การวิเคราะห์ต้นทุนประสิทธิผลของอุปกรณ์ตัดชิ้นเนื้อชนิดใช้ครั้งเดียว เปรียบเทียบกับชนิดใช้ได้หลายครั้ง ณ โรงพยาบาลศิริราช

นางสาววิมลรักษ์ บัณฑิตนิยมานนท์

วิทยานิพนธ์นี้เป็นส่วนหนึ่งของการศึกษาตามหลักสูตรปริญญาวิทยาศาสตรมหาบัณฑิต
สาขาวิชาเศรษฐศาสตร์สาธารณสุข
คณะเศรษฐศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
ปีการศึกษา 2551

COST-EFFECTIVENESS ANALYSIS OF DISPOSABLE VERSUS REUSABLE BIOPSY FORCEPS AT SIRIRAJ HOSPITAL

Miss Wimolrak Bandidniyamanon

A Thesis Submitted in Partial Fulfillment of the Requirements
for the Degree of Master of Science Program in Health Economics
Faculty of Economics
Chulalongkorn University
Academic Year 2008

Thesis Title	COST-EFFECTIVENESS ANALYSIS OF DISPOSABLE VERSUS REUSABLE BIOPSY FORCEPS AT SIRIRAJ HOSPITAL
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Field of Study	Health Economics
Advisor	Associate Professor Pongsa Pornchaiwiseskul, Ph.D.
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Accepted by the Faculty of Economics, Chulalongkorn University in Partial Fullfillment of the Requirement for the Master's Degree

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##518 5728829 : MAJOR HEALTH ECONOMICS

KEYWORDS : COST-EFFECTIVENESS/ BIOPSY FORCEPS/ DISPOSABLE/ REUSABLE

WIMOLRAK BANDIDNIYAMANON : COST-EFFECTIVENESS ANALYSIS OF DISPOSABLE VERSUS REUSABLE BIOPSY FORCEPS AT SIRIRAJ HOSPITAL: ADVISOR : ASSOC. PROF. PONGSA PORNCHAIWISESKUL, Ph.D., CO-ADVISOR : PROF. PIROM KAMOL-RATANAKUL, M.D., 57 pp.

This research documents which choices of biopsy forceps between disposable and reusable biopsy forceps is more valuable. The criterion which choice is better is the cost effectiveness. The research does not only take into consideration the direct cost but it also includes any indirect cost, i.e., environmental cost. The criterion used in determining the effectiveness of the biopsy forceps are divided as followed: (1) ease of passage through the endoscope, (2) ease of opening and closing and (3) adequacy of the tissues. Each category has the benchmark indicated by the well known and respectful endoscopist to judge whether it is effective. The first choice based on the real circumstance in the government hospitals that both reusable and disposable biopsy forceps are being used. Obviously, the reusable biopsy forceps choice is cheaper as the disposable biopsy forceps costs 3.68 times. The second choice assumes that a large portion of disposable biopsy forceps is used in the hospital; therefore, the whole sale disposable biopsy forceps' unit cost decreases. The difference then falls sharply to only 23%. Nevertheless, if the effectiveness is considered, the result shows that the cost-effectiveness of the reusable choice is 15% higher than the disposable choice.

Moreover, to further enhance the research, we also analyze which factors affect the scores. The results suggest that the number of biopsy sample(s) is opposing the choice of the reusable biopsy forceps while it is supporting the disposable biopsy forceps alternative. Furthermore, the objective option, whether it involves with the pathology analysis, also advocates the choice of the disposable biopsy forceps.

Based from the research, if the number of biopsy forceps used is high and the whole sale price is achieved, the disposable choice is recommended.

Field of Study : Health Economics Student's Signature :.....

Academic Year : 2008 Advisor's Signature :.....

Co-Advisor's Signature :.....

วิมลรักษ์ บัณฑิตนิยมานนท์ : การวิเคราะห์ต้นทุนประสิทธิผลของอุปกรณ์ตัดชิ้นเนื้อชนิดใช้ครั้งเดียวเปรียบเทียบกับชนิดใช้ได้หลายครั้ง ณ โรงพยาบาลศิริราช. (COST-EFFECTIVENESS ANALYSIS OF DISPOSABLE VERSUS REUSABLE BIOPSY FORCEPS AT SIRIRAJ HOSPITAL) อ.ที่ปรึกษาวิทยานิพนธ์หลัก : รศ.ดร. พงศา พรชัยวิเศษกุล, อ.ที่ปรึกษาวิทยานิพนธ์ร่วม : ศ.นพ. ภิรมย์ กมลรัตนกุล, 57 หน้า.

การศึกษานี้มีวัตถุประสงค์เพื่อเปรียบเทียบความคุ้มค่าของการใช้อุปกรณ์ตัดชิ้นเนื้อชนิดใช้ครั้งเดียวกับชนิดใช้ได้หลายครั้งในการใช้งานมากกว่ากันโดยใช้เกณฑ์ต้นทุนประสิทธิผลในการวิเคราะห์ ซึ่งวิจัยฉบับนี้ได้นำเอาต้นทุนที่เกี่ยวข้องและเกิดขึ้นจริงทั้งหมดของกระบวนการใช้งานอุปกรณ์ตัดชิ้นเนื้อโดยเฉพาะกระบวนการล้างทำความสะอาดของอุปกรณ์ตัดชิ้นเนื้อชนิดใช้ได้หลายครั้งนำมาวิเคราะห์ให้ครอบคลุมมากที่สุด ต้นทุนที่เกิดขึ้นจริงเช่น ค่าอุปกรณ์ในการทำความสะอาด ค่าแรงงาน ราคาซื้ออุปกรณ์ ต้นทุนที่มองไม่เห็นที่เกี่ยวกับสิ่งแวดล้อมเช่น ค่ากำจัดขยะ สำหรับการวัดประสิทธิผลของอุปกรณ์ตัดชิ้นเนื้อได้แบ่งการประเมินเป็น 3 ลักษณะตามรูปแบบการใช้งาน ซึ่งเกณฑ์ในการวัดประสิทธิผลมีผู้เชี่ยวชาญให้เกณฑ์การประเมิน ผลการวิจัยพบว่า ต้นทุนของอุปกรณ์ชนิดใช้ได้หลายครั้งถูกกว่าชนิดใช้ได้ครั้งเดียวแบบคิดราคาซื้อปลีกค่อนข้างมาก โดยที่ต้นทุนของอุปกรณ์ชนิดใช้ได้ครั้งเดียวแบบคิดราคาซื้อปลีกเป็น 3.68 เท่าของชนิดใช้ได้หลายครั้ง แต่ถ้าเทียบต้นทุนของอุปกรณ์ชนิดใช้ได้ครั้งเดียวแบบคิดราคาซื้อส่ง ส่วนต่างระหว่างต้นทุนราคาส่งของอุปกรณ์ชนิดใช้ได้ครั้งเดียวกับต้นทุนของอุปกรณ์ชนิดใช้ได้หลายครั้ง จะลดลงเหลือเพียง 23% อย่างไรก็ตาม หากคำนึงถึงประสิทธิผลของอุปกรณ์ อุปกรณ์ชนิดใช้ได้ครั้งเดียวจะคุ้มค่าในการใช้งานมากกว่าอุปกรณ์ชนิดใช้ได้หลายครั้ง โดยต้นทุนประสิทธิผลของอุปกรณ์ชนิดใช้ได้ครั้งเดียวจะน้อยกว่าต้นทุนประสิทธิผลของอุปกรณ์ชนิดใช้ได้หลายครั้งเท่ากับ 15%

นอกจากนี้ได้วิเคราะห์ปัจจัยที่มีผลต่อการให้คะแนนในการใช้งานอุปกรณ์ทั้ง 3 ลักษณะการใช้งานคือ ความง่ายต่อการใส่ การเปิดปิดและขนาดของชิ้นเนื้อ ซึ่งปัจจัยที่นำมาพิจารณาการใช้งานของอุปกรณ์ตัดชิ้นเนื้อคือ ลักษณะวัตถุประสงค์ในการใช้งาน จำนวนชิ้นเนื้อที่ได้ในการตัดชิ้นเนื้อ ประสบการณ์ของแพทย์ที่ส่องกล้องและตำแหน่งที่ตัดชิ้นเนื้อ จากผลการวิเคราะห์พบว่า ปัจจัยที่เอื้อต่อการใช้งานของอุปกรณ์ชนิดใช้ครั้งเดียวแล้วทิ้งคือ จำนวนชิ้นเนื้อและวัตถุประสงค์ในการใช้งาน

จากการวิจัยนี้พบว่า ถ้าหากโรงพยาบาลมีจำนวนการใช้งานอุปกรณ์ตัดชิ้นเนื้อเป็นจำนวนมากจนสามารถซื้ออุปกรณ์ชนิดใช้ครั้งเดียวได้ในราคาขายส่งแล้ว ทางเลือกนี้จะเป็นทางเลือกที่เหมาะสม

สาขาวิชา เศรษฐศาสตร์สาธารณสุข ลายมือชื่อนิสิต.....
ปีการศึกษา 2551 ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์หลัก.....
ลายมือชื่อ อ.ที่ปรึกษาวิทยานิพนธ์ร่วม.....

ACKNOWLEDGEMENTS

I would like to thank many persons involved in my thesis. First of all, I would like to express my gratitude to Assoc. Prof. Pongsa Pornchaiwiseskul, Ph.D. my thesis advisor and Prof. Pirom Kamol-Ratanakul, M.D. my thesis co-advisor for their guidance. Valuable comments, advice and enthusiastic support during the preparation of this thesis.

I am very grateful to Asst. Prof. Phitsanes Jessadachatr, Ph.D, as the chairperson in my committee, Assoc. Prof. Manisri Puntularp and Chantal Herberholz, Ph.D, memberof committee for their kindly support and usaeful suggestion. I am indebted the hospital director of GI center of Siriraj Hospital who a kindly allowed me to study and collect data in this center and all staffs for their providing data, assistance on data collection. I would like to take opportunity to thank all lectures who give me the knowledge and all staffs at Health Economics for their help during my study at Chulalongkorn University. Many thanks to best friends, Mrs.Charussri Leeyaphan, Mrs.Chathaya Wongrathanandha and all classmates for their good advice,encouragement and moral support.

Finally, I would like to thank immensely to my family for their love, understanding: my father and my mother who provide things during doing thesis and encourage for my success on thesis.

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LIST OF ABBREVIATIONS

AAMI	Association for advancement of medical instrumentation
AMDR	Association of medical devices reprocessors
AORN	Association of operating room nurses
ASGE	American society for gastrointestinal endoscopy
ASTM	American society for testing and materials
APIC	Association for professionals in infection control and epidemiology
CDC	Center for Disease Control
CBD	Common bile duct
ERCP	Endoscopic retrograde cholangiopancreaticography
ETO	Ethylene oxide
FDA	Food and drug administration
GI	Gastrointestinal
H. pylori	Helicobacter pylori
SGNA	The society of gastroenterology nurses and associates
WGO	World gastroenterology organization

CHAPTER I

INTRODUCTION

1.1 Problem and its Significances

The Endoscopy center at Siriraj Hospital has a high number of visit about 8,000 - 9,000 per year - with the use of biopsy forceps in major intervention of about 4,000–5,000 sessions per year. This shows a high value of cost burden to the hospital and different performance of biopsy forceps when used. Endoscopy Center uses two type of biopsy forceps; disposable and reusable when a doctor needs a biopsy forceps, he does not specify of which type is to be used. Different types of biopsy forceps have different purchase prices and high costs disposable about 1,500-3,000 baht and reusable about 8,000-14,000 baht. Now Endoscopy Center does not have a policy in implication for using. Many endoscopists believe that disposable forceps are more expensive than reusable ones per one use (Rizzo, 2000 and Kozarek, 1998). Normally, endoscopists must weight or look at the three major considerations in the decision to choose which kind of forceps for routine endoscopic procedures: the cost of the biopsy forceps, the safety or the risks of transmission of infection and function or performance of operation (Kozarek, 2001; Rizzo, 2000; Yang, 2000; and Gardon, 2000) In addition, the reprocessing of the equipment must be aligned with the established guidelines standard by FDA or protocol. So, this study concerns and compares about cost and performance of the two types of biopsy forceps. Disposable forceps is used once and discarded ; therefore, it is more expensive than reusable forceps. The use of reusable forceps includes reprocessing costs such as cleaning supplies, labor cost, material cost, etc. We should calculate to see the cost of this price that is the burden of the hospital. Cost is an important issue in product (biopsy forceps) selection in today's managed care environment. However, cost considerations must take performance and safety into consideration as well. Because biopsy forceps is the most common accessory used in endoscopy., It's crucial to study more information and consider the best solution, the one with lower cost. Now we don't know which type of biopsy forceps is more effective or valuable in using. So, we would like to know the cost and effectiveness in terms performance of biopsy that use in one session between disposable biopsy forceps and reusable biopsy forceps.

1.2 Research Questions

Primary Question

Which type of biopsy forceps: disposable or reusable, is more cost effective at Siriraj hospital.

Secondary Questions

1. What is the cost of a biopsy session perform with disposable and reusable biopsy forceps from the provider perspective at Siriraj hospital.
2. What is effectiveness of disposable and reusable biopsy forceps at Siriraj hospital.
3. What factor could have affect on cost-effectiveness of disposable and reusable biopsy forceps at Siriraj hospital.

1.3 Research Objectives

General objective

To evaluate cost-effectiveness of disposable biopsy forceps and reusable biopsy forceps at Siriraj hospital.

Specific objectives

1. To compare the cost of a biopsy session perform with disposable and reusable biopsy forceps at Siriraj hospital.
2. To compare effectiveness of biopsy session perform with disposable and reusable biopsy forceps at Siriraj hospital.
3. To identify factors affecting the score on cost-effectiveness of disposable and reusable biopsy forceps at Siriraj hospital.

1.4 Scope of the Study

This is data about the endoscopy Center at Siriraj hospital. Which service only gastrointestinal disease by Endoscopy. Siriraj hospital sets up this center in 2006 which includes two major departments from medicine and surgery. This center have 9 operating rooms, waiting room have 12 beds and recovery room have 13 beds and must take care of patients before, during and after endoscope and working around 24 hours. The center's target

is to be a one stop service and training center endoscopy in Thailand. The center consists of many specialists and health personnel to coordinate the work: 10 medical doctors, 10 surgical doctors, 2 anesthesia doctors, 6-8 trainee doctors 6, 14 nurses and 16 nurses aid. From the beginning, the Endoscopy Center has had a high number of visit; about 8,000 visits in 2006, 8,700 visits in 2007 and 10,000 visit in 2008. The interventions and diagnosis follow this data: Intervention Gastroscopy, Colonoscopy, ERCP, Flexible sigmoid, Dilate esophagus, Rigid sigmoid, Dilate anus, Ultrasound. Diagnosis: Gastritis, GERD, Peptic Ulcer, upper and lower gastrointestinal bleeding, Hepatitis, Corrosive, Gastric Cancer, Rectal Cancer, Colonic Cancer, Check up, Cholangitis, Cholangio Carcinoma, CBD stone. Etc.

1.5 Expected benefit of the study

This study show true cost from complete processing, it's compare between cost of disposable and reuse for determine that should be use suitable or worthwhile or look on a economic point of view. Change method in use biopsy forceps. The manager of endoscopy center just to plan or forecast about order priority instrument, control cost of reprocessing, know opportunity cost and arrange to suitable method. Then present true cost and administrator of hospital show the more cost effectiveness of two type biopsy forceps to change policy about management the biopsy forceps and it creasing cost saving for hospital to use another side. Moreover it has point inside externality impact to health of personnel and environment that impact policy of hospital should be concern in best direction.

CHAPTER II

REVIEW OF LITERATURES

2.1 Background of the study

2.1.1 Endoscope

The most common procedure that use in investigation and treatment in gastrointestinal system is Endoscopy. The medical apart from the medications is using a tool called "ENDOSCOPY" gastrointestinal endoscopy has became the international forum for the newest developments in the specialty. Which is a high-technology appliance widely recognized in many countries such as in Europe and America. Endoscopic procedures use in the study, diagnosis and treatment of digestive disease. It's now being developed to use in other specialties. The endoscopes have benefit to allow a physician to see internal organs clearly. The tool is also suitable with minimal size of an operation cut, reduce treatment duration and can early detect some disorder in internal organs. Using a tool called "Endoscopy" which it has expensive value or high price. Gastrointestinal system has many disease and popular disease, especially cancer disease that many physicians and everyone concern and interest now. Which relate with gastrointestinal system many organ ex. colon cancer, liver cancer, gastric cancer and rectal cancer etc. From statistic cancer of Thai people both sex, male and female it show cancer in gastrointestinal is high level. If use high technology to early detect it's decrease rate of cancer in gastrointestinal system. It's show more health service need. Endoscopy in Gastrointestinal it have many general diagnosis such as: Peptic Ulcer, Gastritis, GERD, upper and lower gastrointestinal bleeding, Gastric Cancer, Rectal Cancer, Hepatitis, Corrosive, CBD stone etc. These diseases have been clearly as the result of the easy and repeated endoscopy and biopsy. The accessory for endoscopy in gastrointestinal tract is many instruments i.e. needle injection, snare, loop, shooter ligation, hot biopsy, gold probe and biopsy forceps etc. Especially, biopsy forceps are the most common accessories used in endoscopy and frequently for used in gastrointestinal endoscopy. (Yang, 1994 and Fireman, 2006) This instrument important for patients and the doctors because its used to cut the little tissue at internal organ of gastrointestinal tract i.e. stomach, colon, ulcer,

polyp and many locations that endoscopist suspect for direct in diagnosis and plan to right treatment further.

2.1.2 Biopsy forceps

"Biopsy forceps" are widely used in GI endoscope. Biopsy forceps is the important instrument. Which doctors use to cut parts of internal organs or a little tissue in gastrointestinal tract e.g. stomach to find bacteria Helicobacter pylori (H. pylori) or some unusual tumor and forward to the laboratory. The action of biopsy forceps is passing through endoscopy, opening and closing accurately, taking a biopsy tissue sampling, pulling it back easy, can receive adequate tissue from cup of biopsy forceps. The structure or design of biopsy forceps are complex biopsy forceps have spiral shape or designed to accommodate the bends and twists of the curve of the patient's GI tract. Biopsy forceps have long and small diameter lumens; the lumen of the biopsy forceps is open only at the distal end. Biopsy forceps have design and material features that may interfere with cleaning, and reusable devices must be designed to function safely and effectively following sterilization in a healthcare setting. (Fireman,2006). The design or characteristic of forceps for obtaining biopsy specimens has rapidly developed into many characteristics attempt to suitable for used. It's have many shape followed objective of manufacture the producer i.e. oval shape, alligator shape, ellipsoid shape, have needle, not have needle etc. Disposable forceps were made of plastic and reusable made of stainless steel. (Yang, 2000). Biopsy forceps available in both a reusable biopsy forceps and disposable biopsy forceps form. Reuse and disposable biopsy forceps are both widely available for use in gastrointestinal endoscope units and especially disposable biopsy forceps have big market in the world (Kozarek, 2001). During the last decade, endoscope accessories have evolved from reusable to disposable in many part of the world so disposable biopsy forceps have big market as cost effective, convenient to use (Fireman, 2006). Reusable must be designed to withstand multiple exposures to sterility or disinfectants and designed to function safely and effectively following sterilization in health care setting. An ideal accessory would be a disposable accessory that is priced very competitively so that it is affordable even in the developing countries. Yang (2000) explained about some the ideal biopsy forceps for GI endoscope would

(1) provide adequate tissue specimens for histological evaluation

(2) have no mechanical problems

(3) be easy to use

(4) allow no possibility of cross-contamination to patients or healthcare workers

(5) be inexpensive.

Biopsy forceps are different in term of characteristic each type, reusable and disposable. This is some condition of biopsy that previous study explains. First, advantage of disposable biopsy forceps. Disposable endoscope medical accessories were developed for convenience, reliability and fear of cross infection. Kozarek (1996) said Disposable biopsy forceps have been heavily marketed as cost-effective, convenient, and safer to use than conventional forceps. Robert (2000) said the disposable forceps are sharper than the reusable forceps. Reusable forceps can become dull with repeated use and mechanical cleaning. In addition, the hinge and cable mechanism of the disposable forceps are likely to operate more smoothly and reliably and are less likely to malfunction because they are used only once. There is another advantage to disposable forceps, sterility. There is a very small but real risk of transmitting infection with reusable equipment, despite the most zealous efforts at disinfection. In summary, he found that the use of disposable forceps provided more adequate biopsies for a study of mucosal proliferation. He believes that the disposable forceps were sharper and that the mechanism was more reliable. The disposable forceps also provide an added margin of safety against infection. Better biopsies, higher quality data, and reduced technician time balance the modest increase in the cost of the forceps. Petersen (2000) mentioned disposable accessories provide greater variety, complexity, and utility. They carry a cost burden that may be acceptable when the devices are difficult to reprocess. The use of disposable endoscope accessories has grown tremendously. They offer simplicity of use, certain sterility, and reduced labor costs in exchange for higher purchase costs per procedure and the burden of waste disposal. Fireman (2006) related using disposable biopsy forceps eliminates the risk of cross-contamination, enhancing both patient and staff safety. From, Kauzuei (2000) said the single use or disposable accessories suffer from the disadvantage of cumulative cost and cumulative medical waste. There is increasing interest in the use of reusable accessories and reprocessed single use items because of concerns over health care cost, cost-effectiveness,

and environmental contamination. Although use of disposable devices helps reduce the potential risk of cross-contamination and spread of infection, there remains the factor of cost. The reprocessing expense some studies, does not include labor, materials, or side-effects to health workers from the high levels of disinfectant or sterilizing solutions.

Many marketed at present of biopsy forceps from reported of Kauzuei (2000) showed Olympus, Pentax, Fujinon, W.Cook, Microvasive, Zeon, Sumitomo and clarify in both type of biopsy forceps as reusable biopsy forceps are marketed by Olympus Optical Co.(Japan) and Wilson Cook Co. (USA) produce only reusable biopsy forceps. For disposable biopsy forceps are market by Boston Scientific Co. (USA) makes only disposable biopsy forceps. This market to be likely manufacture in Thailand. Inside Purchase price. Many disposable are marketed at a lower price than comparable reusable accessories. This table show that biopsy forceps can reuse: Guidelines for classification of specific accessories.

Table 1:Guidelines for classification of specific accessories. The factor to consider when selecting endoscopic biopsy forceps are various and include acquisition cost, reprocessing expense, instrument performance and risk of transmission of infectious agent (Yang, 2000). Reusable have high purchase price and cleaning cost which next topic just only focus on reprocessing.

Accessory	*Reusable after cleaning/ disinfection according to manufacturers' instructions*	*Single use only*	*Reusable or single use items. Choice depends on local factors. Do not reuse "single use" devices*
Oesophagogastroduodenoscopy			
Forceps			✓
Cytology brushes		✓	
Oesophageal dilatation devices			✓
Varices injection needles		✓	
ERCP			
Cannulae			✓
Sphincterotomes			✓
Dilatation balloons		✓	
Retrieval balloons		✓	
Dormia baskets			✓
Lithotripters			✓
Stents		✓	
Stent guiding catheters			✓
Stent pushers			✓
Guide wires		✓*	
Stent retrieval forceps	✓		
Soehendra stent retriever		✓	
Colonoscopy			
Snares			✓
Forceps			✓

Data from : Report of the Working Party of the Endoscopy Committee of the British Society of Gastroenterology on the reuse of endoscopic accessories.

2.1.3 Reprocessing

The method for reprocessing device arrange following standard form of institute, The American CDC description of medical device in 3 group as

(1)non-critical

(2)semi-critical

(3)critical

which in each group has many detail about definition or level disinfection thus, 1non-critical have definition: making contact with intact skin and level of disinfection is low 2.semi-critical have definition: making contact with mucous membrane, non-intact skin and level of disinfection is high and 3. critical have definition: making contact with penetrate skin, invade sterile parts of the body and level of disinfection is sterilization. Defines in endoscopes, being equipment used across intact mucous membranes, as being semi critical i.e. endoscope and requiring high level disinfection. For biopsy forceps and any other accessory which penetrates the mucosa must be defined as critical and, therefore, should be sterile. It same with previous research, Fireman (2006) said major concerns for reuse of endoscopic accessories contour on two majors, sterility and capability of the equipment perform its function satisfaction after reprocessing use and sterilization. The United State Centers of Disease Control and Prevention (CDC) describe equipment as non-critical, semi-critical and critical. Endoscopes are in the semi-critical (high-level disinfection) category, while biopsy forceps are considered critical (sterility required). The transmission of infectious agents such as Helicobacter pylori, Salmonella spp., Pseudomonas aerugenosa, Strongyloides sterocoralis, and hepatitis B and C virus has been reported to occur as results of GI endoscopy.

It interesting in some point about this instruction inside safety. Data from many researches ago show is the same detail about the biopsy or suction channel of an endoscope

is not sterile and the gastrointestinal tract is certainly not sterile too. Kinney (2002) showed that sterile single-use biopsy forceps are highly acceptable to contamination during passage through the accessory channels of adequate cleaned endoscopes. Fireman (2006) indicated maintaining sterility of a device that passes through the biopsy or suction channel of an endoscope is impossible because the endoscope, accessory handling, the endoscopy suite and the GI tract are not sterile. The last data from Kauzuei (2000) reported endoscopic accessories direct risk factor for cross infection if they are not cleaned and disinfected compleyely. Because it has seen that using sterile biopsy forceps through an un-sterile biopsy channel of the endoscope can still cause infection, both the scope and accessories should be disinfected completely. Nevertheless, the avoidance of cross-contamination remains an important consideration by use right or suitable method for cleaning instrument i.e. Showed the proper cleaning technique i.e. a 20-minute soak in 2% glutaraldehyde is effective in disinfecting endoscopes and in eliminating the infection of pathogenic GI flora when using sterile single-use biopsy forceps. Which Siriraj hospital use this advance method for patient safety in GI endoscope centre.

The strict in reprocessing is important so, it have many institute which establish in many country which consist the current position of regulatory agencies and professional organization on reprocessing companies or to control and including complying with all standards from and it's have many institute to recommend the method to reprocessing endoscope accessories i.e.

1. The Society of Gastrointestinal Nurses and Assistants (SGNA)
2. American society for gastrointestinal endoscopy (ASGE)
3. The society of gastroenterology nurses and associates (SGNA)
4. The association of perioperative registered nurse (AORN)
5. The American society for testing and materials (ASTM)
6. The Food and Drug Administration (FDA)
7. The Association of Medical Devices Reprocessors (AMDR)
8. The Association for Advancement of Medical Instrumentation (AAMI)
9. The Association for Professionals in Infection Control and Epidemiology (APIC)
10. The Center for Disease Control (CDC)

This is example of the manage from Germany, Heudorf (1999) studied about the reprocessing, it strictly to control the reprocessing following protocol. The aim of study was to examine the current endoscope reprocessing practices in a German. The survey investigated compliance with German guidelines by endoscopist assessed using a checklist based on the recommendations of the German guidelines. By the end of studied, 90% of private practices had adequate storage facilities for reprocess endoscopes Sterilization of endoscopic accessories was satisfactory and routine testing of Endoscopes after reprocessing. So the appropriate quality control reprocessing by institute strictly from Germany with from to checklist cleaning and sterilization guidelines may be another factor in the potential risk for cross contamination or infection. The transmission of infectious agents such as Helicobacter pylori, Salmonella spp., Pseudomonas aerugenosa, Strongyloides sterocoralis, and hepatitis B and C virus has been reported to occur as results of GI endoscopy with the use of reusable biopsy forceps.

For the important point, the step reprocessing in Thailand, the reprocessing in Endoscopy Center at Siriraj hospital following international guideline and The forceps are decontaminate and sterilize by the personal of the endoscopy unit and the central sterilization unit of Siriraj hospital. Reprocessing with High standard base on FDA (Food and Drug Administration). National and international guidelines recommend that a standardized protocol consisting of cleaning, ultrasound cleaning, and sterilization should be used for the reprocessing of endoscopic accessories in order to reduce the risk of transmission of infection (Rizzo, 2000). For step reprocessing it many step various from many country or up on endoscope unit to apply but involve just keep the same standard. These are many studied about step reprocessing start at Kauzuei (2003) studied reusable accessories should be washed and sterilized strictly according to the protocol. A practice such as washing biopsy forceps with water after use, then wiping them off with alcohol and immediately using them for the next patient must be strictly prohibited. All endoscope accessories that come in contact with blood have been classified as critical device and thus should be used either as single use disposable or reused only after sterilization. Kinney et al (2000) showed that the proper cleaning technique i.e. a 20-minute soak in 2% glutaraldehyde is effective in disinfecting endoscopes and in eliminating the infection of pathogenic GI flora when using disposable use biopsy forceps. Fireman (2006) presented the reprocessing technique about lumen devices

involves flushing cleaning fluid through the lumen. The reusable biopsy forceps have lumen of the biopsy forceps is open only at the distal end so flushing is not a perform option a cleaning step by flushing detergent and rinse water through their internal shaft. Attempts to clean the biopsy forceps by flushing and specific aspirating or suction fluid for drying fluid through the lumen it useful to decrease the chance for contaminants in addition to Fireman (2006) to analyzed reprocessing step for reuse biopsy forceps includes 14 steps: transport, soaking, brushing/cleaning vigorously, rinsing, ultrasonic cleaning, functional testing, inspection, drying, flush alcohol (70%) through channel lubrication, repacking, ethylene oxide gas sterilization, aeration (12 hr.) and return transport. Rizzo (2000) reported reprocessing of reusable biopsy forceps includes the following 12 steps which this step to differ from Rizzo, transport, soaking, brushing-cleaning, rinsing, ultrasonic cleaning, inspection, drying, lubrication, repackaging, sterilization, transport back to unit and preparation for use. Heudorf (1999) studied and investigate about reprocessing standard in the endoscpic all hospitals and private practices in Frankfurt, Germany he compared two methods reprocessing as washer disinfectors and manual reprocessing practical in terms of the number of endoscopic procedures performed per year. Among the practices performing >1000 procedures per year, 70%used automatic washer-disinfectors, while70% of the practices performing <1000 procedures per year relied on manual reprocessing and the end of studied he recommended followed The main problems in the Private practices were lack off facilities for ultrasonic cleaning and sterilizing, errors in reprocessing, improper storage of endoscopes, leading to risk of recontamination, and lack of routine testing of endoscopes after reprocessing and the assisting two type, personnel had Not received any specific training in endoscope reprocessing, so special courses were recommended. There are two protocols being outlined. The first protocol is for manual cleaning, applicable in small centre that do not have a high endoscopy load or cannot afford the facilities for ETO sterilization or steam autoclaving. The steps are:1.Inspect for deformity and discard if defective. 2. Clean in running water. 3. Presoak in detergent enzyme solution for 10min. 4. Scrub the accessory. 5. Rinse with water. 6.Clean accessory by ultrasonic cleaner for 10min. 7.Rinse. 8. Soak in 2% glutaraldehyde for 10min. 9.Rinse. 10. Air dry (overnight). 11. Place in peel pack. 12. Return to stock. Centre with a high endoscopy load have 11 step should follow the following protocol: 1.Inspect for deformity and discard if defective. 2. Clean in running water. 3. Presoak in detergent enzyme

solution for 10min. 4.Rinse with water. 5. Clean accessory by ultrasonic cleansing for 10min. 6.Rinse. 7. Air dry. 8. Place in peel pack. 9. Sterilize using a steam autoclave or ethylene oxide. 10. Aerate for 24h if ethylene oxide used. 11. Return to stock. Then Catherine (2001) focused method in centralized sterilization of reusable material at her institution and the mechanization of the different steps using an instrument washer and autoclaves had an effect on the low cost of sterilization in her study but some research focus the criterion for chooses reprocessing method. Rizzo (2000) reported manual cleaning is best achieved by paying attention to basic. Washing should be make more attend time to clean firmly of all accessories. manual cleaning of the accessory immediately after use is a major step. Then soaking the soaking solution should contain an enzymatic agent. The cleaner will digest and dissolve proteinaceous and mucoid material and any organic contaminants. Ultrasonic cleaner is considerably more effective for such complex or structure spiral. It is important that the accessories are cleaned in an ultrasonic cleaner before going to sterilization. Making adequate in ultrasonic cleaning and sterilization of the instrument essence should be practice.

Due to manual cleaning is not adequate to remove mucus and blood that adhere in the spiral of biopsy forceps so equipment that important to support cleaning is ultrasonic cleaner according to Kauzuei (2000) proposed. Cleaning is best method by paying attention to the accessory that after use. Mucus and blood adhere to basic for the accessory after use. If these secretions are allowed to dry up, they will clot and strict the action of the disinfectant solution. Therefore, manual cleaning of the accessory immediately after use is a important step. A soaking solution should be available in the endoscopy suite or unit for immediately presoak or immersion of accessories. The soaking solution should contain an enzymatic agent. The cleaner will digest and dissolve proteinaceous and mucous material and any organic contaminants. A complete submersion is required. All accessory lumen should be flushed and any visible debris should be swab off. After a 5-10 min soak, the accessories should be rinsed with warm water, because some enzymatic solutions may impair the activity of the sterilizing solution. Soaps are an inadequate substitute for enzymatic cleaners. Accessories such as biopsy forceps have a spiral shape, so manual cleaning is not adequate to remove mucus and blood that has been deposited in the spiral structure. Ultrasonic cleaner is ample more effective for such spiral structure based accessories. Most accessories consist of a tip section, a coil wire section and a control section. It is particularly difficult to remove

mucus and blood that get into the coil. Therefore, it is important that the accessories are cleaned in an ultrasonic cleaner before sending to sterilization. (Kauzuei, 2003). In part sterilization is important because it's step make sure that sterile. Sterilization is defined as the process of killing all microbial life, including bacterial spores, and is accomplished with either heat or ethylene oxide gas (ASGE, 1988) After cleaning, the accessories should undergo sterilization using ethylene oxide (ETO) or autoclave using heat it is an effective agent. For ETO sterilization to be effective, complete drying of accessories is required. The efficacy of any disinfectant is dependent on direct contact with the organism. This requires effective removal of all visible debris, flushing of channels and disassembly of some instruments. The limitations of achieving direct contact with all surfaces of an accessory using liquid disinfectants necessitates a gas sterilization process, therefore the need for gas sterilization or autoclaving of the accessories. Because ETO sterilization requires a longer time, it is not generally used for quick sterilization. For ETO sterilization to be effective, complete drying of accessories is required. Moisture in long tubes decreases the efficacy of ETO sterilization. Residual gas poses danger for patients and medical personnel involved. Autoclaving is a method for obtaining a reliable sterilization effect in a short time. However, it has limitation i.e. some high pressure and high temperature are used for autoclaving, it is not suitable for objects that cannot withstand these conditions. Researchers found that residual water remained in the devices after cleaning them with a sequence of bleach, ultrasonic bath with detergent and enzyme, and water rinse. This inability to adequately dry the device lumen may decrease the effectiveness of sterilization. This is recommend from Kauzuei. (2000)

Evidence about cross infection in GI endoscope it just happen if improper cleaning and not enough disinfection procedures, and inappropriate storage of endoscopes. Infections may also be due to problems in the reprocessing of endoscopic accessories such as biopsy forceps. Several recent reports have highlighted followed, Heudort (1999) assessed reusable and disposable biopsy forceps, which had undergone the standard disinfection process, that were contaminated with labeled blood. After a count by means of a gamma camera and electron microscopy, they found that the reusable devices were effectively disinfected but that all the disposable biopsy forceps were contaminated. Kinney (2002) showed that sterile disposable biopsy forceps are highly susceptible to contamination during passage through the accessory channels of improperly cleaned endoscopes. Reported examination of reusable

forceps revealed residual patient debris despite "adequate" cleansing. Residual patient debris on reusable forceps may pose a risk of cross contamination and the spread of infection.

2.1.4 Cost analysis

This research investigates which choices of biopsy forceps between disposable and reusable biopsy forceps is more valuable. The main criterion to decide which choice is better is the cost effectiveness. Therefore, the review begins with the previous study on cost and performance of various types of biopsy forceps. There are 3 major point in the decision to choose disposable or reusable forceps for routine endoscope procedures: cost, function and safety.

For prior study that mentioned only cost it has many paper, Deprez (2000) Studied "Disposable versus reusable biopsy forceps: a prospective cost evaluation" The evaluation of costs included purchase prices, repairs, cleaning (chemicals, equipment, technician time) and autoclaving costs in a centralized sterilization unit. Kozarek (1996) compared "Disposable versus reusable biopsy forceps: a prospective evaluation of costs" In an attempt to defined whether disposable or reusable biopsy forceps were cheaper to use, he prospectively evaluated the purchase price, number of uses, repair record, and cleaning costs of all reusable biopsy forceps used in the outpatient endoscope unit. Bourguignon (2003) compared "Disposable versus reusable biopsy forceps in GI endoscopy: a cost-minimization analysis" it's conclude the use of disposable biopsy forceps seems to be effective and safer than reusable biopsy forceps with respect to the risk of infection transmission. A cost-minimization analysis was carried out from the viewpoint of a hospital. For reusable biopsy forceps, the evaluation of costs included purchase prices, cleaning (chemicals, equipment, technician time), and a fee for sterilization in a centralized facility. The cost evaluation for disposable biopsy forceps included acquisition and destruction costs. Catherine (2001) compared" Disposable versus reusable biopsy forceps. A prospective cost analysis in the Digestive Endoscopy Unit of the Dijon University Hospital" The goal of this study was to compare the cost of a biopsy session performed with a disposable and a reusable endoscopic biopsy forceps. A biopsy session performed with a reusable forceps included its current purchase price, the sterilization cost and the number of uses. The cost of a biopsy

procedure using a reusable forceps was calculated as the sum of the purchase price divided by the number of uses added to the unit cost of sterilization. The cost of a biopsy session with a disposable forceps was taken as the sum of the purchase price and the cost of its incineration this method same Catherine. Fireman (2006) analyzed most gastroenterologists believe that disposable biopsy forceps are more expensive than the reusable type, but they do not calculate the reprocessing costs, such as the materials used, the required personnel, and so on. The reusable biopsy forceps perform a designated number of procedures. Kauzuei (2000) analyzed disposable biopsy forceps are less economical than the reusable accessories. The factors to consider in choosing single use or reusable accessories, such as economy, reliability of disinfection and durability of function.

For research that concern about cost and function are Yang and Rizzo. They studied about faction or performance of biopsy forceps in real situation. Each research have detail followed, Rizzo (2000) talk about "A performance, safety and cost comparison of reusable and disposable endoscopic biopsy forceps: a prospective, randomized trial " he conducted a prospective, randomized study to evaluate the performance, safety and cost of reusable versus disposable biopsy forceps. Forceps were evaluated for ease of passage through the endoscope, ease of opening and closing, adequacy of sample, and overall evaluation following the endoscopy using an ordinal scale. The cost per biopsy session was calculated using the following formula: Acquisition cost plus Reprocessing costs divide number of biopsy sessions. Yang (2000) said"A cost and performance evaluation of disposable and reusable biopsy forceps in GI endoscopy" he prospectively measured the costs and operational performance of disposable and reusable forceps. Calculate total cost per se of the reusable biopsy forceps including acquisitions cost plus the cost of reprocessing as established guideline. Performance was measure by the assessment of the forceps function during the procedure. Forceps malfunction was defined as difficulty in opening or closing the forceps or in passage of the forceps through the endoscopic accessory channel and was qualified as partial or total. Partial malfunction was considered if the forceps were difficult to open or close or pas through the endoscope but were eventually used during the endoscopic procedure and total malfunction of the forceps was defined as inability to open or close the forceps or to pass it through the endoscope same Kozarek. Kozarek (2001) reported top "Reusable biopsy forceps: a prospective evaluation of cleaning, function, adequacy of tissue specimen and

durability" evaluate the form and function of a reusable forceps until malfunction or breakage were prospectively evaluated. He have evaluation form which set up subjective nature of endoscopic grading scales of biopsy forceps have grade from 1 to 4,

4 mean new or like new

3 mean some loss of function but usable

2 mean inadequate for clinical use

1 mean broken.

Unless Kozarek relevant about tissue specimen. In conclusion the reusable forceps used in this study can be sterilized, reused a mean of over 90 times with an admittedly subjective grade of new or like new by diverse endoscopists, and allow adequate tissue sampling to point of failure.

Furthermore some research concern or in deep about characteristic of tissue specimen which effect with the quality of specimens obtained with different forceps. This research provided us the opportunity to compare specimens obtained by reusable and disposable forceps or compare the quality of specimens obtained with different forceps. The method used, reusable forceps were standard sized (not jumbo), sheathed, fenestrated, oval forceps. Disposable forceps were similar in design sheathed, oval, and fenestrated but were used only once. Both the reusable and the disposable forceps were obtained from different manufacturers during the course of the study. In finally the specimens taken with the disposable forceps were better, probably because the forceps were sharper than reusable because not routine sharpened and taken out of service when they malfunction. Danesh (1985) compared of weight, depth, and diagnostic adequacy of specimens obtained with 16 different biopsy forceps designed for upper gastrointestinal endoscopy the methodology use Standard sized forceps (diameter 2.4 mm) and those with ellipsoid cups consistently produced larger specimens than the smaller 'pediatric' forceps (1-8 mm)and those with round cups. Deeper specimens were also obtained using the standard forceps. The standard sized forceps also produced specimens of greater diagnostic adequacy than the pediatric forceps. Danesh (1985) studied mentioned that under closely controlled conditions the precise shape, design, and make of the forceps used are not of practical importance, but that bigger, deeper, and more adequate specimen are obtained by using the standard sized forceps an by applying pressure at the time of biopsy. As however, the quality of the tissue may depend on

the sampling conditions at the time of biopsy multiple biopsies must be taken to ensure provision Of material adequate for diagnostic assessment. But could not detect any influence of the size, shape and presence of forceps spike on the diagnostic adequacy of the specimens. This is in agreement with previous study by Siegel (1983) found that larger standard biopsy forceps obtained specimens of greater size than did standard and pediatric (with bite size 2.5 mm.) Biopsy forceps; however, the larger biopsy forceps did not obtain deeper (with bite size 3.0 mm.)specimens. As in their study was no significant Difference in the adequacy of the specimens obtained. In addition showed that although large forceps yielded to Some extent better specimens the overall diagnostic accuracy of each forceps did not differ significantly. In research of David (1995) focused about characteristic or versions of each forceps. Followed "Standard biopsy forceps versus large capacity forceps with and without needle" Endoscopic biopsy forceps vary in size and design. The purpose of this prospective randomized study was to compare the quality and quantity of gastric tissue obtained by needle and non needle versions of standard biopsy forceps and newly designed large capacity forceps. In conclusion found that large capacity forceps obtained larger specimens than standard biopsy forceps. And the presence of a needle did not influence the size or depth of the specimen obtained. Yang (2000) 12 compared gastric endoscopic biopsy specimens obtained with a standard biopsy forceps (2.3 mm diameter) with specimens obtained with a slightly smaller disposable biopsy forceps (2.1 mm diameter) and found that smaller, shallower specimens with less diagnostic accuracy were obtained with the disposable forceps than with the standard forceps. Therefore, all of these previous studies have compared standard biopsy forceps that vary in size and found similar result suggest that larger biopsy forceps may provide larger mucosal specimens, as expected, with no significant benefit for diagnosis of mucosal lesions. And Karen (1999) studied "Influence of endoscopic biopsy forceps characteristics on tissue specimens" A large variety of endoscopic biopsy forceps are commercially available. However, little is known regarding the influence of forceps characteristics such as disposability, size, shape and presence of a needle on the adequacy of the specimens for histological diagnosis. In conclusion disposable forceps provided specimens of greater size and depth. These factor alligator-shaped forceps improved the depth of the sample equal did the absence of a needle within the cup no significant difference was noted between any of the individual forceps, although collectively oval shaped forceps

were superior to alligator shaped forceps at colonoscopy. Robert (2002) focused "jumbo" forceps. The specimens obtained with the jumbo forceps are larger in size than the standard endoscopy forceps but are also associated with slightly higher risk of bleeding.

Each of study focuses on major cost of biopsy, purchase price, cleaning cost, sterilization cost, labor cost etc. Other considerations are the life span of biopsy forceps, performance of biopsy procedure performed and brand name. The processing in reuse one time it has high expenditure in another cost e.g. washing, cleaning, labor, detergent ex. enzymatic alcohol, chemical, tab water, Ultrasonic cleaner, sterilization, wrapping, electricity etc. Before sterilization or disinfection, device should be cleaning adequately, which it use manpower to clean first step and sent to machine for cleaning and sterilization by ethylene oxide gas again this method show increase job which it increasing cost and manager should be concern about the opportunity costs and health personnel impact with the many chemical in area cleaning room or in reprocessing biopsy forceps. Inside hospitals it has impact cost of storage and cost of waste disposal or incremental costs of pollution. (Kozarek,2001). Find out economic indicators to account for the hidden costs of reusable and disposables ex. storage space, waste disposal and pollution.

If compare cost in each item of many research it result easy to receive main detail just start at purchase prize: Kozarek (1996) assumed a six fold difference in purchase price between reusable and disposable forceps, Current purchase price for reusable biopsy forceps at our endoscopy unit approximates $350, versus a mean purchase price of $55 (range, $40 to $65) for disposable biopsy forceps available from various manufacture. Yang (2000) said The acquisition of reusable cost per forceps was $415. Robert (2002) reported the disposable forceps cost between $18.00 and $60.00, depending on the manufacturer and on whether it is possible to negotiate a bulk discount. Rizzo (2000) said the acquisition cost per use of reusable forceps was $29.17 ($350 per forceps times 4 forceps divided by 48 uses). cost per use of disposable forceps equaled the initial acquisition cost of $35.00. Bourguinon (2003) said reusable biopsy forceps was acquisition $3.59, the cost per use of disposable biopsy forceps varied from $10.72 to $15.63. Additional cost per use of disposable biopsy forceps ranged from $3.88 to $8.79. Catherine (2001) reported the purchase price of a disposable forceps was euro 11.95 (tax included) in November 1998. Deprez (2000) reported

the lowest purchase price for disposable biopsy forceps was $26.90 in 1997and new reusable biopsy forceps were purchased each year at a cost of $455 per forceps. Next the important detail is reprocessing cost which consist the huge detail thus: Catherine (2001) the cost of sterilizing a reusable forceps here was found to be relatively low in absolute values ($ 1.62). This fixed cost accounted for at most 25.5% of the total cost of a biopsy procedure performed with a reusable forceps (assuming 65 uses per forceps). He decided to estimate the cost of each step of the sterilization protocol for a single forceps by dividing the expenditure ascribed to each step by the number of items processed. Results demonstrate that personnel costs account for about three-quarters of the cost of sterilization and equipment and consumable product expenditures accounted for only one-quarter. In his study, equipment costs were low, mainly because the equipment was not new and had already been amortized. Kozarek (2001) reported 3 min per lot of 5 forceps, with a hourly salary of $13.93 for manual labor. Personnel costs, as calculated by Yung (1994) were $8.19 with an hourly wage of $ 15. The cost of incineration of a disposable forceps was calculated from the relative weight of gastric and colonic forceps (50 g and 60 g, respectively). This was estimated to be € 0.03 for gastric forceps and € 0.03 for colonic forceps. Yang (2000).analyzed for 10,15 and 20 uses, reusable forceps costs were $58.06,$44.23,and $37.31,respectively. Total cost per use of reusable forceps was defined as the acquisition cost including purchase price, tax and shipping charge divided by the number of forceps uses plus the reprocessing cost for each use Reprocessing costs included the labor costs (based on an endoscopic technicians time) and costs of materials for each of the following steps in the protocol. For instance, collection of several forceps during the stages of ultrasonic treatment, rinsing, disinfection, transportation, or steam autoclaving could lead to reductions in reprocessing times. Instead of the approximately 33 minutes observed in this study, reprocessing times of 10 and 20 minutes would lower the cost to $10.87 ($5.69 savings per use) and $14.37 ($2.19 savings per use),respectively. However, these cost savings would be offset by the costs of purchasing and stocking a large inventory of additional forceps necessary to make up for the downtime associated with waiting to collect a large number of biopsy forceps for the reprocessing steps that can be performed in common. Moreover, the limited lifespan of the reusable forceps which was demonstrated in this study also would nullify the savings of mass processing of reusable forceps. Kozarek (1996) reported in case per-use repair and cleaning cost of $1.20

and $3.46, respectively, increasing to $5.61 per use if glutaraldehyde soak was substituted for steam autoclave. Rizzo (2000) said the reprocessing cost for reusable forceps was estimated to be $11.77 per use. The total cost per use of reusable forceps was $40.94. The total reprocessing costs in our institution were $11.77 per use. He initially thought that this value was high and may reflect the high cost of labor in the northeastern section of the United States. He were surprised to find, however, that our reprocessing costs compared favorably with those reported from other areas of the country. Bourguinon (2003).cleaning $2.28, centralized sterilization fee $0.97. The overall cost for a biopsy procedure with a reusable forceps from € 1.92 to € 2.14. Deprez (2000) Showed results A mean of 12 new reusable forceps were purchased every year for a total purchase price of $5460.A total of 315 biopsy sessions were performed per forceps (mean time life of 3 years per forceps, including 3 repairs).Yearly repair cost was $3308, equipment $1002, chemicals $3250,central sterilization $8333,and technician salary $4373.Total cost was $25,726 and cost per biopsy session was $6.65. Biopsy forceps are the most frequently used medical accessories in upper and lower GI endoscopy. Although we expected marked differences between costs in Europe and America, purchase prices for reusable forceps were similar to those in the study performed by Kozarek. ($350 vs $455 in our unit); reprocessing costs, excluding purchase and repair costs,were $3.46 in the Seattle study versus $4.38 in our study. Repair costs were also similar ($1.20 vs. $0.85 per biopsy session). The main difference between the two studies was the total number of uses per biopsy forceps,315 in our study and less than 20 in the study of Kozarek. This could be partly explained by the choice to buy high quality and therefore expensive forceps (purchase prices vary from $145 to $455 for a standard biopsy forceps). Most forceps had to be discarded after 3 repairs. We also evaluated the cost of a biopsy performed with a reusable forceps if a lesser number of uses per forceps had been permitted; reusable forceps would become cost-effective after 20 uses with the expensive forceps ($455) used in this study. With less expensive forceps ($155 per piece), cost-effectiveness would be attained as soon as 7 uses. These figures are similar to those of Kozarek. Purchase prices of disposable biopsy forceps are decreasing and could further decrease if purchased in larger quantities. The lowest purchase price in our study was $26.90 as compared with the price of $55 in 1996. The principal step in the process, cleaning, is a manual task usually performed by low wage personnel with high work loads who may receive only minimal training. Next,

another factor is number of reuse the lifespan of a biopsy forceps probably depends on the model the functional performance of reusable biopsy forceps ultimately deteriorates with increased number of uses. The durability can be extended with care in use and reprocessing. Each research reported this factor from collected data following: Kozarek (2001) studies have indicated that reusable biopsy forceps remain contaminated after reprocessing and can only be used a mean of 12 to 25 times without malfunction. This reusable biopsy forceps can be sterilized and used a mean of 91 times with adequate tissue sampling. Kozarek (1996) said a reusable forceps had to be used at least seven times to be cost effective in a study by if the disposable forceps can be obtained at a discounted rate, the number of uses for the reusable forceps would raise proportionately. In the study of Kozarek (1996), 42% of the forceps were used 10 or fewer times, and 36% were used between 11 and 20 times. Yang (2000) Reusable forceps malfunction at 11 to 15 uses was 5%; at 16 to 20 uses was 25%; and at 21 to 25 uses reached 80%. Dismantling of the reusable forceps at the end of the study demonstrated coiled sheath kinking, rust in the forceps closure mechanism, bent spikes and biomaterial contamination. Demonstrated that malfunction of reusable forceps increases after 20 uses and that the costs per use of disposable and reusable forceps were similar after 19 or 20 uses The performance of reusable forceps decreases after 20 uses. Bourguigon (2003) reported the mean number of uses was approximately 90 per reusable forceps. Most of the biopsy forceps were still in service at the end of the study. The number of uses of reusable forceps was thus modelized using a hypothetical number of uses varying from 25 to 150. Then total cost and cost-effectiveness summarized. Deprez (2000) calculated that total purchase and reprocessing costs for reusable biopsy forceps were 25% of those of disposable devices. Rizzo (2000) calculated the total cost per use of reusable forceps was $40.94. The per use cost of disposable biopsy forceps was $5.94 (35-29.17) less than that of reusable forceps. (Bourguinon, 2003). The cost per use of reusable biopsy forceps was $6.84. Catherine (2001) reported the total cost of the biopsy procedure using a reusable forceps was € 7.52 for a gastric forceps and € 8.67 for a colonic forceps. Kozarek (1996) said reusable biopsy forceps became cost-effective after seven uses in our institution. Rizzo (2000) reported disposable forceps were also found to be more cost-effective than reusable forceps with an average savings of $5.94 per biopsy session. Catherine (2001) analyzed reusable gastric forceps were more economical than disposable forceps.

2.2 Past study on cost-effectiveness of biopsy forceps

This is recommendation from previous study that concern about cost. Many detail in each research follow:

Hogan (2008) considered cost minimization analysis by use significant biopsy, jumbo reusable biopsy with disposable biopsy forceps to investigated. He designed a prospective study. Main outcome was mean cost of forceps per procedure, reuse was $3.27 and disposable was $10.0 and survival of reusable forceps 98% were still function after 2 years. Result of this study is jumbo reusable biopsy forceps more cost effective than disposable biopsy forceps.

Fireman (2006) used three types of biopsy forceps in his study. By he focused on economic point of view, he reported reusable biopsy forceps more cost-effective than disposable forceps by use a designated number of use and suitable for the larger gastrointestinal endoscopy because they can use many sessions per day and smaller endoscopy suitable for a few sessions per day. The reusable biopsy forceps performs a designated number of procedures, thus becoming more cost-effective than disposable forceps, which are impossible to clean and sterilize. The potential risk of infectious disease transmission must be taken into account. There is also the consideration that reprocessing of disposable forceps may damage or destroy the fragile devices.

Bourguignon (2003) retrospective studied about cost minimization analysis of biopsy forceps. Evaluation cost included purchase prices, cleaning and fee for sterilization. For disposable included acquisition and destruction costs. Finally, costs of reuse cheaper than disposable biopsy forceps. From a strictly economic point of view, the use of reusable biopsy forceps is advantageous.

Catherine (2001) compared cost and different brand name of biopsy that use in this research. Result cost of 15 reusable biopsy forceps from Olympus forceps, 10 gastric was 7.52 euro and 5 colonic was 8.67 euro. 81disposable from Microvasive Boston Scientific forceps, uses 37 gastric and 44 colonic disposable biopsy forceps was 11.98 euro. The costs of reusable include purchase price plus the sterilization costs and the number of uses. The ratio 75.7% of sterilization costs were personnel costs. The cost of reusable calculate from purchase price divided by the number of uses added the unit cost of sterilization. Disposable

ones taken from purchase price plus cost of incineration. Finally, reusable forceps was cheaper than disposable biopsy forceps.

Kozarek (2001) studied only reusable biopsy forceps about function, specimen and cleaning, 30 reusable biopsy forceps in one brand, Olympus undertaken about 1,339 procedure have 1,507 biopsy sessions in 18 month period. They have mean of use 91 times, can be sterilized and adequate specimen. From reported, no forceps problems about 95% and 5% have technical problems example failure to open or slow to open, sticky forceps, difficult passage through the accessory channel.

Kozarek (2000) studyied prospective about cost effective of reusable biopsy forceps. Total costs calculate from purchase price, number of uses, repair cost and cleaning costs. It has result, reusable biopsy forceps became cost effective after seven uses, it same with Kozarek in year 1996.

Rizzo (2000) who compared disposable versus reusable biopsy forceps in different brand name by randomized study stated that disposable biopsy forceps are cost-effective more than reusable. He use different type of biopsy in each intervention, for reusable he used Wilson Cook and disposable used Boston. From this study, it showed high reprocessing cost, 11.77$ per use plus the acquisition cost per use is 29.17$. The total cost per use is 40.94$ which number higher than the total cost per use of disposable biopsy forceps, 35.00$. In conclusion about performance of biopsy that used four characteristics evaluated by disposable biopsy forceps received a excellent rating and no rating of inadequate or poor, whereas reusable forceps received a good rating and receive 2%-12% in adequate or poor. Reusable with difficulties was reported 10% (5 in 48 biopsy sessions) and disposable not reported. Disposable provides adequate sample of tissue more than reusable biopsy forceps and reusable show adequate cleansing. In summary, disposable biopsy forceps was shown in this study to perform better overall than reusable forceps during elective GI endoscopy. Cost analysis revealed disposable forceps to be more economical per use than reusable biopsy forceps.

Yang (2000) studied prospectively measured the costs and performance of disposable and reusable biopsy forceps in different brand name in 200 biopsy sessions by use only four reusable biopsy forceps and each of reuse have number of use equal 25. The total costs of reuse included acquisition add reprocessing costs. The conclusion of this study

were the costs per use of disposable was $38 and reusable was $58.06, $44.23, $37.31, for 10, 15 and 20 uses, respectively. Costs of biopsy forceps were closely if use up to 20 uses or after 20 uses were reusable biopsy forceps cheaper than disposable biopsy forceps. But contrast, with the malfunction of reusable biopsy forceps just increase if use more than 20 uses.

Deprez (2000) studied in the large number of procedure perform, 7,740 biopsy sessions in 2 years period. Result of this study calculated purchase price and reprocessing costs of reusable biopsy forceps had cost 25% of disposable biopsy forceps.

Kozarek (1996) defined prospectively compare about cost and number of use of disposable or reusable biopsy forceps were cheaper to use in different brand name reusable have brand Olympus and disposable have many brand name. it show different purchase prize too, reuse equal $350 and disposable have mean $55 (range,$40-$65). Evaluation of costs included purchase prices, repairs, cleaning costs. The result same with Raltz and Kozarek (2000). Assuming a six fold difference in purchase price between reusable and disposable forceps, and a per-use repair and cleaning cost of $1.20 and $3.46, respectively, reusable biopsy forceps became cost-effective after seven uses in our institution.

From these study he conclude, these study have closely inside reprocessing but it has more detail that different things in each of factor the first, the estimated the mean of lifespan of the reusable that different, Kozarek (1996) reported a mean use more than 20 times, Yang (2000) found a mean use 25 times, Bourguigon (2003) reported a mean number of uses was 90 times. Deprez (2000) reported a mean 3 years lifespan over 300 uses. Catherine (2001) reported a mean use 25-150 times. Each of study that different brand name. which 2 things it had to effected with calculate cost, example costs of reusable reported by Deprez (2000) was $ 6.65, Bourguignon (2003) was $7.61, Catherine (2001) was $7.42 to $3.68 these conflict with Yang (2000) was $37.31 and Rizzo (2000) was $40.94 that Inside cost of reprocessing that different obviously, because differ area or institute it has cost different too. Different in term costs of labor relate with time that use in reprocessing, ex. High cost of sterilization for Yang (2000) was $16.56 and Rizzo (2000) was $11.77 compared with Catherine (2001) was$ 1.62 and $ 3.46 by Kozarek (1996), Bourguigon (2002) was $2.58. The different the price of disposable forceps ex. $55 for Kozarek (1996), $10.11 for Catherine

(2001), $26.9 for Deprez (2000), $35 for Rizzo (2000). From comparing it can show should be evaluated cost, number of use and performance of biopsy that different country or varied from international data. So should be consideration by made case by case on institution or on implication of hospital that interesting.

Some research have limitation and suggestion appear i.e. Robert (2002) said there are some limitations to this study. The comparisons were not made at the same point in time. Advances in forceps technology or mechanics over time could explain the results. However, the basic design of endoscopic forceps has not changed markedly during this interval. The biopsies were taken by a number of different endoscopists with varying levels of training and experience. However, the biopsy technique is quite simple; in general, between endoscopist variation is negligible Furthermore, each part of the study took place more than 1 years' time, which would serve to average effects of inexperience on the part of endoscopic trainees. Fireman (2006) reported units with small volume may prefer the ease of disposable accessories independent of relative cost issues, while large high-volume units may need to evaluate cost data more carefully to maintain sustainable practices. Although reusable biopsy forceps may be more suitable and cost-effective for larger GI endoscopy centers that perform many procedures per day, the convenience of disposable biopsy forceps may make them a more appropriate choice for centers that are smaller and perform only a few procedures each day. Petersen (1999) said units with small volumes may prefer the ease of disposable accessories independent of relative cost issues, while large high-volume units may need to evaluate cost data more carefully to maintain sustainable practices. Kozarek (1996).Finally, this study did not address the cost of waste disposal either for discarding disposable equipment or for the disposal of chemicals utilized to manually disinfect reusable forceps.

In Thailand the health care have limitation budget. From the fact that Thailand has limited resources, the allocation of resources to hospitals and sanitariums is abbreviated. Therefore, there relate to the public hospital is limited resources too. So it's effect to use medical instruments of endoscope accessories in some method, "Reusable" Many study reported about cost and effectiveness of disposable and reuse biopsy forceps but they have

different equipment, different labor cost and different material from Siriraj hospital. So I want to consider about cost effectiveness in Thailand which focus at Siriraj hospital.

CHAPTER III

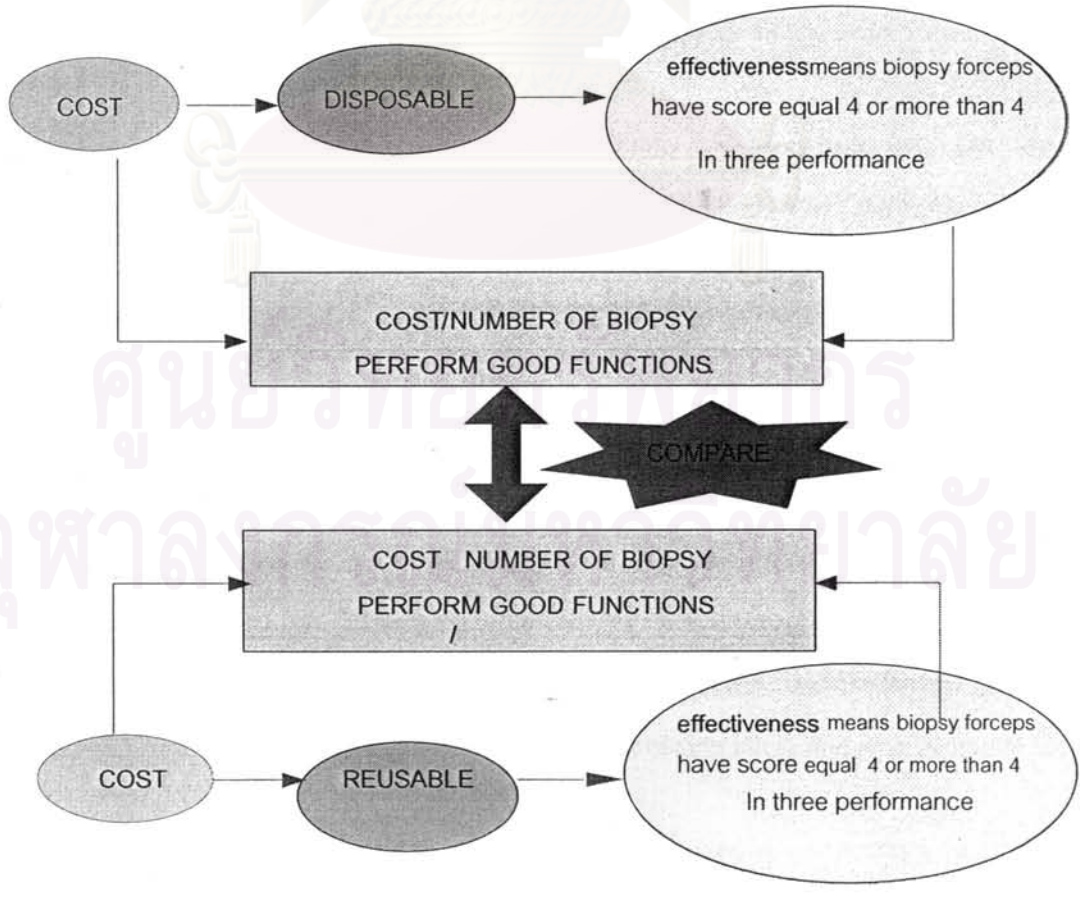
RESEARCH METHODOLOGY

3.1 Research Design

This study is designed to be a descriptive study using primary data from survey for effectiveness measuring and using secondary and primary data for cost measuring. The prospects studied in this research are the performance of the biopsy instrument in the GI endoscope unit and the cost of these instruments in each biopsy session, i.e., purchasing price, reprocessing costs, number of uses of all biopsy forceps uses. To define whether disposable or reusable biopsy forceps is more valuable.

3.2 Conceptual Framework

Figure 1 : Conceptual Framework



3.3 Population and Sample

3.2.1 Population

3.2.1.1 Target population

Patients with GI symptoms in Siriraj Hospital.

3.2.1.2 Population to be sampled

GI symptoms Patients with 2 major curing procedures, gastroscopy (upper endoscopy) and colonoscopy (lower endoscopy). in Siriraj Hospital from February to March 2009.

3.2.1.3 Study site

The endoscope center at Siriraj Hospital.

3.3 Data collection

3.3.1 Definition

- Biopsy forceps = equipment that pass through the endoscope to cut the tissue.
- Disposable = disposable biopsy forceps is used once and discarded.
- Reusable = reusable biopsy forceps is used once per day and goes into the reprocessing process in order to be used once again use again on subsequent day until the mechanic is failure or malfunction.
- Reprocessing = the processes to bring the used reusable biopsy forceps into the prompt for used status. It has many steps, i.e., cleansing and sterilization.

3.2.2 Data collection

- This study gathers primary data from evaluation forms in measuring the effectiveness and use secondary data from the Siriraj hospital record, i.e., elements in reprocessing cost, purchasing price, and environmental cost.

- In each biopsy session, the evaluation form is filled by the endoscopist. And the biopsy forceps is randomly assigned to the performer, who would not know which type of the biopsy forceps is acquired. The evaluation form is then evaluated immediately after each session.
- Both the reusable and disposable biopsy forceps used in this study are new and are single bite.
- The purchasing price obtained from the supplier of Siriraj hospital is the current price.
- The salary and other cost involving reprocessing process are acquired from Siriraj hospital at the date of study.
- The criterions in the evaluation form are suggested by the well-known and respectful endoscopist professor.
- The estimated cleansing time of the technician is averaged from each observation session.
- Each reusable biopsy forceps is labeled as No.1-20 and the colored sticker is stick to it after each use, i.e., yellow after the first use, pink after the second and so forth.
- The evaluation forms are divided into two parts; the scoring, location of biopsy session and the performer's experience are treated by the performer himself while the rest are recorded by the researcher.

3.3 Data analysis

In order to measure which choice of biopsy forceps is more valuable the data analysis is then arranged into 4 main sections. First, we start with the cost analysis. Second, the effectiveness analysis is analyzed in detail to have the wider vision of each biopsy forceps type. Third, the cost effectiveness is then analyzed. Finally, the factor analysis is conducted to advise which circumstance support each type of biopsy forceps choice.

3.4.1 Cost analysis of disposable and reusable biopsy forceps.

The cost analysis includes any costs pertaining to each type of biopsy forceps. Any other cost, i.e., doctoral wages that does not involved with the biopsy forceps is not taken into concern.

The disposable biopsy forceps cost is quite straight forward as it is derived from the purchasing price and the destruction cost. Conversely, as the reusable biopsy forceps is used multiple times, its cost is then calculated by including any occur-once cost with other relevant per used cost. The disposable biopsy forceps' cost, in the other hand, includes only the purchasing price and the destruction cost. First, we begin with the reusable biopsy forceps cost which is comprised of two main cost, the cost which occurs once per biopsy forceps and the reprocessing cost. The cost that happen once is quite simple as it is comprised of only the purchasing price and the destruction cost. However, the reprocessing cost is much more complicate as it concerns various costs, i.e., labor cost, material cost, capital cost and environmental cost. All the reprocessing costs are categorized and described in detail as followed;

Labor cost : nurses, nurse-aid, workers. (opportunity cost, cost of sick from reprocess ex. inhale chemical, secretion or blood to skip or contact body) record allocation by working time criteria or technician's time. Technician time spent processing the forceps are determine by direct observation of 10 separate cleaning sessions.

Material cost or equipment supply: detergent, enzyme, mask, gloves, gown, washing, plastic sacks, consumable products, including purchase prize, maintenance, storage or inventory control. Costs of materials for each of the following steps in the protocol.

Capital cost : ultrasonic cleanser, de-aerator or air cleaning, machine to sterilization.

Environment cost: incineration cost (calculate from the relative weight of biopsy forceps) or disposal of cleaning liquids or cost increasing environment burden.

Other minuscule cost: Some costs are quite inconsequential compared to the above cost and their impacts on the total cost are very marginal; therefore we do not include them in the reprocessing cost, for instance, toothbrush and chemical disposal.

To clearly demonstrate, we summarize the procedure of the reprocessing process in Table 2, which bases on FDA(the food and drug administration) and is directly observed from the practical processes from the GI endoscope center, Siriraj hospital.

Table 2 : Steps for reprocessing biopsy forceps.

Steps for reprocessing biopsy forceps
Flushing or scrub by detergent
Presoak enzyme
Scrub forceps
Water rinse
Ultrasonic cleansing with enzymatic detergent
Water rinse
Air dry / tap water rinse
Place in peel pack and labeling sending to sterilization center
Transportation to the sterilization
Sterilization unit
Processing in sterilization center
Reception/sorting
Washing and drying
Packing in seal plastic sacks
Sterilization using ethylene oxide (ETO) aerate for 24 hr.
Archiving / identifying forceps
Return to endoscopy unit for keep in stock for use

Table 3 concludes which costs are included in computing the disposable and reusable biopsy forceps cost. As previously stated, the summary in Table 3 shows that only the costs that occur once is included in calculating the disposable cost while the reusable cost includes all other reprocessing relevant cost.

Furthermore, the disposable cost is sub-divided into two groups. The reason is that the cost of the disposable biopsy forceps currently used in the hospital bases on the retail price. However, if the choice of biopsy forceps were changed into the disposable, the negotiation

price would be much cheaper whole sale price. Thus, we conduct the cost analysis for both the retail and whole sale price.

Also, the reusable cost is sub- divided into multiple groups. This is because one of the factors having a major impact the reusable cost is the times each reusable biopsy forceps could be used. It is then divided into three main group based on the following concept: (1) the 10-time used of which effectiveness this research records, (2) the 29 average times each reusable biopsy forceps is used acquired from the Siriraj hospital, (3) the 31 average figure obtained from the four previously studies in this field, which are Kozarek (1996), Yang (2000), Rizzo (2000) and Catherine (2001).

Table 3 : Cost identification.

Cost item	Reusable	Disposable
Material cost		
-Purchase prize	✓	✓
-Enzyme	✓	-
-mask	✓	-
-gloves	✓	-
-plastic sack	✓	-
-toothbrush and detergent	✓	-
-wash cloth	✓	-
-central sterilization processing fee	✓	-
Labor cost		
- labor cost (calculate from technician salary and technician time)	✓	-
Capital cost		
- ultrasonic cleanser	✓	-
- de-aerator	✓	-
Environment cost		
- destruction cost	✓	✓
- disposal cost	✓	-

- Total cost are determine using the formula :

Cost of reuse biopsy forceps Per one use:

$$= \frac{(\text{purchase prices} + \text{destruction cost})}{\text{number reuse per forceps}} + \text{reprocessing cost per reuse} + \text{environment cost per reuse}$$

Cost of Disposable biopsy forceps Per one use:

= purchase prices + destruction cost

3.4.2 The effectiveness analysis of each type of biopsy forceps

Before we analyze the effectiveness of each biopsy type we first begin with the assumption underlying the effectiveness result. The assumption in measuring the effectiveness is as followed.

A. Effectiveness assumption

As the analysis in this section is designed to measure the overall quality of the biopsy forceps, the main basic functions of use for each type of biopsy forceps are first determined. Generally, basic functions during the endoscope session are the ability to cut tissue, the ability to pass through the scope and the ease to open and close the forceps cup. Therefore, to be consistent with the biopsy forceps basic functions, the scoring categories in the evaluation form are then designed as follow; (1) The ease of passage through the endoscope, (2) The ease of opening and closing the forceps cup, (3) the adequacy of the specimen.

The score in each category is in ordinal scale and its meaning is as follow;

1 = can't use or change a new one or total malfunction,

2 = poor or inadequate for use,

3 = adequate or some loss of function but usable,

4 = good,

5 = new or like new.

The effectiveness of each biopsy forceps is collected from the scoring each operating endoscopist specifies. This is done by determine if the biopsy forceps scores in all categories are equal or above the benchmark score of four points, which is indicated by the well known and respectful endoscopist Professor.

The evaluation form is then design according to the above assumptions. And, as previously mentioned, the evaluation form is divided into two parts, recording by the researcher and by the biopsy operator. The first part consists of the general data, detail of biopsy forceps in use and the detail of the biopsy session. The second part includes the data involving with the biopsy forceps' performance and the performer's experience. Starting with the general data are the date, time, and endoscope room in the first part. The idea of these data is to identify if there were any error in collecting the data, it would be properly remedied right away. The next section in the first part is the biopsy type and it identification. These data are used both in determining if there is any error and in the analysis. The last section of this part is the objective and the number of tissues in each biopsy session. These data are used in the factors analysis in the last section of this chapter. As for the second part, we begin with the location of the biopsy and the experience of the performer. Both data are used in the factors regression analysis. The next section is the biopsy forceps scoring, it is designed as aforementioned. The last data including in the evaluation form is the recommendation from the biopsy performer. This is to capture if there is any suggestion used both in improving the research and to advise if any extended research is studied. The figure of the evaluation form is shown in the appendix section.

B. Effectiveness analysis

The effectiveness portion of each biopsy type is then computed as followed;

$$\text{Effectiveness portion} = \frac{\text{Number effective biopsy forceps}}{\text{Total biopsy forceps in the sample}}$$

After the effectiveness result is obtained, we then conduct the score break down analysis to determine the distribution of each biopsy score. This is done by counting the number of each score within each category from each biopsy type, resulting in six breaking down bar charts.

3.4.3 The cost-effectiveness analysis of each type of biopsy forceps

The cost-effectiveness analysis is designed to measure which choice is more valuable. The idea is that if we consider only the cost of each biopsy forceps, the winner will be likely the worst quality choice. We then try to balance both the quality and the quantity (cost) and then indicate which choice is advisable. The indicator

used in this research is the cost effectiveness which is the cost divides by the effectiveness portion. The following equations show the detailed calculation of the cost-effectiveness for each biopsy type;

$$\text{cost-effectiveness} = \frac{\text{cost}}{\text{effectiveness}}$$

Thus,

$$\text{the cost-effectiveness for disposable biopsy forceps} = \frac{\text{cost}}{\text{effectiveness of disposable}}$$

$$\text{the cost-effectiveness for reusable biopsy forceps} = \frac{\text{cost}}{\text{effectiveness of reusable}}$$

where

$$\text{Effectiveness of Reusable} = \frac{\text{Reusable biopsy that perform function of biopsy session that receive score equal to 4 points or greater.}}{\text{Total reusable biopsy forceps in this study}}$$

$$\text{Effectiveness of Disposable} = \frac{\text{Disposable biopsy that perform function of biopsy session that receive score equal to 4 points or greater.}}{\text{Total disposable biopsy forceps in this study}}$$

After the cost-effectiveness is determined the sensitivity analysis is then performed. This is done to suggest which factors affect the cost-effectiveness the most. Thus, special cares may be needed when study in other circumstances with considerably difference in these factors. Furthermore, as the costs collected from each biopsy are sub dividing into groups, the cost-effectiveness are compared across all these sub groups. However, since the criterion in dividing the reusable cost in to groups is mainly the time of uses, the break even analysis is then conducted to reveal how many times of uses the reusable biopsy forceps have to endure in order to have the same valuable as the disposable biopsy forceps.

3.4.4 The factors analysis

To estimate the relationship between effectiveness and factor affect on cost-effectiveness of disposable and reusable biopsy forceps are acquire from the following model:

$$Avg\_Score_i = \beta_{0i} + \beta_{1i}OBJ_i + \beta_{2i}No\_SAMPLE_i + \beta_{3i}EXPR_i + \beta_{4i}Hard\&Easy_i \quad (1)$$

$$Passage_i = \beta_{0i} + \beta_{1i}OBJ_i + \beta_{2i}No\_SAMPLE_i + \beta_{3i}EXPR_i + \beta_{4i}Hard\&Easy_i \quad (2)$$

$$Close\_Open_i = \beta_{0i} + \beta_{1i}OBJ_i + \beta_{2i}No\_SAMPLE_i + \beta_{3i}EXPR_i + \beta_{4i}Hard\&Easy_i \quad (3)$$

$$Size_i = \beta_{0i} + \beta_{1i}OBJ_i + \beta_{2i}No\_SAMPLE_i + \beta_{3i}EXPR_i + \beta_{4i}Hard\&Easy_i \quad (4)$$

where i = stand for the sampling groups of the analysis, where i equal (1) "A" if it's all samplings group, (2) "D" if it's disposable biopsy forceps group and (3) "R" if it is reusable biopsy forceps group,

Avg_Score = the average score of all three categories,

OBJ = 1 if the using objective of that biopsy forceps is for pathology analysis and 0 otherwise,

No_SAMPLE = the number of biopsy sample(s),

EXPR = the experience of each operating doctor measured in years,

Hard&Easy = 1 if the difficulty level of the location each biopsy forceps performs is high and 0 otherwise.

As the evaluative scores might be affected by other factors, this analysis aims to measure the affect from each factor. This is crucial since each hospital/area might have external or uncontrolled factors that lead the result of the cost-effective analysis into opposite side. Therefore, the following variables are investigated;

As the objective of the biopsy is divided into two categories, the pathology and the clo-test, the first variable is then the OBJ, which equal 1, if the using objective of that biopsy is for pathology analysis and 0, if it is for clo-test analysis. The rationale is that the characteristic of these two analyses are different. Thus, the scores might bias toward particular analysis. The second variable is No_SAMPLE, which is the number of biopsy sample(s) in each session. The third variable is the EXPR, which is the experience of the doctor performing the biopsy session. This is the proxy to measure

how much the skill of each doctor in operating. The final variable is Hard&Easy, which is equal 1 if the difficulty level of the location each biopsy forceps performs is high and 0 otherwise. It is used as a measurement how difficult the location of the biopsy session will centre. The criterion to judge each biopsy session's difficulty is obtained from the well known and respectful endoscpist professor. For instance, the location is considered hard if it is esophagus, duodenal bulb and polyp or the location requires retroflex posture. In the other hand, the location is considered easy if it is antrum, body, fundus, colon and random colon.

We then analyze further how these variables affect the scores from each scoring category, i.e., the Ease of passage, the Ease of opening and closing and the Adequacy of sample taken per session.

CHAPTER IV

RESULTS AND DISCUSSION

This chapter explores the empirical results of the study. The structure of the results is arranged as follow:

1. The cost of disposable and reusable biopsy forceps.
2. The effectiveness of disposable and reusable biopsy forceps.
3. The cost-effectiveness of disposable and reusable biopsy forceps.
4. The factors affecting the effective scores.

1. The cost of disposable and reusable biopsy forceps.

Table 4 : Cost of disposable and reusable biopsy forceps.

Cost Item	Unit	Disposed (Baht)		Reusable (Baht)		
		Retailed Sales	Whole Sales	10 Uses	29 Uses[1]	31 Uses[2]
Biopsy Forceps Cost						
- Purchasing price	1 pc.	1,500	500	10,000	10,000	10,000
Environment cost						
- destruction cost[3]	1pcs.	0.56	0.56	0.56	0.56	0.56
Total acquisition and destruction cost	**Per use**	**1,500.56**	**500.56**	**1,000.56**	**345.38**	**322.60**
Reprocessing cost						
- enzyme[4]	11 cc.	-	-	9.5	9.5	9.5
- step cleaning	4 cc.					
- ultrasonic cleanser	7 cc.					
- mask	1 pc.	-	-	1	1	1
- gloves	2 pairs	-	-	4	4	4
- wash cloth[5]	1 pc.	-	-	0.5	0.5	0.5
- central sterilization processing fee[6]	1 pc.	-	-	12	12	12
Labor cost[7]						
- labor cost	30 min.	-	-	40.50	40.50	40.50

Capital cost[8] - ultrasonic cleaner	Per use	-	-	16	16	16
Total reprocessing cost		-	-	84.5	84.5	84.5
Total cost per use		1,500.56	500.56	1,085.06	429.88	407.10

Remark 1 The real average number of the reusable biopsy forceps used in Siriraj Hospital calculates from average from two data, first number of tissue sent to laboratory every day. Second the number of biopsy forceps sent to sterilization every day divides by the total number reusable biopsy forceps that record for check stock in February.

2 The number is the average uses of the biopsy forceps from four papers, which are Kozarek (1996), Yang (2000), Rizzo (2000) and Catherine (2001).

3 Base on the destruction cost of 7 baht per kilogram and the weight of biopsy forceps of 80 grams.

4 The cost of the 3e-enzyme is 3,500 baht per gallon.

5 Each wash cloth cost 10 baht and is used entire day. The average number of biopsy forceps cleaned each day is 20 pcs.

6 The central sterilization processing cost is 2,459 baht round. The average number of biopsy forceps sterilized is 200 pcs per round.

7 The labor cost is based on the average salary of 11,177.81 baht per month and the working hour of 138 hours per month. The 138 figures is calculated from 22 working days in a months, the 7 working hours a day and any breaking time between working hours of 10%.

8 Base on the cost as of Jan 2009, the cost of the ultrasonic cleaner is 800,000 baht and the estimated used of the machine is about 10 years with 5,000 uses per year.

2. The effectiveness of disposable and reusable biopsy forceps.

The effectiveness of disposable and reusable biopsy forceps is measure in 3 categories, which are the Ease of passage, Ease of opening and closing and Adequacy of sample taken per session, discussed in detail in research methodology section. The result scores showed in Table 5. Indicate that, out of 5 points, the averages of the Ease of passage category summed scores for disposable biopsy forceps, reusable biopsy forceps and for all the samplings are 4.78 ,4.20 and 4.39 respectively. The averages of the summed scores for the Ease of opening and closing category are 4.75, 4.19 and 4.38 for disposable biopsy forceps, reusable biopsy forceps and for all the samplings respectively. And for the final category, Adequacy of sample taken per session, the averages of the summed scores are 4.73, 4.27 and 4.42 respectively for disposable biopsy forceps, reusable biopsy forceps and for all the samplings respectively. These will result in the average of the average scores from

all 3 categories of 4.75, 4.22 and 4.40 for disposable biopsy forceps, reusable biopsy forceps and for all the samplings respectively. Apparently, the average scores of all 3 categories for disposable biopsy forceps are more than the average scores for reusable biopsy forceps.

Furthermore, by comparing each score with the benchmark score of four points, which is indicated by the respectful endoscopist Professor, we will have the effectiveness portion of both the disposable and reusable biopsy forceps. The comparing is done for all 3 categories and the summary results are reported in Table 7. The effective proportions of the biopsy forceps are reported in the parenthesis under the number of effective biopsy forceps for each category. The effective portion of all biopsy forceps is 253 sessions out of 300 sessions with the effective portions for disposable biopsy forceps and reusable biopsy forceps of 100 and 150 out of 100 and 200 respectively. This will be result in 100%, 75% and 84.3% for disposable biopsy forceps, reusable biopsy forceps and for all the samplings respectively. The effectiveness analyses are also done for each individual category. The results for the Ease of passage category are 100, 168 and 271 from 200, 100 and 300 sessions for disposable biopsy forceps, reusable biopsy forceps and for all the samplings respectively. The effectiveness portions for the Ease of opening and closing category are 100, 170 and 273 from 200, 100 and 300 sessions for disposable biopsy forceps, reusable biopsy forceps and for all the samplings respectively. The effectiveness analysis for the last category, the Adequacy of sample taken per session, shows the proportion of 100, 178 and 271, again, from 200, 100 and 300 sessions for disposable biopsy forceps, reusable biopsy forceps and for all the samplings respectively. Thus, the effectiveness analysis that, for all categories, the effective portions of for disposable biopsy forceps are all 100% confirms the difference in scores between disposable and reusable biopsy forceps.

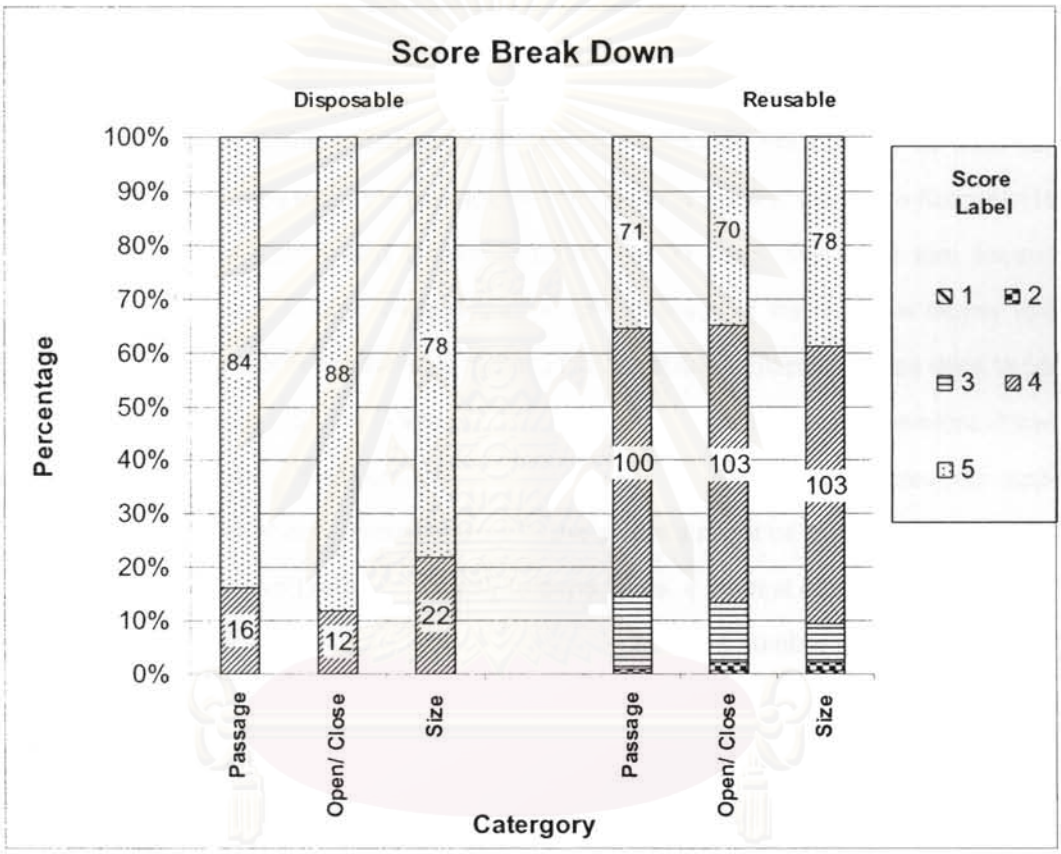
Table 5 : The average scores and the effectiveness of the disposed and reusable biopsy forceps.

	Disposable	**Reusable**
A. Average Score of		
Passage	4.84	4.20
Open Cls	4.88	4.19
Sam. Size	4.78	4.27
Average Score	4.83	4.22
Total Number of Samplings	100	200
B. Effectiveness of		
Passage (Sessions) (%)	100 (100.0%)	171 (85.5%)
Open Cls (Sessions) (%)	100 (100.0%)	173 (86.5%)
Sampling Size (Sessions) (%)	100 (100.0%)	181 (90.5%)
Average Score (Sessions) (%)	100 (100.0%)	153 (76.5%)
Biopsy Forceps (Sessions) (%)	100 (100.0%)	141 (70.5%)

Then analysis distribution of score in each type of biopsy forceps reported in figure 2. Reusable biopsy forceps show score until 1 to 5 score by to explain following, the most receive 4 score in each functions as 100, 103 and 103 respectively for the ease of passage, the ease of opening and closing and adequacy of sample taken pre session. Then next below score 5 with 71, 70 and 78 for the ease of passage, the ease of opening and closing and adequacy of sample taken pre session respectively. For score 3 as mean adequate or some loss of function but usable receive 27, 23 and 15 for the ease of passage, the ease of opening

and closing and adequacy of sample taken pre session. The last score 2 and 1 to exist slice number about one to three only. Which contrast disposable biopsy forceps to perform only 4 and 5 score this result to be show effectiveness 100%.

Figure 2 Score break down.



In addition to score that doctor put in evaluations form. It has the recommend in some evaluation form example reusable biopsy forceps: difficult to passage, not moving freely, tight, slowly opening, to delay opening, unable to open forceps well, biopsy sample loss. And disposable biopsy forceps: good use, excellent passage of forceps, complete remove polyp in one biopsy, ease for hard position ex. retroflex and location ex. Ileum, polyp and esophagus.

3. The cost-effectiveness of disposable and reusable biopsy forceps.

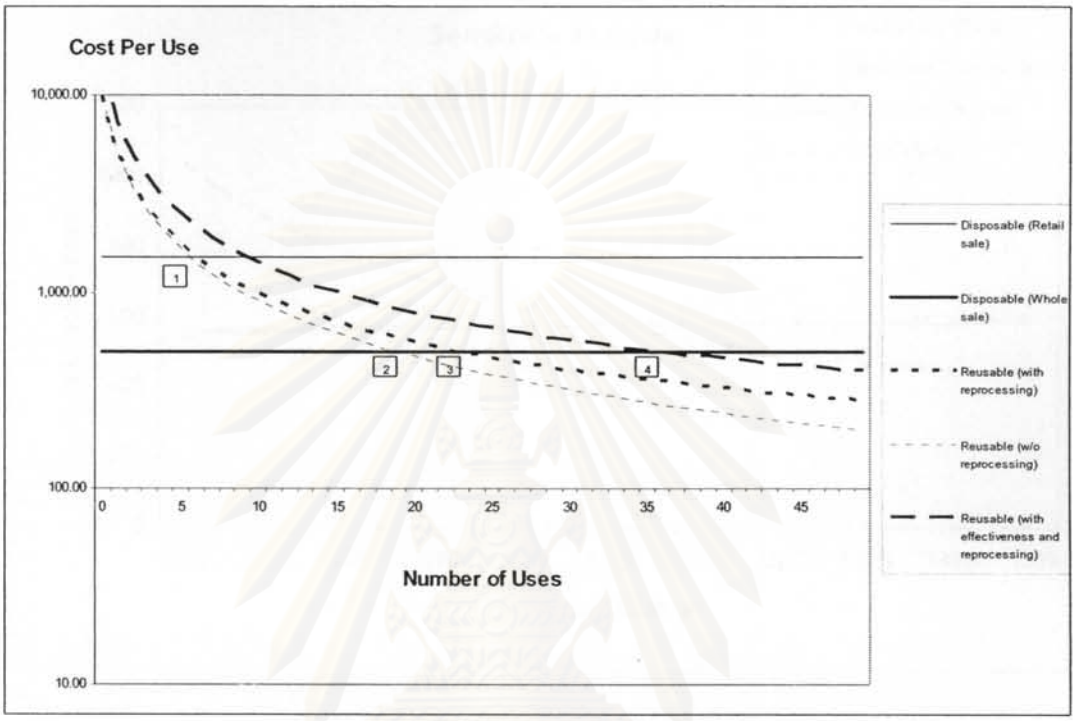
We then calculate for the cost effectiveness of disposable and reusable biopsy forceps. This is done by dividing the cost of the samplings biopsy forceps by their contemporaneous effective portion. Note that the lower the cost-effectiveness, the better and the more valuable the biopsy forceps. The rationale for this calculation is described in detail in the research methodology section. Among three groups of our focused, which are the group of disposable biopsy forceps retail sales, the group of disposable biopsy forceps whole sales and the group of reusable biopsy forceps, the result seems that the whole-sale cost of the disposable forceps is the cheapest. However, if we modify the number of uses for the reusable biopsy forceps to be the average of four previous studies, which are Kozarek (1996), Yang (2000), Rizzo (2000) and Catherine (2001), of 31 uses, the result turn toward the reusable biopsy forceps. Nevertheless, as the effectiveness of the reusable biopsy forceps show only 75%, the cost-effectiveness of the 31-uses reusable biopsy forceps rises to 555.47 baht, 54.91 baht more than the whole-sale disposable cost-effectiveness. Therefore, if we take into consideration the effectiveness, the result goes opposite from the previous cost-only analysis. Further, the effectiveness we used in the analysis might be overstated as the number is from the 10-times used reusable biopsy forceps. Thus, if the real effectiveness figure of the 31-uses reusable biopsy forceps were used, the effectiveness number might be far lower than 75%. Consequently, the difference in the cost-effectiveness between the whole-sale disposable biopsy forceps cost and the 31-uses reusable biopsy forceps should be larger. The results are shown in detail in the Table 6.

Table 6 : Conclusion for the cost - effectiveness of disposable and reusable biopsy forceps.

Identify	Disposable (Baht)		Reusable(Baht)		
	Retailed Sales	Whole Sales	10 Uses	29 Uses	31 Uses
Total cost per use	1,500.56	500.56	1,085.06	429.88	407.10*
Effectiveness	100 %	100%	70.5%	70.5%	70.5%
Cost-effectiveness	1,500.56	500.56*	1,539.09	609.75	577.45

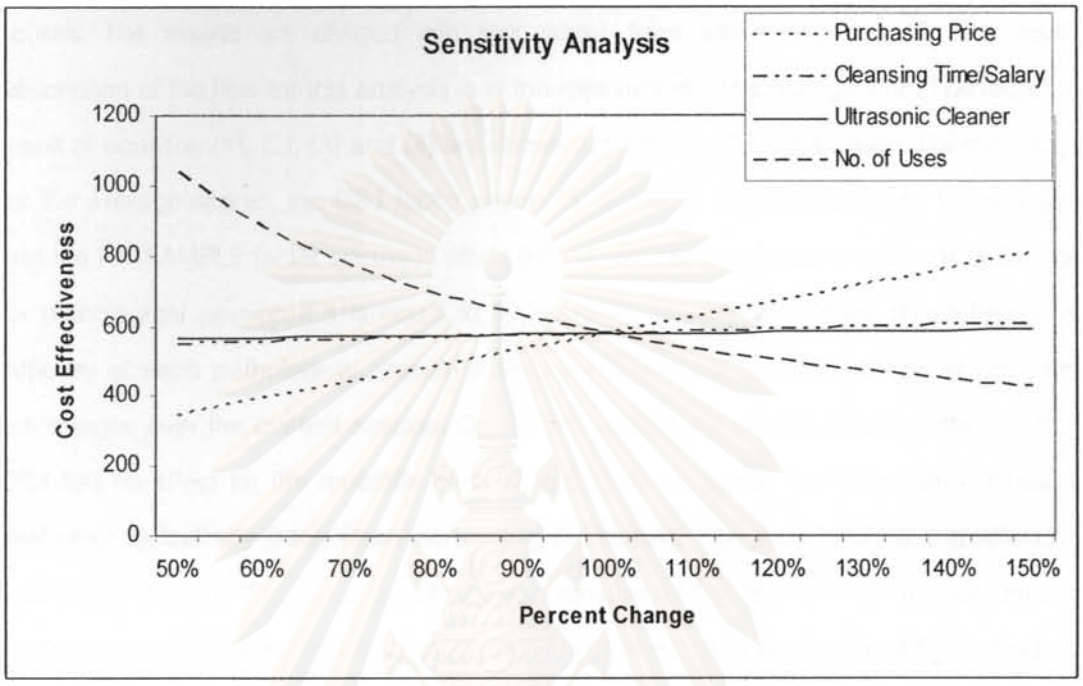
* indicate the best cost-effectiveness (or the cheapest in other word).

Figure 3 : Unit cost of disposable biopsy forceps compares with reusable biopsy forceps.



The break even analysis shown in figure 3 tell us how many sessions the reusable biopsy forceps must be used in order to have the cost of use per sessions equal to disposable biopsy forceps. The break even number of uses for the reusable biopsy forceps, without the reprocessing cost, compared to the disposable biopsy forceps in retail sale price is six times, [1]. However if the whole sale price for the disposable biopsy forceps is used, the break even number then hikes to nineteen, [2]. Nevertheless, if the reprocessing cost for the reusable biopsy forceps is included, the break even number marches further to twenty-three, [3]. Additionally, if we take into consideration the effectiveness figure of 70.5%, the break even then soars to thirty-six, [4]. In sum, the break even analysis recommends that the reusable biopsy forceps must be used at least thirty-six times in order to have its cost more attractive than the disposable choice.

Figure 4: Sensitivity analysis for the cost effectiveness of reusable biopsy forceps.



We also conduct the sensitivity analysis to test how each factors affect the cost effectiveness of the reusable biopsy forceps. The selected factors in the analysis are the unit price, the major reprocessing cost and the effectiveness figure. The sensitivity analysis shown in figure 4 recommend that the factors having the most effect on cost effectiveness for reusable biopsy forceps are purchasing price and the time of uses. The first factor is quite straight forward that it is the largest portion on total cost. The second factor is the number of uses for the reusable biopsy forceps. Although it is not directly effect the cost, the influence on the average cost per use is quite large. However the effect is diminishing while the number of uses goes higher. Other factors in the analysis have only marginal impact in the cost effectiveness. This is as expected since the portion of each factors are minute compared to the purchasing price mentioned above.

4. The factors affecting the effectiveness scores.

This section shows the regression results of the factors affecting the effectiveness scores. The results are divided into four tables from twelve regressions. The detailed description of the flow for this analysis is in the research methodology section. The regression result of equation (1), (2), (3) and (4) are shown in table 7 to 10 respectively. For the analysis for the average scores, the OBJ factor seems to affect the disposable biopsy forceps group and the No_SAMPLE factor seems to affect the reusable biopsy forceps group. As OBJ stand for pathological session if it is equal to 0, the reason might be that the characteristic and difficulty of each pathological session makes the disposable biopsy forceps to have more advantages over the clo-test session. On the other hand, as we can see from the result, the OBJ has no effect for the reusable biopsy forceps group as the forceps might not help the performer to feel any ease when performing the cutting. The next variable that affects the score is the No_SAMPLE. This is quite straight forward as the more number the sample cut in each session, the higher the probability that the reusable biopsy forceps would go wrong.

Table 7 : regression result for the factors affecting the average scores.

Coefficient	Total	Disposable	Reusable
C	4.42	4.75	4.38
	(0.07)	(0.06)	(0.09)
OBJ	0.04	0.07*	0.01
	(0.05)	(0.04)	(0.06)
No_SAMPLE	-0.01	0.00	-0.03*
	(0.01)	(0.01)	(0.01)
EXPR	0.01	0.05	-0.13
	(0.01)	(0.08)	(0.12)
Hard&Easy	-0.03	0.00	-0.01
	(0.1)	(0.01)	(0.01)
R-Square	0.02	0.06	0.04
F-statistic	1.31	1.51	2.15

The number in parenthesis is the standard error of each coefficient and * indicates the significant level of 5%

Table 8 : regression result for the factors affecting the scores of the Ease of passage category.

Coefficient	Total	Disposable	Reusable
C	4.35	4.78	4.26
	(0.08)	(0.08)	(0.11)
OBJ	0.04	-0.02	0.05
	(0.05)	(0.05)	(0.07)
No_SAMPLE	-0.01	0.01	-0.02*
	(0.01)	(0.01)	(0.01)
EXPR	0.01	-0.01	0.10
	(0.01)	(0.11)	(0.14)
Hard&Easy	0.10	0.01	0.00
	(0.11)	(0.01)	(0.01)
R-Square	0.01	0.02	0.03
F-Statistic	1.05	0.56	1.31

The number in parenthesis is the standard error of each coefficient and * indicates the significant level of 5%

As we dig deeper in analyzing the score of each individual category we find that, first, the No_SAMPLE variation also affects the scores from the reusable biopsy forceps group. As we can expect that coil of the reusable biopsy forceps might not be in the perfect state, the more the tissues cut, the higher the probability that the performer feel uneasy in cutting them. Interestingly, this confirms further the result of the overall score in the previous analysis.

Table 9 : regression result for the factors affecting the scores of the Ease of opening and closing category.

Coefficient	Total	Disposable	Reusable
C	4.46	4.84	4.42
	(0.09)	(0.07)	(0.11)
OBJ	0.06	0.10*	0.02
	(0.05)	(0.04)	(0.07)
No_SAMPLE	-0.02*	-0.02*	-0.04*
	(0.01)	(0.01)	(0.01)
EXPR	0.01	0.12	-0.09
	(0.01)	(0.09)	(0.15)
Hard&Easy	0.02	0.00	-0.01
	(0.12)	(0.01)	(0.01)
R-Square	0.03	0.16	0.05
F-Statistic	2.11	4.36	2.63

The number in parenthesis is the standard error of each coefficient and * indicates the significant level of 5%

The second analysis for the scores of the Ease of opening and closing category suggests that the OBJ factor seems to affect the disposable biopsy forceps group and the No_SAMPLE factor seems to affect the all biopsy forceps group. The No_SAMPLE variation also affects the scores from the all group. It can tell that the more number the sample cut in each session, the higher the probability that the biopsy forceps would go wrong. Another variable, OBJ, which affects the ease of opening and closing of disposable biopsy forceps, shows the same reason with Table 7. The reason might be that the characteristic and difficulty of each pathological session makes the disposable biopsy forceps to have more advantages over the clo-test session.The results are shown in detail in Table 9.

Table 10 : regression result for the factors affecting the scores of the Adequacy of sample taken category.

Coefficient	Total	Disposable	Reusable
C	4.45	4.64	4.47
	(0.08)	(0.09)	(0.11)
OBJ	0.03	0.15*	-0.04
	(0.05)	(0.06)	(0.06)
No_SAMPLE	0.00	0.01	-0.02
	(0.01)	(0.01)	(0.01)
EXPR	0.01	0.05	-0.38
	(0.01)	(0.12)	(0.14)
Hard&Easy	-0.22*	0.00	-0.01*
	(0.11)	(0.01)	(0.01)
R-Square	0.02	0.07	0.05
F-Statistic	1.53	1.74	2.73

The number in parenthesis is the standard error of each coefficient and * indicates the significant level of 5%

The last category that is analyzed is the Adequacy of sample taken. (table 10) The results recommend that the OBJ factor seems to affect the disposable biopsy forceps group. The pathological session support the disposable biopsy forceps choice. This is rational as the difficulty of the pathological session is more than the clo-test session. The Hard&Easy factor seems to affect both the total and the reusable biopsy forceps group. As Hard&Easy factor stand for location for cutting in each session, it might be that the difficulty of such location bring some problem to the use of the reusable biopsy forceps. Therefore, the results inform that the reusable biopsy forceps choice should be avoid when the difficult location is focused.

The overall results from Table 7 to Table 10 reconcile and suggest that (1) the number of biopsy sample(s) is opposing the choice of the reusable biopsy forceps while it is supporting the disposable biopsy forceps alternative, (2) the objective choice of pathology analysis pertaining advocates the option of the disposable biopsy forceps.

CHAPTER V

CONCLUSIONS AND RECOMMENDATIONS

5.1 Conclusions

The cost per use comparison of each biopsy forceps type shows that the reusable biopsy forceps is the cheapest. However, further examination including effectiveness analysis suggests that the cost effectiveness of the disposal biopsy forceps turn to be more valuable. Moreover, the sensitivity analysis of the cost effectiveness is as well conducted and shows that the factors having the most affect on the cost effectiveness are the unit price of the biopsy forceps and the number of times each reusable biopsy forceps could endure. In this case, this research also conveys the break even analysis to which number the reusable biopsy forceps must demonstrate to be the more valuable. The result then shows that if the reusable biopsy forceps were to be used more than 37 times, the result would be reverse. In the other hand, if the reusable biopsy forceps could be used less than 25 times, the cost only comparison would then suggest the disposable biopsy forceps cost per use to be the cheapest. Furthermore, as the judgement which biopsy session is effective depends on the score of each work function, the paper then performs the score break down analysis. The analysis confirms the effectiveness result as a large portion of disposable biopsy forceps scores wander in the five-point zone while a large portion of reusable biopsy forceps scores fall in the four-point region. The paper then further analyzes which circumstances the effectiveness score is deterred. The regression illustrate that the disposable biopsy score increases when the session objective is pathological purpose or the number of tissues taken is high.

Also note that the unit price of the biopsy forceps in the previous researches differ diversely. Nonetheless, the unit price of each biopsy forceps type in this study fall in the average price range (from the previous studies). Certainly, one exception might be that the disposable whole sale choice is cheaper than others as the whole sale price is being used. Another one exception might be that the reprocessing cost in this research is quite low as the average wages and material cost in Thailand is quite lower than other country. In sum, the policy executioner should aware of these factors, i.e. the unit price of each biopsy forceps

type, the average times that the reusable biopsy forceps could bear, which scenario each biopsy session is operated, before the choice, which biopsy forceps type, is decided.

5.2 Recommendations

There are some issues that might be of interest to the hospital management/ policy maker. Firstly, if the reusable biopsy forceps alternative is chosen, the cleansing specialist is encouraged. The rationale is that the specialist would have more skill to take care the medical instrument. Furthermore, as the job function of the cleansing specialist is scoped, the improvement in the skill would be boosted further. Also, as the wages cost of nurses cleansing the instruments are very diverse couple with the benefit from the economy of scale, consider that the large number of instruments need to be cleansed, the choice of cleansing specialist would likely to be reduced and the overall effectiveness would likely to be increased. Secondly, the reusable instruments should be diagnosed after each use. The rationale is the instrument should be eliminated if the function satisfaction is not in the well condition. Also note that the periodically maintenance program is promoted to lengthen the life span of the instruments. Thirdly, although it is quite inconsequential, the instrument labels and the numbers of uses for each instrument are encourage to be kept recording. Lastly, if the whole sale disposable choice is pursued, marginal negotiation tip is that the off-take agreement might be made. This is to reduce the storage cost while achieving the whole sale price.

Further suggestion for any extended research are as follow: (1) the effectiveness score might be recorded to the last time each instrument is used to improve the effectiveness figure, (2) other friction cost should be regarded, i.e., the indirect/opportunity cost resulted from ineffectiveness session, the impact/damage on the endoscope, cross-infection occurred from imperfect reprocessing process, (3) special care on the sterilization process is needed as it might break down and delayed the study process.

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APPENDIX

Evaluation form

Date .....time.....endoscopy room.....

Type of biopsy forceps.....Number of session.....

(for reuse, the figure that mark of reuse biopsy.....number of use.....)

The number of put biopsy forceps in endoscopy per session.....

The number of biopsy sample taken per session.....

This section for Endoscopist

Location of biopsy.....

Experience of doctor .....years

Evaluation Form	Can't use or change a new one or total malfunction (1)	Poor or inadequate for use (2)	Adequate or some loss of function but usable (3)	good (4)	New or like new (5)
1.Ease of passage through endoscope.					
2. Ease of opening and closing.					
3. Adequacy of sample.					
Recommend problem	.....				

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