMLA cream in any of the five selected studies. However, nurses need to be alert to possible side effects
such as allergies. EMLA cream should not be used in patients with known hypersensitivity to local anesthetics of the amide type or to any of the excipients.

### 3.3.3 Potential Risks of Maintaining Current Practice

Currently, there are no pain control measures for patients during TRUS-Bx in my local setting. Some patients reject repeat biopsy because of pain in a previous procedure. This could delay a diagnosis of prostate cancer. In case of advanced cancer, treatment costs will increase and the life expectancy and quality of life of the patients will be affected.

### 3.3.4 Costs

Set up costs and running costs per year can be classified into material costs and nonmaterial costs.

The main material costs for the innovation will be EMLA cream, 5ml syringes for cream instillation, and printing and copying materials. Printed materials include education pamphlets, guidelines for nurses and evaluation forms. Prices are estimated to be $0.5 Hong Kong dollar (HKD) each for education pamphlets, (HKD)$1 for guidelines for nurses and (HKD)$1.5 for evaluation forms. The 5 ml syringes are (HKD)$0.5 each, while the EMLA cream costs (HKD)$70 for each procedure.

The nonmaterial costs include training time for nursing staff and time consumed for patient education, EMLA cream application and evaluation.
Nursing staff is expected to attend a 30 minute training course. For each patient, 10 minutes of nursing time is estimated for patient education and application of EMLA cream. An additional 5 minutes is required for evaluation.

According to the Hospital Authority’s employment webpage, the average hourly salary of a nurse was (HKD)$174.5 in 2015.

**Set Up Costs:** Conducting a pilot study for 20 patients will cost $3113 (Details are listed in Appendix F). The costs include material and nonmaterial costs required for training and carrying out the pilot study.

**Running Costs per year:** Running costs per year will be $34837.5 (Details are listed in Appendix G). This includes material and nonmaterial costs required for applying EMLA cream to 300 patients per year.

### 3.3.5 Costs of Not Implementing the Innovation

Costs of not implementing the innovation cannot be determined. There are no statistics investigating how many patients refuse a prostate biopsy due to fear of pain or a previous painful experience. However, life is precious and cannot be counted in money terms. It is not acceptable that patients refuse prostate biopsy because of a lack of pain control measures.

### 3.4 EVIDENCE-BASED PRACTICE GUIDELINES

According to the evidence retrieved from the critical appraisal in chapter 2, an
evidence-based guideline on applying EMLA cream prior to TRUS-Bx will be
developed in this chapter.

The title, background, aim, objectives and targeted population will be clearly
stated.

Seven recommendations were made from the five selected studies.

Recommendations are graded based on the SIGN grading system (Appendix E). The
quality of the studies was appraised in chapter 2 (Appendix D).

The detailed EBP guideline is attached in appendix H and a flow chart for EMLA
cream application is included.
CHAPTER 4 IMPLEMENTATION PLAN

4.1 COMMUNICATION PLAN

A good communication plan is essential to the successful implementation of the proposed innovation. Stakeholders need to be identified in the communication plan in order to obtain their support. A structured communication channel will be established to enhance the success of the innovation.

Critical and relevant information such as duration of the project implementation and resource persons will be provided to those involved in the implementation plan. The communication plan will start from the bottom level and then proceed to the top level (administrative level) of the department.

The communication process is estimated to take 3 months. One month is required to communicate between stakeholders and another month will be needed to get approval from the managerial level. Forming an innovation committee will require another month (Details can be seen in Appendix I).

4.1.1 Stakeholders

Stakeholders are individuals, groups, or organizations who may affect, be affected by, or perceive themselves to be affected by a project (Project Management Institute, 2015). They must be identified and addressed in order to get their support for implementation of the innovation in the local setting. Without stakeholders’ support,
the innovation may be ignored, criticized, resisted, or even sabotaged (Centers for Disease Control and Prevention of USA, 2012).

The stakeholders in the innovation include the administrative level of the department of surgery, the management level of the urology Team (including the nurse consultant in urology and the advanced practice nurse (APN) in-charge of the urology clinic), frontline nurses, and patients who are undergoing prostate biopsy.

The pharmacy is also an important stakeholder in the innovation.

The stakeholders at the administrative level of the department are the department operations manager (DOM), ward manager (WM) of the urology team and the urology division head. These are key persons who will approve and affect change in the local setting’s policies and standards. In addition, they have the power of funding allocation. They help in manpower allocation and provide material for implementing the innovation. Administrative support in funding material resources such as EMLA cream and printout of pamphlets is required. Thus, the proposed project must get their approval before it is carried out.

The management level of the urology clinic includes the nurse consultant and APN in the local setting. They are a group of experienced nurses who help with training and updating the knowledge and nursing skills of the staff. They will also help in setting up new guidelines for the innovation.
Frontline staff are those who implement the innovation. Therefore, it is essential to get their consent and support.

Patients are the actual recipients of the innovation. Consent must be obtained before they receive the innovation.

The pharmacy is responsible for supplying EMLA cream. The availability of EMLA cream greatly affects the success of the innovation.

### 4.1.2 Communication Progress

The communication channel adopted in this project will be in a “bottom-up” approach, which implies proactive team input in the process of executing the project (Flievi, 2008). Before getting support from the management and administrative levels, it is important to get frontline staff support. As manpower in the local setting is very tight, agreement and support from frontline colleagues is needed to ensure smooth implementation of the innovation. The need for pain control during prostate biopsy and evidence on the use of EMLA cream in reducing procedural pain will be discussed during informal sharing or chats at lunch time / tea time.

After getting support from frontline staff, the project will be further introduced to the management level (nurse consultant and APN). Details of the project will be presented, including project justification, the proposed EBP guideline on using EMLA cream in prostate biopsy, the implementation plan of the project, the detailed
budget plan and the detailed proposed timeline.

After approval from the management level, this project will be presented to the clinic WM. With support from the WM, the project will be introduced to the DOM during the weekly DOM meeting and then, with the help of the nurse consultant, to the urology division head during weekly urology team meeting.

After getting support from the frontline staff, management level and administrative level, an innovation committee will be formed to lead the change. It will be composed of one registered nurse (RN) who proposed the innovation, one urologist, the APN of the urology clinic, and a representative pharmacist. The innovation will be guided by the innovation committee.

A half hour training workshop including a thorough explanation of the EBP guideline and demonstration of EMLA cream application will be given by the RN and APN from the innovation committee to ensure the competence of nurses in delivering the innovation. The training workshop will be carried out with the support of the urologist on the innovation committee. Illustrated guidelines will be available at the nursing station to serve as a quick reference for nurses. Education pamphlets stating the purpose of EMLA cream application will be distributed to patients during the nursing interview before the procedure to inform them of the innovation.

To ensure enough stock of EMLA cream, communication between the pharmacy
and clinic will be well-maintained by the APN and representative pharmacist on the committee.

4.1.3 Sustaining Change

The RN and APN on the innovation committee will be the resource persons for the innovation and frontline staff will be able to ask questions and report difficulties encountered during implementation of the project. Feedback from the nurses will be collected and reviewed during the weekly clinic meeting. The EBP guideline will be updated by the innovation committee based on recommendations from the stakeholders.

4.2 PILOT STUDY PLAN

A pilot study is a fundamental phase of the research process. It aims to examine the feasibility of an approach which is intended to be used in a larger scale study.

4.2.1 Objectives

The pilot study aims to test the feasibility of applying EMLA cream in reducing patients’ procedural pain during TRUS-Bx.

4.2.2 Patients

The eligibility criteria for patients in the pilot study corresponds to that in the EBP guideline mentioned in Chapter 2.1. All patients without cognitive problems undergoing TRUS-Bx will be recruited for the pilot study. The expected sample size of
the pilot study is 20. It will be conducted for 4 weeks in the urology clinic.

4.2.3 Preparation

Before the launch of pilot study, one month will be required for the innovation committee to prepare the required materials and for the training workshop for nurse. EMLA cream will be stocked by the pharmacy before commencing the pilot study. Education pamphlets and illustrated guidelines will also be prepared, so their usability can be evaluated.

4.2.4 Measurements

For outcome measurements, one set of VAS (0-10) pain assessment tools will be used. Pain scores after ultrasound-guided (USG) probe insertion and after the biopsy procedure will be assessed. Moreover, questionnaires will be available to collect nurses’ comments their overall satisfaction with the implementation process and their self-evaluated competence in delivering the innovation.

4.2.5 Procedures

The pilot study will be conducted for four weeks. EMLA cream will be applied to 20 patients before TRUS-Bx. Pain assessment will be done by nurses during the procedure. Feedback from frontline staff will be collected after the pilot study.

4.2.6 Data analysis and evaluation:

Data analysis and evaluation will be done at the end of the study and will take one
month to complete.

The evidenced-based guideline will be modified by the innovation committee after data analysis. The effectiveness of the project, the level of satisfaction among nurses, the difficulties encountered in the pilot study and the modified guideline will be presented to the management and administrative levels.

A report on the project and the modified EBP guideline will be presented to all frontline staff in a special meeting.

A full-scale program will be implemented after getting the results from the pilot study. The estimated timeframe of the whole implementation plan is shown in Appendix I.

4.3 EVALUATION PLAN

Full-scale implementation of the innovation will start after the pilot study.

Evaluation of the full-scale program will then be conducted. This will take round two months.

4.3.1 Objective

The objective of the evaluation plan is to assess the effectiveness of the innovation.

4.3.2 Patients

The study will be carried out in a urology clinic. The eligible clients in this study are
those patients referred from urologists for TRUS-Bx. They are male patients who are mentally capable and able to give informed consent, and are admitted for TRUS-Bx. According to statistics at the local setting, around 300 patients undergo TRUS-Bx every year. Patients will be admitted to the local setting with an admission letter. Frontline nurses will assess the eligibility of patients. They will also obtain verbal consent from the patients during the interview section before delivering the innovation.

In the identified studies, VAS (0-10) pain score reductions of 1.8 - 3.9 points after USG probe insertion (Giannarini, et al., 2009; Kandiralia, et al., 2009;) and 1.3 -3.06 points after prostate biopsy (Basar, et al., 2005; Giannarini, et al., 2009; Kandiralia, et al., 2009; Galosi, et al., 2005) were reported by patients who had EMLA cream application compared with those in the control groups.

Using a conservative calculation, an effect size of 1.5 could be used to prove the effectiveness of the innovation.

The online statistical software “Java applets for power and sample size“ by Lenth, was used to calculate the sample size and the one-sample t-test was selected. Since there are two primary outcomes, the level of significance used in the sample size calculation was 0.02. The overall level of significance was 0.05. Assuming an effect size of 1.5 with a standard deviation of 4, given a power of 0.8 and a level of
significance of 0.02, the estimated sample size will be 74. Although most of the identified studies did not report a dropout rate, for conservative considerations, a 5% attrition rate will be taken into account and 80 patients will be recruited. It is expected to take 3 months to recruit enough participants to evaluate the effectiveness of the innovation.

4.3.3 Outcomes Measures

Three major sets of outcomes will be evaluated, client outcomes, healthcare provider outcomes and system outcomes.

Client outcomes:

The two primary outcomes in the program are the pain score after USG probe insertion and the pain score after TRUS-Bx. The pain level will be directly assessed by the VAS (0-10), which is a valid, reliable and simple to use scale to measure pain (Hawker, et al., 2011). The VAS (0-10) pain score is divided into 11 categories from 0 to 10, with “0” representing no pain and “10” representing extreme pain (Appendix J).

The pain score will be collected by the frontline nurse who assists the doctor during TRUS-Bx. The pain score will be assessed immediately after probe insertion and immediately after the prostate biopsy.

Healthcare provider outcomes:
A staff evaluation form (Appendix K) will be given to frontline nurses to explore their satisfaction level, competence and compliance with the application of EBP guideline. The evaluation consists of 7 questions with a 5-point Likert scale with responses ranging from “Strongly disagree” to “Strongly Agree”. The evaluation form will be filled out by nurses after the study.

**System Outcomes**

The effectiveness of the system will be measured in system outcomes. The number of patients receiving the innovation, manpower, costs (set up and maintenance costs) and adverse events due to the innovation will be evaluated. The above data will be recorded and analyzed at the end of the implementation period. Moreover, the patients’ satisfaction level will be determined by a questionnaire with a 5-point Likert scale to evaluate system effectiveness. (See Appendix L)

**4.3.4 Timing and Frequency of Measurement**

For patient outcomes, the VAS (0-10) pain score will be collected at two time points, immediately after USG probe insertion and immediately after taking all 12 biopsies.

For healthcare provider outcomes, the staff satisfaction level will be collected after the implementation period of the innovation.

For system outcomes, the patient satisfaction questionnaire will be completed
before patient discharge from the clinic. The number of patients receiving the innovation, manpower, costs and adverse events due to the innovation will also be calculated at the end of the implementation period.

**Data Analysis**

To analyze the collected data, SPSS version 22 for Windows will be used. For client outcomes, the VAS pain score will be expressed as mean and standard deviation and all estimates with 95% confidence intervals. The one sample t-test will be used to statistically analyze the pain level in the selected patients. By comparing the generated VAS pain score and the existing data in the selected studies, a reduction in the pain score could be identified among patients.

For healthcare provider and system outcomes, the satisfaction levels of nurses and patients with the innovation will be calculated and summarized using descriptive statistics.

**4.4 BASIS FOR IMPLEMENTATION**

Based on the identified patient, health care provider, and system outcomes, criteria will be set to determine the effectiveness of the innovation in the local setting.

For patient outcomes, the identified studies showed VAS pain score reductions around 1.8-3.9 after USG probe insertion 1.3-3.06 after the biopsy. Therefore, a
decrease of 1.5 in the pain score after USG probe insertion and prostate biopsy will reflect effectiveness of the innovation.

The target for the satisfaction level of healthcare providers and patients is that more than 70% of them will respond ‘Strongly agree’ or ‘Agree’ to the questions in their respective evaluation forms.

For system outcomes, an overall utilization rate of 80% will be set to prove the effectiveness of the innovation in the local setting.

When all the above criteria are met, the new EBP guideline will be considered effective for full implementation by the innovation committee.
## Appendix A: Database Search Strategy and Results (Prisma Flow Diagram)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1 eutectic mixture of local anesthetics</td>
<td>1114</td>
<td>10</td>
<td>454</td>
<td>204</td>
</tr>
<tr>
<td>2 EMLA</td>
<td>1104</td>
<td>47</td>
<td>3232</td>
<td>611</td>
</tr>
<tr>
<td>3 lidocaine and prilocaine</td>
<td>1684</td>
<td>40</td>
<td>2460</td>
<td>634</td>
</tr>
<tr>
<td>4 prostate biopsy</td>
<td>60441</td>
<td>107</td>
<td>6375</td>
<td>1299</td>
</tr>
<tr>
<td>5 Pain</td>
<td>649076</td>
<td>33851</td>
<td>736688</td>
<td>90735</td>
</tr>
<tr>
<td>6 (1) OR (2) OR (3)</td>
<td>1870</td>
<td>74</td>
<td>4597</td>
<td>848</td>
</tr>
<tr>
<td>7 (4) AND (5) AND (6)</td>
<td>19</td>
<td>16</td>
<td>22</td>
<td>12</td>
</tr>
<tr>
<td>8 Full text available</td>
<td>17</td>
<td>16</td>
<td>8</td>
<td>12</td>
</tr>
<tr>
<td>9 After reading title</td>
<td>11</td>
<td>0</td>
<td>8</td>
<td>0</td>
</tr>
<tr>
<td>10 Selected literatures after elimination according to the inclusion and exclusion criteria</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>0</td>
</tr>
<tr>
<td>11 Subtotal of selected literatures after elimination of the duplicated</td>
<td></td>
<td></td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>12 Manual Search from references of selected literatures</td>
<td></td>
<td></td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>13 Total literatures</td>
<td>5</td>
<td>0</td>
<td>5</td>
<td>0</td>
</tr>
</tbody>
</table>

Search period from 10/9/15-11/06/16
Appendix A - PRISMA 2009 Flow Diagram

Records identified through database searching
(PubMed, OvidSP, The Cochrane Library and CINAHL) (n=19)

Additional records identified through other sources
(n = 0 )

Records after duplicates removed
(n = 19 )

Records screened by titles
(n = 19 )

Records excluded
(n =8 )

Full-text articles assessed for eligibility (n=11)

6 Full-text articles excluded:
- studied EMLA cream application compared with other pain control methods
- Not RCT or clinical trials

Studies included in quantitative synthesis
(n = 5 )
Appendix B: Bibliographic citation of selected studies


### Appendix C: Table of Evidence

<table>
<thead>
<tr>
<th>Bibliographic Citation</th>
<th>Patient Characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Outcomes Measures</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basar, et al., 2005 RCT 1+</td>
<td>Male patients: elevated PSA levels or with normal PSA values but with prostate nodules on digital rectal examination (DRE)</td>
<td>Group 2 (EMLA cream): 1ml EMLA cream was spread gently on the prostate using a DRE. Biopsy were taken 15 minutes after biopsy (n=20)</td>
<td>Group 1: (Placebo) Application of placebo cream (USG Gel) was spread gently on the prostate using a DRE (n=20)</td>
<td>Pain score by using 10-point VAS</td>
<td>Pain score after biopsy: Group 2: (EMLA cream): VAS 2.91 Group 1: (Placebo group) VAS 5.5 (P&lt;0.05)</td>
</tr>
<tr>
<td>Giannarini et al., 2009 RCT 1+</td>
<td>Patients with PSA levels 4 ng/ml or greater, with or without abnormal DRE or abnormal TRUS</td>
<td>5ml Emla cream applied intra-rectally by using a syringe and massaged into the anterior wall anal canal and perianal skin 30 minutes before procedure (n=70)</td>
<td>No anesthesia (n=70)</td>
<td>Pain score by using VAS of 0-10</td>
<td>Pain score after probe insertion: Intervention (Emla cream): 1.41+/-0.98 P&lt;0.001; No anesthesia: 5.31+/-1.27 P&lt;0.001; Pain score after prostate biopsy Intervention (EMLA cream): 1.27+/-1.4 P&lt;0.001; No anesthesia: 4.33+/-2.26 P&lt;0.001;</td>
</tr>
<tr>
<td>Bibliographic Citation</td>
<td>Patient Characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcomes Measures</td>
<td>Result</td>
</tr>
<tr>
<td>------------------------</td>
<td>--------------------------</td>
<td>--------------</td>
<td>------------</td>
<td>-------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Kandiralia, et al., 2009.</td>
<td>Patients with PSA levels 4ng/ml and/or having suspicious findings on DRE</td>
<td>5 ml EMLA cream to perianal and intra-rectal skin 30 minutes before procedure n=20</td>
<td>Apply 5ml EMLA cream to perianal only n=20</td>
<td>Pain score by using VAS of 0-10</td>
<td>Pain score after Probe insertion: EMLA cream to perianal and intra-rectal anesthesia: 2.67+/-1.64 (P&lt;0.001); EMLA cream to perianal: 2.86+/-1.97 (P&lt;0.002); EMLA cream to intra-rectal: 5.08+/-2.10 (P&lt;0.002); Control: 5.21+/-2.30 (P&lt;0.001)</td>
</tr>
<tr>
<td>RCT 1+</td>
<td>Mean age: 64.52+/-7.5</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>There were no statistically significant differences in age, PSA, size of prostate between the groups</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Placebo: application of 5 mL of hydrophilic gel (Glissen), a lubricating gel containing a 5% concentration of the antiseptic clorexidin N=40</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Control group: no medication, only a small amount of sonographic gel to allow ultrasound examination N=60</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pain score after Biopsy: EMLA cream to perianal and intra-rectal anesthesia: 1.92+/-1.31 (P&lt;0.001); EMLA cream to perianal anesthesia: 2.11+/-1.61 (P&lt;0.002); EMLA cream to intra-rectal anesthesia: 3.63+/-1.80 (P&lt;0.002); Control: 3.89+/-1.50 (P&lt;0.001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Galosi, et al., 2005</td>
<td>Patients PSA &gt;4ng/ml and/or suspicious DRE results</td>
<td>5 ml EMLA cream was applied to the rectum, anal plicae, and perianal skin 10 minutes before the procedure N=60</td>
<td>Placebo: application of 5 mL of hydrophilic gel (Glissen), a lubricating gel containing a 5% concentration of the antiseptic clorexidin N=40</td>
<td>Pain score by using VAS of 0-10</td>
<td>Pain score after Biopsy: EMLA cream: 2.6+/-1.4 Placebo: 3.0+/-1.6 Control: 3.9+/-1.8</td>
</tr>
<tr>
<td>Bibliographic Citation</td>
<td>Patient Characteristics</td>
<td>Intervention</td>
<td>Comparison</td>
<td>Outcomes Measures</td>
<td>Result</td>
</tr>
<tr>
<td>------------------------</td>
<td>-------------------------</td>
<td>--------------</td>
<td>------------</td>
<td>-------------------</td>
<td>--------</td>
</tr>
<tr>
<td>Raber, et al., 2005. RCT 1++</td>
<td>Patients abnormally high PSA levels and/or suspicious DRE results</td>
<td>5 ml EMLA cream to perianal and intrarectal. 1 mL of the cream is applied topically to the anal ring before the tip of the syringe enters the anal canal, and the rest is delivered into the anal canal and rectum. N=100</td>
<td>5ml gel as placebo applying N=100</td>
<td>Pain score by using VAS of 0-10</td>
<td>Pain score after Probe insertion:</td>
</tr>
<tr>
<td></td>
<td>Age range 46-87 Median age 66.8</td>
<td></td>
<td></td>
<td>For young man (under 67)</td>
<td><strong>EMLA cream to young man:</strong> 0.9 +/-1.4, p&lt;0.04; <strong>Placebo to young man:</strong> 1.7 +/-2.3, p&lt;0.04;</td>
</tr>
<tr>
<td></td>
<td>There were no statistically significant differences in age, PSA, size of prostate, histological results between the groups</td>
<td></td>
<td></td>
<td></td>
<td><strong>EMLA cream to old man:</strong> Pain score by using VAS of 0-10 For young man (above 67)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td><strong>EMLA cream to old man:</strong> 1.9 +/-2.7, p&lt;0.33 <strong>Placebo to old man:</strong> 2.4 +/-2.6, p&lt;0.33;</td>
</tr>
</tbody>
</table>
### Appendix D: Quality Assessment of Studies

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1) The study addresses an appropriate and clearly focused question.</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.2) The assignment of subjects to treatment groups is randomized.</td>
<td>Yes, patients were randomized</td>
<td>Yes, patients were randomized by a computer program</td>
<td>Yes, patients were randomized</td>
<td>Yes, patients were randomized by a computer program</td>
<td>Yes, patients were randomized</td>
</tr>
<tr>
<td>1.3) An adequate concealment method is used.</td>
<td>Can’t say, did not mention</td>
<td>Can’t say, did not mention</td>
<td>Can’t say, did not mention</td>
<td>Can’t say, did not mention</td>
<td>Can’t say, did not mention</td>
</tr>
<tr>
<td>1.4) Subjects and investigators are kept ‘blind’ about treatment allocation.</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes, single blind to patients</td>
</tr>
<tr>
<td>1.5) The treatment and control groups are similar at the start of the trial.</td>
<td>Yes, Subjects allocated into groups are balanced with no significant differences.</td>
<td>Yes, Subjects allocated into groups are balanced with no significant differences.</td>
<td>Yes, Subjects allocated into groups are balanced with no significant differences.</td>
<td>Yes, Subjects allocated into groups are balanced with no significant differences.</td>
<td>Yes, Subjects allocated into groups are balanced with no significant differences.</td>
</tr>
<tr>
<td>1.6) The only difference between groups is the treatment under investigation</td>
<td>Yes EMLA cream vs Placebo</td>
<td>Yes EMLA cream vs Placebo; EMLA cream+PPNB Vs PPNB</td>
<td>Yes EMLA cream vs Placebo</td>
<td>Yes EMLA cream vs Placebo</td>
<td>Yes EMLA cream vs Placebo vs no intervention</td>
</tr>
<tr>
<td>1.7) All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes</td>
<td>Visual analogue scale (VAS)</td>
<td>Yes</td>
<td>Visual analogue scale (VAS)</td>
<td>Yes</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>1.8) What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Dropout rate was not reported</td>
<td>Dropout rate was not reported</td>
<td>Dropout rate was not reported</td>
<td>Dropout rate was not reported</td>
<td>No drop out in EMLA cream group, 10% in placebo group, 7.6% in no treatment group</td>
</tr>
<tr>
<td>1.9) All the subjects are analyzed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>1.10) Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td>One site only</td>
<td>One site only</td>
<td>One site only</td>
<td>One site only</td>
<td>One site only</td>
</tr>
<tr>
<td>2.1) How well was the study done to minimize bias?</td>
<td>Acceptable</td>
<td>Acceptable</td>
<td>Acceptable</td>
<td>High quality</td>
<td>Acceptable</td>
</tr>
<tr>
<td>Question</td>
<td>Option 1</td>
<td>Option 2</td>
<td>Option 3</td>
<td>Option 4</td>
<td>Option 5</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>2.2) Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Can’t say</td>
</tr>
<tr>
<td>2.3) Are the results of this study directly applicable to the patient group targeted by this guideline</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2.4) Summarize the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above</td>
<td>Concealment and blinding to researcher is inadequate No sample size calculation mentioned Randomized method did not mention</td>
<td>Concealment and blinding to researcher is inadequate No sample size calculation mentioned</td>
<td>Concealment and blinding to researcher is inadequate No sample size calculation mentioned</td>
<td>Concealment is inadequate No sample size calculation mentioned</td>
<td>Concealment is inadequate No sample size calculation mentioned P value did not mention</td>
</tr>
</tbody>
</table>

Level of evidence

| Level of evidence | 1+ | 1+ | 1+ | 1++ | 1- |

P value is reported with significant difference noted

P value is reported with significant difference noted

P value is reported with significant difference noted

P value is reported with significant difference noted

P value did not mention
### LEVELS OF EVIDENCE

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

### GRADES OF RECOMMENDATIONS

- **A** At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or
  - A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

- **B** A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or
  - Extrapolated evidence from studies rated as 1++ or 1+

- **C** A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or
  - Extrapolated evidence from studies rated as 2++

- **D** Evidence level 3 or 4; or
  - Extrapolated evidence from studies rated as 2+
## Appendix F: Set up Costs of Conducting the Innovation

### Material Set Up Cost

<table>
<thead>
<tr>
<th>Item</th>
<th>Budget Estimation (in HKD)</th>
<th>Cost (in HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EMLA Cream (Training + pilot study of 20 patients)</td>
<td>$70 \times 26</td>
<td>$1820</td>
</tr>
<tr>
<td>5ml syringe for (Training + pilot study of 20 patients)</td>
<td>$0.5 \times 26</td>
<td>$13</td>
</tr>
<tr>
<td>Printing &amp; Photocopy of (Training + pilot study)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Education Pamphlet (1 page)</td>
<td>$0.5 \times 26</td>
<td>$13</td>
</tr>
<tr>
<td>Guideline for nurses (2 pages) (For training Only)</td>
<td>$1 \times 6</td>
<td>$6</td>
</tr>
<tr>
<td>Evaluation Forms (3 pages)</td>
<td>$1.5 \times 26</td>
<td>$39</td>
</tr>
<tr>
<td>Total: $1891</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Non-material Set Up Cost

<table>
<thead>
<tr>
<th>Manpower and Time Consumed</th>
<th>Budget Estimation (in HKD)</th>
<th>Cost (in HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manpower for Attending training course (30 minutes)</td>
<td>$174.5/\text{hour} \times 0.5\text{ hour} \times 4\text{ nurses}</td>
<td>$349</td>
</tr>
<tr>
<td>Time for Patient Education and EMLA Application (10 minutes) (pilot study)</td>
<td>$174.5/\text{hour} \times 1/6\text{ hour} \times 20\text{ patients}</td>
<td>$582</td>
</tr>
<tr>
<td>Time for Evaluation (5 minutes) (pilot study)</td>
<td>$174.5/\text{hour} \times 1/12\text{ hour} \times 20\text{ patients}</td>
<td>$291</td>
</tr>
<tr>
<td>Total: $1222</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Grand Total for set up costs: $3113**

- The average hourly salary for a registered nurse in the Hospital Authority is (HKD)$174.5
Appendix G: Running Costs of Conducting the Innovation per year

<table>
<thead>
<tr>
<th>Material Running Cost per year</th>
<th>Budget Estimation (in HKD)</th>
<th>Cost (in HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Item</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EMLA Cream (300 patients/year)</td>
<td>$70 x 300</td>
<td>$21000</td>
</tr>
<tr>
<td>5ml syringe for (300 patients/year)</td>
<td>$0.5 x 300</td>
<td>$150</td>
</tr>
<tr>
<td>Printing &amp; Photocopy of Education Pamphlet (1 page)</td>
<td>$0.5 x 300</td>
<td>$150</td>
</tr>
<tr>
<td>Evaluation Forms (1 page)</td>
<td>$1.5 x 300</td>
<td>$450</td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td><strong>$21750</strong></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Non-material Running Cost</th>
<th>Budget Estimation (in HKD)</th>
<th>Cost (in HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Manpower and Time Consumed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Time for Patient Education and EMLA Application (10 minutes) (300 patients/year)</td>
<td>$174.5/hour x 1/6 hour x 300 patients</td>
<td>$8725</td>
</tr>
<tr>
<td>Time for Evaluation (5 minutes) (300 patients/year)</td>
<td>$174.5/hour x 1/12 hour x 300 patients</td>
<td>$4362.5</td>
</tr>
<tr>
<td><strong>Total:</strong></td>
<td><strong>$13087.5</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Grand Total for Running Costs per year: $34837.5**

- The average hourly salary for a registered nurse in Hospital Authority is (HKD)$174.5
Appendix H: EBP Guideline on applying EMLA cream prior to TRUS-Bx

Title:

“An evidence-based practice guideline for applying Eutectic mixture of local analgesia cream prior to Transrectal prostate biopsy to reduce procedural pain”

Background:

Prostate cancer is the 3rd most common cancer in males in Hong Kong (Hong Kong Cancer Registry, 2014). The incidence rate of prostate cancer was around 1600 cases in 2012. Transrectal ultrasound guided prostate biopsy (TRUS-Bx) is a diagnostic test for patients with suspected prostate cancer. During the biopsy procedure, an ultrasound probe is inserted into the rectum and a biopsy needle is inserted into the prostate gland through the rectal wall to obtain prostate tissue for pathologic analysis.

Despite the importance of early detection of prostate cancer, many urologists and nurses in Hong Kong neglect pain control for TRUS-Bx. Most hospitals do not use any analgesia for pain control. Only one hospital uses a periprostatic nerve block (PPNB) with application of 1ml EMLA cream to the anal area prior to TRUS-Bx. The pain during TRUS-Bx procedure is considered an unpleasant experience by patients. PPNB injection is a standard means of pain control currently. However, it is not commonly used in Hong Kong. In recent studies, alternative pain control methods such as
application of EMLA cream to the rectum prior to TRUS-Bx was found effective in relieving the pain involved in conducting TRUS-Bx. Moreover, it can provide better pain control than a PPNB alone when it is combined with PPNB.

The target setting is a urology clinic in a public hospital. Around 300 TRUS-Bx procedures are performed every year. No pain control measures are currently used for TRUS-Bx. Nurses have a relatively weak role in pain control for TRUS-Bx.

The lack of pain control measures in current practice for TRUS-Bx in Hong Kong indicates a need for new measures for pain control. EMLA cream application prior to TRUS-Bx is safe and easy (Cormio, et al., 2011). Nurses can provide pain relief for patients with TRUS-Bx via EMLA cream application.

Despite the effectiveness of EMLA cream application, an evidence-based guideline is needed to support the new innovation.

Five studies were evaluated concerning the effectiveness of EMLA cream application prior to TRUS-Bx in reducing the procedure pain. All five studies support the use of EMLA cream in reducing the pain level for patients with TRUS-Bx. An EBP guideline can be synthesized from the data extracted from the five studies.

Aim:

To reduce procedural pain for patients undergoing TRUS-Bx

Objectives:
• To provide evidence-based recommendations for patients undergoing TRUS-Bx
• To standardize procedural pain relief by promoting preapplication of EMLA cream to patients undergoing TRUS-Bx

**Target Population:**

• Patients having TRUS-Bx
• Patients without cognitive problem

**Target Users:**

Nurses working in urology clinics

**Recommendations:**

**Recommendation 1:**

EMLA cream should be chosen as the topical anesthesia for TRUS-Bx

[Grade of Recommendation: A]

**Available evidence:**

EMLA cream was chosen as the topical anesthesia because its established efficacy, rapid absorption and shown to have no side effects (Raber, et al., 2005; Giannarini et al, 2009; Galosi, et al.; Kandiralia, et al., 2009; Basar, et al., 2005) (1++, 1+, 1-, 1+, 1+)

**Recommendation 2:**

Allergy should be rule out before application of EMLA cream

[Grade of Recommendation: A]
Available Evidence:

“Except for the rare patient with allergies to local anesthesia, EMLA cream should be considered in all men undergoing TRUS-Bx” (Noh, et al., 2010) (1++)

**Recommendation 3:**

5ml EMLA cream should be used to reduce procedural pain of TRUS-Bx

[Grade of Recommendation: A]

Available evidence:

5ml EMLA cream was administered in 4 of the 5 selected studies with pain score comparatively lower in the studies using 5ml EMLA cream (Raber, et al., 2005; Giannarini et al, 2009; Galosi, et al.; Kandiralia, et al.) (1++, 1+, 1-, 1+)

**Recommendation 4:**

Apply EMLA cream 30 minutes to perianal and intrarectal area prior to TRUS-Bx

[Grade of Recommendation: A]

Available Evidence:

Findings from the selected studies supported applying EMLA cream 30 minutes prior to TRUS-Bx procedure into perianal and intrarectal area. (Raber, et al., 2005; Giannarini et al, 2009; Galosi, et al.; Kandiralia, et al., 2009) (1++, 1+, 1-, 1+)

**Recommendation 5:**

Use syringe to instill EMLA cream into perianal and intrarectal area
Available evidence:

Syringe was used in 2 studies to instill EMLA cream into perianal and intrarectal area

(Raber, et al., 2005; Giannarini et al, 2009;) (1++, 1+)

**Recommendation 6:**

Massage of EMLA cream to perianal area and intrarectal area by using fingers after instilled of EMLA cream

[Grade of Recommendation: A]

Available evidence:

Massage EMLA cram into the anterior rectal wall, anal canal and perianal skin.

(Giannarini et al, 2009) (1+)

**Recommendation 7:**

Pain score interview should be done immediately after probe insertion and biopsy procedure

[Grade of Recommendation: A]

“Pain was assessed in prospective fashion, i.e. a score was recorded immediately after each procedural step. Thus, the potential for recall bias was avoided.”

(Giannarini et al, 2009) (1+)
Flowchart of applying EMLA cream

1. • Provide education pamphlet to patients when they attend to clinic

2. • Explain EMLA cream application and get consent from patients during nurse interview session
   • Rule out patients with allergy history to local anaesthesia

3. • Applying 5 ml EMLA cream to patients by using a 5ml syringe and instilling into perianal area and intrarectal area. Then use fingers to massage it thoroughly to perianal and intrarectal area

4. • Perform TRUS-Bx 30 minutes after EMLA cream application

5. • Assess pain score by using VAS (0-10) after USG probe insertion

6. • Assess pain score by using VAS (0-10) after biopsy completed

References:


## Appendix I: The Estimated Timeframe for Implementation Plan

<table>
<thead>
<tr>
<th>Month</th>
<th>Task</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Preparation of Proposal Guideline by Author</td>
</tr>
<tr>
<td></td>
<td>Communication between stakeholders (Frontline staff, APN, NC, WM)</td>
</tr>
<tr>
<td></td>
<td>Approval from managerial level (DOM, Urology Division Head)</td>
</tr>
<tr>
<td></td>
<td>Innovation Committee Team Formation</td>
</tr>
<tr>
<td></td>
<td>Guideline revision base on stakeholders’ suggestion and members of innovation committee</td>
</tr>
<tr>
<td></td>
<td>Staff Training and equipment preparation</td>
</tr>
<tr>
<td></td>
<td>Pilot Test</td>
</tr>
<tr>
<td></td>
<td>Evaluation on pilot test</td>
</tr>
<tr>
<td></td>
<td>Guideline amendment base on pilot test evaluation</td>
</tr>
<tr>
<td></td>
<td>Full-scale program implementation</td>
</tr>
<tr>
<td></td>
<td>Evaluation on full-scale program</td>
</tr>
<tr>
<td></td>
<td>Reporting</td>
</tr>
</tbody>
</table>
Appendix J – Perceived Score Pain Using VAS (0-10)

No. of patient: _____________

1. What is your pain score for the insertion of the USG probe? (0: no pain, 10: extreme pain)

   ![VAS Scale]

2. What is your pain score for the prostate biopsy? (0: no pain, 10: extreme pain)

   ![VAS Scale]
**Appendix K - Staff Evaluation Form**

Please put a tick in the appropriate boxes below to indicate your views on the following statements:

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The guideline is easy to use</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>I attained adequate knowledge and training to use the guideline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>I had enough confidence to apply this guideline in my clinical setting</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>I will use this guideline for all patients undergoing TRUS-Bx</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.</td>
<td>The workload is reasonable even after implementation of the new guideline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6.</td>
<td>My colleagues and supervisor provided adequate support to implement the guideline</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7.</td>
<td>Overall, I am satisfied with the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
## Appendix L - Patient Satisfaction Questionnaire

<table>
<thead>
<tr>
<th></th>
<th>Strongly Disagree</th>
<th>Disagree</th>
<th>Neutral</th>
<th>Agree</th>
<th>Strongly Agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>The nurse provided a clear explanation and clarified my concerns about the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.</td>
<td>The education leaflet contained adequate information on the innovation and was easy to understand</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.</td>
<td>With the launch of the innovation, I will am more willing to have another biopsy if needed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.</td>
<td>Overall, I am satisfied with the innovation</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>