The best clean catch method to collect none contaminated sample in non-toileted child

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COLLEGE OF NURSING AND MIDWIFERY

Candidate Declaration

Declaration

This is to certify that:

i. The dissertation comprises only my original work;

ii. Due acknowledgement has been made in the text to all other materials used;

iii. No portion of the work referred to in the dissertation

has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

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List of Abbreviation

AAP	American Academy of Paediatric
CASP	Critical Appraisal Skills Programme
CAUTI	Catheter associated Urinary Tract Infection
CCU	Clean Catch Urine
CG	Control Group
CI	Confident of Interval
CSU	Catheter Specimen Urine
EG	Experimental Group
MESH	Medical Subject Heading
NICE	National Institute for Health and care Excellence
PH	Potential of Hydrogen
RBC	Red Blood Cell
RCT	Randomised Controlled Trials
UNCRC	United Nation Convention on the Right
UTI	Urinary Tract Infection
WBC	White Blood Cell
WHO	World Health Organization

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Abstract

Title: The best clean catch method to collect none contaminated sample in non-toileted child

Background: Urinary tract infection (UTI) is the most common bacterial infections affected infants and younger children. To discover UTI, urinalysis is the test used to identify bacteria in the urine. Urinalysis is examined by three methods, visual examination, microscopic exam, and dipstick test. The common methods for sampling in non-toilet-trained children involve clean catch, urine bag, urine pad, in-out catheterisation urine, and suprapubic aspiration.

Aim: The aim of this literature review is to explore the best methods to collect CCU sample from non-toilet-trained child without contamination.

Methodology: When searching the literature, the systematic approach method was used. The search strategy used PIO from (population, intervention, and outcomes). The search results were generated using three electronic databases relevant to the review: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, and PubMed. The quality of each study was evaluated using CASP tool. Searches were conducted between November 2020 to April 2021 because of the due of the deadline. An inclusion and exclusion criteria were established to determine which literature will be included in the review and which will be excluded. Included articles were eligible if they were in English language, full text article, published between 2010 and 2020, the sample is children or infants needs clean catch urine collection, nontoilet child and infants who need urine collection, and qualitative and quantitative papers and not systematic review.

Results: Total of seven papers, four were randomised controlled trials and three were cohort studies addressed the clean catch method in non-toileted infants to collect none contamination urine sample.

Conclusion: The most used method to collect urine sample in this age is obtaining a clean-catch urine sample, however this method took an average of more than one hour to collect sample.

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Chapter One- Introduction/ Background

This dissertation aims to illustrate the broad concept of the urinary tract infection UTI in children and will present what is the best way to collect mid-stream urine sample to them. This will be followed by five chapters, background, methodology, finding, discussion, and conclusion. First chapter which is the introduction/ background, will identify the topic in broad concept, it will define the urinary tract infection in children and what is the test to be done to assess urine sample to detect infection and treat it. The second chapter is methodology, this chapter will present the methods used to do this review, what is the rationale for using this method, how data was collected, how data was analysed, and what type of critiquing tools were used to see the quality of the included studies. Third chapter is finding, this chapter present the results of the included studies, what the studies found, and what is the main finding in the studies, and critical appraisal of the studies in the review. The fourth chapter is discussion, this chapter will focus on describing and evaluating what is found in the studies, demonstrating how it relates to the literature review and research questions, and making an argument in support of the overall decision. The final chapter is conclusion, it will present the summary of the research findings.

1.1 Definition of Urinary Tract Infection

National Institute for Health and Care Excellence guideline (NICE, 2018) stated that urinary tract infection (UTI) is one of the most common bacterial infections in infants and younger children Urinary tract infections in children can be the sign of a severe underlying congenital anomaly which includes obstruction if no longer relieved, will lead to renal damage (NICE, 2018). In the other children, the infections can be related to progressive lack of kidney

function both in association with renal dysplasia and with recurrent episodes of acute pyelonephritis/upper urinary tract infection (NICE, 2018).

1.2 Used of Urinalysis

A urinalysis is a test of urine used to discover and control a variety of disorders, including urinary tract infections, kidney disorder and diabetes, and it is examined by the appearance, concentration, and content of urine (Mayo Clinic, 2021). Mayo clinic (2021) showed the three methods of examining the urine, visual examination, microscopic exam, and dipstick test. The purpose of examining urine samples is to identify and treat infections to prevent pyelonephritis with renal scarring, end stage renal failure and hypertension (NICE, 2018).

1.3 Methods Used to Test the Urine

The first method of testing the urine is through visual exam. The healthcare professional observes the coloration and clarity of the urine, and examines the smell of the urine, if it's foam it could be a signal of kidney disease, even as cloudy urine may indicate infection (Mayo Clinic, 2021). Urine is normally clear, however if there is protein contains in urine it makes it look foamy. According to Mayo Clinic, (2021) during the physical examination if the urine colour looks red or brown, it means there is blood in the urine, and it is abnormal. The second method is a microscopic exam, to test red blood cells (RBC), white blood cells (WBC), bacteria, and crystals. If the result showed high WBC, it indicates on infection in the urine, high RBC indicate of problem in kidney, bladder, and urinary tract, and high crystal in urine indicate that there is stone in the kidney. Third method as stated by Mayo Clinic (2021) is the dipstick test, which makes use of a thin plastic strip treated with chemical substances, it is dipped into the urine, and the chemical substances at the stick

react and change coloration if levels are above normal. Dipstick used to test urine potential of hydrogen (PH), concentration, protein, glucose, white blood cell, nitrites, bilirubin, and blood withinside the urine. Urine PH if its acidity which is PH is less than 7, it indicates of kidney stones, a urinary tract infection (UTI), or other disorder. The amount of concentration shows how concentrated the particles are in the urine, if it is high concentration, it is a cause of not drinking enough fluids and might having dehydration (Mayo Clinic, 2021). When there is protein in the urine, it indicated of the impaired kidney's function. Urine glucose or sugar, if it is elevated is an indication for diabetes, and it is needed to have follow-up testing for diabetes. White blood cells are a signal of infection or inflammation, both within the kidneys or in the urinary tract. Nitrites, shows infection with certain types of bacteria. Bilirubin, sign for liver function Blood in the urine, is an indication of infections or other diseases (Mayo Clinic, 2021).

1.4 Challenges in Urinalysis in Children and Contamination

Hay (2016) described that when there is difficulty in collecting sample for urinalysis and the specimens showed contaminated prior to culture from skin, faeces, and other causes, may contribute to the overdiagnosis of UTI. This mean that the child will have unnecessary investigations and treatment, and this will lead for risk of complications and psychological stress to the child and family (Hay, 2016).

NICE (2012) stated that UTI must be taken into consideration in each child with high fever or urinary symptoms, the diagnosis must be showed by urine culture sample and then following the treatment of illness. All infants and youngsters more than 7 years must do renal

imaging and receive prophylactic antibiotics to manage UTI till those investigations had been completed, and must have a regular follow-up (NICE, 2012).

In a study by Diviney (2021) it is important to use the best method to get urine samples from the child to confirm or exclude the diagnosis, and it is a challenging in non-toilet-trained children because it is associated in severe morbidity with delayed in treatment. According to Herreros et al. (2015) when comparing clean catch with catheter sampling method with a contamination rate, clean catch urine (CCU) 5%, and 8% for catheter samples which is no significant difference. Teo et al. (2016) reported that contamination rates are differed by gender, male urine samples contain 10.5% of contamination rate and 16.4% in female. Another study by Jacob (2019) reported that contamination sample is significantly higher in females and in those aged 0–3 months and over 12 years. Pathogenic bacteria arise from the perineum and inflicting the UTI (Bono & Reygaert, 2021). The greater susceptible or chance to have UTI in female is because they have shorter urethras than male and it is located closer to the anus, where stool comes out and making it easier for an infection to happen. The reason of why male have low contamination rate is because in male the urethral opening is a longer distance from the bladder than in female, also there are secretions from the prostate gland that can kill bacteria, so the frequency of a urinary tract contamination is not high (Bono and Reygaert, 2021). In the study by Ahmed (2017) reported that accurate diagnosis of UTI is important to keep away from over treatment or mistreatment with antibiotics and to achieve accurate goal of the investigations. This is specifically in younger children who aren't toilet-trained and who frequently present with nonspecific symptoms, making the decision about UTI difficult. The big challenge in obtaining a urine sample by clean catch for non-toilet trained children that is time consuming (Ahmed, 2017).

1.5 Incidence and Prevalence of the UTI in Children

NICE guidelines (2012) stated that by the age of sixteen years, from 1 in 10 girls and 1 in 30 boys may have had a UTI. First prevalence of UTI is most common in infancy and influences boys usually in the first three months of life at the same time as in girls the peak prevalence is after 6 months. Infants are regularly systemically sick and have acute pyelonephritis/upper urinary tract infection at the same time as older children more regularly have decrease UTI and traditional signs of cystitis (NICE, 2012). The prevalence of first UTI falls with age in each sex, however UTI is much less common in boys than in girls after the first 6 months. Recurrent infections in boys are unusual while they're very common in girls (NICE, 2012).

1.6 Children in the Health Care

In this literature review, the population is infants/children. The issues in this age group are different than other populations. This age group need careful attention, care, and ethical concentration. The World Health Organization (WHO, 2019) define the reason for why the child needs different care and support is because children have different and unique exposures to environmental hazards from those of adults, because they have sensitive skin, immature of body systems, and low immunity than adult people. It is important to address children's health from a child-rights view, that is each child has the right to survive, grow and develop physically, supporting them emotional and social well-being (WHO, 2019).

The United Nations Convention on the Rights of the Child (UNCRC, 2013) adopted by the United Nations is a legally binding global address the civil, political, economic, social, and cultural rights of each child, irrespective of their race, faith, or abilities (UNCRC, 2013). The UNCRC as human beings who deserve dignity and human rights (Mama, 2010). According to

the UNCRC (2013) It is important to approach children's health from a child-rights point of view that all children have the right to survive, grow up and develop, in the perspective of physical, emotional, and social well-being. It is important to allow children to be involved in prevention, promotion, treatment, rehabilitation, and palliative care services. The health-care system should report the information to related authorities for cases of rights violations and injustice in children (UNCR, 2013). Since 1989 the UNCRC stated that children rights must be highlighted and protect. A study by Mama (2010) showed the types of child protection which are protected from neglect, physical or mental abuse, unfairness, and exploitation. Allow children in participation is also one of their right. It means to give them the right to be heard in decision making.

1.7 Methods of Urine Collection

Diviney (2020) defined UTI as a common infection associated with significant illness in the paediatric population, and the common methods for sampling in non-toilet-trained children who diagnosed with UTI involve clean catch urine (CCU), urine bag, urine pad, in-out catheterisation, and suprapubic aspiration (SPA). The National Health and Services (NHS, 2010) stated that CCU sample is used for urinalysis to detect bacteria in the urine, and for this reason, it is important to avoid contamination of the urine sample from skin contact. The technique of CCU was adopted in the early 1950s, as another choice to catheterization (NHS, 2010).

CCU samples are acquired through holding a sterile container underneath the urethra with the removal of the nappy, till passing urine, with being aware to keep away from any skin touch with the sample container to prevent contamination (Diviney, 2020). The advantages of CCU reported by Diviney (2020) that it has a lower rate of contamination, it could be more

efficient through stimulation of voiding in more children, it is the most accurate urine sampling method, and it is easy to obtain. By contrast, the disadvantage of CCU reported in Daviese (2008) and Kaufman (2016) studies is that CCU is a time consuming, and it takes long time to collect sample from the child. According to NICE (2020) guidelines CCU sample is the recommended method for infants but if it is unapproachable, then other non-invasive methods such as a pad urine collection should be applied (NICE, 2020).

In this literature review, the focus is on CCU method. According to Tran (2018) midstream CCU is method used to diagnose UTI, however, this method is useless in infants before toilet training, because in midstream collection it needs to discard the first and the last drop of urine to prevent contamination from the skin, hand, and the container, and for non-toilet infants they are not aware about this technique to apply it.

Urine Bag method requires connecting a sterile plastic bag to the perineum (the area between the genitals and the anus), with adhesive around the bag opening, and the voided urine falls inside the bag (Diviney, 2020). In a study of Hadjipanayis *et al.* (2015) it is the favoured technique of collection in Europe, 53% selected a urine bag for collection as the first choice for infants < 3 months and 59% for children 4–36 months of age). The advantage of urine bag is the method consider as a non-invasive sampling technique, and it is the best choice for the clinician's because it does not cause harm and stress to the child. However, this method has the highest rate of contamination, usually with periurethral flora (Diviney, 2020). Another study conducted by Tosif *et al.* (2012), aimed to examine contamination rates in CCU, SPA, catheter specimen urine (CSU) and urine bag specimen collections reported that urine bag is inappropriate for culture because contamination regularly causes false-positive findings.

A study of Finnell *et al.* (2011) showed that rine culture collected from a bag is not recommended due to unsuitable high false-positive rates (85%) to contamination by periurethral flora. Furthermore, American Academic of Peadiatric guideline (AAP, 2011) states that urine bag cultures have unacceptably high false-positive rates of contamination, reporting that the rate of false positives range from 88 to 99%.

Moreover, the other method of urine sample is pad urine defined by Diviney (2020) it includes the insertion of a syringe into the child's nappy to draw urine after voiding. The main advantages of the urine pad collection are that the process is passive and needs less effort with less upsetting the child, and it there were fewer missing samples compared with CCU collection (Diviney,2020). The NICE guidelines (2020) suggested nappy pads to be used for children who wear nappies and for those parents who refused CCU. By contrast, while describing urine pad methods as a clinically useful sampling, it has a higher contamination rate and less accurate compared with CCU sampling (NICE, 2020).

The National Health Service (NHS, 2020) defined the last urine collection methods which is urinary catheterisation as a technique used to drain the bladder and collect urine sample by a tube called catheter. This method is usually collected by doctors or nurses in hospital, or the community and it can be inserted through two ways, by urethral catheter, which is a tube that carries urine out of the bladder or by a small opening made in the lower tummy called suprapubic catheter (NHS, 2020). The catheter is usually left in the bladder, and it allows the urine to flow through it and into a drainage urine bag (NHS, 2020). Common complication of urethral catheterization reported in a study of Garg *et al.* (2016) is catheter associated UTI (CAUTI), it is the period of catheterization that find out the improvement of bacteriuria. Suprapubic collection is the best choice method to avoid specimen contamination

with bacteria, especially in the distal urethra, however, this technique is painful and causing discomfort to the patient (Sinawe and Casadesus, 2021). According to Peters and Medina-Blasini (2021) SPA is a sterile technique that makes samples uncontaminated in patients, and it is known as a gold standard for urinalysis in children. Distal urethra or perineal area are always colonized by feces bacteria, while bacteria are not appear in bladder urine, a low colony count may be present in a specimen collected by voiding or catheterization, especially in boy with phimosis or girl with labial adhesion (Finnell *et al.*, 2011). As a result, a serious colony count relies at the techniques of urine collection and clinical presentation. The selection of various cut-off values depends on the risk of infection of various techniques of urine collection (Finnell *et al.*, 2011). Diagnosis is complicated by contamination from faecal bacteria that settle the perineal area and distal urethra. Without contamination of perineal flora, suprapubic aspiration has been considered the standard method for urine culture in young children (Finnell et al., 2011).

Roberts (2011) suggests for diagnosis of UTI if antibiotics are to be given to the patient, the sample needs to be collected through catheterization or SPA, because the diagnosis of UTI cannot be reliably through culture of urine collected in a urine bag However, if urgent antibiotics are not needed to be given, then then urine should be collected by either catheterization or SPA for culture and urinalysis. In Roberts (2011) study reported if the urinalysis results suggest a UTI positive leucocyte esterase or nitrite test or microscopic analysis positive for leucocytes or bacteria, a urine sample should be collected by catheterization or SPA and cultured, they do not suggest clean catch, pad, or bag sampling.

1.8 What is Known on this Review?

Standard methods to find a urine specimen in the febrile infants is clean catch. Obtaining a CCU sample in this age group takes time and with some of contamination rate (Morris *et al.*, 2018). Non-invasive bladder stimulation technique to obtain CCU sample in infants was developed instead of just waiting for a long time for the patients to void, with no difference in contamination rate.

According to NICE guideline (2018) techniques used to collect urine samples can be result in contamination with bacteria from outside the body, which lead to an incorrect diagnosis, require unnecessary treatment, or need to repeat another sample. NICE describes the CCU as a gold standard to collect sample for the children, which requires catching a urine sample by holding a sterile sample bottle in the urine stream to prevent germs from genital area. However, urine collection bags and pads are more at risk of contamination than the CCU method, because of the close contact with the skin across the genital area. Genital cleaning of child may lessen the risk for false positives and keep away from unnecessary antibiotic and investigations (NICE, 2018).

1.9 Gap of the Review

The aim of this literature review is to introduce the reader to the broader topic under review, this is about the best way to collect CCU sample from non-toilet-trained child without contamination. The purpose of this study is to review the literature to determine best practice in collecting urine sample by clean catch for non-toilet-trained children without being contaminated. The reason of choosing infants as a population for this study is because of seeing different practice in collection urine sample for children and the samples are contaminated, which make the child receive unneeded treatment. The main issue for

conducting this review, is when the physician asking for a urine sample- for the urinalysis for the child, it is difficult to collect it for this age group. This is an age where urine samples are difficult to obtain. CCU specimens are recommended where it is possible to obtain one (NICE, 2020). Children will start crying and moving which will take time to collect the sample or it will be contaminated.

1.10 Chapter Summary

A UTI diagnosis needs collection of urine generally by one of the five methods: sterile urine bag, urethral catheterization, SPA, urine pad, and CCU. Together catherization and SPA are the most reliable results by minimizing false-positive results, but these methods are invasive and painful, on the other hand CCU, urine bag and pad are non-invasive, have a chance of contamination in lower and higher percentage. The contamination rate on each method is possible because of the techniques of collection and the method itself. The reason for choosing to investigate CCU for this literature review is because it is the most common method for paediatric patients, have less contamination rate, and is non-invasive.

Chapter two- Methodology

2.1 Systematic Literature Review

In a study of Lee *et al.* (2021) an integrative review helps adding of numerous methodologies, can play a role in evidence-based practice and has the ability to construct nursing science, inform research, practice, and policy. The use of a systematic method increases the accuracy of the process and reduces the risk of error (Lee *et al.*, 2021). By carrying out a research for all the literature relevant for this review, the aim is to appraise and compare all the findings of what the methods are used to collect clean catch urine sample in nontoilet trained children to have noncontaminated result. The method used in this study aims to uncover what is the best technique to collect urine sample for nontoilet child with noncontaminated urine sample. When searching the literature, the systematic approach method was used.

Study of Maggio *et al.* (2016) showed the basis for high-quality medical education research for the literature. They stated that the literature review allows any researcher to be part of the conversation through providing context, informing methodology, figuring out innovation, minimizing duplicative studies, and making sure that requirements are met. Understanding the current literature promotes learning, the review allows the researcher to show clear goals, show evidence of good enough preparation, choose suitable methods, communicate applicable outcomes, and interact in reflective critique. Failure to show a high-quality literature review is related to numerous issues recognized withinside the clinical schooling literature, which include research which are repetitive, not focus on theory, and methodologically weak. Good studies need for trained investigators who can articulate applicable research questions, outline variables of interest, and select the great approach for

specific research questions. Conducting an acceptable literature review allows each beginner and expert researchers choose accurate studies methodologies. The literature review is a critical a part of medical education studies and need to arise at some stage in the studies manner to assist researcher's layout a strong study and successfully communicate study results. To obtain those goals, researchers are recommended to plan and perform the literature review carefully (Maggio *et al.*, 2016).

A methodological review using an integrative, systematic method became used from Whittemore and Knafl (2005). This review aims to explore and evaluate the methods for getting a clean-catch urine used in children to have noncontaminated or noninfected urine sample. This chapter aim to describe search strategy used when choosing literature for this review. It includes how the question was defined, data collection, sampling, and ethical issue of the review. The keywords used for the search strategy in the three databases used will be introduced, with inclusion and exclusion criteria. The goal of this chapter is to ensure that the search results are transparent and replicability. Theoretical framework method of Vinz (2015) were used for carrying the review. The first stage was to decide on the framework of the review to examine the research question. At the beginning, the key terms were chosen were the key terms from the problem and research questions which is the contaminated urine sample in children, and then evaluate and provide an explanation for applicable articles by undertaking thorough literature review to decide how different researchers have described relationships between key concepts.

2.2 Scope of the Review

Five steps framework for Integrative reviews were used. Steps are as follows: problem identification, literature search, data evaluation, data analysis and presentation. Through the discission and trying to have the final review question, the question was defined to make it manageable, to not be too broad and not too narrow. Defining the question is important because the remaining search will be based on this question. The research question for this review is “What is the best clean catch method to collect none contaminated urine sample for non-toilet trained children?”. A CCU sample defined by Kirkwood (2017) as a plastic container placed under the patient genital area, then start urination and collect the urine sample. Additionally defined it as the lowest irritating methods for a urine culture or urinalysis, and it aimed to prevent bacteria from the skin and cause contamination, and it used to diagnose the urinary tract infection (UTI). To avoid contaminated sample, the nurse should do the hand hygiene first and then wear gloves and clean the genital area by using a soap or wiped with water and try to not touch the skin when placing the container (Royal Children's Hospital, 2018). To collect a CCU sample, it is important to collect it midstream, which mean that when the patient will start urination do not put the container, let the first drop of urine to release then start to collect (Kirkwood, 2017).

2.3 Systematic Search Strategy

A search strategy was developed to identify relevant literature for this review. The search strategy used PIO framework from population, intervention, and outcomes. (See Table 1). In study of Aslam (2010) established that this strategy helps in breaking the question into three components which enable the researcher to facilitate the identification of relevant papers. (P) population is addressing a specific participant and its important features and demographic information. In this review the population is paediatric patients who needs urine collection by clean catch method. The key words used to find the samples were Infant, children, none-toilet, toddler, pediatric or paediatric. Those children were chosen because of the author having experience in working with the pediatric patients and facing that it is difficult to collect urine sample for them and it take more time or failed to collect, due to their moving and crying. The main reason is that the urine sample from the child can have mixed growth bacteria which it means that it is a contaminated sample. In this case the child may receive a wrong antibiotic and treatment that he did not need, or he may have a delay in the treatment. (I) Intervention, it can be a treatment, procedure, diagnostic test, and risk or prognostic factors. The intervention for this review is a procedure. The key words used for the intervention are clean catch, clean voided urine, best clean catch method, quick wee, bladder stimulation, and urine collection. Clean catch was chosen because it is the method that need to be included in the review, and the remaining key words were taken from other reviews. The mentioned search words were used to be specific and custom when searching for the paper to help in finding only the CCU method and not include catherization or urine bag collection. (O) Outcome is the result of the intervention to see if it is effective or not.

Therefore, the outcome in the review is non contaminated urine sample. The key terms used were none contaminated urine sample, not infected urine sample, urine sample, and midstream. Those terms used to answer the review question and to have paper that their finding is non contaminated sample only and not mixed growth bacteria or contaminated sample. All terms that used in the search was using the PIO to make it easy, searchable, and also meant that the search could be repeated by another researcher, and so would be reliable and consistent.

Searches were conducted between November 2020 to April 2021. Challenges exist when conducting a literature review using a systematic approach, these include some websites have duplicated the articles, and it takes long time to collect and sort the articles. It is also important to identify the last time the search was carried out. The search results were generated using three electronic databases relevant to the review: Cumulative Index to Nursing and Allied Health Literature (CINAHL), Medline, and PubMed. The reason of choosing these three databases was because they provide information from articles in nursing and health science which is useful for this review. The databases used provides access to health care books, nursing dissertations and everything that is supportive for the health care team. The using of it was easy with advance search, and it help in retrieve searches that did it before and it is following the structure of the Medical Subject Headings (MESH) which is helping to find the articles. Key to this review was the publications of empirical studies and not systematic reviews or discussion papers. The studies included in this review were randomised controlled studies and cohort studies.

Table 1: PIO Framework

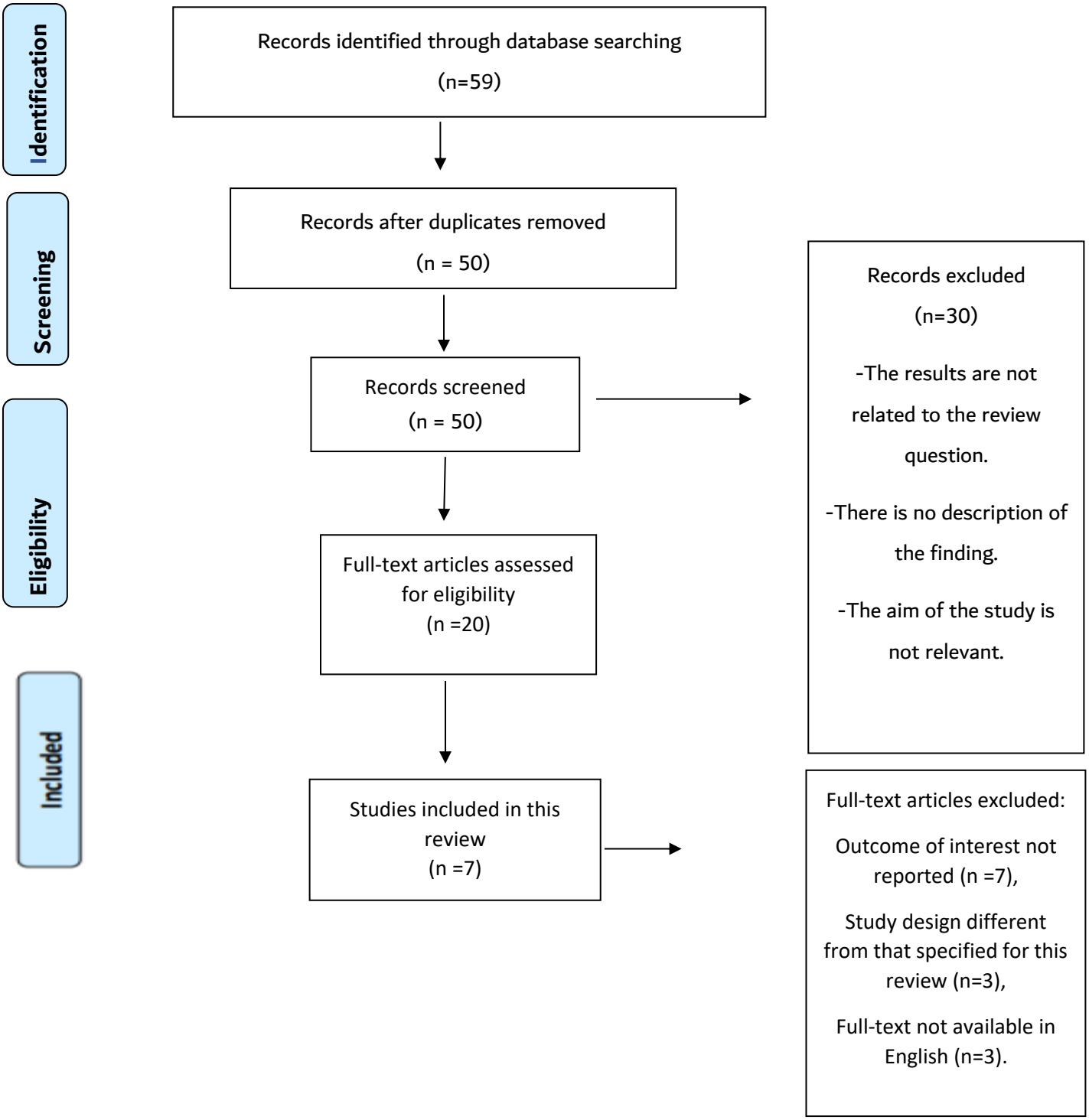
P	I	O
Infant*	Quick wee	Midstream
Child*	Bladder stimulation	None contaminated urine sample
Baby	Urine collection	Not infected urine sample
Non toilet	Clean Catch	Urine sample
Paediatric	Clean voided urine	
Pediatric	Best clean catch method	

2.4 Inclusion and Exclusion Criteria

Inclusion and exclusion criteria were established to determine which literature will be included in the review and which will be excluded. Inclusion and exclusion criteria were established after a studies question is confirmed. For included articles were eligible if they: only in English language publications, full text article, published between 2010 and 2020, the sample is children or infants needs CCU collection, qualitative, quantitative and not systematic review articles focusing on CCU technique in children, nontoilet trained child and infants who need urine collection.

Articles were excluded if they were in Spanish language, secondary article, the sample were adults, included methods such as catheterization and urine bag, and published before 2010. When selecting the relevant studies from the searches, first step done was screening the studies title and abstract and save it in folder, and the second step is looking again at the studies and reading the whole papers to decide which studies met the inclusion and exclusion criteria of the review. The final step is selecting the qualified studies based on relevant to the research question, recent year of publication, language, and sample. The information was collected from different articles in different databases and compared used to realize the evidence and if they agreed with the findings or not. PRISMA were used to help to record the number of published studies got from each database (See Figure1). PRISMA help to show value of the review and assess strengths and limitation of the study.

Figure1: PRISMA Research Flow Chart



2.5 Critiquing Articles and Appraisal

For critiquing the studies, Critical Appraisal Skills Programme (CASP) tool were used to assess quality of the articles and to find the weakness and the strength of them. A study of Long *et al*. (2020) defined the CASP tool as a common tool used to evaluate the strengths and limitations of the research methodology. The questions of the CASP tool are help researcher to know whether the studies' design appropriate and the findings are presented well and significant. The reason of choosing CASP tool because it is suitable to the studies in this review, and it is taken into consideration to be a good choice for a quantitative study and is recommended by Cochrane and the WHO and it is used with health-associated studies and became consequently deemed suitable for the context of this review (Long *et al*., 2020). Critical thinking used when evaluating the studies to see whether the results reliable, researcher opinions, the way of presenting the data, identifying proper research methods and design used in the study, and see whether the researcher conclusion are valid and built on good evidence and reasonable. Two CASP tools were used in this review, randomised CASP tool (See Table 2) and cohort CASP tool (See Table3), each tool was used depends on the study design.

Randomised Controlled Trials (RCT) CASP tool is considered to help to make sense of evidence from clinical trials. This is accomplished via a series of 11 questions that evaluate the validity, results, and applicability of an RCT (Abioye, 2013). The questions are divided into three sections, Section (A) about the validity of the results, Section (B) explore the results, and Section (C) about to see if the result can be applicable into the practice or not (CASP, 2018).

Davies' *et al.* (2008), Mamta' *et al.* (2019) and Altuntas' *et al.* (2015) are RCT studies included in this review, were conducted in different countries, England, Turkey, and Nepal. For critiquing these studies, RCT CASP tool was used because it is suit with the study design. Those three studies' had clearly addressed the targeted issue in their study which is evaluating CCU methods to collect urine sample for the non-toilet- trained child. The researchers assigned their study's participants randomly to the treatment which is the appropriate way in RCT study to minimise bias and not to affect the results. All the participants in the three randomised studies were treated equally. The quality of the studies was strong and can be applied in the practice. The results of the studies were presented clearly, they presented their data in a clear table. According to Fah (2006). Presenting data in tables are helpful to emphasize accurate statistical values, moreover tables are useful to summarise big number of data clearly and let differences to be identified between groups of variables.

TABLE 2: RANDOMIZED CRITIQUING APPRAISAL

	Davies et al. (2008).	**Altuntas et al. (2015).**	**Mamta et al. (2019).**
1-Did the trial address a clearly focused issue?	Yes	Yes	Yes
2-Was the assignment of patients to treatments randomised?	Yes	Yes	Yes
3- Were all of the patients who entered the trial properly accounted for at its conclusion?	No	Yes	Yes
4- Were patients, health workers and study personnel 'blind' to treatment?	Non blind	Non blind	Non blind
5- Were the groups similar at the start of the trial	Yes	Yes	No
6- Aside from the experimental intervention, were the groups treated equally?	Yes	Yes	Yes
7- How large was the treatment effect?	-Minutes to pass urine or leave department in advice and devise group P=0.20 - Percentage waiting for less than 1 h P=0.15	-The success rate in collecting urine samples was significantly higher in the Experimental Group than in the Control Group (p<0.0001). - The median time for sample collection	- The success rate of urine collection was significantly higher in the Experimental Group than in the Control Group p<0.001. - There was significant difference

	- Number leaving without a sample P=0.27	was 60 s (64.5 s) in the Experimental Group and 300 s (95 s) in the Control Group (p<0.001). - There was no statistical difference in gestational age (p 0.719), birth weight (p 0.413), postnatal age (p 0.165), and gender (p 0.933) between the Experimental Group and the Control Group.	in the sample collection time in two genders in the Experimental Group (p=0.008)
8- How precise was the estimate of the treatment effect?	95% CI used	Can't till (No CI limits)	Can't till (No CI limits)
9- Can the results be applied to the local population, or in your context?	Yes	Yes	Yes
10- Were all clinically important outcomes considered?	Yes	Yes	Yes
11- Are the benefits worth the harms and costs?	No benefit	Yes	Yes

Additionally, the other four studies included in this review were cohort studies conducted by Labrosse' *et al.* (2016), Kumar' *et al.* (2019), Fernández' *et al.* (2013), and Crombie' *et al.* (2020). The studies covered in different countries, India, Canada, and Spain. Particularly, cohort research recruit and observe participants who share a common characteristic, including a particular occupation or demographic similarity. A study of Barrett and Noble (2019) reported that several cohorts can be exposed to a particular chance element or characteristic; through measuring outcomes, then discover the effect of this variable. There are several advantages of using cohort study. Barrett and Noble (2019) highlighted that using cohort study helps in testing the cause and effect relationship between the variables, it also take long time to conduct the study which helps in gathering more data. In regard to science and health, cohort study helps in identifying the risk factors and diseases. However, gathering prospective data on large number of participants over many years is complicated, but none of the included studies for the review take longitudinal. Cohort study is expensive, participants may withdraw, and this will increase the risk of bias. The evaluation of statistics from those massive-scale research is likewise complex, with large numbers of confounding variables making it tough to link cause and effect (Barrett & Noble 2019).

To critique these articles, cohort CASP tool were used because it is appropriate to the study design. It has 12 questions enable to make sense of a Cohort Study. These questions are divided into three sections to consider the issue of the cohort. Section (A) about the validity of the study results, Section (B) about describing the results, and Section (C) to consider if the results are help locally or not (CASP, 2018).

The studies of Labrosse *et al*. (2016), Kumar *et al*. (2019), Fernández *et al*. (2013), and Crombie *et al*. (2020) clearly addressed the main issue of the study, the groups of the participants being studied and shows how many of the people asked to take part in the study. The follow up of the participants were not applicable in the study. The results of the study were clearly addressed, the researcher showed the finding of the timing of the collection, the successful rate of the technique and the contamination rate.

TABLE 3: COHORT CRITIQUING APPRAISAL

	Labrosse et al. (2016)	Kumar et al. (2019)	Fernández et al. (2013)	Crombie et al. (2020)
1- Did the study address a clearly focused issue?	Yes	Yes	Yes	Yes
2- Was the cohort recruited in an acceptable way?	Yes	Yes	Yes	Yes
3- Was the exposure accurately measured to minimise bias?	No	No	No	No
4- Was the outcome accurately measured to minimise bias?	Yes	Yes	Yes	Yes
5(a)- Have the authors identified all important confounding factors?	No	No	No	No
5(b)- Have they taken account of the confounding factors in the design and/or analysis?	No	No	No	No .
6(a)- Was the follow up of subjects complete enough?	No	No	No	No
6-b) Was the follow up of subjects long enough?	Not applicable	Not applicable	Not applicable	Not applicable
7(a)-What are the results of this study? And whether there is contamination or not?	- Clean Catch procedure was successful in 61% of infants aged 0 to 29 days, 54% of children aged 30–	The success rate of urine collection was 90% (108 of 120) which was found to	-The success rate for collecting the sample was 86% (n=69/80).	-62.6% of infants voided with bladder stimulation, urine

	59 days, 62% of children aged 60 to 89 days, and 26% of children aged 91–180 days. - Age group was (P< .001). -The contamination rate was 16%, 95% CI: 8%–27%) in the clean catch group compared with 4 of 62 (6%, 95% CI: 3–15) in the invasive method group. -Clean Catch Urine sample group looked lower than in the uncontaminated group (3 of 9 [33%] and 32 of 48 [67%].	be statistically significant p=0.05	-There are no statistically differences with sex were found in success rate, and time of sample collection.	collection was successful in 53.1%. -14 infants voided with unsuccessful midstream urine collection. -78 infants with successful urine collection (50%) had contaminated sample. -Age and sex were found to be significant predictors of success. -The majority of contaminated sample were reported as "no significant growth" or "growth of 3 or more organisms" (79.5%).
7(b)- What is the timing of the production of a urine sample	-52% of infants provided a urine sample within 5 minutes of stimulation procedure. - 4 samples were failed; the reason is because of (3) inadequate urine amount to accept urinalysis and culture and (1) because stool presence in the sample, leaving 62 (49%; 95% CI: 40%– 58%) successful procedures with a median time of 45	The mean time to collect urine was 64.24sec, while for males it was 62.55sec and for females 65.93sec, which were statistically the same. The mean time p=0.664	-The mean time for sample collection was 57 s (SD 48.6). The mean time spent collecting the sample in males was 60.48 s, median 55 s and IQR 30 s. For females, the mean time was 52.04 s, median 30 s and IQR 30 s.	The median time for full protocol completion was 32 minutes (IQR, 25–41 minutes) in all patients. For the 78 infants with successful midstream urine collection time was 45 seconds (IQR, 20–120 seconds).

	seconds (first quartile 14 seconds and third quartile 158 seconds.			
8-How precise are the results?	The contamination percentage was 16%, 95% CI: 8%–27%) in the clean catch group compared with 6%, 95% CI: 3–15 in the invasive method group.	Authors expected significance at the 5% level ($p<0.05$)	95% CI used	95% CI used
9- Do you believe the results?	Yes	Yes	Yes	Yes
10- Can the results be applied to the local population?	Yes	Yes	No	No
11- Do the results of this study fit with other available evidence?	Yes	Yes	Yes	Yes
12- What are the implications of this study for practice?	Bladder stimulation technique is effective to obtain clean catch urine sample for infants in short time	The technique has been established to be easy, safe, quick, and effective with good success rate for children.	The technique has a high success rate and a mean time for passing urine of less than 1 min.	The finding was safe, easy, and effective method for noninvasively urine collection in this age group and could be a massive move in the pursuit of an ED experience.

Chapter Three – Results

3.1 Introduction

The study design of the articles included in the review was quantitative studies. Three of the articles were randomised controlled trials, four were cohort studies, and one study was cross-sectional. This section will explain the findings of the randomised controlled trials studies and cohort studies.

3.2 Assignment of Patients to the Treatments

The three studies of Davies' *et al.* (2008), Mamta' *et al.* (2019) and Altuntas' *et al.* (2015) were randomly assigned the patients to the treatment in different ways. Davies *et al.* (2008) and Mamta *et al.* (2019) used envelopes into two equal groups after they signed the consent form to see in which group, they will be allocated for the treatment.

In Mamta *et al.* (2019) study, consecutive numbers were given to the 54 participants (n=27were in the experimental group were and n=27 in control group) on admission to the hospital. Randomization list was created to generate two parallel groups (1:1 ratio), with the help of a software program. The numbers were written in a sealed envelope and the parents or nurse will take one envelope to see in which group the infant will be allocated. Envelopes can be used as a strong method of allocation concealment. If they are used in a research design, they should be created rigorous and reported clearly ensuring all necessary methodological information is included (Clark *et al.*, 2021). Davies *et al.* (2008) also used sealed opaque envelopes in his study into two equal groups, device and advice group. The advice group have been given a sheet contains of details about the methods of stimulating urine with the aid of using massage, tapping the stomach, and supplying drinks.

However, in the “device” group have been shown a way to function the stimulator and advised to apply this for 1 min out of each 5, in addition supplying drinks to them.

The way of using sealed, opaque envelopes were an appropriate in RCT study because it means that the participants does not know which treatment allocation will be, they cannot see what is inside the envelopes and they can’t open it. It is important because it prevents selection bias (Schulz, 2001). Because the participants in Davies’ and Mamta’ studies are children so the researcher, examiner, or parents are the one who will open the envelopes to know which treatment will be given to each infant.

Altuntas’ *et al.* (2015) used consecutive numbers to the participants on admission. The numbers were randomly assigned to the participants in balanced blocks of 10 by using a random software program, and the infants were divided into two groups, the experimental group (EG) and the control group (CG). Nurses and physicians were needed to perform the technique in the EG.

3.3 Loss of Participants During the Study

According to Bankhead (2017) attrition happens when participants leave during a study, and it can cause bias into a study’s results. In Davies *et al.* (2008) study the patients who enrolled the trial were not accounted for its conclusion and they did not mentioned what happened to the others participants. Data from 110 patients in Davies *et al.* (2008) were randomised in the study, and they found only 97 valid data points, 48 infants were in advice group and, 49 in device group. The researchers did not explain whether the participants either they withdraw from the study, or they had excluded them.

Mamta *et al.* (2019), and Altuntas *et al.* (2015) participants were properly accounted to the final study and the researcher explained the excluded patients with a reason. The participants in Altuntas *et al.* (2015) study are hundred and forty neonates (140) in hospital between August 2013 and December 2013 were assessed as appropriate for the study. The researcher mentioned that six neonates were excluded because of dehydration (n=3) or low oral intake (n=3), and seven mothers refused to participate in the study. 127 neonates remain in the study, and they were randomly allocated to either EG (n=63) or CG (n=64). Mamta *et al.* (2019), had a total of 54 neonates in the study, random allocated 27 infants in EG and 27 were in CG. 4 were excluded because of not meet the inclusion criteria and parents refuse to participate.

3.4 Were patients, health workers and study personnel 'blind' to treatment

A study of Adhikari (2021) described that blinding in research means the study population and researcher who participating in research are not allowed from knowing the treatment, which may affect the study findings, reduce bias, increases validity of the results, and improves the reliability of clinical research results. In Misra (2012) study mentioned the three types of blinding. Single blind is when either the patient is blind or an investigator, and it is usually, the participant is blinded and is unaware of what treatment will receive. Second type is double blind, when the patient and the investigator are blind to the treatment and the researcher not aware who receive the treatment. Third type is triple blind, when the patient, researcher and data analyser are blind (Misra, 2012)

In Davies *et al.* (2008), Mamta *et al.* (2019), and Altuntas *et al.* (2015) studies they were mentioned that the patients were non blinded to the treatment. According to Karanicolas (2010) if individuals aren't blinded, understanding of group assignment may also influence their behaviour in the trial and their responses to subjective results measures. This does not really apply to infants in this review because they are not aware about the study and the treatment. The researchers not mentioned if they itself were blinded to the treatment and if the staff and parents who did the stimulation to the infants' studies were blinded also. It would not be possible to blind the people doing the clean catch.

3.5 Factors Might Affect the Outcome of the Group

The groups of the participants of Davies *et al.* (2008) and Atuntas *et al.* (2015) study were similar at the start of the trials. However, it is different in Mamta *et al.* (2019), there was significant difference in the gender participants in the CG and EG (p=0.04). In CG was 59.5% of the new-borns were male and common 70.6% of new-borns were males in the EG. In Davies *et al.* (2008) study there were no significant difference between the sex in advice and device group (P= 0.25). Additionally, there were no difference between age group in advice and device group (P=0.98). In Atuntas *et al.* (2015) study there were no significant difference between Gestational week (P=0.719), birth weight (P= 0.413), gender (P= 0.933), and Postnatal age (P= 0.165) in control group and experimental group.

3.6 Intervention of the Groups

The groups were treated equally in the following three studies of Davies *et al.* (2008), Mamta *et al.* (2019), and Altuntas *et al.* (2015). In Altuntas *et al.* (2015) study bladder stimulation and lumbar paravertebral massage manoeuvres were applied to the babies in the EG only by three nurses or physicians. While the new-borns in the CG were held under the axillae with legs dangling until they pass urine. New-borns in both groups were fed with formula or breast milk pumped, according to their age and weight. After Twenty-five minutes of feeding, both groups of the new-borns received non-pharmacological analgesia (non-nutritive sucking or 2 % sucrose syrup). In Mamta *et al.* (2019) study new-borns in EG and CG were given breast-fed, or formula fed. The stimulation technique was applied in the EG though in the CG the new-borns were just held with their legs hanging for 5mins. This intervention was similar to Altuntas *et al.* (2015) study. In Davies *et al.* (2008) study both groups were offering them drinks. The advice group were given a sheet describing methods of stimulating urine by massage, tapping the abdomen. And the device group were shown how to operate vibrating bladder stimulator and advised to use this for 1 min out of every 5.

3.7 Effectiveness of the Length of Time Taken to Produce a Urine Sample

According to the affective of the treatment, in Altuntas *et al.* (2015) and Mamta *et al.* (2019) studies the treatment was success in both groups. Altuntas *et al.* (2015) the success rate in collecting urine samples was significantly higher in the EG than in the CG ($p<0.001$), and the median time (IQR) for the collection was 60 s (64.5 s) in the EG and 300 s (95 s) in the CG ($p<0.001$). In Mamta *et al.* (2019) study the effective of the bladder stimulation method for collection of urine sample in new-borns showed the success rate. It was

significantly higher in the EG (88.9%) than in the CG (25.9%), (p<0.001). Davies *et al.* (2008) study showed the treatment was not success, boys had no difference in the average time to pass urine (1 h 2 min) to girls (1 h 4 min). There was a non-significant to earlier urine production in younger children (2 min 14 s slower per month of additional age), 80% passed urine in under 2 h.

3.8 Clinically Important Outcomes

The clinical outcomes should be considered if it is beneficial to the patients, so in Altuntas *et al.* (2015) and Mamta *et al.* (2019) outcomes were benefits, because the success rate of passing urine was high and there was difference in the age and gender groups. In Mamta *et al.* (2019) there was significant difference in the sample collection time in two genders in the EG (p=0.008). In males the median sample collection time was 1.52mins, while it was 1.02mins in females in CG. In Altuntas *et al.* (2015) showed the success rate in obtaining urine samples 76 % in females, 80 % males (p 0.767) in the EG and 32 % females, 33 % males (p 0.999) in the CG. However, in Daviese *et al.* (2008) study have no benefit from the outcomes because all the group were similar when passing the urine (P= 0.20).

3.9 Cohort Studies' Findings

On the other hand, here will explain the findings of the four cohort studies of Crombie *et al.* (2020), Fernández *et al.* (2013), Kumar *et al.* (2019), and Labrosse *et al.* (2016).

3.10 Inclusion and Exclusion

According to the inclusion and exclusion criteria, all the researchers of this review explained clearly the included and excluded participants in their studies. Crombie *et al.* (2020), Fernández *et al.* (2013), Kumar *et al.* (2019), and Labrosse *et al.* (2016) included infants who needs urinalysis according to the doctor order. In terms of the exclusion criteria, most of the criteria were same in each study. Crombie *et al.* (2020) excludes critically ill patients with Pediatric Canadian Triage Acuity Scale Level, dehydrated child, having feeding issues for example suspected pyloric stenosis, experiencing injury or infection over bladder stimulation site, and if they previously participated in the other studies. Fernández *et al.* (2013) and Kumar *et al.* (2019) have the same exclusion criteria. They excluded poor feeding patients, and dehydration, however, Fernández *et al.* (2013) exclude patients who needs urgent sterile urine sample by an invasive method, having any clinical condition, and patients who had drug administration before urine collection. Labrosse *et al.* (2016) excluded infants with a medical illness that unable to find a clean catch sample such as infants with urostomy, absence of parental authority, and hemodynamic instability.

3.11 Bias in the Studies

According to Pannucci *et al.* (2010) biases can be found in all stages of research, and they are large in their types. Pannucci *et al.* (2010) defined bias as a process when there is systematic error investigation to arrive at certain outcomes and sampling, it can happen in different phases of the study, and it occurs in the study design, data collection, data analysis and publication. Bias can arise withinside the planning, data collection, analysis, and publication stages of studies. Understanding studies bias lets in readers to overview the scientific literature critically and independently and keep away from treatments which might be suboptimal or harmful. Additionally, understanding of bias and the way it influences study results is important for the practice of evidence-based medicine Types of the research bias are design bias, selection, or participant' bias, publication bias, procedural bias, and Interviewer bias (Pannucci *et al.*, 2010).

3.11.1 Design bias

Design bias it occurs when the research design, survey questions, and research method is affected by the researcher rather than what works best for the research context (Pannucci *et al.*, 2010). In many cases, poor studies design, or a group of synergy among the specific contributing variables on the systematic research can cause bias into the studies process. Research bias additionally takes place while the personal reviews of the researcher affect the selection of the studies question and methodology. Blinding the researcher to the patient's exposure and final results status, or if it can not happen, having different examiners to measure the outcome than individuals who evaluated the exposure, also can lower bias. To keep away from having study design bias is to clearly outline risk and

outcome, ideally with goal or confirmed methods, and standardize and blind data collection (Pannucci *et al.,* 2010).

3.11.2 Selection/Participants bias

According to study of Smith and Noble (2014) selection or participants bias pertains to each method of recruiting members and examine inclusion criteria of the study. Successful studies start with recruiting individuals that meet the research aims. For instance, recruitment bias should arise if members had been invited to take part in a survey published at the internet, which automatically excludes people without internet access. Inclusion bias in quantitative studies usually relates to choosing members that are representative of the study population, and wherein relevant allocation of members to make sure similarity among evaluation groups (Smith &Noble, 2014). In addition, accounting for the variations among those who stay in a study and people who withdraw can be essential in a few study designs. To avoid participants bias, select participants using precise criteria to avoid confounding results, participants should be from the same general population, well designed, prospective studies help to avoid selection bias as outcome is unknown at time of enrolment (Pannucci *et al.,* 2010).

3.11.3 Publication Bias

Publication bias is occurring in peer-reviewed journals and different published educational papers. This bias is regularly imposed on them by the guide standards for studies papers in a specific field. Researchers work their papers to satisfy those standards and may ignore information or techniques that aren't in step with them (Pannucci *et al.,* 2010). Smith and Noble (2014) stated that published research have a few degrees of bias, in

quantitative research, studies are much more likely to be posted if reporting statistically significant findings, and non-publication in qualitative research is much more likely to arise due to a loss of depth while describing study methodologies and findings are not actually presented.

3.11.4 Procedural bias

Allen (2016) mentioned that procedural is a type of studies bias that takes place while the participants in a study aren't given sufficient time to finish surveys or the questionnaire. Insufficient time to answer survey can lead to larger amounts of missing data of the questions, decreased variability in answers the questions, shorter responses to open-ended questions, and shorter response times. Sahlqvis *et al.* (2011) stated the length of the questionnaire has been determined to impact the response. Response rates lower when the period of the questionnaire take long time. The final result is that respondents end with incomplete information that doesn't offer a real illustration in their mind. When asking participants to finish a survey fast to get right of entry to an incentive, can also pressure them to fill in fake information to get things over with (Pannucci *et al.,* 2010).

3.11.5 Interviewer Bias

The last common type of the bias is Interviewer bias. It refers to a systematic difference among how information is requested, recorded, or interpreted. Interviewer bias is much more likely while disease status is understood to interviewer. Interviewer bias may be minimized or removed if the interviewer is blinded to the final results of interest or if the final results has not happened, as in a prospective trial (Pannucci *et al.,* 2010).

There were no known types of bias in Crombie *et al.* (2020), Fernández *et al.* (2013), Kumar *et al.* (2019), and Labrosse *et al.* (2016) studies. None of the studies lose their participants or participants refuse to take a part in the study, the researchers already know the inclusion and exclusion criteria before they begin the study, they also give the participants enough time to complete questions. However, in the intervention of the study, the researchers didn't measure the exposure. All the studies' mentioned that they are doing the bladder stimulation, tapping and massage for the children but without measuring the power of the tapping, if they tap strongly for all infants or softly for some and the other have strong tapping. Moreover, the researchers did not explained if they used the same tapping technique in all children, such as if they tap In a circular motion, or in which abdomen region they have tapping. This can cause bias in the treatment because the child who got effective tapping and massage can pass urine while the other child who receive tapping and massage also but not on the same strength will not pass urine.

3.12 Confounding Factors in the Studies

A study of Skelly (2012) reported the purpose of confounding variables is they are the ones that could compete with the treatment in explaining the results of the study, and they offer a greater suitable estimate of the true association that is because of the exposure. Pourhoseingholi *et al.* (2012) stated the existence of confounding variables in research makes it hard to set up a clean causal link among treatment and results until suitable strategies are used to regulate for the impact of the confounders. A confounder is an extraneous variable whose presence impacts the variables being studied in order that the results do now no longer replicate the real relationship among the variables in the study (Pourhoseingholi *et al.,* 2012). In this review, the confounding factors that could impact

passing urine in children are child with high fever, crying and moving, dehydrated child, the timing of last feeding, poor feeding, and gender. None of these factors were addressed in cohort and randomised controlled studies.

3.13 Data Analysis of RCT and Cohort Studies

According to the precision of the results in cohort studies of Labrosse *et al.* (2016), Fernández *et al.* (2013), and Crombie *et al.* (2020) studies they used CI 95%, however Kumar *et al.* (2019) set p= 0.05 as the level of significance.

Salkind (2010) defined the confident of interval (CI) shows the improves if the size of the sample is enough and if results came from the intervention or randomly, the narrowest the CI the greater can be the understanding that the sample represents the population. Moreover, the size of the sample and the CI, the "p" value allows outline the precision of the results of the study (Salkind, 2010). On the other hand, Davies *et al.* (2008) used CI 95% for the minutes to pass urine however, on Altuntas *et al.* (2015) and Mamta *et al.* (2019) study can not till the precising because no CI limits showed in their studies. The term precision refers to how exactly an object of study is measured and the degree to which numerous measurements of the same item show the equal or comparable results (Salkind, 2010). Kara-Junior (2014) defined P value signifies the opportunity of the variations among the results found randomly and now no longer because of the intervention. In general, one considers the value of p< 5% or 0.05, so the risk of the effects not being actual is minimum, much less than a risk amongst 20 results.

3.14 The Successful Rate of the Bladder Stimulation in Cohort Studies

Regarding to the results, all the studies showed a successful rate of urine collection but in different percentage. All four cohort studies have the same intervention, they do bladder stimulation manoeuvre and provide feeding for the baby before doing the stimulation. All infants in the cohort studies were carried under the axillae with their legs dangling in a standing-like position. Then two investigators either a nurse or physician were doing bladder stimulation by gently finger tapping on the lower abdomen just above the pubic symphysis at a frequency of 100 taps/minute. In Crombie *et al.* (2020) study showed ninety-two infants from 147 infants voided with bladder stimulation (62.6%), urine collection was successful in 78 of them (53.1%, 95% CI 45–60.9). Between these 78 infants, 39 of them had contaminated specimens, (50%, 95% CI, 39.2–60.8%). Males had a higher percentage of midstream urine collection than females. 14 infants voided with unsuccessful midstream urine collection, three patients given insufficient volume of urine and the staff were unable to collect an adequate amount of urine. In addition, the successful rate of urine collection in Fernández *et al.* (2013) study showed that there was 86% success rate in urine collection. Labrosse *et al.* (2016) and Kumar *et al.* (2019) showed the success rate in urine collection which was found to be statistically significant. The success rate in Kumar et al. (2019) study was 90% (p=0.05). Additionally, Labrosse *et al.* (2016) showed that CCU method was successful in 61% of infants aged 0 to 29 days, 54% of children aged 30–59 days, 62% of children aged 60 to 89 days, and 26% of children aged 91–180 days. Age group was success (P < .001). When compared with the group of children aged >89 days, age groups 0 to 29 days, 30 to 59 days, and 60 to 89 days were all statistically

associated with a higher proportion of success. According to Fernández *et al.* (2013) and Crombie *et al.* (2020) findings, it presented that the intervention had no benefits for the infants, because there is no significant difference in technique between the infants' group. However, the findings in Labrosse *et al.* (2016) and Kumar *et al.* (2019) study can be applying to the practice because the finding in Labrosse *et al.* (2016) showed that there is a success rate of urine sample in age group (P< .001), and Kumar *et al.* (2019) showed there is success rate was found to be statistically significant.in 90% infants, which mean that the stimulation mauver is successful for the infants.

3.15 Timing of the Bladder Stimulation

According to the time of passing urine after the intervention in Crombie *et al.* (2020) from 78 infants with successful midstream urine collection, the median bladder stimulation time was 45 seconds (IQR, 20–120 seconds). However, in Fernández *et al.* (2013) study the mean time for sample collection was 57 s (SD 48.6), median 45 s which similar time spent in Crombie *et al.* (2020) study and IQR 30 s. In addition, the mean time spent in collecting the urine sample in males in Fernández *et al.* (2013) study was 60.48s while in Kumar et al. (2019) study males were 62.55 s, and for the females, the mean time was 52.04s while in Kumar *et al.* (2019) study the female spent more time 65.93s. There is no statistically differences regarding sex were found in success rate and time of sample collection in Kumar *et al.* (2019) and Fernández *et al.* (2013) study. Labrosse *et al.* (2016) showed 52% of infants provided a urine sample within 5 minutes of stimulation procedure.

Chapter Four- Discussion

4.1 Introduction

Annesley (2010) stated the purpose of the discussion is to interpret and clarify the importance of the findings in the topic being examined and to explain any new information or insights that occurred because of the review question. The discussion will usually help researcher of using way of the studies questions or hypotheses posed and the literature reviewed. The discussion clearly explains how the study advanced the reader's information of the studies problem from wherein left them on the end of the review of earlier studies'

The purpose of this review is to explore at the best technique of urine collection by CCU from nontoilet infant/child without contamination. This review critically reviewed seven empirical studies published in English language from 2010 to 2020. This chapter will show the summary of the main findings of the studies and will support it with other evidence. The studies included in this review were randomized controlled trials and cohort studies. Evaluation and analysis of those papers determined that bladder stimulation through different technique is a successful technique to accumulate urine sample from children through CCU. The main key outcomes from the studies were the contamination rate in the urine sample of the infants, the mean time consuming to collect urine sample, and the successful rate of urine collection from the bladder stimulation. There were a few limitations and a few advantages about the techniques found in those papers will be mentioned on this section.

4.2 Best Practice To collect Urine Sample in Children

In study of Frazee *et al.* (2012) showed the barriers to collect proper urine sample include not training the nurses on how to collect sample in appropriate way, poor instructions, poor understanding of instructions by patients due to a language barrier and their age, lack of ability of the patient to perform the instructions.

The study of Gallagher (2018) reported that the aseptic technique is a strategy to avoid contamination from body sites or from specimens This technique is connected to some of nursing skills, which include the collection of patient samples, and essential to the delivery of quality care because if it's undertaken incorrectly, the affected person might also go through negative results including contamination or faulty laboratory results. Furthermore, Gallagher (2018) showed the need to avoid contamination of specimens is important, a specimen received on the laboratory in inappropriate way of collection could have severe implications for patient care, diagnosis, and treatment. The quality of a specimen is very important to be considered when collecting it, the technique of collection and hygiene, the timing to send sample to the lab, explaining the purpose of collection, identification of the patient, and setting of collection, (Gallagher, 2018).

Gallagher (2018) described the prober steps of specimen collection. The first step of any specimens collection is to introduce self to the patients, explain the procedure and the purpose of doing the collection, and take their consent Informed consent cannot always be taken if the patient is a child or has impaired cognitive ability, but even in this situation the nurse should try to explain the procedure in ways that the patient can understand. This is not only for the human rights, but also helps to ensure that patient will be accepting the

treatment and that their anxieties will reduce. The second step of collection is to ensure the appropriate time to collect the specimen. The timing and mode of collecting of the urine sample affect the assessment of haematuria, proteinuria, leukocyturia, nitrituria, and the uropathogenic bacterial colony count in the urine culture (Utsch *et al.,* 2016). The quality of the sample can be altered by the time of collection and length of time before it goes to the laboratory (Gallagher, 2018).The best practice in this case to make sure that the sample reaches the laboratory immediately once it has been collected from the patient. It is good quality to collect a urine sample from the first voided urine in the morning for mycobacterial culture as this will contain the highest concentration of bacteria present. This means that the result will be reliable to consider if the patient has infection or not (Gallagher, 2018). The third step is to make a sufficient place in the area of the specimen collection to enable clear access for the patient and the nurse to safely use the equipment required and to reduce risk of contamination sample. Fourth step is applying standard precautions. Wearing personal protective equipment (PPE) which is a standard infection-control procedure when there is contact with body fluids. Ensure to use gloves and disposable aprons while collecting the sample to reduce risk of contamination (Gallagher, 2018). Fifth step is to keep patient in a private room and keep them in comfortable and appropriate position and surroundings. Maintain patient privacy, respect, and comfort to ensure their comfort and reduce anxiety (Gallagher, 2018). Sixth step is to be aware that microbiological investigation should be collected before patient receive the antibiotic treatment, this may influence on detection of the bacteria.

The role of the nurse to inform the laboratory of all therapy the patient is receiving or has recently taken (Gallagher, 2018). Best practice in cleaning when collecting sample is avoid contamination. Contaminated sample is also related to the gender. Many studies conducted to evaluate contamination rate in the urine sample showed that there is significant difference between male and female. In Selek *et al.* (2017) study reported contamination rates in 26.5% of female patient and 16.4% in male patients.

Reported preparation prior to taking the sample is cleaning the genital area of the patient. It is important in urine collection to clean the genital area before collecting the sample because of the possibility to contaminate the urine with bacteria from the surrounding skin during collection. Start first by hand hygiene, then for female need to unfold the labia of the vagina and clean from the front to lower back by using of a wipe supplied from the healthcare practitioner or the laboratory. For the male, it should wipe the tip of the penis (Selek et al., 2017). Study of Selek *et al.* (2017) aimed to assess the effect of urogenital cleansing by using chlorhexidine cleansing wipes containing genital region on contamination rates, they examined two groups, EG and CG. The patients on EG used chlorhexidine cleansing wipes to clean the genital area, and on the CG used only water to clean the genital area. There was significant difference in contamination rate (P= 0.0001). The contamination rate on CG was higher (15.8%) than in EG (7.7%). Another study evaluated the effective of the cleaning the genital area before collecting urine sample by Shrestha *et al.* (2013), the researchers divided patients into three groups. First group was collected midstream urine sample with cleaning the genital area with paper soap, the second group was collected midstream urine sample with cleaning the genital area with water only, and the third group was informed to collect only the urine without cleaning the genital area.

There was statistical difference in the three groups (P<0.05). The contamination rate in first group was 6%, second group was 13% and the last group was 27.5%.

A study conducted by Vaillancourt *et al.* (2007), aimed to evaluate the effect of genital cleaning on bacterial contamination rates of midstream urine collections. The result showed that children who were randomly assigned to clean their genital area were having a low contamination urinalysis (20.6%) than those in the none-cleaning group (36.8%). Urine contamination rates are developed in midstream urine when collected without genital cleaning. The study showed that cleaning the genital area decrease the risk for repeating urine cultures and for receiving needless antibiotic treatment and investigations (Vaillancourt *et al.,* 2007).

According to the above studies stated that the best ways to clean the genital area for the patients before collecting the urine sample were hand hygiene, using chlorhexidine wipe and paper soap. The results showed that the researchers who used this practice to the patients, the contamination rate showed less than those who were not clean the genital area or clean in it by water only.

4.3 Contamination Rate in the Urine Sample Collection

Selek *et al.* (2017) and Shrestha *et al.* (2013) addressed the issues of this study review regarding to the contamination rate in the urine sample of children. Contamination is probable if bacteria grow in urinary cultures. Sample describes as contaminated if they contain with mixed flora, skin flora, vaginal flora, or multiple isolates. A study of Mary (2019) reported that most microbiology laboratories use a urine contamination of equal to or higher than (≥)10,000 CFU/mL, with ≥ 2 isolate.

Contaminated samples occurs when microorganism that comes from the skin or genital area, and no longer from the urinary tract (Mary, 2019). This is frequently defined by the scientific laboratory as 'mixed growth bacteria (Lough, 2019). Study of Hay (2016) showed that the most common sources of infection in urine from younger child are faeces and skin, and the common faecal organisms are E. coli and enterococci and might be represented highly in contaminated urines; however, E. coli is also the most common reason of UTI In this case when the patient' urine sample result showed contamination, this will not expect to diagnosed the patient with UTI because E.coli is the cause of UTI, the contamination expect from the skin and the procedure of collection.

Crombie, Labrosse, Mamta, and Altuntas' studies reported contamination in the urine sample collection during the study conducted. From 78 infants, 39 (50%) had contaminated sample in Crombie *et al.* (2020) study. The contamination was possibly caused by the stimulation technique applied by the investigators during the study. The bladder stimulation was applied by the nurses and the physician, and they were tapping and doing the massage in the lower abdomen of the infants. There was no evidence mentioned by the researchers if the investigators were wearing gloves, or they were doing hand hygiene before the procedure. According to NICE (2017) a lack of hygiene might lead to contamination. Additionally, the study stated that after 45 second of the stimulation, some infants pass urine, so in this short time there were no evidence if the investigators had a chance to wash their hand after the stimulation and prepared a sterile sample container or if the infants were in a good position which enable them to not touch the infant's skin while they are collecting the sample. Other reason of having low percentage in contamination sample found result of the cleaning resources used in the study for sterilization, the investigator used soap

and water 0.05% chlorhexidine and the way of using the contamination criteria (Crombie *et al.,* 2020). Chlorhexidine is the best practice used in killing large number of bacteria (Ben-Knaz-Wakshlak *et al.,* 2019).

Labrosse *et al.* (2016) reported that the most contaminated specimens were stated in the study were no significant growth or growth of 3 or more organisms. From 119 sample, there were 13 contaminated (11%). Contamination rate was 9 of 57 in the clean catch group compared with 4 of 62 in the invasive method group. The reason in reports of contamination for standard CCU samples in infants in this study is because of differences in collection techniques, and the parents were the one who held infants under their armpits, and they may they were not aware about the infection control. There was no evidence to support this reason to evaluate the impact of parents when they involved with their child in the research study and if they need practice about the infection control before conducted the study or not. The evidence was only about the guidelines for the nurses to collect sample in sterile ways. The other reason of why in Labrosse's study the contamination rate was higher than in Crombie study is because the urine in Labrosse' study was immediately sent to the laboratory, and the samples were incubated for an 18- to 48-hour period. There is evidence stated by Delanghe (2014) that an expanded time among sampling and analysis, a loss of temperature control and a loss of addition of a preservative to samples for which urinalysis can't be carried out within hours of collection, will decrease the quality of urinary test results. Hoppin *et al.* (2006) described ways to prevent bacterial growth in the urine sample is includes putting the urine samples on ice or use of preservatives, which was in Labrosse' study when the investigator stored the sample after the collection, timely sample shipment usually involves sample receipt within 24 hours of collection.

Altuntas *et al.* (2015) detected contamination in samples between 14% and 24% depending on the cut-off values for contamination. This low contamination rate was because of the evidence that investigators collected the clean catch samples in sterile wide-mouth containers, which is helping to not touch the genital area of the infants, also they sent the sample immediately to the microbiology laboratory and they were not delayed. In Mamta *et al.* (2019) showed 1.9% contamination rate was found in the whole study group and not found in the urine samples collected by bladder lumper stimulation technique in the EG. However, 3.70% sample (one urine sample) was contaminated in the CG. The reason of having high contamination rate in CG rather than in EG is because in CG the new-borns were just held for 5mins, so in this case because the time of standing and holding the infants cause stress to the infants and they were crying and moving, and their skin will touch the container of the sample and cause the contamination. On the other hand, in EG the investigator stimulates the bladder by gently tapping the suprapubic area at a frequency of 100 taps per minute for 30 seconds and they repeated until micturition begins, and the urine sample was caught in sterile container. This technique is a result of less contaminated in the experimental group. Moreover, another study conducted by Kaufman (2017) aimed to determine whether gentle suprapubic cutaneous stimulation with cold fluid-soaked gauze can increase the rate of voiding for CCU within 5 min in young pre-continent children. The study conducted in 354 infants aged from 1 to 12 months who needs urine sample collection, it showed the contaminated rate in the clean catch technique was (45%) compared with the quick-wee method (27%). The variance in contamination between quick-wee method and CCU was not significant (P=0.29). The reason of having no significant in both group is because not all participants had a urine sample processed for culture Kaufman

(2017). These evidence of still having contaminated urine sample in the studies of collection urine sample from the infants, the most common reason is because of not applying the proper washing and cleaning of the genital area of the infants. Another study conducted by Herreros *et al.* (2015) supported that there is a contamination of the clean catch urine sample in infants. The study aimed to assess the accuracy of diagnosing urinary tract infections using a new standardized clean-catch collection technique. A Cross-sectional study conducted in infants less than 90 days old admitted to the hospital because of having fever without a source. Two different methods were used, CCU standardized stimulation technique and bladder catheterization. The contamination rate of CCU samples was (5%) and (8%) in catheter method. This low percentage in the methods because there was evidence reported in the study that the investigators avoiding handling the urethra and the immediately of finding the sample. Hold the sample container away from child's skin when collecting the urine sample is important to reduce contaminating urine sample with bacteria from child's skin (Kaufman, 2019). Properly managing the factors affecting the preanalytical phase of urine culture impacts significantly to the culture results that eventually affect patient diagnosis and management. Urine culture contamination can be reduced with appropriate techniques for urine collection, protection, storage, and transport (Larocco *et al.,* 2016).

4.4 The Successful Rate for Bladder Stimulation Technique in Urine Collection in Infants

Study of Weill *et al.* (2019) showed urethral catheterization and SPA have been taken into consideration as a usual technique of acquiring urine samples from children who aren't toilet trained, however those strategies are annoying, painful, and invasive A new, quick, and safe approach to achieve CCU has currently been defined for new-borns, and this technique includes combining fluid consumption and non-invasive bladder stimulation manoeuvres, repeated till micturition starts. In previous studies, the success rate was different with different aged group, and it was depending on the researchers' techniques in stimulate the bladder (Weill *et al.,* 2019). According to Crombie *et al.* (2020) the finding showed ninety-two infants from 147 (62.6%) voided with bladder stimulation. The success rate in collection the urine sample occurs in the study because of the evidence that the researchers tested the bladder stimulation method by enrolling patients who needs urine analysis before they conducted the study. Moreover, evidence supports the success rate of urine collection in Crombie *et al.* (2020) study that the researchers controlled how the technique will achieved, they trained and tasked emergency staff with the urine collection for the study, the other reason is because of the bladder stimulation by softly finger tapping on the lower abdomen just above the pubic symphysis at 100 taps/minute, and f they were not passing urine after 30 seconds, they exchanged to stimulating the lower back in the lumbar paravertebral by lightly massaging in a circular motion using both thumbs for a maximum of 30 seconds. Bladder stimulation technique was similar applied in Fernández *et al.* (2013) however the success rate of the bladder stimulation method in their study was 86% success rate (n=69/80). The reason of success rate of urine collection in the participants of

Fernández *et al,* (2013) study because the researchers planned a stimulation technique and completed a study after nurses and physicians had been trained. Addition evidence is that the method includes a mixture of fluid intake breast feeding or formula and non-invasive bladder stimulation manoeuvres which make the child to pass urine. Moreover, the staff placed a sterile collector near the baby to avoid losing urine samples, and before starting the technique, they administered non-pharmacological analgesia such as non-nutritive sucking or 2% sucrose syrup, to prevent infants crying. These are the techniques they did in the study enable them to have this high success rate in collection urine sample from the infants, and it is the best practice in urine collection.

4.5 The Length Time of the Procedure

The length of time to collect a urine sample in infants by the stimulation was different in each study. The mean time they found for the child to pass urine is within 5 minutes. Timing is a confounding factor that the researcher needs to be aware about it because it will affect the result of the study. The nurses, physicians and parents were holding the infants for long time till they pass urine and collect it. It's not a realistic to hold baby like a standing for long time, this will impact on the infants and the investigator. Infants will cry and move, and the investigator will get tired from holding the infants, in this case the timing will affect on the intervention. Furthermore, the infants can't stand for long time, and they will keep moving. According to WHO (2008) children are ethically powerless; they are defenceless, they can't stand of their own. The researcher should be considered on the child and the people who will do the intervention at the same time to get a realistic finding.

4.6 Child Rights When Participate in the Research Study

John (2007) stated the needs for children's participation in research have been encouraged by the children's rights agenda, it has happened in the UK which provides a framework for the development of national policies and laws to protect the rights of children. According to the studies included in this review, the stimulation technique which applied for the infants, the researchers did not consider nor were they aware about the child' stress or traumatize during the procedure because of the long-time of holding the child and because of the different positions of holding them. There were no evidence regarding to the if the infants and children were crying. Because it is impossible for this age of participants can be calm during the procedure. This will affect the results of the study. All the researchers when they need to carry out a research study, they should be aware on the rights of the participants, and they should provide inform consent that includes all the information about the study. Because the population in this review are infants and children, parents will take a part to agree in this study on behalf of their child. Recruiting children, infants who are considered as a vulnerable population into the research study are needs careful thought and planning before starting the study and applying intervention (Pickler, 2010). In the example of participation of infants and children in research, the child's parents are recruited and give them the informed consent for their child's participation. For grant review, it should be more examination of investigator plans for recruitment of participants regarding the appropriate inclusion in the research studies, and an important human rights to be consider (Pickler, 2010). According to Nijhawan *et al.* (2013) informed consent is an ethical and legal requirement for studies concerning human participants It is the procedure

wherein a participant is informed about all aspects of the study that are important for the participant to decide and analysing all aspects of the trial, and after that the participant should confirms of accept to take part in the study or not (Nijhawan et al., 2013). Obtaining informed consent, informing the concerns about participants rights, the purpose of the study, procedures to be undertaken, capability risks and benefits of participation, predicted length of study, extent of confidentiality of personal identity and demographic data (Nijhawan et al., 2013). All the studies included in this review provided informed consent to their participants, and because the participants are infants the informed consent were signed by the parents. However, no one considered on the child rights mentioned above, only the one the researcher did for the child rights is the informed consent. When the nurses, physician and parents were holding the infants/child in the studies, they were expose the infants/child, they were not wearing clothes. This impact on the child temperature, child privacy, and as human being. Clarke (2015) mentioned researchers should be aware of full human being of the child with honesty and personality and the ability to participate freely in the research. It is a proper way to remove clothes when the child needs urine collection, but it should expose the genital area only not all the cloth, and the privacy of the child is very important. Providing children's rights allows children to be safe. Realistic issues inside studies typically consist of time and sources in addition to a lack of understanding amongst children concerning their right to be members as opposed to objects. The lack of equality to access participation as children are depending on the adult to be an effective advocate as well as a gatekeeper that actively appreciates and allows participation, however with an essential to safeguard (Clarke, 2015).

Shivayogi (2013) stated researchers needs accurate guidance from regulatory authorities with regards to realistic problems faced at some stage in behaviour of those varieties of research. Responsible, experienced, sensitive researchers guiding groups to deal with vulnerable groups with concern, patience, respect, fairly, permitting free will, ruling out any form of inducement, insensitivity or bias is needed to protect infants right when conducted a study. Protection of rights, well-being, protection with measurements of risk-benefit, privacy and confidentiality of vulnerable participants and determining added safeguards are rights of ethical review boards ERBs (Shivayogi, 2013).

Chapter Five - Conclusion

Study of O'Brien *et al.* (2013) described infants with UTI has been linked with renal scarring and serious long-term complications, including hypertension, preeclampsia, and renal failure, and guidelines focus on the importance of quick diagnosis and early treatment of UTI in children. Collecting a urine sample from pre-toilet-trained children can take long time. Morris (2018) stated the most used method to collect urine sample in this age is obtaining a CCU, however this method took an average of more than one hour to collect sample More useful techniques were used to collect urine sample were, placing a cotton ball in the diaper or using a perineal collection bag, however they were having a contamination rate of up to 63% (Morris, 2018). To have accurate diagnosis of UTI is by obtaining a sample of urine for culture with minimum contamination before beginning of the treatment. Urine collected in a bag or through a CCU approach is appropriate for urinalysis however some specimens specifically urine bag sample are less suitable for culture because of the contamination rate (AAP, 2016). If a culture obtained by bag is positive, the probability of a false positive is very high, so the result needs to be showed by culturing urine obtained by a greater reliable technique; if an antimicrobial agent is present in the urine, the possibility for confirmation is probably to be lost. Although samples of urine collected by transurethral catheterization may be contaminated by urethral flora (AAP, 2016). This review explored a new technique to collect urine sample in non-toileted infants without being contaminated and reduce the need of invasive sampling, which is bladder stimulation techniques.

An easy SPA stimulation method expanded the range of infants who provided a CCU sample within five minutes, a clinically applicable and satisfying outcome. In suitable patients, the use of the quick-wee technique to achieve a CCU voided sample for preliminary urinalysis, instead of trying techniques with known high contamination rates, may also probably lessen the need for invasive sampling using catheterization or SPA (Morris, 2018). The included studies in this review explained the stimulation technique and the successful rate of this technique with the contamination rate and timing if the technique. The studies include different age of children, but they are non-toileted and need the urine analysis. The studies still have contamination in their methods but the reason was because of the way of collection and it was mentioned in previous paragraph.

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