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FLEXIBLE ENDOSCOPE REPROCESSING IN THE REPUBLIC OF IRELAND-

STAFF EDUCATION AND TESTING OF AUTOMATIC ENDOSCOPE REPROCESSORS

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ABSTRACT

Background

The focus of this research was flexible endoscope reprocessing in the Republic of Ireland, focusing on staff education and testing of Automatic Endoscope Reprocessors (AER's).

A study of this kind is important as flexible endoscope reprocessing has been recognised as being fraught with difficulties from all around the world due to breaches in the multistep processes involved in reprocessing (Spinzi *et al.*2008, Dirlam Langlay *et al.* 2013, Bajolet *et al.*2013).

Incidents of patients being exposed to infection as a result of ineffective cleaning are still making headlines despite the best efforts of international bodies producing standards, guidelines and recommendation on flexible endoscope reprocessing. This research is important as no research had been conducted into staff education and AER testing in the Republic of Ireland.

Objective

To ascertain the education and training that endoscope reprocessing staff received and are their competencies assessed. To establish the level of compliance with AER testing's as outlined in the Health Service Executive (HSE) (2012) Standards and Recommended Practices for Endoscope Reprocessing Units.

Methods

A survey was carried out by means of a postal questionnaire sent to 31 hospitals in the Republic of Ireland in January 2014. A total of 20 hospitals completed and returned the questionnaire giving a response rate of 65%.

Results

The findings show that staff education is primarily delivered by commercial companies, education that is difficult to assess. Competency assessment in all areas of endoscope reprocessing is very low.

Training from in house infection control teams or HSElands online training is not utilised. All hospital see the HSE as responsible for providing training however it provides only an online training programme.

Conclusion

Although all hospitals that responded considered themselves to have adequate education and training, the survey reveals gaps in certain areas of training. The compliance with AER testing was poor; again hospital initially indicated that they carried out testing but when the tests were broken down into individual test, compliance fell dramatically.

The results of this study shows there is a need for the HSE to put resources into staff education and training, both in the form of a new or updated guidance document and the provision of hands on training on all aspects of reprocessing including testing of AER's. There is a need for the HSE to mandate training and AER's testing in order for managers of reprocessing units to receive the necessary resources from hospital managers.

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CHAPTER 1 INTRODUCTION

1.1 BACKGROUND

Flexible endoscopes are Reusable Invasive Medical Devices (RIMD) which can be passed into the body's natural orifices for both diagnostic and therapeutic purposes. They are manufactured from heat liable material and as a result are unable to undergo sterilisation by moist heat which is considered the gold standard in medical device decontamination (Spach, Silverstein and Stamm, 1993).

Some newer, smaller endoscopes can be sterilised by either ethylene oxide and or hydrogen peroxide gas plasma sterilisation. The British Department of Health (2013) Choice Framework for local Policy and Procedure 01-06 (CFPP 01-06:3) states that endoscopes that enter sterile body tissue directly need to be sterile, whilst endoscopes that enter sterile tissue via contaminated body require High Level Disinfection (HDL) therefore the level of decontamination and sterility is dependent on which area of the body it is used.

In order to prevent cross contamination between patients, Rutala and Weber (2008) state that flexible endoscopes must undergo proper reprocessing before the scope is used on a patient and after each patient use, they must undergo a multistep reprocessing procedure involving manual cleaning, followed by automated cleaning and HDL in a Automated Endoscope Reprocessor (AER) followed by drying and storage.

Klevan and Martinez (2013) state the transition to flexible endoscopes, allowed for visibility into areas of the body never before accessible without open surgery. With the major advancements in the development of the flexible endoscope, they have become very important medical devices that are now used widely in a variety of medical specialities across the world.

Despite the major advancements with the flexible endoscope, numerous studies throughout the world have shown that the most common medical device found to have caused cross contamination are flexible endoscopes (Weber and Rutala 2001,Nelson 2003, Heeg 2004, Mehta *et al.* 2005, Seoane-Vazquez *et al.* 2007).

Kovaleva *et al.* (2013) in their review of transmissions of infections by flexible gastrointestinal endoscopes and bronchoscopes between 1970 and 2010 highlighted 98 studies from around the world, which found that transmission occurred due to inadequate reprocessing; inappropriate cleaning and disinfection; contaminated AER's; insufficient drying or incorrect storage and or defective endoscopes. The effect of these transmissions ranged from colonization to death. One study by Alvarado, Stolz and Maki (1991) found 99 patients were exposed to *P.aerginosa* which caused bacteraemia/ sepsis, cholangitis and pneumonia following a gastroscopy as a result of a contaminated AER. In another Centre for Disease Control (1999) study, it was found that patients were exposed to *M.avium complex* as a result of contaminated bronchoscopes, the study concluded that the staff reprocessing these scopes had not received device specific training, and as a result were using wrong set ups or wrong connectors.

Dirlam Langlay *et al.* (2013) claim that Internationally more and more national reprocessing guidelines are being produced, which they feel is due to the ever increasing numbers of endoscopic procedures being carried out, coupled with an increase in the design and complexity of the endoscope, also there is increasing economic pressure on hospitals/hospital groups to treat more patients and despite these publication of guidelines lapses in reprocessing are an ongoing and widespread problem.

Kimmey *et al.* (1993) published figures of 1 in 1.8 million as a ratio of infection associated with endoscopic procedures, following a survey by the American Society of Gastrointestinal Endoscopy. These figures were later disputed by Seoan-Vazquez *et al.* (2007) who found that the incidents were much higher.

Seoan-Vazquez *et al.* (2007) carried out a review of the literature and found that between 1974 and 2004, contaminated flexible endoscopes were responsible for 63 outbreaks which exposed 21,000 patients worldwide. This publication advised that more than 94% of these outbreaks could have been prevented had they adhered to proper decontamination processes.

Audits and reviews have been carried out and published into endoscope reprocessing in both Northern Ireland and other parts of the United Kingdom (Gamble, Duckworth and Ridgeway, 2007,Hine 2004, HPS 2005, Ruddy and Kibbler,2002), and across the world (Bajolet *et al.* 2013, Bou *et al.* 2006, Rutala and Weber 2004, Gillespie *et al.* 2008).

In the Republic of Ireland, a review for the Irish Health Service Executive (HSE) of decontamination services for RIMD in publicly funded hospitals in Ireland did not published its final results; however each hospital received its own evaluation, highlighting areas that required addressing. The National Cancer Screening Service (NCSS) published a report on an audit into endoscopy services in the Republic of Ireland in 2011; the audit included a small section on decontamination. The audit was carried out by Quality Solutions for Healthcare on behalf of Joint advisory Group on Gastrointestinal Endoscopy (JAG) into endoscopy services in 31 endoscopy units in the Republic of Ireland. The audit identified decontamination as the area that required most reform (NCSS, 2011).

1.2 Research Rationale

Failure to adequately clean the flexible endoscope and failures associated with AER's have been cited in the literature as the main contributing factors to breaches in reprocessing guidelines, which have in turn have led to cross infection amongst patients (Srinivasan,2003. Banerjee *et al.* 2008, Nelson *et al.* 2003, and Kovaleva *et al.* 2013). This research focuses on staff education in relation to the processing of flexible endoscopes and adherence to AER testing, as specified in the HSE (2012) Standards and Recommend Practices for Endoscope Units.

The Department of Health, Social Services and Public Safety published the Hine (2004) report on the Independent Review of Endoscopes Decontamination in Northern Ireland which highlighted shortcomings in the whole area of reprocessing from governance to staff education. One issue highlighted in the report was the requirement to have adequate training and that it is planned and appraised. Following the incident in Northern Ireland, an Endoscope Task Force was set up in England to review incidents that occurred between 2003 and 2004 and in Scotland a review of endoscope decontamination from November 2004 to May 2005 was undertaken.

The English task force also found insufficient training, suboptimum performing AER's, in addition to non conformance in relation to microbiological testing which was the requirement of the HTM 2030 validation and verification requirements. Its recommendation included developing staff training which was also identified as lacking and recommended strict adherence to AER's maintenance schedules (HPS, 2005)

Similarly the Scottish report (HPS, 2005:71) recommended the need to commence ongoing staff training, so that they have better awareness and understanding of the whole process. It recommended "a standardised method for delivering training and assessing competency and skills."

Many articles on cross contamination have highlighted that it was breaches in the reprocessing that caused it so why is this occurring? There is no published data available on training in the Republic of Ireland despite the evidence that it is paramount to have training.

The HSE (2012) Standards and Recommended Practices for Endoscopy Units does mention staff training, but it fails to expand on type of training, who should deliver it and it fails to address the need for competency assessments.

The Hine report (2004) was published following an incident in Northern Ireland where it was established that an auxiliary channel was not reprocessed as staff were unaware of it.

Subsequent reports into endoscope decontamination in England and Scotland, identified deficiencies in staff education and compliance with validation, periodic testing and planned maintenance of AER's and were contributing factor to incidents there (Schelling and French 2000, HPS 2005, Gamble, Duckworth and Ridgeway 2007).

In Ireland in 2007 the HSE established a review of Decontamination Services for re-useable invasive medical devices in publicly funded hospitals, one of the interim report's recommendations was the need to establish training criteria for all staff, and that consideration should be given to provide training courses to meet these criteria (Ryan, 2007). The final report on the review was never published, and individual's hospitals only received their own results.

To date, no HSE run training courses have been established, with the exception of the HSE's online education and learning centre (www.hselands.ie) which provides a national decontamination programme with one module entitled "Lifecycle for Endoscopy" which provides an overview of endoscope decontamination.

1.2.1 Staff Education

Staff education is vital for the safe reprocessing of flexible endoscopes; the focus of this research includes empirical data collection which will centre on-

- What grades of staff are reprocessing the scopes
- Are they dedicated to this role
- What type of training do individuals working in endoscope reprocessing received
- Who provides staff with training and are they themselves adequately trained to be providing training
- Is staff educational needs assessed
- Have units developed staff competency tools for each employee
- Who assess these competencies
- Are they competent to assess
- On manual cleaning of scope
  - Are all steps of the manual cleaning process covered

- What support documents or educational aids are available to the staff e.g. standard operating procedures for each type of scope, reprocessing manuals for each type of scope, AER manuals, and material safety data sheets

To further understand the staff education, a better understanding of the process is needed. A comprehensive review of the literature to ascertain what current research findings are in relation to this, and also by collecting data from endoscopy/decontamination units as to how staff education is delivered.

1.2.2. Automatic Endoscope Reprocessors Testing

The second focus of this research concentrated on the testing of the AER's.

In the Republic of Ireland, installation, commissioning, maintenance and validation of AER's are carried out in accordance with European standard EN 15883-4(2009) Requirements and tests for washer-disinfectors employing chemical disinfection for thermolabile endoscopes and EN15883-1(2006) Washer-disinfectors General requirements, terms and definitions and tests.

All hospitals in the Republic of Ireland employ external companies to carry out installation, commissioning, maintenance and validation in accordance with the schedule set out in the standards and all reports are then audited by an Authorising Engineer of Decontamination AE (D) employed by the hospitals.

As well as the testing by the service/ validation companies the hospitals should carry out testing in accordance with the HSE (2012) Recommended practices for endoscope reprocessing units which sets out daily and weekly testing required for AER's in order to ensure that they are performing consistently and have not deviated from when they were last validated.

Unlike the United Kingdom, hospitals in the Republic of Ireland don't employ "test person" for testing of AER's and testing is carried out by staff working in the relevant areas.

This research will collects empirical data on what tests are carried out on a daily and weekly basis, and identify who is responsible for carrying out these tests.

Again the focus was on who educated and trained the staff, as well as assessing if they were competent in carrying out these tests. An in-depth literature review was also carried out to determine the need for the testing requirements, and the importance of having adequately maintained AER's.

1.3 Aims and Objectives

The overall aim of this research is identify the current practice in relation to staff training and AER testing, and to assess whether testing complies with the HSE (2012) Standards and Recommended Practices for Endoscope Reprocessing units.

The research will look at existing Irish and International guidelines and international literature on the focus topics, and carry out an in depth review of relevant literature. Empirical data will be collected by means of a postal questionnaire distributed to 31 endoscopy reprocessing unit in the republic of Ireland.

The objectives of this research are to:

1. Identify from the literature how lack of staff training and the non adherence to AER testing is contributing to breaches in flexible endoscope reprocessing.
2. Evaluate what education and training staff that reprocess flexible endoscopes receive, and to what extent their competencies are assessed.
3. Evaluate hospitals' compliance with the HSE (2012) Recommended Practices for Endoscopy Reprocessing Units in relation to AER's daily and weekly testing.
4. Based on the findings of the research, make recommendations on how current procedures could be improved.

1.4 Value of this Research.

This research is important for a number of reasons. To date there is no published data in the area of staff training and AER testing in the Republic of Ireland, despite evidence in the literature of the importance of both in endoscope reprocessing.

Incidents of cross contamination as a result of inadequately reprocessed flexible scopes occurred in neighbouring countries, where they established reviews bodies and published reports into why incident occurred and put in place alerts and recommendations to prevent reoccurrence (MHRA 2004, HPS 2005, Hine 2004).

It is probable that these incidents were occurring in the Republic of Ireland as equipment and scopes were supplied by the same manufacturers and suppliers within the Republic of Ireland.

In the Republic of Ireland the driving force behind the only published study involving decontamination of flexible endoscopes was the roll out of national colorectal screening (NCSS 2011), and whilst the author welcomes the spotlight it has put on decontamination, this research will look at decontamination specifically.

CHAPTER 2: LITERATURE REVIEW

2.1 Introduction

Aveyard (2007:5) states that a literature review is a “comprehensive study and interpretation of literature related to a particular topic”.

A review of the literature in relation to endoscope reprocessing and incidents that have arisen due to poor staff training and failure to comply with AER testing was carried out.

The review will enable the reader to see current thinking and evidence in relation to studies on these topics. Particularly attention will be paid to breaches that occurred due to lack of staff education and lack of testing of AER’s.

Within this literature review the study will focus on objectives 1 and 2, whilst objective 3 will be studied from the empirical data collected and analysed. The final objective will be achieved by analysing the findings from objective 1, 2 and 3.

1. Identify how lack of staff training and the non adherence to AER testing is contributing to breaches in flexible endoscope reprocessing.
2. Evaluate what education and training staff that reprocess flexible endoscopes receive, and are their competencies assessed.
3. Evaluates hospitals’ compliance with the HSE Standards and Recommended Practices for Endoscopy Units in relation to AER’s daily and weekly testing.
4. Formulate recommendations on staff education and AER testing in hospitals in the republic of Ireland.

It is envisaged that by the end of this chapter, a clear understanding of the key issues surrounding endoscope processing will be visible, and that the reader will be able to identify the need for the collection of empirical research in reprocessing of flexible endoscopes in the Republic of Ireland.

2.2 Methodology

The literature review was conducted between Jan 2013 to March 2014 inclusive. To access the literature, a multitude of data bases were used including JSTOR, PubMed central, Science direct, Google scholar, Springer Link and Academic search complete.

The University of Highlands and Island library search engine “Multi Search Plus” was also used; these searches include UHI Library catalogue, newspaper articles, e-journal articles, e-books as well as conference proceedings

National and international guidelines on reprocessing of flexible endoscopes were also reviewed by both websites and or published articles.

The following search terms were used individually and or in combination

Endoscope Reprocessing.	Staff Competencies.
Infections and Endoscopy	Staff Training.
Cross contamination.	Risk Classification.
Reprocessing guidelines and endoscopy.	AER’s
Mechanisms of cross infection.	Endoscope washers.
Cross contamination due to AER’s.	Decontamination.
Disinfection.	Testing.

2.3 Selection criteria

English language articles published between the years 2004 and the present were selected for review. These yielded further older referenced, some of which were deemed pertinent to the literature review. Literature was obtained from all over the world including America, Canada, UK, France, Germany, Spain, Italy, Australia, China and Ireland. National guidelines from these countries were also reviewed.

Once the literature was reviewed it was categorized into the following themes.

1. **Endoscope Classification**

2. **Mechanisms of Cross Infection in endoscopy**

3. **Decontamination of Endoscopes**

4. **Role of Reprocessing Staff in Cross Contamination**

5. **AER's as a factor in Cross Contamination**

6. **Incidence of Cross Contamination**

7. **Endoscope Reprocessing in the Republic of Ireland**

2.4.1 Endoscope Classification

Spaulding (1968) developed the classification of medical devices for the disinfection and sterilization based upon the possible risk of transmission of infection and divided into three groups. The required level of decontamination is determined by the instrument's classification.

This classification system (Table 1) has been retained despite being over 45 years old and is still used today as rule for planning the disinfection and sterilization of medical devices (Favero and Bond, 2001, Rutala and Weber, 2013). Others have suggested that we need to reflect and perhaps reconsider some of Spaulding's expectations of disinfection and sterilization methods, as Mc Donnell and Burke (2011) claim that some studies have shown that some micro-organisms have developed biocidal resistance which has lead to infection outbreaks.

Whilst both authors accept, that Spaulding's classification is still the foundation of decontamination, they argue that some studies have shown examples where some viruses, mycobacteria and protozoa have questioned his definition and expectation of disinfectants.

Rutala and Weber (2008) support this view by saying that Spaulding's classification is an excellent guide but additional modifications may be required to prevent the possible transmission of infection by inadequately decontaminated medical devices.

Spaulding classification divides medical devices into 3 categories.

Table 1. Guide to Spaulding's classification of infection risk associated with the decontamination of RIMD

RISK	APPLICATION	RECOMMENDATION	EXAMPLES*
CRITICAL	Items that enter sterile tissue/ sterile body area or the vascular system	Requires sterilisation	Surgical reusable invasive medical devices, biopsy forceps.
SEMI-CRITICAL	Items in contact with mucous membrane or non-intact skin.	Sterilisation preferred but at a minimum, requires High Level Disinfection.	Flexible endoscopes, Specula, Respiratory therapy equipment.
NON-CRITICAL	Items in contact with intact skin but not mucous membrane or not in contact with the patient.	Can be processed by cleaning(and low level disinfection where necessary)	Blood pressure cuffs, oximeters, ECG leads, denture fabrications equipment, apex locators, impression material locators.

*Examples are for illustrative purposes only: the manufacturer's recommendation for reprocessing must be followed.

(HSE 2012:20)

From this risk classification we see the majority of flexible endoscopes are identified as semi critical devices e.g. gastroscopes, colonoscopes, bronchoscopes etc.

These therefore require a minimum of HDL but a preferred method would be to have them sterilised.

The British Department of Health (2013) Choice Framework for local Policy and Procedure 01-06 (CFPP 01-06:3) illustrates by diagram “the principle relative risks and endoscope variety with regard to decontamination requirement”.

This covers the low risk endoscope e.g. non lumen scope, through to high risk scopes entering sterile body tissues and as such has recognised the new risk now associated with this type of procedure and scope.

Table 2. The principle relative risks and endoscope variety with regard to Decontamination requirements.

HIGH RISK	**Endoscopes that enter sterile body tissues:** Manual cleaning, automated cleaning and disinfection; rinse-water with limited bacterial Contamination, followed by sterilization.
↑	**Endoscopes that enter sterile body cavities via contaminated body cavities:** Manual cleaning, automated cleaning and disinfection; rinse-water with very low bacterial contamination
	Endoscopes that enter contaminated body cavities: Manual cleaning, automated cleaning and disinfection; rinse-water with limited bacterial contamination
LOW RISK	**Endoscopes without lumens:** Manual cleaning and manual disinfection as EQR and use of manual cleaning followed by an endoscope washer-disinfector (EWD) as possible Best Practice

(Department of Health, 2013:3)

Some smaller flexible endoscopes are now capable of being sterilised e.g. Ureterorenoscopes, cystoscopes, bronchoscopes by means of low temperature sterilisation by Hydrogen peroxide and or ethylene oxide, however the numbers are limited, but flexible endoscope companies are working at making their endoscopes compatible with these sterilisation processes.

Rutala and Weber (2008) established that that most cross infections associated with medical devices in the literature are related to semi-critical devices, when compared to critical and non critical devices. This, they suggest is due to a number of factors; critical devices will undergo automated washing with thermal disinfection followed by sterilisation; the sterilisation is by means of moist heat and has an over kill approach.

The sterilisation process has the equivalent log reduction of log 10^{12}, whilst a log reduction of 10^{6} is considered sterile. This means that following sterilisation there is a less than 1 in a million chance that a contaminant will survive the sterilisation process. Coupled with this is the fact that critical devices have a lower number of microorganisms following surgery, much lower to that of a flexible endoscope.

Rutala *et al.* (1998) estimated that 85% of medical/surgical devices are contaminated with less than 100 bacteria following surgery; whilst Chu *et al.* (1999) estimate that a gastroscope could be contaminated by 1 billion bacteria due to the part of the anatomy they enter being heavily contaminated with microbial contamination (bioburden). Following cleaning and HLD, Favero (2001) claims that the flexible endoscope will have a Sterility Assurance Level of 10^{0} to 10^{3}, which means less than 1 in a 1,000 chance of a contaminant surviving. The margin of safety with semi-critical devices is therefore dramatically lower than that of critical devices and Rutala and Weber (2013) stresses that as a result of this, any deviation in the multistep reprocessing can lead to the survival of micro-organisms and potential for cross infection

2.4.2 Mechanisms of Cross Infection in Endoscopy

Cross contamination from a flexible endoscope can occur from three sources.

2.4.2.1 Endogenous Infection

This occurs when the patient's own natural flora accesses their own normally sterile tissues by use of the flexible endoscope, therefore infections of this kind are not to related to reprocessing of the scope. Pneumonia as a result of aspirating oral secretions during a bronchoscopy is one example of an endogenous infection that can be seen as an endoscopy related infection.

Shaukat and Nelson (2007) claim that this mode of transmission is the cause of the vast majority of endoscopy related infections, and concludes that it is not in any way related to the processing of the endoscope.

2.4.2.2 Exogenous Infection

These types of infection are related to patient becoming infected as a result of a contaminated endoscope. This can occur due to either:

1. Microorganisms being passed from one patient to another by a contaminated or inadequately decontaminated endoscope or its accessories.

2. Microorganisms from within the hospitals environment contaminating the endoscope or its accessories and infecting the patient who is having the scope procedure performed. In this case the microorganisms can come from anywhere in the hospital, its water supply or from a contaminated AER (Spach Silverstein and Stamm 1993, Srinivasan *et al.*2003).

The most common infections in this group according to Nelson and Muscarella (2006) would include *Pseudomonas aeruginosa* and *Salmonella spp.* and in bronchoscopy P. aeruginosa and *Mycobacteria spp.* Srinivasan *et al.* (2003) states that strict adherence to the reprocessing procedure during the manual wash; disinfection in well maintained AER's and following correct drying and storage will prevent this type of infection.

2.4.2.3 Pseudo-Infections

This type of infection occurs as a result of an endoscope not being correctly reprocessed, and most commonly occurs with bronchoscopes. It occurs when a fluid sample taken via the bronchoscope, will be contaminated by the scope and therefore will give a false positive result. Corne *et al.* (2005) discovered this in a study investigating an outbreak of *Pseudomonas aeruginosa* in the ICU of a teaching hospital in Montpellier France where there had been an unexpected increase in cases.

The investigation identified 2 different bronchoscopes with damaged internal channels caused by defective biopsy forceps; therefore these bronchoscopes weren't being adequately cleaned or disinfected due to the internal damage of the lumen. Only 4 real cases of *Pseudomonas aeruginosa* out of the 16 patient with positive results were actually confirmed and treated.

2.4.3.1 Decontamination of Flexible Endoscopes

Endoscopes are described in the literature as complicated, highly developed Re-usable Invasive Medical Devices (RIMD). Spach, Silverstein, and Stamm (1993), British Society of Gastroenterology (2008),Rutala and Weber (2004) are some of the numerous authors who claim that the challenges with reprocessing flexible endoscopes are due to them having numerous valves and channels which are long and narrow. Whilst Weber (2012) concurs with this claim, he also claims that other factors also make this challenging "because they have cross-connections; matted surfaces; sharp angles and valves; occluded dead ends; absorbent material; and rough or pitted surfaces".

As well as the issues surrounding the design, another factor that causes a problem is, as Weber and Rutala (2013) calculated that levels of bioburden found on a gastroscope after use can range between 10^5 colony forming units (CFU)/ml to 10^{10} CFU/ml with the suction caps showing the highest levels, whilst they found that a bronchoscope after use had bioburden levels of 6.4 x 10^4 cfu/ml.

Kovaleva *et al.* (2013) asserts that since nearly all outbreaks relating to flexible endoscope use are related to failures in reprocessing procedures, it is vital that the multistep reprocessing procedure is followed correctly.

The British Department of Health (2013:4) CFPP 01-06 identifies more clearly the steps and states that decontamination process of flexible endoscopes with lumens include:

1: Manual cleaning: this includes brushing with specific single use cleaning device, rinsing and then exposing all external and accessible internal components to a low foaming detergent known to be compatible with the endoscope. The procedure is uncontrolled and relies on the training of the operative for success.

2: Automated cleaning: this is carried out in an AER. The stage may include the use of powerful sprays and pulsed liquid flows down lumens. This stage is reproducible and the cleaning effect can be measured.

3: Automated disinfection: followed by rinsing with water that offers only very low pathogenic risk, and drying or air purge of all exposed surfaces of the endoscope.

2.4.3.2 Cleaning

The Medicines and Healthcare products Regulatory Agency (MHRA) (2010:9) published the Microbial Advisory Committee (MAC) guideline which states that cleaning is a "prerequisite of equipment decontamination to ensure effective disinfection or sterilization". According to the MHRA (2010:10) manual cleaning-

1. "Lowers the microbial challenge (bioburden) to the disinfectant.
2. Removes barriers to disinfectant penetration.
3. Removes substances that may inactivate the disinfectant e.g. protein residue."

The failure to remove soil creates the potential for cross contamination as the efficacy of the subsequent disinfection and sterilization could be compromised (Hoffman, Bradley, and Ayliffe 2008). It is apparent from this that cleaning is a prerequisite to high level disinfection, the main problem associated with manual cleaning, is according to the MHRA (2010), that it is impossible to validate the process, and its repeatability is not guaranteed.

To ensure manual cleaning is carried out correctly, it requires adequately trained staff that are competent and whose competency is assessed annually (BSG 2008, JAG 2009).

Hanson and Collins (1989:780) highlighted the importance of what he called "timely and meticulous manual cleaning". In this study, it was found that the key to removing high titre level of HIV serum was the manual cleaning; they found that manual cleaning alone removed the HIV activity in all but one case, which was subsequently removed following 10 minutes soaking in detergent. In studies where the endoscope was tested after being used on HIV patients, all had the HIV presence removed by manual washing alone.

2.4.3.3 Disinfection

McDonnell and Burke (2011:163) best describe this as the "cornerstone of infection prevention and control" and define it as "the antimicrobial reduction of micro-organisms to a level previously specified as appropriate". Disinfection can be carried out by either chemical or physical means. Physical would include heat and radiation whilst chemical disinfection would use biocides, e.g. alcohol, aldehydes and halogen compounds.

The process of HLD "refers to complete inactivation of all infectious microorganisms (vegative bacteria, mycobacteria, enveloped and non enveloped viruses) in or on a device, but not necessarily bacterial spores" (HSE 2012:20). High level disinfection should be carried out in a dedicated area away from the patient treatment area. It should be carried out in an AER that is validated and tested in accordance with the European standard BS EN ISO15883:1 (British Standard Institution 2006) and BS EN ISO 15883:4 (British Standard Institution 2009) and only after manual cleaning (HSE 2012).

2.4.3.4 Sterilization

This is a process that destroys all microbial life including both viruses and bacterial spores (HSE 2012). It can be carried out by either physical or chemical means. Due to the materials used in the manufacture of flexible endoscopes, ethylene oxide and gas plasma/hydrogen peroxide are the only means available and this is only when recommended in the manufacturer's instructions.

In accordance with Spaulding's classification, it would be preferable to have flexible endoscopes sterilised but this is not always possible. Ethylene oxide sterilisation of flexible scope is not economically viable due to the length of the sterilisation cycle, and the time required for aeration following sterilisation and hence is rarely used for sterilising flexible endoscopes. Advances in gas plasma sterilisation of flexible endoscopes are ongoing, some smaller scopes can be sterilised but this is dependent on both the diameter of lumen and the overall length of the scope.

2.4.4 Role of Reprocessing Staff in Cross Contamination

Around the world, studies have cited lack of appropriate staff training, and lack of ongoing staff competency assessment for staff as a contributory factor to cross contamination by flexible endoscopes (Gamble *et al.* 2007, Spinzi *et al.*2008, Dirlam Langlay *et al.* 2013, Bajolet *et al.*2013).

One case of cross infection relating to staff failing to follow proper reprocessing guidelines resulted in 4 patients in a French teaching hospital developing multi-drug resistant *Pseudomonas aeruginosa* (MDR-PA). Bajolet *et al.* (2013) in their study to identify the cause found that all patients had undergone a gastroscopy with the same endoscope.

When the endoscope was examined the MDR-PA strain was identified with > 100 Colony Forming Units (CFU's). All other gastroscopes in the unit were negative for the strain. Investigation into the AER's as a potential source, showed maintenance had been in accordance with the manufacturer's instructions and filters had changed accordingly and samples taken were negative for the strain.

The study then focused on the manual reprocessing stages and it was observed that there were deviations from the agreed protocol, including parts of the manual wash. They spent less than the recommended time on brushing; suction cylinders used were only disinfected daily instead of sterilised as specified in the unit SOP's; and only one size brush was being used for all scopes.

The study concluded that exposure of the patient to the MDR-PA could have been prevented if the staff had adhered to the decontamination guidelines.

The BSG (2008:1) Guidelines for Decontamination of Equipment for Gastrointestinal Endoscopy summary states that decontamination of endoscopes should be carried out by trained staff and that there should be an established training programme that is implemented and documented. The training should include staff awareness of all scopes and their individual channel configuration, and awareness of the different irrigation adaptors available for the AER's.

Dirlam Langlay (2013) found numerous non adherences by staff to guidelines, poor standard operating procedures and poor staff records of staff competencies. This study focused on peer review and non peer literature into identified lapses in reprocessing which could have lead to cross infection in North America from 2005 and 2012. It concluded by saying that improper reprocessing was a continuing problem and not just localized and that we must always assess the reprocessing effectiveness. One problem associated with standard operating procedures (SOP) for endoscope reprocessing is that every endoscope is unique and each model is different, therefore an individual SOP will have to be available for each type of scope, along with staff reading the manufacturer's instruction manual for each scope which can be 80-90 pages long, this all leads to a major challenge for reprocessing staff.

Russell *et al.* (2004) identified the flexible endoscope as being the hardest medical device to clean disinfect and sterilise, and highlighted increased staff training was one way of reducing the likelihood of endoscopy related infections.

Fraser *et al.* (1993) and Vickery *et al.* (2009) attributed human error as a major issue in endoscope related infection and also found >2% bacterial contamination in endoscopes ready for use on a patient having being reprocessed according to best practice infection control guidelines.

The Northern Ireland Adverse Incidents Centre (NIAIC) notified the United Kingdom's (U.K.) Medicine and Health Products Regulatory Agency (MHRA) advisory board of an incident in May 2004 in Northern Ireland. This incident involved staff noticing a "stained fluid" leaking from the end of a flexible scope. Upon investigation staff discovered an extra single channel in the endoscope which was not known to any of the staff who reprocessed it; therefore it had not been decontaminated.

2.4.5 AER's as a factor in Cross Contamination

In both Ireland and the United Kingdom (UK) and around the world all governing bodies would recommend that flexible endoscope be reprocessed in AER's (BSG 2008, JAG 2009, and HSE 2012).

The benefits according to Srinivasan (2003) include a validated, reproducible process which gives documented evidence that the scope has undergone a chemical disinfection process ensuring essential steps are not missed and also it reduces the reprocessing staff exposure to high level disinfectants and sterilants.

Contaminated AER's have been associated with endoscopy related infection outbreaks throughout the world, Rosengarten *et al.* (2010) found a cluster of pseudo-infection in 3 patients in a bronchoscopy unit in Jerusalem three bronchoalaveolar lavage samples all tested positive for *Burkholderia cepacia*, following their investigation into this outbreak. They found that the AER had been set up without a microbial filter which resulted in contamination of all the bronchoscopes being used. This identified that staff were unaware of the set up of the AER's and that no microbial testing was being carried out.

Hübner *et al.* (2011) carried out a study sampling AER rinse water in 18 hospitals in northern Germany. Their aim was to investigate the potential for AER's to act as a possible source of cross infection.

They concluded that AER's can be a potential source of infection and that guidelines should include routine quality control monitoring of rinse waters, finding 14% of AER's had microbial contamination of greater than 20,000 (cfu)/ml.

Schelenz and French (2000) found that the failure to have adequate professional servicing and training was the most probable cause of 11 cases of multi-resistant *Pseudomonas aeruginosa* outbreak in ITU patients over a 2 month period. In this case a new AER was purchased by the hospital in response to health and safety concerns of the staff reprocessing the scopes and the chemical disinfectant used i.e. glutaraldehyde. The AER's were installed but the hospital failed to supervise the running and maintenance.

The authors concluded that AER's have potential hazards, and that it is imperative that controlled professional maintenance, servicing, testing and training of staff involved with the AER is paramount.

This was similar to the findings following the review of endoscope decontamination practices in Scotland, HPS (2005). This review found suboptimal performing AER's, in addition to non conformance in relation to microbiological testing which was the requirement of the HTM 2030 validation and verification requirements.

2.4.6 Incidence of Cross Contamination

Kimmey *et al. (*1993) published estimates of the infection risk associated with gastrointestinal endoscopic procedure was following a survey by the American Society of Gastrointestinal Endoscopy, they produced the figure of 1 in 1.8 million. However following one outbreak in Florida where more cases were seen in the one outbreak than were expected in a whole year, the previous figures were evaluated to determine their accuracy.

Ofstead *et al.* (2013) conducted research to substantiate the previous 1993 figures, and they found that the calculation was based on incorrect numbers of procedures as well as discovering mathematical error in the way they were calculated. They said the figure should be 1: 276,000, a six fold difference than that which was reported and used since 1993.

It is evident in the literature that capturing the correct numbers of incidents is nearly impossible, and there is a number of suggestions as to why.

Hervé and Keevil (2013) suggested one reason is that the infection usually transmitted, often has a very long incubation time and when it does become symptomatic, it may not necessarily be traced back to having been caused by the endoscopy procedure. They also propose that majority of patients undergoing endoscopy procedures usually attended on an outpatient basis, and these patients, they suggest, have relatively little follow-up unless something is identified during the procedure.

Kovaleva *at al*. (2009) points out that one major problem with finding the correct incidence is due to poor surveillance or no surveillance, or no clinical symptoms. Weber (2012) states that with long incubation periods for key blood borne viruses e.g. HIV, HBV, and HCV which may also occur with the infection being asymptomatic, it is nearly impossible to attribute the infection to failure in the endoscopic procedure.

One thing we are sure about is that due to the increased numbers of procedures involving flexible endoscopes, it could be that one scope may be used on thousands of patients in one year. Therefore Alfa (2013) suggests that if a problem occurs with reprocessing a scope it potentially could lead to a large number of patients being affected.

Only one incident has been published in relation to potential cross contamination with flexible endoscopes in the republic of Ireland. Griffin and Wall (2013) published a report in the Irish Times about an incident in the national children's hospital- Crumlin children's hospital in Dublin. The article stated that one colonoscope used in the hospital was said to have potentially infected 18 children with Extended Spectrum Beta-Lactamase ESBL.

Following investigations by the hospital, it announced that it had identified 2 contaminated scopes, which potentially could have cross infected more patients. The information released by the hospital also highlighted management lack of knowledge and understanding of decontamination of endoscopes.

IrishHealth (2013) published part of the hospital's statement which read "The contamination of the scopes was likely to have been due to them not functioning properly, rather than their not being properly sterilised. Contamination had remained on both scopes after sterilisation, which raised "red flag" of concern about them". From the press release, it is evident that the spokesperson was not competent to be talking about this issue, and had been given inaccurate information.

2.4.7 Endoscopy in the Republic of Ireland

Endoscopy procedures in the Republic Ireland are carried out in both public and private hospitals, According to the Economic and Social Research Institute (2012) annual report for the Activity in Acute Public hospital, the following table enumerates some of the flexible endoscopy procedures carried out in 2011 (Table 3)

Gastroscopy	56,028
Colonoscopy	40,452
Duodenoscopy	2,496
Bronchoscopy	6800

Table 3. Flexible endoscopic procedures in public hospital in 2011. (ESRI,2012)

Figures for flexible cystoscopes, nasopharyngoscopes, hysteroscopy's are not compiled specifically so usage numbers could not be extracted. The number of flexible endoscopy procedures carried out in the private sector in Ireland is estimated by Professor John Hyland to be in the region of 250,000 (Feely 2011).

These figures indicate that the total figure for flexible endoscope used in 2011 would be in excess of 500,000, and with the dramatic expansion in colorectal screening in Ireland since these figures were compiled, the current figures will be significantly higher.

In Ireland the Health Service Executive published its first Standards and Recommended Practices for Endoscope Reprocessing Units in 2007, which was updated in 2012. Prior to these standards, users mainly relied on the UK's British Society of Gastroenterology (BSG) for guidance.

The current HSE (2012) Standards and Recommended Practices for Endoscopy Units cites the need for trained staff to work in these areas however it fails to highlight both the need for planned education programmes for all staff. It also fails to address the need for a core competency tool to be developed for each member of staff.

As outlined in the literature, staff failure to follow the appropriate guidelines has been the number one cause of hospital acquired infection (Nelson and Muscarella, 2006).

Faigil (2006) states that competency is the most basic level of skill, knowledge and expertise that is acquired from training and experience in order for one to be capable to perform their job without any risks and without any help or further instruction. It is vital that all endoscopy or decontamination units develop staff competencies for all staff, and that these competencies are assessed at least yearly.

2.5 Joint Advisory Group Audit

In 2010 the HSE commissioned through the National Cancer Screening Service (NCSS) a series of baseline assessments on thirty one publicly funded endoscopy units in the Republic of Ireland.

The audit was carried out by Quality Solutions for Healthcare (QSH) on behalf of the Joint Advisory Group on Gastrointestinal Endoscopy (JAG).

The baseline methodology was based upon the original UK JAG multi-professional assessment process used in the UK to help identify weakness and underperformances, and to speed up and facilitate change to best practice (NCSS,2011).

The decontamination part of the audit was based on the HSE (2007) Recommended Practices for Endoscope Reprocessing Units which has now been updated.

The initial baseline assessment found eighty per cent of the units not fully compliant with the standards, citing weaknesses such as poor reprocessing area, areas which were old, lack of personal protective equipment, and a lack of dedicated endoscopy technicians which they felt would be of huge benefit to the service. Table 3 shows the results of the baseline assessment.

BASIC STANDARDS IN DECONTAMINATION ASSESSED	**%**
Separation of clean/dirty	17%
One way flow for scopes	20%
Correct PPE	30%
AER's compliant to EN15883-4	13%
Double Sinks	20%
Tracking of endoscopes and valves	30%
Appropriate transportation + storage of scopes	27%
Knowledge of current decontamination practices	27%

Table 4. JAG baseline audit on basic standards in decontamination in 2010 (NCSS, 2011:34)

The decontamination aspect of the audit was seen as the worst performing part of the endoscopy service, and it could be seen that there had been a lack of investment and perhaps a lack of understanding of the importance of decontamination in the endoscopy service.

The report also highlighted that within the nursing workforce the practices being taught relating to the decontamination of endoscopes and their accessories were out of date and needed to be changed.

Whilst the audit highlighted poor facilities and practice, it was not a surprise to the author who said there were similar findings in the UK in 2006 when they undertook the JAG audit there; over half of all services had similar challenges to the Irish ones (NCSS,2011)

When they were reassessed in December 2010, there was a significant improvement. There were more adherences to the Standards and Recommended Practices for Endoscopy Units where possible.

However, some units were restrained by space and having to have make major investment to comply with the environmental aspects of the code. There had also been an increase in the number of dedicated endoscope technicians, from 30 to 38%. The key recommendations of the audit were

1. All hospitals should ensure that they are fully compliant with the HSE (2012) Decontamination Standards and Recommended Practices for Endoscopy Units.
2. All decontamination risks should be clearly identified and placed on the hospital at risk register.
3. Staff working in decontamination should have the required skills and knowledge to perform their roles.

(NCSS, 2011; 53)

2.5 Conclusion

The review of the literature stresses the challenges that are associated with reprocessing flexible endoscopes which according to Srinivasan *et al.* (2003:467) is due firstly to their design, second due to the nature of the material they are made of as they are unable to withstand severe cleaning, and finally due to the part of the anatomy they are used in as they may become heavily contaminated with bioburden.

The author goes on to confirm that despite the focus on reprocessing, the causative factor of all these cases of outbreaks amongst contaminated scopes is nearly always the same i.e. a failure somewhere in the cleaning and disinfection protocol.

This supports the studies by Culver, Gordon and Mehta (2003), Langenberg *et al.* (1990), Ramakrishna (2002) Andrieu *et al.* (1995), Patterson *et al*. (2011).

Leung (2003) identifies flexible endoscope reprocessing as being susceptible to numerous errors due to the multiple steps involved, which is dependent on both humans and machinery. He states that untrained and inexperienced staff carrying out reprocessing can easily breach the multistep process of reprocessing.

They suggest that having defined roles and responsibility, written and clear policies and SOP's are required to support staff undertaking reprocessing.

This lack of compliance with the multistep process is evident in the literature back in the 1980's and was highlighted by Aylifee (2000) and Knieler (2001). Despite this and with the introduction of policies, procedures and guidelines, widespread incidents of cross contamination throughout the world still exist (Srinivasan *et al.* 2003, Tosh *et al.*2011, Cetre *et al.* 2005, Corne *et al.*2005, Gonzalez-Candelas *et al.* 2010, and Aumeran *et al.* 2010).

The fact that the numbers of procedures using flexible endoscopes is rising rapidly, more and more people are potentially being exposed to inadequately reprocessed endoscopes and the risk of more cross contamination increases.

Hildebrand (2011;18) said that “humans have specific abilities and limits, current Information For Use (IFU) design instructions for use do not match end users needs”.

Within a reprocessing unit staff will be reprocessing a variety of types of scopes and maybe a variety of models all with a reprocessing manual of nearly 100 pages. This identifies the real challenges facing these staff.

Hildebrand claims that these reprocessing manuals are not beneficial to the person carrying out the decontamination and that the data they need from the manual should be clearly identified in steps that are colour coded and more user friendly. There is no point learning about or using an AER if the scope hasn’t been properly cleaned first.

The literature stresses the need to have in place training programmes based upon competencies associated with flexible endoscope reprocessing, training programmes that need to be ongoing as well as assessing competency of staff on an ongoing basis. Guidelines, Standards and Standards Operating Procedures are important but only if staff reprocessing the scopes are trained upon them and understand their importance. In a similar way the installation, validation and testing of an AER has been identified to be key in ensuring that they don’t become a source of cross contamination. Again education and an assessment of staff’s ability to use and test an AER correctly is vital to any reprocessing service.

Unfortunately to date in the Republic of Ireland, there is no empirical data on either staff education or AER testing. To get a better understanding and to establish how hospitals are training their staff, empirical research was carried out. Specifically the research was designed to find out how staff are being trained, what areas are they being trained in and who is providing the training. Are hospitals assessing the competencies of their staff? The research sought the views of people responsible for reprocessing endoscopes on whether they thought their staff were receiving sufficient training and if not what do they see as the barriers.

The research also gathered empirical data on testing of AERs to see if there was compliance with the HSE Standards and Recommended Practices for Endoscopy Units for AER testing.

3. Methodology

3.1 Introduction

This research study has a number of related objectives associated with the reprocessing of flexible endoscopes in the Republic of Ireland: These are to:

1. Identify from the literature how lack of staff training and the non adherence to AER testing is contributing to breaches in flexible endoscope reprocessing.
2. Evaluate what education and training staff that reprocess flexible endoscopes receive, and to what extent their competencies are assessed.
3. Evaluate hospitals' compliance with the HSE (2012) Recommended Practices for Endoscopy Reprocessing Units in relation to AER's daily and weekly testing.
4. Based on the findings of the research, make recommendations on how current procedures could be improved.

A valuable aspect of this research work relates to objectives 2 and 3. In chapter 2, the literature review provided evidence of the importance of both staff education and AER testing is to ensuring adequate endoscope reprocessing. It also highlighted a gap in the research in relation to the Republic of Ireland where no published studies are available into this important area. This research will therefore provide an important contribution by collecting empirical data, which will identify how reprocessing staff are trained, assessed and if hospitals are adhering to the HSE Standards and Recommended Practice for Endoscopy Units for daily and weekly testing of AER's.

It will also explore manager's opinion on whether they feel there is sufficient training and support and if not what are the perceived barriers to this. By comparing the literature review findings with practices in hospitals in the Republic of Ireland; this research will gain a better understanding of staff education, training and AER testing.

Gerhardt (2004) claims that some types of research actually create more questions than they answer, however if carried out correctly it will add greatly to our overall knowledge of a subject.

3.2 Ethical Considerations

Ethical implications must be considered in all parts of the research process (Parahoo 2006). Biggam (2011:248) identifies “core ethical principles” which have been used in this research project, these principles include-

1. Transparent-
   The full purpose of the study will be clear to all participants.
2. Confidential –
   Participant’s identity will remain anonymous and all information will be treated confidentially.
3. Voluntary-
   All participants are free to either undertake the questionnaire or not.
4. Do no Harm-
   The research will not put participants or the researcher in any danger.
5. Impartial-
   The researcher will declare any conflict of interest in the research which may be perceived to be bias.

Ethical approval was sought for the research from the Irish Health Service Executive Clinical Research Ethics Committee as the research was carried out in Ireland. Ethical approval was received on 22nd November 2013 (Appendix 1).

Ethical approval was applied for from University of Highlands and Islands, ethical approval from the Irish HSE was also included with the application; ethical approval from UHI was granted on December 3rd 2013 (Appendix 2).

A cover letter (Appendix 3) was sent to each participant in the sample asking them to participate in the research. The letter gave a background to why the research was being carried out, asking them to participate in the research.

An assurance that no hospital or individual would be indentified was also given to ensure confidentiality, and that all questionnaires would be destroyed once the dissertation had been completed. Oppenheim (2000) suggests that giving clear and precise information, and ensuring confidentiality improves response rates. If replies were received, it was taken to constitute informed consent.

Both a contact telephone number and an e-mail address were provided for any participant that required any further information on the questionnaire.

3.3 Research Strategy

"What matters is not the label that is attached to a particular strategy, but whether it is appropriate for your particular research" Saunders *et al.* (2000:92) informs us of the importance of getting the correct design for your research.

There is a variety of research strategies available including:

- Surveys
- Case studies
- Experiments
- Ethnography
- Phenomenology
- Grounded theory
- Action research
- Mixed methods

It is claimed that no single strategy can be identified as being superior to the others in all circumstances. In determining which strategy is best for the research, it is suggested that researcher should address 3 important questions when choosing a strategy:

1. Is it suitable?
2. Is it feasible?
3. Is it ethical?

(Denscombe 2010)

The answers should direct the researcher to one of the research strategies, and in this research the strategy decided upon was a survey as it was ideally suited and answered all 3 important questions.

The literature review highlighted the fact that there is evidence based knowledge from worldwide studies on the implications of failing to adhere to testing of AER's and the importance adequately training staff in preventing incidents of cross contamination.
Therefore the purpose of this study is to gather empirical data on both staff education and AER's testing in the Republic of Ireland and a quantitative approach is appropriate for this.
.
Diem (2002) also found surveys are best to determine current status or situation of a topic, and to collect factual data relating to groups. Crook and Davies (2004:76) state that surveys, allow us to get a "snapshot" and to find out "what's going on?"

3.4 Data Collection

There are a number of various methods of data collection, including:

- Interview
- Questionnaire
- Observation
- Documents

The use of interviews for data collection is an ideal method and has the benefit of obtaining a more in depth understanding of topic than would be established through a postal questionnaire, however staff would be less likely to participate particularly if the study could identify weaknesses in their practices.
The time and expense involved with travelling to all hospitals and conducting a face to face interview also made this option not possible.

Observations would also be an excellent method of data collection, and had been seen in the literature review as being of benefit as it collected real data and opposed to being told what practices in use, the researcher could observe practice in situ. Observational study would be the best method of data collection; however the cost in terms of time and travel would make this impossible.

Documentation as a method of data collection, would involve reviewing departments documentation such as standards operating procedures, risk assessment, availability of training records, competency assessment forms. This would be extremely time consuming and would not be acceptable to lot of participants in the study and therefore would have a low response.

Postal questionnaires allow people to complete them in their own time and without fear of influence which can occur with both face to face and telephone questionnaires (Parahoo 2006).
The cost is minimal compared to other methods as there is no travel and is less time consuming.
Different types of approaches are available in carrying out research, these include qualitative, quantitative and mixed.

Bell(2010) say quantitative research deals with facts and studies the relationships between them, whilst Bowling (2004) states that it is research that is based on quantities where the evidence has already been established, and therefore this facilitates standardisation methods for data collection.
Qualitative research deals with people's interpretation and motivation, and focuses on people words as categories for analysis (Porter 1996).

According to Crookes and Davies (2004:98) a questionnaire that is badly designed will deliver data of poor quality. With this in mind the research followed the steps of Lydeard (1991) who developed a tool to keep the questionnaire on target, which included:

(a) Defining the area of investigation
(b) Formulating the questions,
(c) Selecting the sample and maximising the response rate
(d) Piloting
(e) Recognising sources of errors.

3.4.1 Defining the area for investigation

This was identified by carrying out the literature review, and according to Howie (1989) this should establish 3 criteria for the research:

(a) That it is important
(b) Interesting
(c) Answerable.

These criteria were established by the literature review, which gave a broad spectrum of knowledge on causes of incidents as well as identifying weaknesses, and providing recommendation to prevent this re occurring.

3.4.2 Formulating the questions

The formulation of the questionnaire was developed after reviewing the Irish HSE (2012) Standards and Recommended Practice for Endoscopy Units, the English BSG (2008) guidelines, JAG (2009) guidelines, and CFPP-06 (2013) documents particularly focusing staff education and training, and AER testing. Questions were developed in order to extract the exact information required (Questionnaire -Appendix 5).

A postal survey was deemed best as it is suited the needs of both the research and researcher. Looking at the choice of surveys, internet surveys were seen as not guaranteeing confidentiality and this could lead to reduced responses, whilst telephone surveys are very labour intensive and time consuming from both the researcher and respondent perspectives and are also prone to bias by the interviewer (Denscombe 2010:13). Face to face interviewing would have been impossible due the geographical spread and the number of sites.

It was felt that a personal letter to each participant, giving the background and purpose to the study would achieve a bigger response.

Different types of questions can be asked using questionnaires. It was deemed closed questions were best suited to extract the data that was required. According to Denscombe (2010:166) the benefit of using these types of questions is that it provides structured responses that are easily quantified and analysed, it was felt that open questions could turn people off and hence can lead to a low response rate. To facilitate specific answers in relation to the questions, closed questions with a choice of predetermined answers were used. Using closed questions also makes it easier to process with using statistical packages such as Statistical Package for the Social Sciences (SPSS).

A postal questionnaire was sent to the person responsible for the decontamination of flexible endoscopes, either the endoscopy manager or the decontamination lead. The names of endoscopy managers or decontamination lead persons from the sample hospitals were obtained from the national decontamination lead for the purposes of this research only. The questionnaires were posted on the Thursday 9th Jan 2014 to 31 hospitals with a cover letter and a stamped address envelope, requesting replies by Friday 24th January. This allowed for a 2 weeks time period for the questionnaire to be filled in and returned.

3.4.3 Selecting the sample

Convenience sampling was used to select the research population. Thirty one hospitals in the Republic of Ireland were chosen for the population of this study, they were selected as they had previously been audited for colorectal screening. The list of hospitals was published in the National Cancer Screening Service publication -National Progress Report on Endoscopy Services (NCCS 2011). The researcher felt that this grouping encompassed a broad range of hospitals from the widest geographical area and with a large range of hospital bed numbers. These hospitals had also undergone an assessment by Quality Solutions for Healthcare for JAG on behalf of the Irish HSE.

3.4.4 Piloting

The author also took into account the view of both Bell (2010) and Oppenheim (2000) that a good questionnaire is far harder to produce than one thinks. For this reason once the questionnaire was developed, it was reviewed by colleagues working in the area of endoscope decontamination. It was then forwarded to my dissertation supervisor. Due to the small number of hospitals reprocessing endoscopes, the pilot study was carried out with 4 nurse managers who were responsible for running local endoscopy units; these units were not included in the main study. Each was given an envelope containing the questionnaire and cover letter. When they had completed the questionnaire, they were then asked to fill out an evaluation form of both the questionnaire and the cover letter; this was based upon the questions designed by Bell (2010:151) (see Appendix 4).

Slight alterations were made following these reviews, one to the phrasing of one question and the other to concern about 2 of the tests identified in the questionnaire. In the HSE Standards and Recommended Practice for Endoscopy Units the tests are identified as weekly tests but the EN 15883 has the identified the residual soils as a quarterly test as opposed to weekly. Following discussion both tests were left in the questionnaire as the research was assessing compliance to the HSE (2012) Standards and Recommended Practice for Endoscopy Units. Parahoo (1997:263) claims that the more the questionnaire is piloted prior to being sent out the more it will be improved and that this will also increase its validity and reliability.

It must be acknowledged that the sample pilot was small and included clinical nurse managers running endoscopy units, and not specifically managers running endoscope decontamination units. The feedback on the pilot from manager exclusively managing endoscope decontamination may have differed considerably from that of clinical nurse managers who have traditional run such units but now find their role changing in favour of hospitals designating a specific manager to deal with endoscope decontamination.

Bell (2005:18) best describes the validity of the results of a questionnaire as “complex” and advised it best to consult colleagues working in the area to evaluate the validity of the questionnaire.

3.4.5 Recognising sources of errors/ limitations

It was felt that because of the small number of hospitals in the country, hospitals could be easily identified if questions in relation to gender and qualifications. This could have affected the response rate adversely and it was therefore decided not to include these questions. As a result the position of the person who completed the questionnaire is not evident.

Lydeard (1991) states the inclusion of closed questions with selection of answers can sometimes facilitate getting an answers that may not necessarily have been given otherwise, however the benefits of the closed questions outweigh this source of error.

Whilst the use of postal questionnaires was seen as the most suitable way of obtaining the information required, it must be noted that it also has disadvantages with this. The disadvantages include:

1. Tendency to focus on data more than theory.-
   With the focus of the survey been involved with the collection of data, the implications or significance of the data could be lost.
2. Detail and depth of the data.
   This type of research can lack depth or detail in favour of breadth especially in quantitative studies such as this. A qualitative study using interviews would generate a more detail account; however participation in this type of surveys would likely to be low.
3. Easily ignored.
   Postal questionnaires usually have a low response rate, and the challenge for the researcher is to get a reasonable response rate.

(Denscombe 2010:49)

3.5 Data Analysis

Statistical analysis was carried out on the data generated in this study by using IBM Statistical Package for the Social Sciences (SPSS) version 21. Descriptive statistic was presented in the form of pie charts, tables and bar graphs.

CHAPTER 4 Results and Discussion

4.1 Introduction

Thirty one questionnaires were posted to the selected hospitals and twenty completed questionnaires were returned, giving a response rate of 65% (20). The following survey results were obtained.

4.2 Results

1. What is the bed capacity of your Hospital?

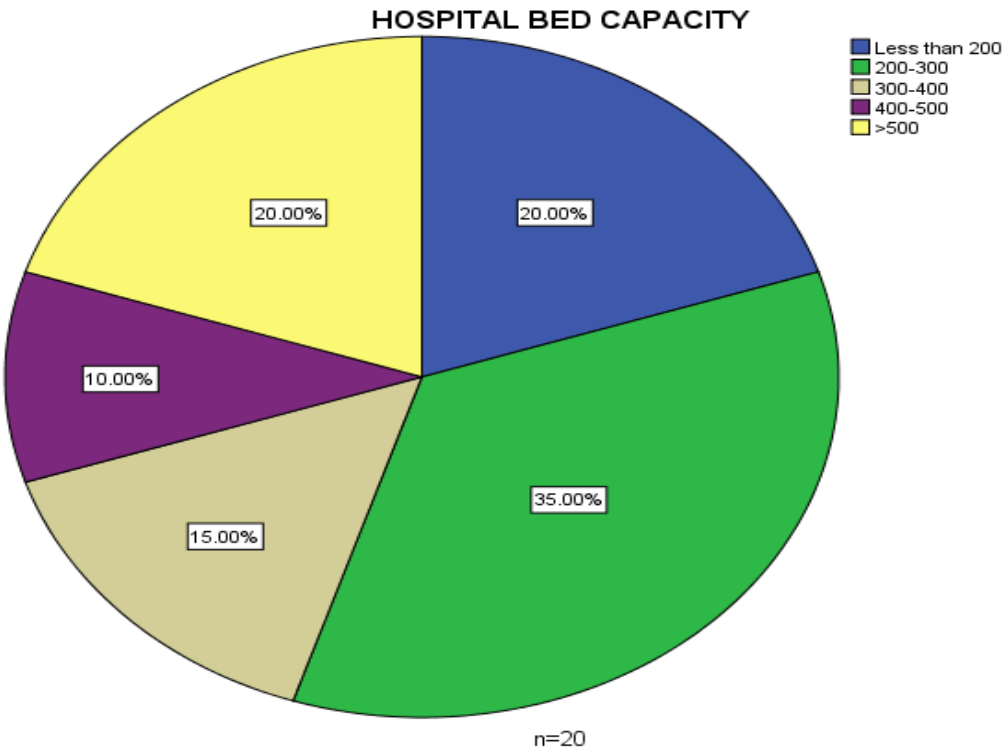


Figure 1.

The twenty hospitals that participated in this research ranged in size from less than two hundred (20%) beds to greater than five hundred beds (20%). This provided a good range of hospital bed capacity. Six (30%) hospitals also had a capacity of more than 400 beds and fourteen (70%) had less than 400 beds indicating a good geographical spread. This means that the study captured a good representative section of hospitals in the Republic of Ireland.

2. Does your hospital reprocess any of the following scopes?

Gastroscopes	20(100%)
Colonoscopies	20(100%)
Duodenoscopes	9(45%)
Cystoscopes	17(85%)
Urethrorenoscopes	7(35%)
Bronchoscopes	14(70%)
TOE Probes	12(60%)
Other	11(55%)

Table 5- Types of flexible endoscopes.

All hospitals (n=20) reprocessed both gastroscopes and colonoscopes.
Five (20%) of hospitals surveyed reprocessed eight or more types of flexible endoscopes. These hospitals all had a bed capacity of >400 beds with only one exception.
One (5%) of the hospitals was reprocessing just two types of scopes- gastroscopes and colonoscopes. The average number of different types of scope reprocessed was six.
It has been recognised that the more types of endoscopes and different models of the same endoscope increase the memory demand on technician in a busy endoscopy reprocessing unit. This was seen as contributing factor to errors in reprocessing pressure (Hildebrand *et al*. 2011).

Cognisant of this, education and training in units reprocessing a greater variety of endoscope will require more training and assessment. Hospital procurement staff should be made aware of this factor when purchasing or upgrading endoscopes.

3. What is the approximate number of scopes reprocessed annually?

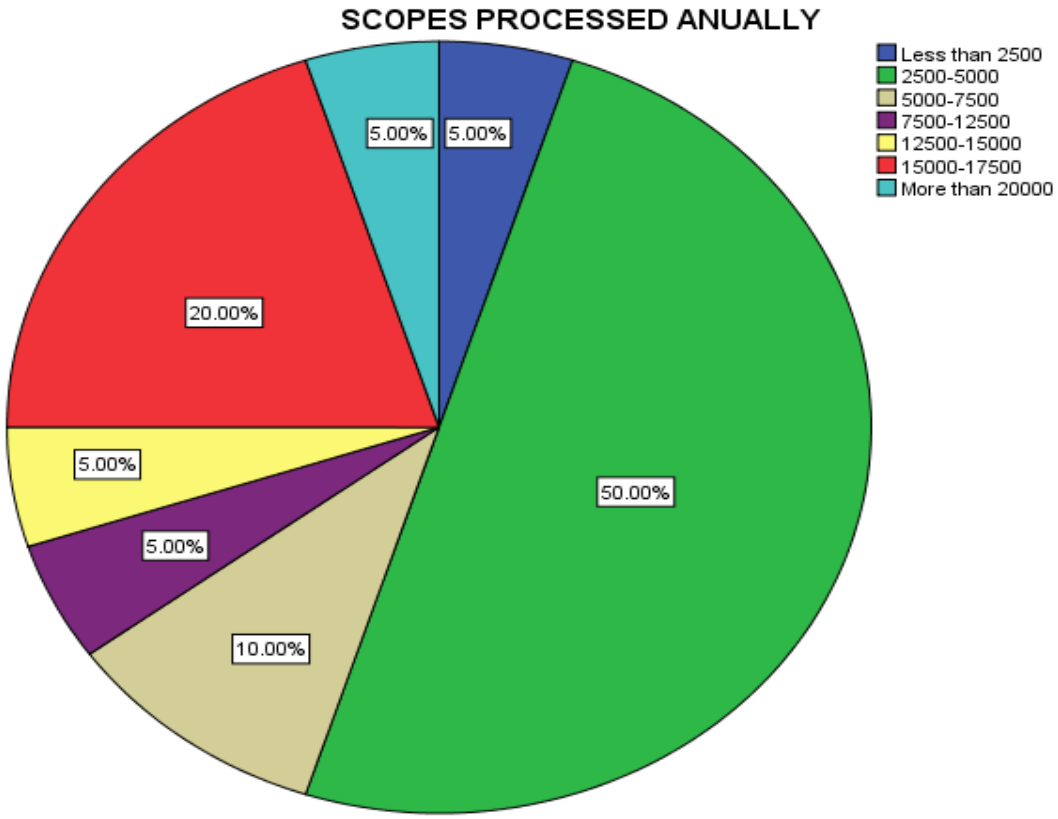


Figure 2. Number of scopes reprocessed

Table 6 : HOSPITAL BED SIZE * SCOPES PROCESSED ANUALLY Cross tabulation

Count

		SCOPES PROCESSED ANUALLY							
		Less than 2500	2500-5000	5000-7500	7500-12500	12500-15000	15000-17500	Greater 20000	Total
HOSPITAL BED SIZE	<200	1	2	1	0	0	0	0	4
	200-300	0	7	0	0	0	0	0	7
	300-400	0	1	1	1	0	0	0	3
	400-500	0	0	0	0	0	2	0	2
	>500	0	0	0	0	1	2	1	4
Total		1	10	2	1	1	4	1	20

The range of endoscopes reprocessed ranged from <2500 to >20,000 with ten (50%) reprocessing less than 5,000 flexible scopes a year. The six (30%) larger hospitals with >400 beds carry out in excess of 15,000 procedures annually. Only one (5%) reprocessed in excess of 20,000, with five (25%) reprocessing more than 15,000.

4. How many areas within the hospital reprocess flexible endoscopes?

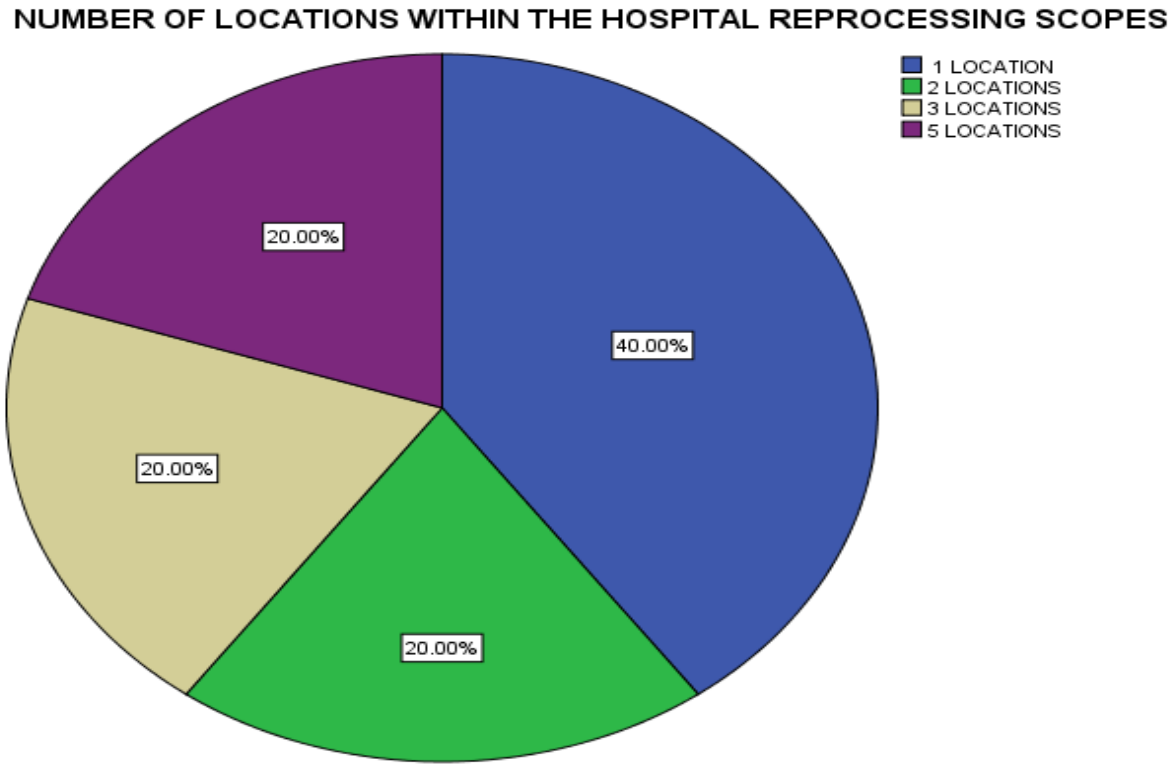


Figure 3.

Table 7: HOSPITAL BED SIZE * AREAS REPROCESSING SCOPES Crosstabulation

Count

		AREAS REPROCESSING SCOPES				
		1	2	3	5	Total
HOSPITAL BED SIZE	<200	4	0	0	0	4
	200-300	2	3	2	0	7
	300-400	1	1	1	0	3
	400-500	0	0	1	1	2
	>500	1	0	0	3	4
Total		8	4	4	4	20

The number of reprocessing facilities within the hospital surveyed varied widely, ranging from 1 location to greater than 5 locations within one hospital.
Eight (40%) reprocessed flexible endoscopes in one locations, with four (20%) reprocessing scopes in 5 locations or more. The larger the hospital bed capacity, the more AER's reprocessing, with one exception, one hospital with greater than 500 beds reprocessed in one location.

The move to having one location reprocessing, which is the preferred option by both HSE (2012) Recommended practices for endoscope reprocessing units and Department of Health (2013) CFPP 01-06 may be delayed due to financial implications of investments in buildings, facilities, equipments and staffing.

The NCSS (2011) highlighted in their report that major financial investment was required to bring some decontamination units, which they described as being of suboptimal size and in bad location, up to desired standard.
One hospital had over 5 locations reprocessing endoscopes and had just completed the development contrary to the drive towards having one location or centralization of endoscopy reprocessing.

Centralization can seem like a mammoth task, particularly in larger hospitals, but it has been implemented in larger hospitals in the UK such as Charing Cross which had 7 reprocessing locations, and Hammersmith hospital having 6 locations.
Both of these locations now each have one centralized endoscopy reprocessing unit (Alexander 2012).

Eleven (55%) hospitals did indicate that they were in the process of developing reprocessing facilities, so hopefully there will be a drive for more centralization.

Both Bonner (2007) and Alexander (2012) cited many benefits of centralization, but most importantly it facilitates a quality control system being put in place which ensures that reprocessing is consistent, validated and controlled.

Other benefits of centralization include dedicated trained staff, safer working environment, with modern equipment and provide value for money (Bonner 2007). Centralization therefore facilitates a quality control system in endoscope reprocessing which would prevent 91% infection associated with flexible endoscopes (Kimmey 1993, Seoane-Vazquez 2006).

5. How many Automated Endoscope Reprocessors are used in your hospital?

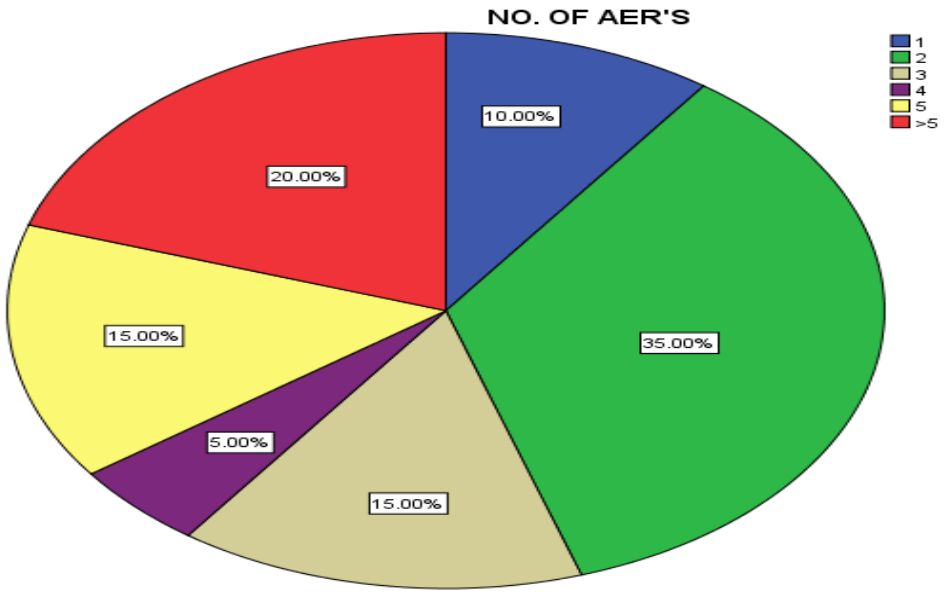
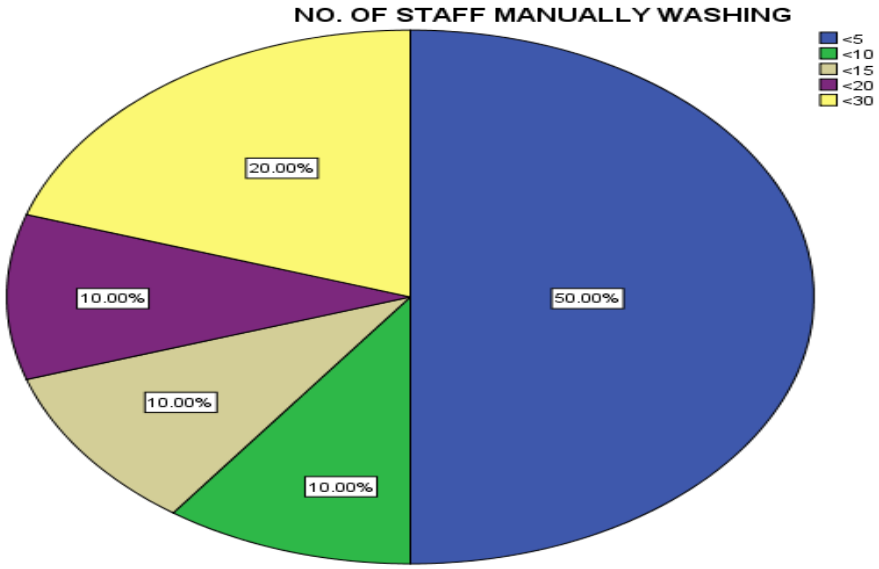


Figure 4.

Two (10%) of the hospitals surveyed had just 1 AER, seven (35%) contained 2 AERs, three (15%) having 3 and eight (40%) accommodated 4 or more AER's.

6. How many staff is involved in manual washing of endoscopes?



n=20 Figure 5.

In figure 5 we see ten (50%) hospitals indicated that they have less than 5 staff manually washing endoscopes,two (10%) having less than 10 staff , two (10%) with less than 20 staff whilst four (20%) hospitals had less than 30 members of staff manually washing flexible endoscopes.

The number of staff manually washing the endoscopes ranged from fewer than 5 to less than 30. Ten (50%) indicated that they had less than 5, whilst others had more and this was dependant on the number of locations carrying out endoscope reprocessing.

7. What grade of staff carry out manual washing of scopes

Dedicated endoscopy reprocessing staff	3(15%)
Dedicated endoscopy staff+Nurses	4(20%)
Health Care Assitants (HCA)+Nurses	5(25%)
Dedicated endoscopy staff+HCA's+Nurses	5(25%)
Dedciated endoscopy staff+Hospital Sterile Sterile Department staff+Nurses	2(10%)
Health Care Assitants Nurses+other	1(5%)

Table 8: Grade of staff carrying out manual washing of endoscopes.

The NCSS (2011) report emphasised the importance of dedicated endoscopy decontamination technicians, which was only 30% at the first baseline assessment increasing to 38% by December 2010.

This study shows that all twenty (100%) hospitals indicated that they now had dedicated endoscopy decontamination technicians. However seventeen (85%) hospitals also had other grades of staff carrying out endoscope reprocessing.

This will hopefully reduce as hospitals develop and become more centralized in the future.

8. Have staff received training on the following?

Leak test/ manual cleaning	20(100%)
AER	20(100%)
Specific endoscope Training	19(95%)
Infection control + decontamination	18(90%)
Health and Safety	17(85%)

Table 9.Training received on flexible scopes

All areas here have a very good response, and it is a positive indication of attitudes towards training, and it appears that all the key areas have been addressed albeit not 100% for all topics.

Training is required for each specific flexible endoscope and each model if a number if in use, all hospitals except one (5%) carried out this specific training.

International standards and guidelines on endoscope reprocessing advocate that staff receive training on infection control and microbiological aspects of decontamination (Department of Health 2013, SGNA 2013, HSE 2012**,** JAG 2009 BSG,2008**)**

9A. Regarding AER's, do staff decontaminating scopes receive training on-

How to operate AER	20(100%)
How to carry out testing of AER	19(95%)
How to carry out thermal disinfection	19(95%)
Chemical safety/handling/changing/disposal	19(95%)

Table 10. Training on AER's

AER training in the broad sense appears to be excellent with all hospital incorporating all key areas.

Seventeen (85%) hospitals were carrying out training on all 4 areas, with three (15%) hospitals omitting just one part of the training questioned. Despite all hospitals answering that their staff had been trained in question 8, it is apparent that the training didn't cover the important areas of testing, thermal disinfection or dealing with chemicals.

CDC (1999) identified an increase in cases of *M. avium-intracellulare* (MAI), following an investigation it was confirmed that the cause was incorrect connectors been used between the AER and the bronchoscopes, and staff had not be shown at training these specific connection sets.

9B. What type of training was provided?

Onsite workshops	20(100%)
Offsite workshops	16(80%)
Presentations/lectures	11(55%)
Notes/Handouts	6(30%)
Other	3(15%)

Table 11 Training type.

Twenty (100%) hospitals had workshop training on site, sixteen had attended some form of offsite workshops, whilst three identified other types of training.

Two hospitals (10%) said staff had undertaken the "HSELanD online training course" and one (5%) hospital identified "FETEC training". HSELanDs is an online learning programme which provides programmes, resources, assessments, and planning tools to support staff in their current position and to assist them in personal and professional development (HSE 2013).

Unfortunately due to data protection legislation the number of people who have undertaken this online training is unknown (McKeon, 2014).

The Further Education and Training Awards Council (FETAC), which is a statutory body for further education and training in Ireland, had introduced a course, entitled Care of Endoscopic Equipment which is run by the Bon Secours Hospital in Cork. From 2008 to May 2013 this course has been completed by 26 people (Balfe 2013).

9C. Who was your training provider?

AER manufacturer/Agent	20(100%)
Chemical supplier	9(45%)
In house infection control	7(35%)
Line managers	8(40%)
Other users	3(15%)
Other	2(10%)

Table 12. Training provider

As established earlier, training on the AER from the provider is the accepted norm, and adherence is excellent. Training provided by chemical suppliers appears infrequent; these chemicals can be extremely dangerous, the MAC (2010:13) guideline states that these “chemical disinfectants are often toxic to skin mucous membrane and /or by vapour inhalation. They may also be corrosive and flammable”.

Staff require adequate training on storage, handling, use and disposal, to ensure the product is used as intended, and hospitals must be in compliance with the Irish Safety, Health and Welfare at work (chemical agents) Regulations 2001.

However the result could be affected by the fact that the chemicals used are type tested and validated by the AER manufacture, in this case the AER’s manufacturer would be in a position to carry out the training on the chemicals.

The results indicate a low number of hospitals benefiting from their infection control teams in developing staffs skills and knowledge on infection control and microbiology. Similarly the percentage of line managers (40%), who provide education to staff, is very low; line managers have a role in staff education.

Question 9D.

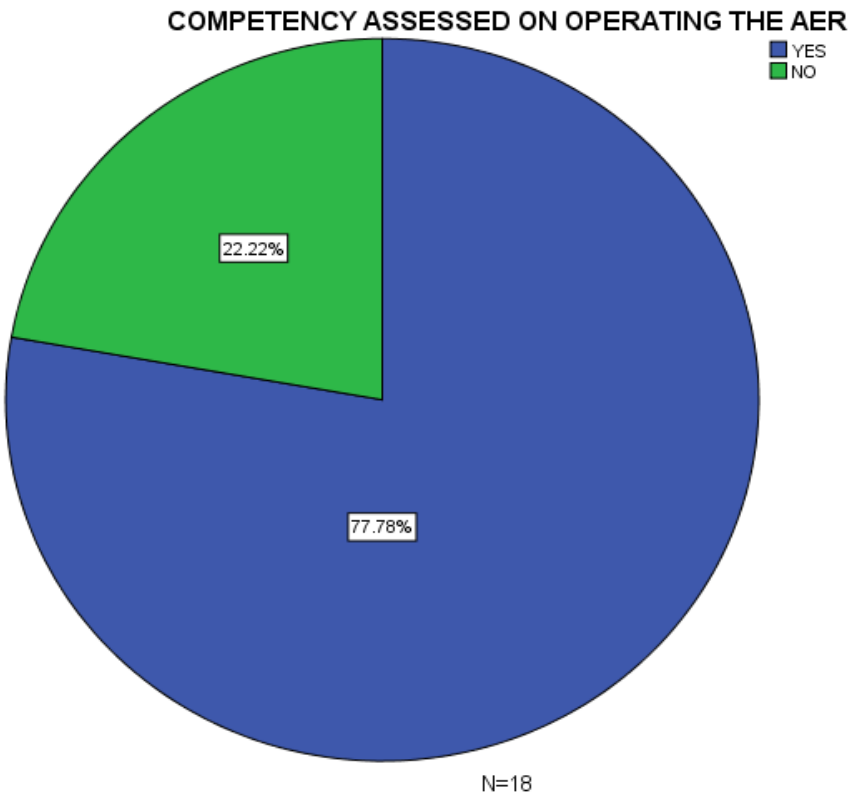


Figure 6. Was staff competency assessed in using AER'S?

Asked if staff competency was assessed in relation to the use of AER, fourteen (77.78%) hospital said their staff were assessed on their competency on operating an AER, and four (22.22%) said no competency assessment was carried out. Two (10%) hospitals failed to answer this question.

9E. Is staff competency assessed annually on AER's

Table 13.
IS STAFF COMPETENCY ASSESSED ANNUALY ON AERS

		Frequency	Valid Percent	Cumulative Percent
Valid	YES	9	45.0	45.0
	NO	11	55.0	100.0
	Total	20	100.0	

When asked if annual competency was assessed, nine (45%) indicated they did whilst eleven (55%) hospitals didn't carry out annual assessments of staff using AER's.

It has been found that better education programmes would improve the effectiveness of reprocessing, but that continuous monitoring of staff is essential to recognise weaknesses and deal with them accordingly (Ofstead *et al.*2010). The low level of annual competency may be either, lack of understanding of the impact they can have or it may be due to lack of resources in order for them to be carried out

Weber and Rutala (2004) also state that annual competence is the only way of ensuring that guidelines and current standards are being adhered too.

From the cross tabulation of annual competencies and hospital size, over 50% of hospitals in all hospital sizes didn't assess annual competency.

Table 14. HOSPITAL BED SIZE * IS STAFF COMPETENCY ASSESSED ANNUALY Crosstabulation

Count

		IS STAFF COMPETENCY ASSESSED ANNUALY		
		YES	NO	Total
HOSPITAL BED SIZE	<200	1	3	4
	200-300	3	4	7
	300-400	2	1	3
	400-500	1	1	2
	>500	2	2	4
Total		9	11	20

9F.

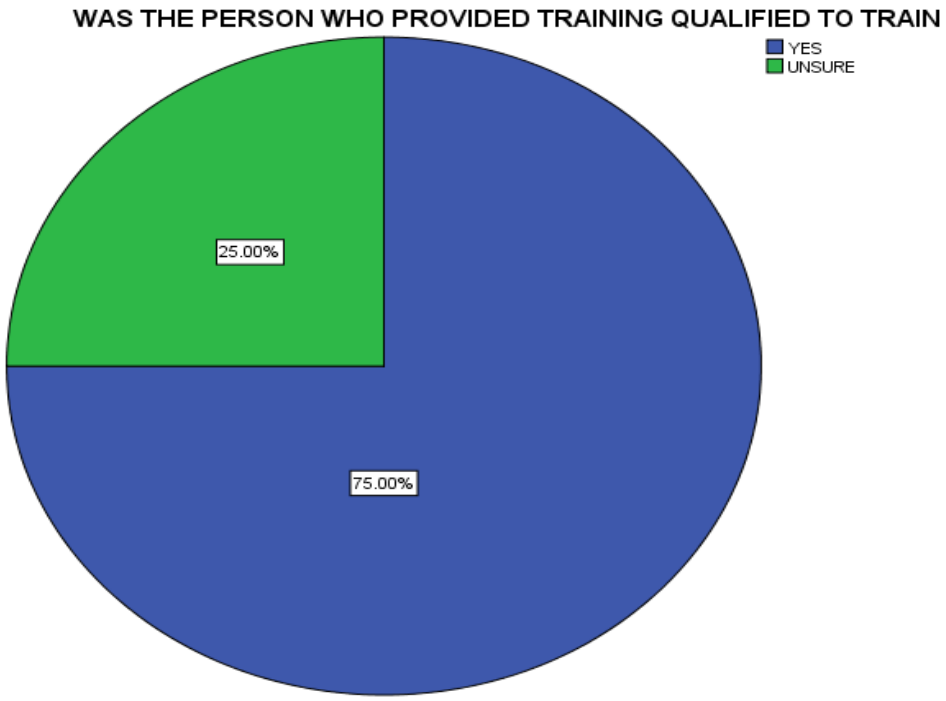


Figure 7.

The result concludes that 25% of hospitals were unsure if the person providing was qualified to train. In light of the response the researcher realises that better information could have been gathered had the question been phrased differently. Had the question been posed with a choice of multiple choice answers, it may have been able to determine exact qualifications of those tasked with delivering training.

10A. Regarding flexible endoscopes, do staff receive training on

Working mechanism and function of scope	18(90%)
Leak testing/washing and brushing of scope	18(90%)
Care and maintenance of scope	20(100%)
Identify damage to scope	20(100%)

Table 15. Training received on endoscope

These 4 items represent the core principles of manually cleaning a flexible endoscope.

Alarmingly two (10%) indicated that the staff hadn't received training on the working mechanism or function of the scope, and didn't receive training on leak testing/brushing of the scope. These are 2 critical key steps in manual reprocessing, and training on them is paramount.

10.B what type of training was provided.

Onsite workshops	20(100%)
Offsite workshops	16(80%)
Presentations/lectures	11(55%)
Notes/Handouts	3(15%)
Other	0(0%)

Table 16. Type of training received

In tandem with findings on AER training, all hospitals had in house training, with 80% attending off site workshops.
This study didn't, however establish who was attending the offsite workshops: was it technicians or the person responsible for managing the unit?

Offsite training has been seen to have more benefits for reprocessing departments, the benefits of external training for even one member of staff were found by Honeybourne and Neumann (1997:713) to be extremely beneficial to a department.
When they analysed comparisons between in house training, off site external and a three week external ENB course, they found "beneficial effects of the external training of at least one member of staff on the efficiency of disinfection procedures in routine and high risk".
They also found that dedicated endoscopy units adhered better to national guidelines and had better facilities, when their staff had offsite training.

10. C Who was your training provider.

Scope manufacturer/Agent	20(100%)
In house infection control	9(45%)
Line managers	7(35%)
Other users	8(40%)

Table 17. Training providers

The role of both Infection control teams and the line manager in providing training is disappointingly low. In house infection control teams were providing more training in smaller hospitals than in larger hospitals, as opposed to line managers providing more training in larger hospital, but still both types of training are disappointingly low.

		Training Provider				
		Scope manufacturer	**In house infection control**	**Line managers**	**Other users**	
HOSPITAL BED SIZE	<200	4	2	1	2	
	200-300	7	3	2	2	
	300-400	3	1	1	1	
	400-500	2	2	1	1	
	>500	4	1	2	2	
Total		**20**	**9**	**7**	**8**	

Table 18. HOSPITAL BED SIZE * TRAINING PROVIDERS cross tabulation

10D.

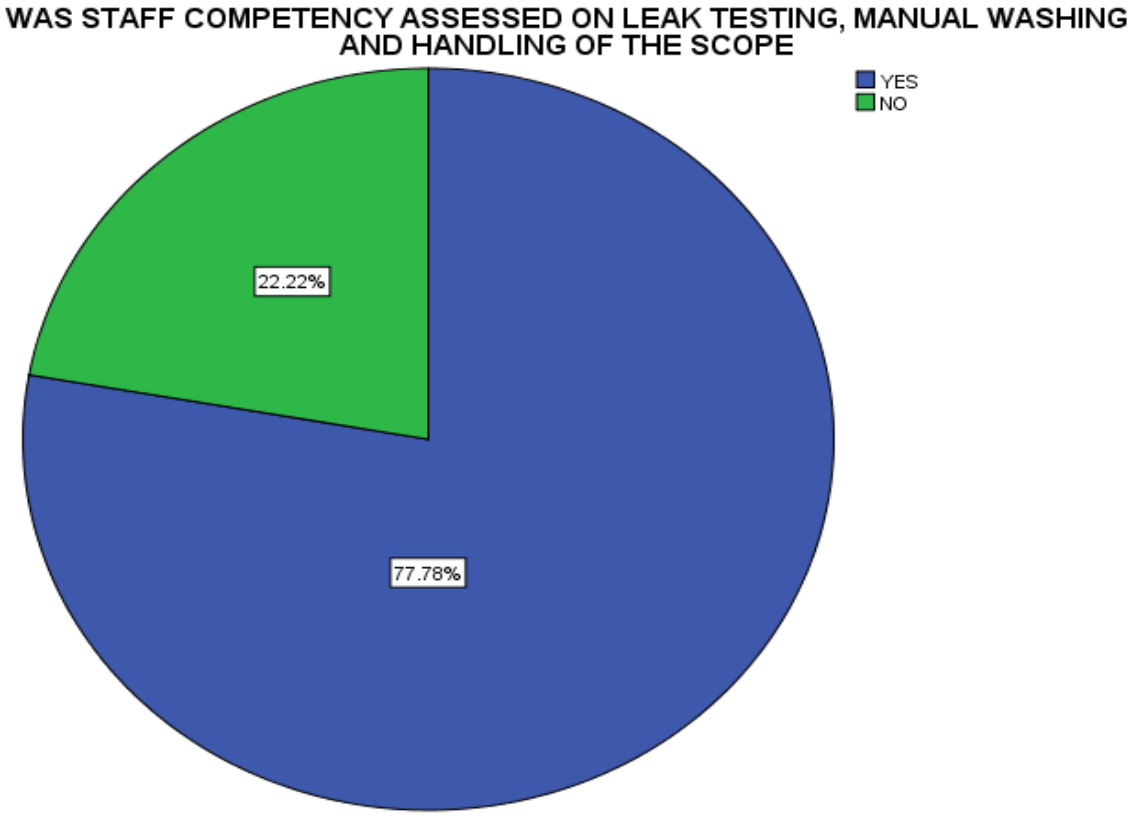


Figure 8.

When questioned about competency assessment of staff who reprocessed flexible endoscopes, fifteen (75%) of hospitals carried it out. From table 18, it is evident that at least 50% of hospitals of in each bed size group had assessed staff on competency.

Table 19. HOSPITAL BED SIZE * WAS STAFF COMPETENCY ASSESSED ON LEAK TESTING/MANUAL WASHING Crosstabulation

Count

		WAS STAFF COMPETENCY ASSESSED ON LEAK TESTING/MANUAL WASHING		
		YES	NO	Total
HOSPITAL BED SIZE	<200	3	1	4
	200-300	5	2	7
	300-400	2	1	3
	400-500	2	0	2
	>500	3	1	4
Total		15	5	20

10E.Is staff competency assessed annually?

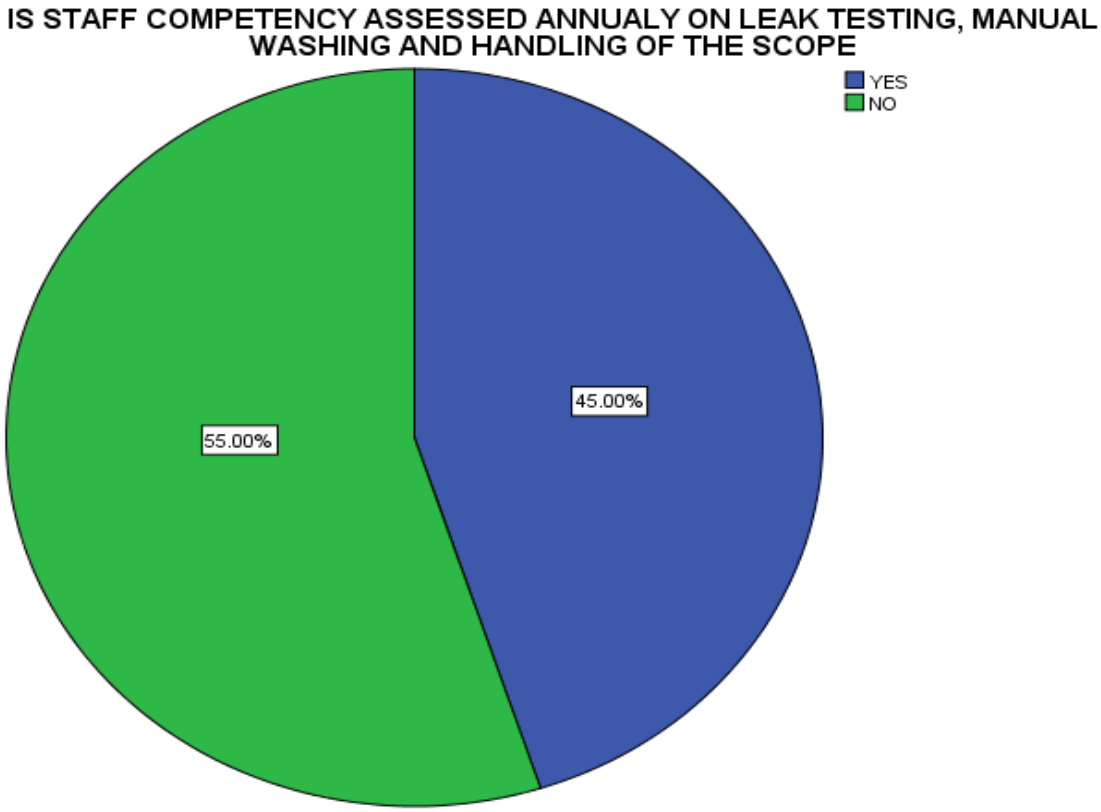


Figure 9. Annual staff competency assessed

Unfortunately when we looked at annual testing of competency in relation to leak testing/ manual washing and handling of the scope, the results are poor.

Whilst fifteen (75%) had indicated they carried it annually, only nine (45%) hospitals carried this out annually. This result corresponds with the annual testing of competency on operating AER's.

The work of Ofstead *et al.* (2010) Weber and Rutala (2004) cited earlier highlighted the importance of annual assessment in ensuring adherence to guidelines and identifying weaknesses in reprocessing.

10F. Was the person providing the training qualified to do so?

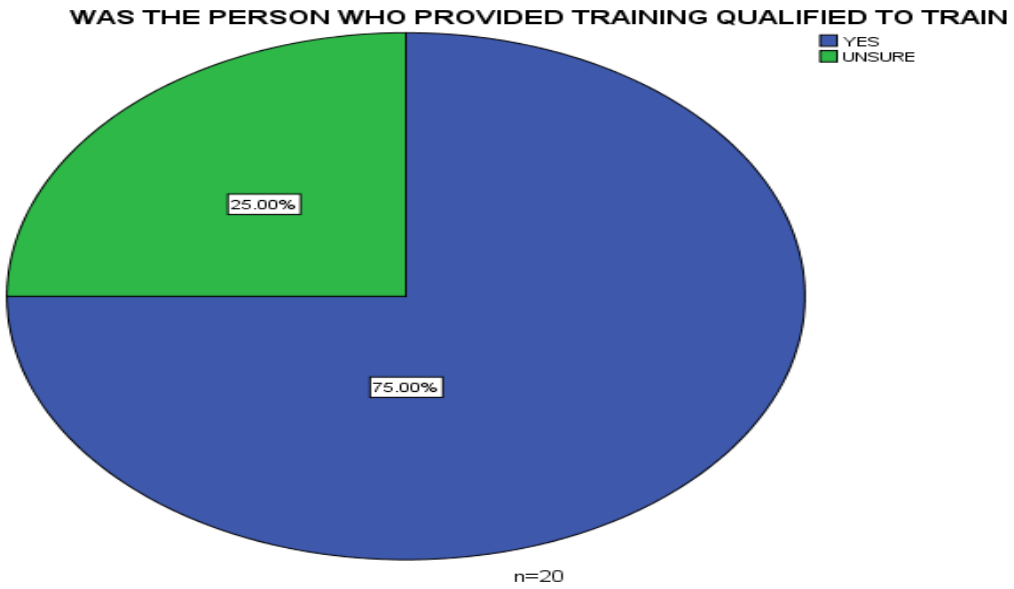


Figure 10 . Was the person providing the training, qualified to train

Records should be kept of all training carried out, and similar to details held in validation, the qualification of the person providing the training should be included.

Similar to the question on the trainer on AER's (9F) this question could have been devised better and had the question been posed with multiple choice answers, it may have determined the exact qualification of those delivering training.

Hospitals with between 200 and 400 beds appear to be more aware of the qualifications of trainer; this may indicate a better communications or familiarity with the training provider

Table 20. HOSPITAL BED SIZE * WAS THE PERSON WHO PROVIDED TRAINING QUALIFIED TO TRAIN Crosstabulation

		WAS THE PERSON WHO PROVIDED TRAINING QUALIFIED TO TRAIN		
		YES	UNSURE	Total
HOSPITAL BED SIZE	<200	2	2	4
	200-300	6	1	7
	300-400	3	0	3
	400-500	1	1	2
	>500	3	1	4

11. Does a staff competency document exist for each member of staff involved in reprocessing endoscopes?

Table 21. IS STAFF COMPETENCY ASSESSED ANNUALY

		Frequency	Valid Percent	Cumulative Percent
Valid	YES	9	45.0	45.0
	NO	11	55.0	100.0
	Total	20	100.0	

Table 22. HOSPITAL BED SIZE * DOES A STAFF COMPETENCY DOCUMENT EXIST FOR EACH MEMBER OF STAFF Crosstabulation

Count

		DOES A STAFF COMPETENCY DOCUMENT EXIST FOR EACH MEMEBR OF STAFF		
		YES	NO	Total
HOSPITAL BED SIZE	<200	3	1	4
	200-300	4	3	7
	300-400	1	2	3
	400-500	1	1	2
	>500	1	3	4
Total		10	10	20

It is suggested by Ofstead *et al.* (2010) that some human factors cannot be changed by education exclusively and that established routine monitoring is best used to ensure compliance.

A competency document for each member of staff should cover all critical areas of reprocessing including manual washing, using AER's as well as other area outlined in JAG (2009) guidelines.

When we cross ref the results with hospital bed size (table 21), we see competency documents are more frequent in smaller hospitals, in hospital with fewer than 300 beds, seven had them in place. Hospitals with more than 300 beds (n=9) however were poorer, with only three (33%) hospitals having competency assessment document for each member of staff.

12. Are the following documents available to all staff at all times in the reprocessing areas.

	YES	NO
Material safety data Sheet	20(100%)	0
SOP's	19(95%)	1(5%)
AER manuals	20(100%)	0
Endoscope manuals for all scopes	20(100%)	0
Connection cards	13(65%)	7(35%)
AER log book	13(65%)	7(35%)

Table 23. Documents available to all reprocessing staff.

All hospital surveyed indicated that staff in the reprocessing area had access to SOP's, material safety data sheets and AER manual for referencing.

Connection cards were only available to staff in 13(65%) of hospitals surveyed, which is poor. These connection cards are a vital tool to ensure that the endoscope is correctly connected to the AER to ensure that there is a correct match**.**

Hildebrand *et al.* (2011) found in their study that participants gave high ratings of difficulty to attaching the endoscope to AER's, and that connection cards are an important tool for reprocessing staff.

AER log books were only present in 13 (65%) of the hospitals. The purpose of a log book for each AER is to document all records in relation to maintenance, periodic tests and performance history. It is important as a source of reference for the operator as they can check the status of the AER; it can also be used as evidence in the case of an adverse incident and also provides an audit trail of testing and maintenance.

13A. In your opinion do staff carrying out the decontamination of endoscopes receive sufficient training and support.

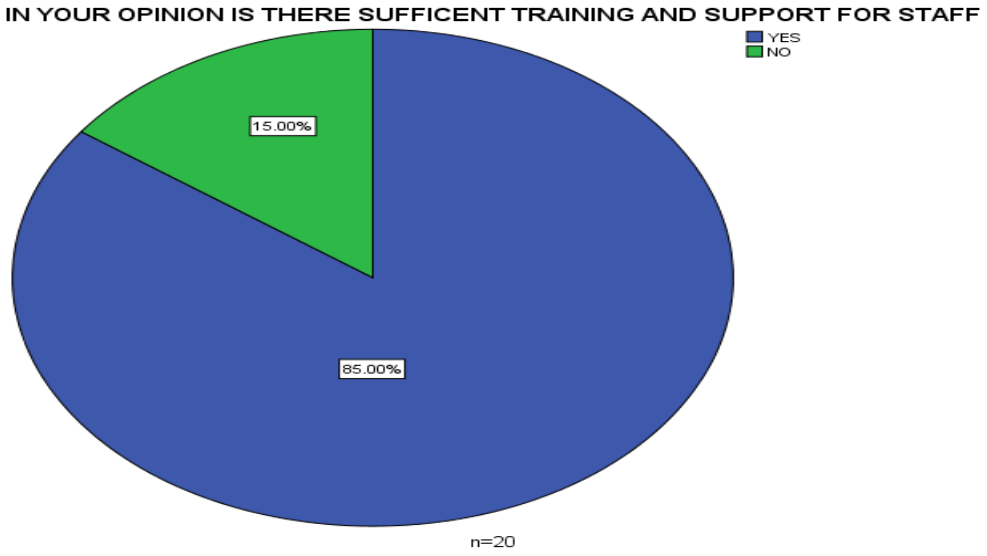


Figure 11.

		IN YOUR OPINION IS THERE SUFFICENT TRAINING AND SUPPORT FOR STAFF		
		YES	NO	Total
HOSPITAL BED SIZE	<200	4	1	5
	200-300	7	0	7
	300-400	3	0	3
	400-500	1	1	2
	>500	2	1	3
Total		17	3	20

Table 24. Cross tabulation HOSPITAL BED SIZE * IN YOUR OPINION IS THERE SUFFICENT TRAINING AND SUPPORT FOR STAFF.

When the opinion of managers was sought on whether sufficient training and support was available to reprocessing staff seventeen (85%) hospitals indicated there was. Three (15%) hospitals felt there was not.

Two (10%) of the three hospitals that felt there was not sufficient support for staff were from larger hospitals with >400 beds with one from a hospital with less than 200 beds.

13B. If NO, what in your opinion is the reason for this.

	n=3
No training support available	2 (66%)
No time allocated for training	3(100%)
Decontamination is not seen as an area that requires training and can be carried out by untrained staff.	1 (33%)

Table 25. Reasons Managers felt why their staff didn't receive insufficient training/support

All hospitals (n=3) that said that there was insufficient training cited "no allocated time for training" as the reason. Two (10%) hospitals said no training support was available and one (5%) hospital indicated that this is an area that doesn't require staff training; this alarmingly highlights a serious lack of awareness by the hospital concerned.

Q14. Who should provide training for staff involved in decontamination?

HSE National Training programme	20 (100%)
Individual hospitals developing their own training programmes	11 (55%)
AER manufacturer	19 (95%)
Endoscope manufacturer	19 (95%)
Chemical suppliers	16 (80)
Infection control teams	10 (50%)
Support organisations e.g. IDI ISGN	9 (45%)
Other please state	2 (10%)

Table 26. Who should provide staff training?

All hospitals surveyed saw the HSE as the body responsible for providing training and support for staff reprocessing flexible endoscopes.

With the exception of the online training they provide no other training is available and this is regrettable. From the survey it is evident that there is an over reliance on courses and workshops run by manufacturers or suppliers of chemicals, endoscopes or AER's which is similar to the findings of Hine (2004) in Northern Ireland in 2004. Hine (2004) stated that it is difficult to assess the quality of this type of training.

Q15. Which guidance document do you follow with regard to AER/ Endoscope reprocessing?

AER/Endoscope manuals	15(75%)
HSE Standards and Recommended practices for Endoscopy Units	15(75%)
British HTM's/CFPP	4(20%)
European standards	14(70%)
Jag Standards	17(85%)
BSG guidelines	12(60%)
Other please state	2(10%)

Table 27. Guidance document used.

It is apparent that the JAG accreditation process has been a major driving force in the development of endoscopy service in the Republic of Ireland. Its overall aim was to "improve the endoscopy service by identifying deficiencies, underperformance and accelerating the adoption of change to ensure best practice" (NCCS 2011:5).

The fact that seventeen (85%) hospitals identified JAG guidelines as a guidance document, whilst only fifteen (75%) identified the HSE Recommended Practice for endoscope reprocessing units, highlights the influence JAG accreditation has had on hospitals seeking accreditation. The JAG (2009) Decontamination Standards for Flexible Endoscopy are very unambiguous, which is a major asset for people responsible for endoscopes reprocessing and hence the reason why many departments are using it.

The HSE Recommended Practice for endoscope reprocessing units is a large document. At 173 pages long, it fails to have a specific chapter on staff training despite the evidence of its importance.

The JAG (2009) Decontamination Standards for Flexible Endoscopy is only 13 pages; it clearly highlights staff training as one of its key standards and break down training into various components such as induction, training programmes, and ongoing competency training package.

Q16. Which of the following tests/ cycles are carried out daily on all AER'S?

No daily test	0
Check spray arms for rotation	19(95%)
Check spray arms for blockage	18(90%)
Remove and clean strainers	18(90%0
Check chemical expiry date	19(95%)

Table 28. Daily tests cycles carried out.

Nineteen (95%) hospitals confirmed that they were carrying out daily testing on their AER's in accordance HSE (2012) Recommended Practice for endoscope reprocessing units, one hospital failed to answer this question. Overall the result for daily tests is excellent.

Question17. Are weekly tests carried out on all AER'S?

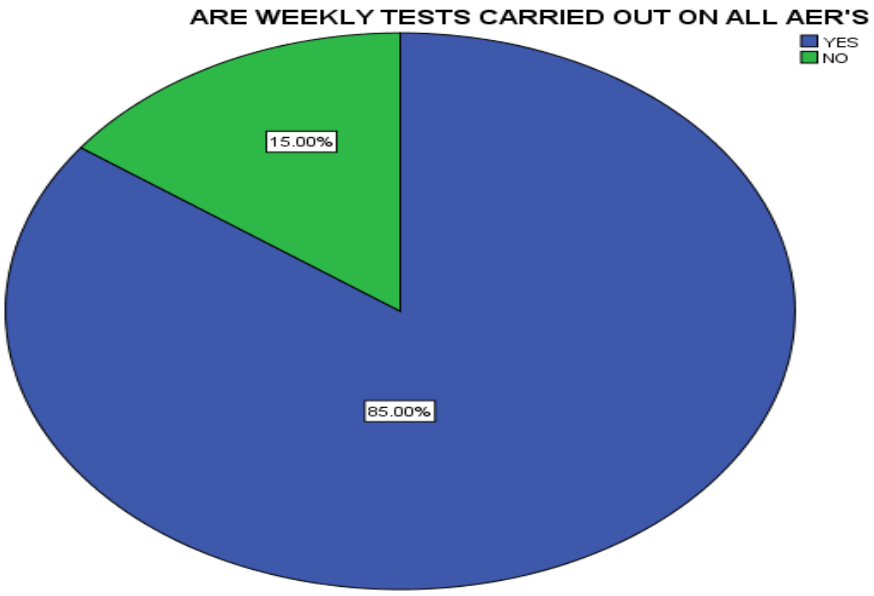


Figure 12.

Seventeen (85%) hospitals indicated that they carry out weekly testing on all AER's, this again is an indication of hospitals' acknowledgement of the importance of testing. The fact that 15% are failing to carry out weekly testing is poor and needs addressing. From Table X we can see that the hospitals that weren't carrying out testing on all AER's were all hospitals with more than 400 beds.

From question 4, we also know that these hospitals were reprocessing scopes in more than three areas. One hospital had put the comments "in certain areas" beside this question.It is imperative that all AER's have weekly testing to ensure they are safe and performing consistently and within specification.

Table 29. HOSPITAL BED SIZE * ARE WEEKLY TESTS CARRIED OUT ON ALL AER'S Crosstabulation

		ARE WEEKLY TESTS CARRIED OUT ON ALL AER'S		
		YES	NO	Total
HOSPITAL BED SIZE	<200	4	0	4
	200-300	7	0	7
	300-400	3	0	3
	400-500	1	1	2
	>500	2	2	4
Total		17	3	20

18. Are the following tests/cycles carried out weekly on all AER'S?

Weekly test/cycles	YES	NO
Weekly safety checks	19 (95%)	1 (5%)
All daily checks	18 (90%)	2 (10%)
Automatic control test	12 (60%)	8 (40%)
Thermal disinfection	20 (100%)	0(0%)
Cleaning efficacy by residual soil	14 (70%)	6 (30%)
Water hardness	14 (70%)	6 (30%)
Water conductivity	14 (70%)	6 (30%)
Water for CFU's and *Ps.Aerginosa*	11 (55%)	9 (45%)
Ninhydrin test	9 (45%)	11 (55%)

Table 30.Weekly test cycles on AERs

Whilst seventeen (85%) hospitals indicated in question 17 that they carried out weekly testing of AER's, when the weekly testing was broken down some tests fell to a disappointing 9 (45%) for Ninhydrin testing. An additional comment on one questionnaire again stated "on some AER's in certain areas" which also suggests that there may be different practices in hospitals where there is multi location reprocessing and numerous people responsible.

Eleven (55%) hospitals were carrying out microbiological testing of their AER's weekly in line with the HSE recommended practices for endoscopy reprocessing units, with one hospital noting on the questionnaire that they carry it out monthly.

One hospital was only carrying out a thermal disinfection weekly and no other testing was being carried out. The testing of AER's as a means to ensure that it is safe and performs within the specifications has been indicated in the literature review, as well as the importance in microbiological testing as a means of quality assurance.

The surveys did not address the reason these tests were not all carried out, however, we can speculate that testing of AER's wasn't the norm, until the spotlight was placed upon the service following the JAG.

When the JAG progress report was published it identified 80% of units not in compliance with the HSE Standards and Recommended practices for Endoscopy Units and drastic changes were required.

When we address testing of AER's it is evident that they require a lot of time, Department of Health (2013) CFPP suggests an estimate of the time required in Health Building Note 13 (HBN 13) (2004) "sterile service department" which states that between 30-40% of available time may be required for non-patient work such as testing and maintenance.

This amount of time and resources for testing will have to be factored into existing reprocessing locations and future development in endoscopy reprocessing. The questionnaire didn't ask why these tests weren't been carried out, but it may have to do with the vast time needed to carry out all the testing.

Question 19.Who is responsible for carrying out weekly testing of AER's?

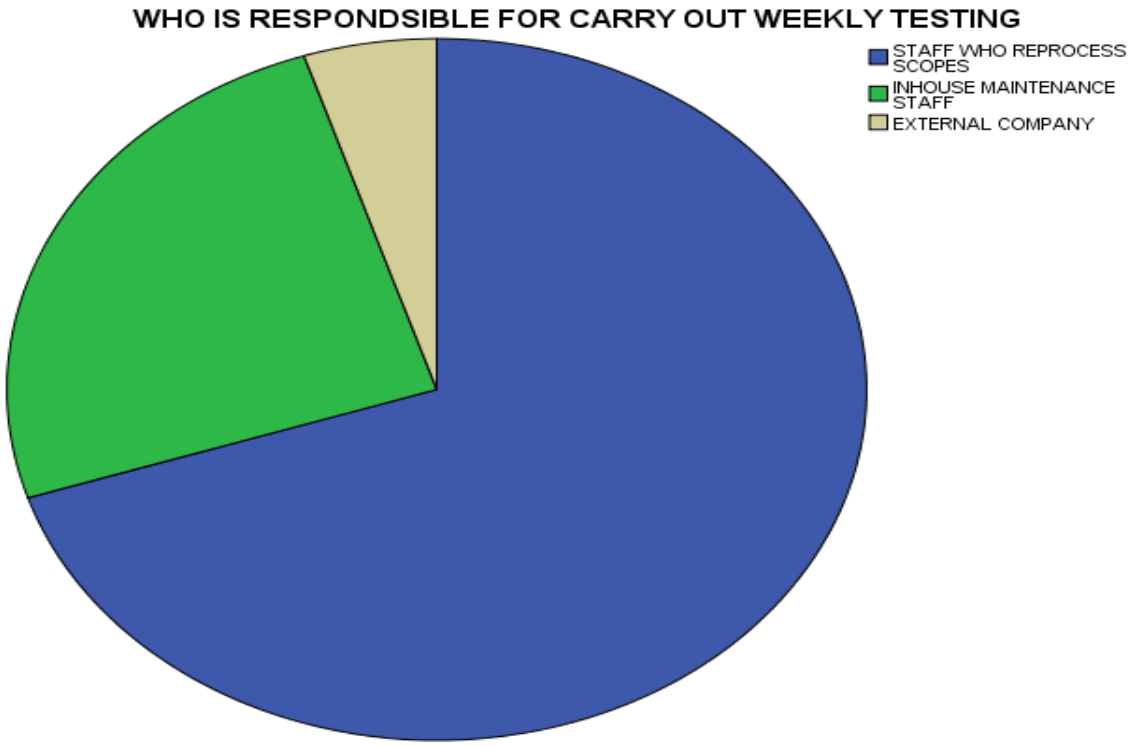


Figure 13.

Table 31. HOSPITAL BED SIZE * WHO IS RESPONDSIBLE FOR CARRY OUT WEEKLY TESTING Crosstabulation

Count

		WHO IS RESPONDSIBLE FOR CARRY OUT WEEKLY TESTING			
		STAFF WHO REPROCESS SCOPES	INHOUSE MAINTENANCE STAFF	EXTERNAL COMPANY	Total
HOSPITAL BED SIZE	<200	3	1	0	4
	200-300	5	2	0	7
	300-400	3	0	0	3
	400-500	0	1	1	2
	>500	3	1	0	4
Total		14	5	1	20

Only one (5%) hospital employed an external company to carry out their weekly testing. This might have to be an option for hospitals which to date are only carrying out a very few of the weekly tests. Only five (25%) hospitals allocated the responsibility to the maintenance staff.

Question 20. JAG Hospital status

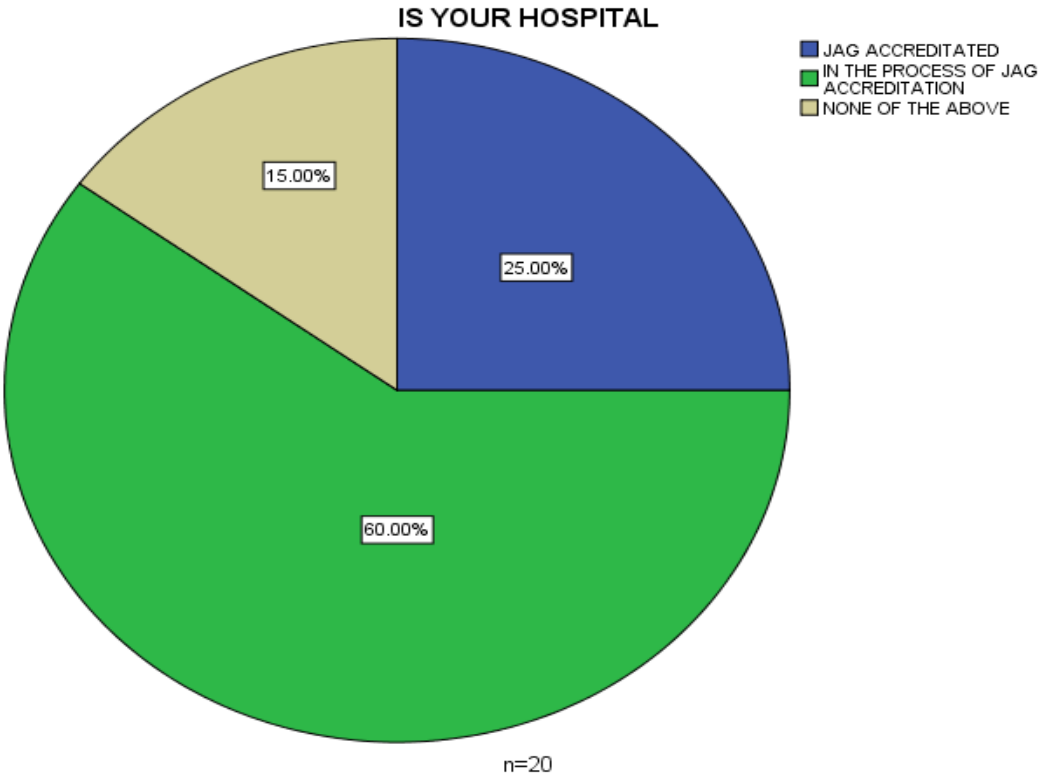


Figure 14. JAG status

It is evident from the results of this question that the majority of hospitals are in the process of seeking JAG accreditation and therefore are undergoing great transition. Hospitals with JAG accreditation were undoubtedly adhering best to education and training aspects as well as compliance with AER testing in order to obtain JAG accreditation.

Table 32. HOSPITAL BED SIZE * IS YOUR HOSPITAL- JAG Crosstabulation

		IS YOUR HOSPITAL			
		JAG ACCREDITED	IN THE PROCESS OF JAG ACCREDITATION	NONE OF THE ABOVE	Total
HOSPITAL BED SIZE	<200	0	4	0	4
	200-300	2	5	0	7
	300-400	0	1	2	3
	400-500	1	0	1	2
	>500	2	2	0	4
Total		5	12	3	20

Q21. Is your Hospital planning to develop endoscopy reprocessing facilities?

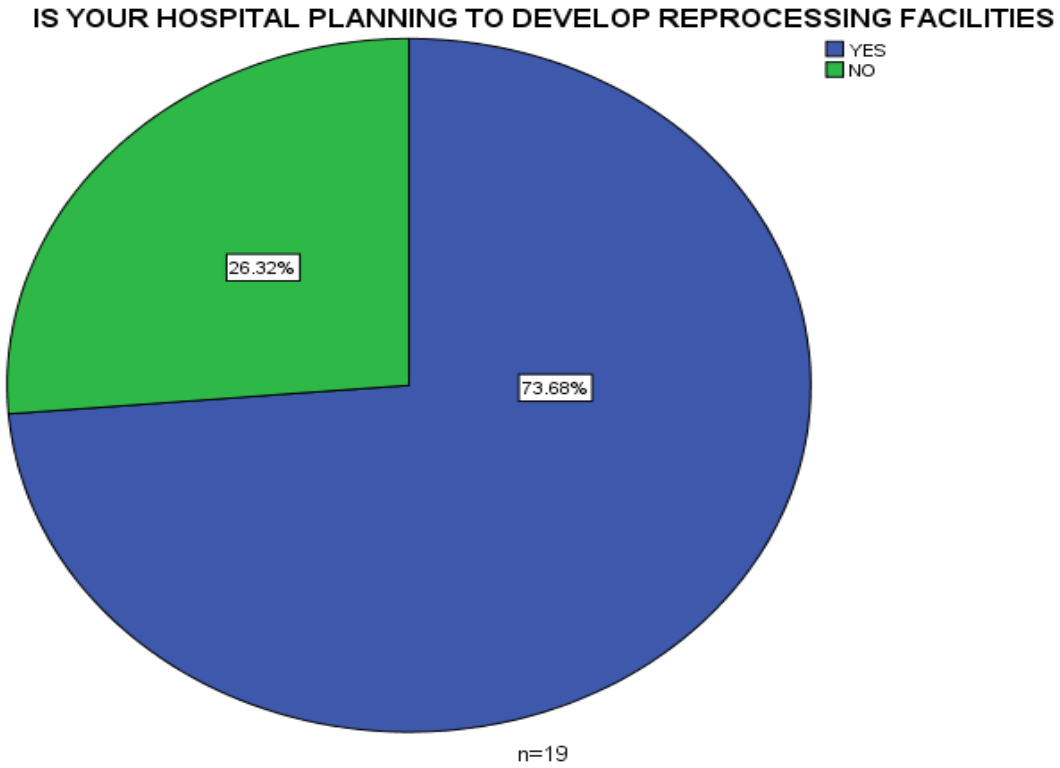


Figure 15. Hospitals planning further development.

It was also apparent that hospitals are adopting change with fourteen out of the nineteen hospitals that answered this question indicated they are in the process of developing endoscopy reprocessing facilities. The NCSS (2011) highlighted that when hospitals in the Republic of Ireland were assessed in December 2010 only 61% of facilities had acceptable decontamination facilities.

Table 33. HOSPITAL BED SIZE * IS YOUR HOSPITAL PLANNING TO DEVELOP REPROCESSING FACILITIES Crosstabulation

		IS YOUR HOSPITAL PLANNING TO DEVELOP REPROCESSING FACILITIES		
		YES	NO	Total
HOSPITAL BED SIZE	<200	2	1	3
	200-300	4	3	7
	300-400	3	0	3
	400-500	2	0	2
	>500	3	1	4
Total		14	5	19

Chapter 5 Conclusions and Recommendations

5.1 Introduction

The overall aim of this research is to identify the current practice in relation to staff training and AER testing, and to assess compliance with the HSE (2012) Standards and Recommended Practices for Endoscope Reprocessing units.

The study was carried out by postal questionnaire and was not designed to be critical of current practices, but to establish a baseline of what level of training and testing is happening, and to provide if needed recommendations on endoscope reprocessing in the Republic of Ireland in this area.

5.2 Objectives

The specific objectives of the study were to:

1. Identify from the literature how lack of staff training and the non adherence to AER testing is contributing to breaches in flexible endoscope reprocessing.
2. Evaluate what education and training staff that reprocess flexible endoscopes receive, and to what extent their competencies are assessed.
3. Evaluate hospitals' compliance with the HSE (2012) Recommended Practices for Endoscopy Reprocessing Units in relation to AER's daily and weekly testing.
4. Based on the findings of the research, make recommendations on how current procedures could be improved.

5.2.1 Identify how lack of staff training and the non adherence to AER testing is contributing to breaches in flexible endoscope reprocessing.

This objective was achieved by means of the literature review. In the literature review and throughout this study, incidents of cross contamination by means of inadequately reprocessed endoscopes were identified which were attributed to either insufficiently trained staff or to AER's that were not adequately maintained.

Ofstead *et al.* (2013) claimed that despite patients being exposed to contaminated scopes, incidents are rarely reported in medical journals, and hence those that are published may be the tip of the iceberg.

The studies examined in the literature review, as well as recommendations from national and international bodies have highlighted both the importance of education and ongoing assessment for endoscope reprocessing staff (Dirlam Langlay *et al.* 2013, Bajolet *et al .*2013 Society of Gastrointestinal Nurses and Associates (SGNA) 2010)

It also highlighted the importance of maintaining AER's by carrying out testing to ensure the AER's are safe to use and that they are performing within their specification (JAG 2009, HSE 2012, and BSG 2008).

Caesar (2013) questions if hospitals should look upon flexible endoscopes as the Pandora's Box of hospitals due to all the international studies which have identified failures in adhering to reprocessing guidelines leading to cross contamination. Knieler (2001) has claimed that flexible endoscopes were never designed for easy cleaning.

The review found that the flexible endoscope was the number one medical device to have caused cross contamination (CDC 2008, Ofstead *et al.* 2010 and Greenwald 2011), and that in part is due to the design of the device, it facilitates the deposition of contaminates which if not reprocessed correctly will provide a formidable environment for the microorganism colonisation and the formation of a biofilm thus increasing the risk of cross contamination between patients (Pajkos, Vickery and Cossart 2004).

Some even suggest that its design is so complicated that it was never designed for cleaning (Knieler 2001).

The literature review therefore highlights the impact lack of training and testing of AER's has on the cross contamination of patients through infected endoscopes.

5.2.2 Evaluate what education and training staff that reprocess flexible endoscopes receive, and to what extent their competencies are assessed.

It is evident from the literature review that flexible endoscope reprocessing should only be undertaken by competently trained staff. Staff should attend an established ongoing training programme, their competencies should be assessed and all of this information should be documented.

The initial questions in relation to training were very positive, indicating that staff received training on manual cleaning and operating AER's in all 20 hospitals surveyed. However as the questionnaire delved further into both manual cleaning and operating AER's it becomes apparent, that the training is not adequately covering the key areas and/or that managers are unaware of the key areas that require training, which is of concern.

Endoscope and AER manufacturers appear to be the number one source of education and training with all twenty hospitals identifying them as trainers. This was similar to the findings of the Hine report in Northern Ireland in 2004. In that report, suppliers were found to be the primary trainers and that this type of training is impossible to assess, and wonders if there is an overreliance on this type of training.

The use of in-house infection control staff in providing training was disappointingly low and is untapped asset for endoscope reprocessing units. It has been identified in the literature during this study that education on infection control and microbial aspects of decontamination are important aspects for all staff reprocessing.

Eighteen (90%) hospitals had indicated that they had training in this area, yet only eight or nine hospitals reported that they had received training form their infection control teams which begs the question who were staff in the remaining hospitals receiving this training from?

Only one (5%) hospital indicated that they had used the HSElands online training resource, and in tandem with the use of the infection control team, this training is available to all staff and totally under used. Efforts to establish the numbers who have completed this online course couldn't be obtained as the HSE said it was "protected by data protection legislation" which is unfortunate.

As well as training support documentation such as manuals for endoscopes/ AER's, safety data sheets and Standard Operating Procedures (S.O.P.) were in place in almost all units according to the survey.

Disappointingly, access to connection cards was only 65%. This should be a basic requirement cards should be in position near all AER's so that staff can ensure they are using the correct connections for the scope and AER.

These connection cards are a vital tool to ensure that the endoscope is correctly connected to the AER to ensure that there is a correct match. CDC (1999) identified an increase in cases of *M. avium-intracellulare* (M.A.I), following an investigation it was confirmed that the cause was incorrect connectors being used between the AER and the bronchoscopes, and staff had not been trained on these specific connection sets.

A competency assessment tool, to assess staff on their competency on the different aspects of decontamination is advocated by JAG (2009), this competency tool is designed to be a continuous assessment to ensure guidelines are being adhered to and any weaknesses identified, with a plan put in place to remedy the weakness. Competency levels for leak testing, manual cleaning and handling the scope was carried out in fifteen (78%) falling drastically to nine (45%) hospitals which were carrying this out annually. Competency assessment levels were not affected by hospital size.

Competency assessment in relation to operating AER's was slightly lower as two hospitals failed to answer this question, fourteen (70%) hospitals indicated they carried out assessment and this fell to nine (45%) for annual competency.

A competency document existed for each member of staff in only ten (50%) hospitals, another unsatisfactory result.

Overall there appears to be a misunderstanding of what training is required, and outside of commercial companies there is little support available. Managers require more education on staff training needs in order to improve decontamination procedures

It was surprising that seventeen managers thought there was sufficient training and support for staff. Only one hospital surveyed with less than 400 beds thought there was insufficient training and support. The hospitals that thought there was insufficient training all agreed that there was no time for training, whilst two felt there was no training support available. One hospital cited that decontamination is seen as an area that doesn't require training and can be carried out with untrained staff.

The NCSS (2011) report said that the assessors felt that practices taught were out of date in relation to the decontamination of endoscopes and endoscopic accessories. It is evident from the findings of this study, that there is a need for a comprehensive training programme to educate all involved in reprocessing and to bring units up to date in order to meet best national and international guidelines and practice.

It is also evident from the findings that line managers appear not to have a role in educating their staff in these reprocessing units; perhaps if they were adequately trained and resourced they would be in a better position to provide training.

Guidelines, Standards and Standards Operating Procedures are important but only if staff reprocessing the scopes are trained to use them and understand their importance.

Lessons need to be learned from incidents that have occurred in the past and there is a need to be proactive and learn from previous incidents and ensure that we avoid a reoccurrence of previous incidents.

5.2.3 Evaluate hospitals' compliance with the HSE 2012 Recommended Practices for endoscopy reprocessing units in relation to AER's daily and weekly testing.

Initially a lot of hospitals indicated that they were compliant with the daily (95%) and weekly (85%) testing indicated in the HSE Recommended Practices for Endoscopy Decontamination units. Daily tests were carried by nearly all hospitals however when the weekly tests were broken down into individual tests, compliance fell drastically to 45%.

Hospitals said they were carrying out weekly tests, but on breakdown only some tests and not all were being carried out. It also questions if testing is being adequately covered by AER manufacturers in training or in manuals?

NCSS (2011) claimed that compliance with EN 15883-4 was only 13% in 2010; this study would show that compliance has slightly improved in some hospitals but not to an acceptable level.

The fact that only eleven (55%) hospitals indicated that they check final rinse water for Colony Forming Units' and *Ps.aeruginosa* is extremely poor, and requires addressing. It can only be presumed that staff are unaware of the significance of this test. In the literature review, the study by Hübner *et al.* (2011) concluded that all AER's should be viewed as being a potential source of cross contamination and therefore should have routine quality control monitoring of its rinse water.

One hospital did indicate that they carried water sampling monthly, which would be satisfactory if this had been agreed after a long period with consistently negative results and after it was risk assessed with a microbiologist.

It was evident from the results that smaller hospitals seem to carry out more testing and this may be due to them reprocessing in fewer locations, and also reprocessing less scopes.

In the literature, it became apparent that the time involved in testing is great and units that don't undertake testing up to now will require resources to get their testing up to the recognised standards. This will only be achieved if management are made aware and allocate resources or perhaps like one hospital surveyed, that this job could be outsourced. In order for units to get these resources it will require the HSE to make the tests mandatory and not leave them as guidelines.

All hospitals surveyed agreed that the HSE should have a role in training; however this appears to be limited to online training at present and is not sufficient for the practical role of reprocessing flexible endoscopes.

The centralisation of endoscopy reprocessing would be of great benefit, it would provide a purpose built unit, with dedicated trained staff whose specific role is the reprocessing of flexible endoscopes. Centralization would resolve a lot of weakness identified in this research as dedicated trained staff would be acutely aware of the associated risk. Evidence from this study supports the literature in finding that staff operating from one location are more compliant with training and testing, albeit these were also the smaller hospitals.

5.2.4 Based on the findings of the research, make recommendations on how things could be improved.

Based on the high level of participation in the survey, it can be inferred that managers involved in reprocessing are keen to support changes to improve practice.

The findings of the study suggest the following recommendations would benefit endoscope reprocessing in the Republic of Ireland.

1. Publish a new or revised HSE Recommended Practice for Endoscopy units, with a specific chapter dedicated to staff education and AER testing. The new document needs to be more focused and more user friendly. The new chapters should focus on:

   A) Staff Education

   This chapter should focus on providing all the necessary knowledge and skills required for staff reprocessing flexible endoscopes. Ongoing training and ongoing assessment should be mandated by the HSE in order for resources to be provided by hospital management.

   Training should include induction, training and revalidation and be based on a competency assessment tool, similar to JAG (2009) Decontamination Standards for Flexible Endoscopy.
   External training by commercial companies should be used to support hospital education programmes and not be the primary source of educational support to these units.

   B) AER testing

   Testing must be made mandatory, and the frequency of each test stated. Until such time as this happens, managers will not receive the resources required from hospital management to carry out all the testing required.

2. The HSE should provide resources to periodically run training courses in Ireland. The training should initially be for managers in order for them to be up skilled and gain better understanding and knowledge of the resources they require to run an endoscope reprocessing unit.
   This may involve bringing in a non commercial training company from the United Kingdom or elsewhere. This could be followed up by running training for all other levels of staff involved in reprocessing flexible endoscopes.

3. The HSE national procurement should when issuing tenders for new decontamination equipment, make specific requests for initial training as well as yearly refresher training in supporting the new equipment. This would both highlight the importance the HSE place on training, and also indicate to suppliers that they need to be able to provide trainers, and not field engineers or sales representatives with little or no experience of reprocessing.

5.3 Limitation of the Study

Despite the careful preparation of this research, the author is aware of its limitations. Questionnaire by there design, don't offer the respondent to expand or clarify their answer. They also don't facilitate the opportunity for the respondent to seek clarification on questions and may not interpret the question the same way as the researcher had intended.

5.4 Dissemination Plan

This study will initially be presented to University of Highlands and Islands (UHI) towards the MSc in Medical Device Decontamination. Following successful completion, a summary of the study, its findings, conclusion and recommendations will be made available to the following relevant bodies and individuals:

- Irish Decontamination Institute (IDI)
- Irish Society of Endoscopy Nurses (ISEN)
- National Decontamination Lead
- Lenus- Irish Health Repository- repository of research carried out by HSE staff

5.5 Further Research

Another source of cross contamination identified in the literature, but not covered in this study is damaged flexible endoscopes. A damaged endoscope cannot be decontaminated correctly or undergo high level disinfection. Due to the structure of the endoscopes it is impossible to identify damage to the lumen. As a result damaged flexible endoscopes are usually identified by laboratories when an unusual cluster of infection is found with non symptomatic patients and it is usually traced to one endoscope.

I believe further research into periodic microbiological testing of all flexible endoscopes is necessary in order to prevent cross infections of patients.

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Appendix 1

Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

Merlin Park University Hospital
Ospidéal na h-Ollscoile, Páirc Mheirlinne
GALWAY UNIVERSITY HOSPITALS

Clinical Research Ethics Committee
Main Administration Building
Merlin Park Hospital
Galway.

22nd November, 2013.

Mr. John McNamee
HSSD Supervisor
HSSD Department
University College Hospital
Galway.

Ref: C.A. 990 – Reprocessing of flexible endoscopes in the republic of Ireland-Staff Education and Automatic Endoscope Reprocessors (AER's) testing.

Dear Mr. McNamee,

I have considered the above project, and I wish to grant Chairman's approval to proceed.

Yours sincerely,

p.p. Colette Collins
Dr. Shaun T. O'Keeffe
Chairman Clinical Research Ethics Committee.

Merlin Park University Hospital, Ospidéal na h-Ollscoile, Páirc Mheirlinne,
Galway, Ireland. Tel: 00 353 (0)91 757631

Appendix 2

Gayle Sinclair <gayle.sinclair@uhi.ac.uk> to JOHN, Christina.Brad., me

Good afternoon John,

We have received your completed REC1 form in application for UHI ethical approval of your dissertation 'Reprocessing of flexible endoscopes in the Republic of Ireland – Staff education and Automatic Endoscope Reprocessor (AER) testing'.

No further review of your study is required therefore I am pleased to confirm that UHI ethical approval has been granted. Please retain this email as confirmation.

Kind regards
Gayle

Gayle Sinclair

Grants & Contracts Administrator
University of the Highlands and Islands, Executive Office, Ness Walk, Inverness, IV3 5SQ

Phone: 01463 279 354 Fax: 01463 279 001 Web: www.uhi.ac.uk

Appendix 3

ENDOSCOPE DECONTAMINATION UNIT,

UNIVERSITY HOSPITAL GALWAY,

GALWAY.

08/01/14

Postal questionnaire- reprocessing of flexible endoscopes in the Republic of Ireland- staff education and AER testing.

Dear Sir/ Madam,

My name is John Mc Namee, and I work as a supervisor in the HSSD and the Endoscope Decontamination Unit in University Hospital Galway.

Currently I am completing my Masters of Science in Medical Devices Decontamination at the University of Highland and Islands, Inverness, Scotland.

As part of this MSc, I am required to undertake a piece of research on the decontamination of medical devices. I am carrying out my research on the Reprocessing of Flexible Endoscopes in public hospitals in the Republic of Ireland focusing on staff education and AER testing.

I would be very grateful if you would complete the following questionnaire and return it to me in the prepaid envelope provided.

All information gathered will remain confidential, and no hospital or person will be identified by the research. All questionnaires returned will be destroyed once research has been completed.

I appreciate that everyone is extremely busy at this time, but if you could give a few minutes filling in the questionnaire I would be so grateful.

Yours sincerely

_____

John Mc Namee

COMPLETED QUESTIONNAIRE SHOULD BE RETURN BY FRIDAY 24th January 2014

If you have any questions in relation to this research please feel free to contact me on 091544774 or john.mcnamee@hse.ie

Appendix 4

Questions to evaluate questionnaire and cover letter.

“1. How long did it take you to complete?

2. Is the instruction clear?

3. Were any of the questions unclear or ambiguous? If so, will you say which and why?

4. Did you object to answering any of the questions?

5. In your opinion, has any major topic been omitted?

6. Was the layout of the questionnaire clear/attractive?

7. Any comments.” Bell (2010:151)

Appendix 5

PLEASE COMPLETE BY TICKING THE APPROPRIATE BOX/ BOXES

1 WHAT IS THE BED CAPACITY OF YOUR HOSPITAL

		PLEASE TICK √
1	<200	
2	<300	
3	<400	
4	<500	
5	>500	

2 DOES YOUR HOSPITAL PROCESS ANY OF THE FOLLOWING SCOPES

		PLEASE TICK √
1	GASTROSCOPES	
2	COLONOSCOPES	
3	ERCP'S	
4	CYSTOSCOPES	
5	URETHRORENOSCOPES	
6	BRONCHOSCOPES	
7	T.O.E. PROBES	
8	OTHER	

PLEASE STATE.....

3 WHAT IS THE APPROXIMATE NUMBER OF SCOPES REPROCESSED ANUALLY

		PLEASE TICK √
1	<2500	
2	<5000	
3	<7500	
4	<10000	
5	<12500	
6	<15000	
7	<17500	
8	>20,000	

4 **HOW MANY AREAS WITHIN THE HOSPITAL REPROCESS ENDOSCOPES**

PLEASE TICK √

1	1	
2	2	
3	3	
4	4	
5	5	
6	>5	

5 **HOW MANY AUTOMATIC ENDOSCOPE REPROCESSOR ARE USED IN YOUR HOSPITAL?**

PLEASE TICK √

1	
2	
3	
4	
5	
IF > 5 HOW MANY_____	

6 **HOW MANY STAFF ARE INVOLVED IN THE MANUAL WASHING OF ENDOSCOPES**

PLEASE TICK √

MANUAL WASHING BEING LEAK TESTING/WASHING/BRUSHING/FLUSHING/RINSING

1	<5	
2	<10	
3	<15	
4	<20	
5	<25	
6	<30	

7 **WHAT GRADE OF STAFF CARRY OUT THE MANUAL WASHING OF ENDOSCOPES**

PLEASE TICK √

1	DEDICATED ENDOSCOPE REPROCESSING STAFF	
2	HEALTH CARE ASSISTANCES	
3	HSSD TECHNICIANS	
4	PORTERS	
5	NURSES	
6	CLINICAL NURSE MANAGER	

7 OTHER

PLEASE STATE.....

8 **HAVE ALL STAFF RECIEVED TRAINING ON THE FOLLOWING**

PLEASE TICK √

1	LEAK TESTING/MANUAL CLEANING	
2	AUTOMATIC ENDOSCOPE REPROCESSOR (AER)	
3	SPECIFIC ENDOSCOPES TRAINING ON ALL SCOPE IN USE	
4	INFECTION CONTROL/DECONTAMINATION	
5	HEALTH AND SAFETY	

9A **REGARDING AERS, DO THE STAFF DECONTAMINATING SCOPES RECIEVE TRAINING ON-**

PLEASE TICK √

1	HOW TO OPERATE THE AER	
2	HOW TO CARRYING OUT TESTING OF THE AER	
3	HOW TO CARRY OUT SELF DISINFECTION	
4	CHEMICALS - SAFETY/HANDLING/CHANGING AND DISPOSAL	

9B **WHAT TYPE OF TRAINING WAS PROVIDED**

PLEASE TICK √

1	WORKSHOPS ONSITE	
2	WORKSHOPS OFFSITE	
3	PRESENTATION/LECTURE	
4	NOTES/ HAND OUT	
5	OTHER. STATE_____	

9C **WHO WAS YOUR TRAINING PROVIDER ON THE AER**

PLEASE TICK √

1	AER MANUFACTURER /AGENT	
2	CHEMICAL SUPPLIER	
3	IN HOUSE INFECTION CONTROL STAFF	
4	LINE MANAGERS	
5	OTHER USERS	
6	OTHER PLEASE LIST	

_____

9D **WAS STAFF COMPETENCY ASSESSED IN USING AER'S**

PLEASE TICK √

1 YES ☐

2 NO ☐

9E **IS STAFF COMPETENCY ASSESSED ANNUALLY**

1 YES ☐

2 NO ☐

9F **WAS THE PERSON PROVIDING THE TRAINING QUALIFIED TO DO SO**

PLEASE TICK √

1 YES ☐

2 NO ☐

3 UNSURE ☐

10A **REGARDING FLEXIBLE ENDOSCOPES, DO THE STAFF RECIEVE TRAINING ON**

PLEASE TICK √

1 WORKING MECHANSIMS AND FUNCTION OF EACH SCOPE ☐

2 LEAK TESTING/WASHING AND BRUSHING OF SCOPE ☐

3 CARE AND MAINTENANCE OF SCOPE ☐

4 IDENTIFYING DAMAGE TO SCOPE ☐

10B **WHAT TYPE OF TRAINING IS PROVIDED**

PLEASE TICK √

1 WORKSHOPS ONSITE ☐

2 WORKSHOPS OFFSITE ☐

3 PRESENTATION/LECTURE ☐

4 NOTES/ HAND OUT ☐

5 OTHER. STATE_____

10C **WHO WAS YOUR TRAINING PROVIDER**

PLEASE TICK √

1 SCOPE MANUFACTURER/ AGENT ☐

2 IN HOUSE INFECTION CONTROL STAFF ☐

3 LINE MANAGERS ☐

4 OTHER USERS ☐

5 OTHER ☐

PLEASE LIST.....

10D **WAS STAFF COMPETENCY IN RELATION TO LEAK TESTING, MANUALLY WASHING AND HANDLING OF THE SCOPE PART OF THE TRAINING**

PLEASE TICK √

1 YES ☐

2 NO ☐

10E **IS STAFF COMPETENCY ASSESSED ANNUALLY**

PLEASE TICK √

1 YES ☐

2 NO ☐

10F **WAS THE PERSON PROVIDING THE TRAINING QUALIFIED TO DO SO**

PLEASE TICK √

1 YES ☐

2 NO ☐

3 UNSURE ☐

11 **DOES A TRAINING COMPETENCY DOCUMENT EXIST FOR EACH MEMBER OF STAFF INVOLVED IN REPROCESSING ENDOSCOPES**

PLEASE TICK √

1 YES ☐

2 NO ☐

12 **ARE THE FOLLOWING DOCUMENTS AVAILABLE TO ALL STAFF AT ALL TIME IN THE REPROCESSING AREA**

PLEASE TICK √

1 MATERIAL SAFETY DATA SHEET (MSDS) FOR ALL CHEMCIALS ☐

2 STANDARD OPERATING PROCEDURES FOR ALL ACTIVITIES ☐

3 AER MANUALS ☐

4 ENDOSCOPE MANUAL FOR ALL SCOPES(REPROCESSING SECTION) ☐

5 CONNECTION CARDS FOR ALL ENDOSCOPES USED- (SUPPLIED BY AER MANUFACTURER) ☐

6 AER LOG BOOK ☐

13A **IN YOUR OPINION DO STAFF CARRYING OUT THE DECONTAMINATION OF ENDOSCOPES RECEIVE SUFFICIENT TRAINING AND SUPPORT**

PLEASE TICK √

1 YES ☐

2 NO ☐

13B IF NO, WHAT IN YOUR OPINION IS THE REASON FOR THIS

PLEASE TICK √

1	NO TRAINING SUPPORT AVAILABLE	
2	NO TIME ALLOCATED FOR TRAINING	
3	DECONTAMINATION IS NOT SEEN AS AN AREA WHICH REQUIRES TRAINING AND CAN BE CARRIED OUT BY UNTRAINED STAFF	
4	OTHER. PLEASE GIVE DETAILS_____	

_____

14 WHO SHOULD PROVIDE TRAINING FOR STAFF INVOLVED IN DECONTAMINATION

PLEASE TICK √

1	HSE NATIONAL TRAINING PROGRAMME	
2	INDIVIDUAL HOSPITAL S DEVELOPING THEIR - OWN TRAINING PROGRAMME	
3	AER MANUFACTURERS	
4	ENDOSCOPE MANAUFACTURERS	
5	CHEMICAL SUPPLIERS	
6	INFECTION CONTROL TEAMS	
7	SUPPORT ORGANISATIONS- ISGN, IDI	
8	OTHER PLEASE STATE	

_____

15 WHICH GUIDANCE DOCUMENT DO YOU FOLLOW WITH REGARD TO AER/ENDOSCOPE DECONTAMINATION

PLEASE TICK √

1	AER/ ENDOSCOPE MANUALS	
2	HSE CODE OF PRACTICE	
3	BRITISH HTM/ CFPP	
4	EUROPEAN STANDARD e.g. EN 15883	
5	JAG STANDARDS	
6	BSG GUIDLINES	
7	OTHER. PLEASE STATE _____	

_____

16 WHICH OF THE FOLLOWING TESTS/ CYCLES ARE CARRIED OUT DAILY ON ALL AER'S

		PLEASE TICK √
1	NO CYCLE TESTS RUN DAILY	
2	CHECK SPRAY ARM FOR ROTATION?	
3	CHECK SPRAY ARM FOR BLOCKAGES?	
4	REMOVE AND CLEAN STRAINERS	
5	CHECK CHEMICAL EXPIRARY DATE	

17 ARE WEEKLY TESTS CARRIED OUT ON ALL AER'S

		PLEASE TICK √
1	YES	
2	NO	

18 ARE THE FOLLOWING TESTS / CYCLES CARRIED OUT WEEKLY ON ALL AER'S

		PLEASE TICK √
1	WEEKLY SAFETY CHECKS	
2	ALL DAILY CHECKS	
3	AUTOMATIC CONTROL TEST	
4	THERMAL DISINFECTION	
5	CLEANING EFFICACY BY RESIDUAL SOIL	
6	WATER HARDNESS	
7	WATER CONDUCTIVITY	
8	WATER FOR CFU'S AND *Ps. Aerginosa*	
9	NINHYDRIN TEST	
10	NONE OF THE ABOVE	

19 WHO IS RESPONSIBLE FOR CARRY OUT WEEKLY TESTING OF AER'S

		PLEASE TICK √
1	STAFF WHO REPROCESS SCOPES	
2	INHOUSE MAINTENANCE DEPARTMENT	
3	EXTERNAL COMPANY	

20 IS YOUR HOSPITAL

	PLEASE TICK √
JAG ACCREDITATED	
IN THE PROCESS OF SEEKING JAG ACCREDIATION	
NONE OF THE ABOVE	

21 IS YOUR HOSPITAL PLANNING TO DEVELOP ENDOSCOPE REPROCESSING FACILITIES

PLEASE TICK √

1	YES	
2	NO	

MANY THANKS FOR COMPLETING THIS QUESIONNAIRE.

PLEASE RETURN IT IN THE ENVELOPE PROVIDED.