PRODUCTION OF ENTERAL FEEDS:

MANUAL VS MECHANISED VS "READY TO HANG"

BY: Polly Joubert

Thesis presented in partial fulfilment of the requirements for the degree of

Master of Nutrition at the University of Stellenbosch

Study leader: Prof D Labadarios

Co-study leader: Dr R Blaauw

December 2003

I the undersigned, hereby declare that the work contained in this thesis is my own original work and that I have not previously in its entirety or in part submitted it at any University for a degree.

Signature: Date:

ABSTRACT

INTRODUCTION

Many patients seen by dietitians in Tygerberg Academic Hospital require feeding via the enteral route. Prior to this study all enteral feeds were mixed individually by hand, and production was time consuming and very labour intensive. The purpose of this study was, therefore, to compare the current method of production, with mechanised bulk production (MP) and "Ready to hang" (RTH) products, taking time, safety and cost effectiveness into consideration.

MATERIALS AND METHODS

A machine was designed and built to produce and decant bulk volumes of enteral feed. Production methods were evaluated and data was obtained regarding the time taken to produce a feed, and the true cost of the feeds produced. Microbiological samples were collected and the safety of all the three systems was determined and compared.

RESULTS

MP production time was significantly longer than hand production (HP), but MP decanting was significantly more accurate. RTH feeds cost 152% more than HP feeds, and MP feeds cost 95% of HP feeds. Seventy-one per cent of HP feeds, 74% of MP feeds and 34% of RTH feeds were contaminated just after administration had began.

CONCLUSIONS

Mechanisation is less labour intensive than HP and helps to decrease total costs. RTH feeds quickly become contaminated after administration decreasing their other advantages.

ABSTRAK

INLEIDING

Baie van die pasiënte wat deur dieetkundiges in Tygerberg hospitaal gesien word, benodig buisvoedings. Voor hierdie studie geloots was, was alle buisvoedings by Tygerberg hospitaal met die hand gemaak. Hierdie metode is baie tydsaam en arbeidsintensief. Die doel van hierdie studie was, om die voorlopige sisteem van produksie te vergelyk met gemeganiseerde grootmaat produksie en "ready to hang" (RTH). Die studie het die volgende in ag geneem: produksietyd, mikrobiologiese veiligheid en koste effektieweteit.

METODE

'n Masjien was ontwerp en gebou om grootmaat buisvoedings aan te maak en aftegiet. Produksie metodes was geëvalueer en inligting bymekaar gemaak met betrekking tot produksietyd, en die ware koste van die voedings. Mikrobiologiese monsters was versamel en die mikrobiologiese veiligheid van al drie sisteme is bepaal en vergelyk.

RESULTATE

Produksie met die masjien was betekenisvol langer as die voedings wat met die hand gemaak was, maar die masjien het betekenisvol meer akkuraat afgemeet met afgiet. RTH voedings se koste beloop 152% meer as voedings wat met die hand gemaak word, en voedings wat deur die masjien gemaak word kos 95% van die wat met die hand gemaak is. Een en sewentig persent van die voedings wat met die hand gemaak was, 74% van die masjiengemaakte voedings en 34% van die RTH voedings was besmet net na toediening begin was.

GEVOLGTREKKINGS

Meganisasie is minder arbeidsintensief as voedings wat met die hand gemaak is en help om die kostes af te bring. RTH voedings word vinnig besmet met organismes na die begin van toediening en dit verminder hulle ander voordele.

ACKNOWLEDGEMENTS

I would like to thank the following people who helped to make this a reality:

Professor Labadarios - my study leader for all his advice, constant support and patience

Dr Renée Blaauw - my co-study leader for all her help and guidance

The staff of the tubefeed room (especially Sonja and Maureen) - for their positive attitude and help

My husband Johan, who has lived with "it" for as long as he has known me - thank you for your love, support and patience!

My angels Francois and Bianca, for being a constant source of distraction – it was worth it!

My family for their love, support and interest and for always being there

Financial support from Abbott and Pharmacia is acknowledged

INDEX

Page

TABLE OF CONTENTS

TABLE INDEX

Page

FIGURE INDEX

ABBREVIATIONS, DEFINITIONS AND SYNONYMS

TEN Total Enteral nutrition
RTH Ready to Hang
MP Mechanised Production
HP Hand Production
TPN Total Parenteral Nutrition
TBH Tygerberg Academic Hospital
ICU Intensive Care Unit
GIT Gastrointestinal tract

Total Enteral Nutrition	Provision of effective nutritional support, via a tube, for patients unable to take in adequate nutrients via the oral route
Commercially sterile	No viable organisms can be normally detected by the usual microbiological culture methods employed
Standard concentration	Tubefeed reconstituted to have an energy content equal to 1 kcal/ml
Non-sterile feeds	Feeds that may contain live bacteria, e.g. reconstituted powdered complete feeds
Sterile feeds	Industrially produced pre packed liquid feeds, which are "commercially sterile"

Please note that, throughout this thesis, the following interchangeable terminology will be used: enteral nutrition = enteral feeding = tubefeeding and tubefeeds = enteral feeds = feeds. This is due to the fact that enteral feeds are produced at TBH in the tubefeed room, and that in TBH wards enteral feeds are referred to as tubefeeds. Articles used as references also use differing terminology to refer to TEN. The terminology bulk production, mechanised production, large-scale production and machine production will also be used interchangeably.

CHAPTER ONE
INTRODUCTION

1.1 INTRODUCTION:

Many patients seen by dietitians in Tygerberg Academic Hospital (TBH) require feeding via the enteral route. During the period of July - December 1996 the tubefeed room at Tygerberg Academic Hospital produced a weekly average of 279 enteral feeds and 310 supplementary drinks. Production of enteral feeds and supplementary drinks at TBH, at the time of this study, required a full time staff complement of three general assistants and one supervisor. Enteral feeds and supplementation drinks are mixed individually and therefore production is time consuming and very labour intensive, a daily average volume of seventy two litres of reconstituted powder formulae is mixed and used for enteral feeds and some supplementation drinks.

STUDY AIM

To identify the most effective system of tubefeed production for Tygerberg Academic Hospital (TBH) so that the following objectives can be achieved:

- Increased productivity/time saving
- Decreased risk of microbiological contamination
- Production / use of the most cost-effective feed
- Provision of an up to date facility for student training

HYPOTHESIS

The null hypothesis in each case is that there is no difference in the three methods of tubefeed production.

1.2 FORMULATION OF THE PROBLEM AND MOTIVATION FOR THE STUDY:

Manual production of enteral feeds (where feeds are mixed individually by hand) is time consuming and very labour intensive. TBH has limited finances due to budget cuts and it is therefore essential to identify the most practical and cost-effective method of enteral feed production. At the present time staff shortages and labour problems can lead to disruption of services in the tubefeed room. This is due to the fact that the tubefeed room cannot function effectively unless at least three staff members are available. At the time of the study financial constraints prohibited the employment of further staff members as replacements for those being on maternity leave, sick or on holiday. When staff shortages are experienced it is not always possible to maintain ideal standards of hygiene, which can hold a risk for the immune-compromised patient. Tygerberg Academic Hospital fulfils the role of a tertiary hospital and a large number of its patients are extremely ill and may be immune-compromised. The tubefeed room must be able to expose dietetic students to the most up to date facilities in the field of enteral feeding. It is also important that training covers all methods of tubefeed production. The financial situation within the province and hospital is not likely to improve in the near future; it is therefore essential to find the most cost-effective way to provide safe enteral feeds for patients.

This study began initially as a comparison between the present manual system used for tubefeed production and mechanised bulk production. Since the initial implementation of the study "Ready to Hang " products (RTH) have become available in South Africa. These products have not been used at Tygerberg Academic Hospital except in emergency situations such as strike/labour unrest or stock problems. This is because the cost per litre of RTH far exceeds the cost per

litre of re-constituted powder formulae (not taking labour costs into consideration) and because of the fact that at the time of the study a totally different administration system was used.

This study is now going to be a detailed examination of the difference between various forms of tubefeed production and delivery, with emphasis on bacteriological safety, cost and productivity. The present system (Manual (hand) production (HP)) is going to be compared with enteral feeds produced using a large-scale enteral feed production unit (Mechanised production (MP)) and with the now available "Ready to Hang " products. It involves the manufacturing of a mechanised large-scale enteral feed production unit that will be used in the tubefeed room to produce up to 60L of reconstituted powder formulae at a time. All three systems will be compared under the following sections: time saving/productivity, cost and microbiological safety. Once the three systems have been compared it will be possible to determine exactly which system will best fulfil TBH needs. At the present time, the true cost of manual production is not known.

1.3 IMPACT OF THE STUDY

At present no commercial equipment has been specifically designed for bulk mechanised production of tubefeeds. Fagerman et al.[1] used normal household appliances and photographic equipment (timer) to produce larger amounts of feeds but did not produce a machine specifically designed to produce feeds. Mechanised bulk production will allow advanced preparation of large quantities of enteral feed powder, which requires re-constitution.

The study will help to identify which method of production will be the most cost-

effective, taking all possible factors into consideration.

The study will identify which form of tubefeed production produces the most microbiologically safe feed and which is the safest over a period of 24 hours. The study will allow the Nutrition Product Committee of the Department of Human Nutrition to decide which method of production is most suited to the TBH situation based on factual information and not assumption. Questions, which will be asked, include the following: Will the present manual system used be maintained? Will the manual system be replaced by mechanised bulk production of enteral feeds? Or will the present facilities be down scaled and "Ready to Hang" products used for all enteral feeds? Or will a combination of the above fulfil the TBH situation best? This will allow for cost saving and the information can be used for determining budget allocations.

The study will enable the Nutrition Product Committee, of the Department of Human Nutrition, (with advice from the Department of Microbiology) to make a decision with regard to what microbiological cut-off point will be seen to be acceptable at TBH. It will help to identify the true microbiological risk of the present system in comparison to mechanised bulk production, and "Ready to Hang" products. The study will determine the efficiency of mechanised bulk production when compared to normal manual production and "Ready to Hang" products.

CHAPTER 2

REVIEW OF THE LITERATURE

2.1. CONCEPT OF TOTAL ENTERAL NUTRITION (TEN):

Enteral feeding is the administration of a nutritionally balanced liquid formula directly into the stomach or small intestine via a feeding tube.[2] The rationale for prescribing enteral nutrition rather than parenteral nutrition (TPN) stems from the beneficial effects of enteral nutrition on intestinal structure and function. Animal studies done mainly with rats have shown that starvation or feeding with TPN causes intestinal atrophy and dysfunction.[3]

The presence of luminal nutrients stimulates the production of a number of hormones which are trophic to the gut mucosa namely: gastrin, epidermal / epithelial growth factor, glucagon and neurotensin.[4] Enteral feeding allows for villi growth and increased production of crypt cells and regeneration of absorptive epithelium. Food in the intestine mediates these effects both directly and indirectly. Direct effects on the mucosa are due to mechanical contact of intraluminal nutrients - these include biliary and pancreatic secretions, which stimulate epithelial growth and regeneration. Local presence of nutrients has the same function as well as the production of intestinal brush border enzymes.[5] Enteral feeding has a more efficient plamsa insulin response, and is safer and more cost-effective than TPN. Enteral feeds are easy to prepare and administer, as they do not require sterile techniques.[2]

2.1.1 HISTORY OF ENTERAL NUTRITION

Randall has reviewed the history of enteral feeding. [4] The practice of providing nutrients to the gastrointestinal tract (GIT) whilst bypassing the mouth originated in ancient times with the Egyptians, who used nutrient enemas for preservation of good health. Greek physicians treated diarrhoea and provided nutrients by using

enemas containing wine, whey, milk, and barley broth. [4,6] By the end of the 19th century feeding via the orogastric route, using milk, eggs, meat extracts, meat powders, wine, and brandy was accepted. [6] John Hunter reintroduced the concept of nasogastric tubefeeding in the late 1850's; complications such as gastric reflux, aspiration and nasal necrosis were common due to poorly tolerated tubes. One hundred years later Pareira reported 240 cases of extended tube feeding which resulted in weight gain and a positive nitrogen balance. Despite these successes widespread clinical acceptance was prevented due to the complications experienced. Sedillot first attempted gastrostomies in 1839; the mortality rate was 100%. All patients operated on died from peritonitis, secondary to leakage of gastric contents. Sydney Jones of St Thomas Hospital in London performed the first successful gastrostomy in 1874. In 1855 the concept of jejunostomy feeding evolved as a method of enteral feeding. [7] Scientific knowledge of the biochemistry and physiology of digestion and metabolism advanced rapidly during the first half of the 20th century that allowed for the improvement of formulations for tube feeding. The availability of more sophisticated formulas, small bore nasoenteric tubes, infusion delivery systems, and advances in clinical nutrition specifically designed for enteral use have led to renewed interest in enteral nutrition. [7]

2.2 INDICATIONS FOR THE USE OF ENTERAL NUTRITION:

Total Enteral Nutrition (TEN) is the preferred method of feeding patients who have an inability to ingest adequate nutrients by mouth but who have a gastrointestinal tract that can be used safely and effectively. Safe and effective use is defined as the presence of intestinal function and the absence of conditions of dysfunction such as gastroparesis, intestinal obstruction, paralytic ileus, high output fistulas and the initial phase of short bowel syndrome. If the GIT cannot be used safely then TPN should be provided. [5]

In general terms, the indications of TEN can be classified as follows:

a) Reduced Food intake / inability to consume sufficient food:

- Neurological problems e.g. coma, stroke
- Severe psychiatric problems e.g. Anorexia Nervosa, severe depression
- Senility - any cause
- Cachexia - due to pulmonary and / or cardiac chemotherapy

b) Mechanical GIT Problems:

- Facial, mandible or dental injuries / operations
- Head and neck malignancies
- Severe stomatitis or mucosal damage due to chemotherapy
- Dysphagia
- Intestinal obstruction
- Low output small intestine or colonic fistula

c) GIT Dysfunction:

- Reduced ability to digest or absorb nutrients e.g. pancreatitis, malabsorption syndrome
- Inflammatory Bowel disease e.g. Chron's disease, Ulcerative colitis, Short bowel syndrome

d) Hypermetabolic Conditions:

- Increased nutrient requirements secondary to catabolism and severe metabolic stress together with an inability to take in sufficient nutrients to meet the increased requirements e.g. large burn wounds, fever, trauma or sepsis.[2,6]

2.3 CONTRA-INDICATIONS FOR ENTERAL NUTRITION:

Enteral tube feeding is contra-indicated for patients with diffuse peritonitis, intestinal obstruction, which prohibits the use of the bowel, paralytic ileus, intractable vomiting and / or severe diarrhoea that makes metabolic management difficult. Other potential contra-indications that depend on clinical circumstances include, enterocutaneous fistulae, severe pancreatitis, gastrointestinal ischemia [8], and upper GIT haemorrhage.[2] Enteral feeding is also not recommended during the early stages of short bowel syndrome or if severe malabsorption is present.[8] Enteral tube feeding should also not be provided if patients have an adequate oral intake or in those who are at risk of aspiration.[2]

2.4 PROVISION OF ENTERAL NUTRITION:

The route, which one selects for provision of enteral nutrition (tube feeding) depends on a number of factors: the anticipated duration of feeding, the condition of the GIT, and the potential of aspiration. The intestine can be accessed at the patients' bedside (nasointestinal tube, percutaneous endoscopic gastrostomy -PEG) or in the operating theatre (gastrostomy, jejunostomy).

2.4.1. TRANSNASAL ROUTE:

2.4.1.1 Nasogastric / Nasoenteric feeding:

Nasal intubation for nasogastric feeding is the simplest and most frequently used method for provision of enteral nutrition. This technique is preferred for use in patients who are expected to resume oral feeding. A soft feeding tube with a small diameter allows for maximal patient comfort and acceptance. Longer feeding tubes can be used to access the duodenum and jejunum in patients who are at risk of aspiration.

If long term tube feeding is required then tube enterostomies are indicated, or when obstruction makes nasal intubation impossible. A conventional gastrostomy or jejunostomy requires a surgical procedure.[9]

2.4.2 TRANSABDOMINAL ROUTE:

2.4.1.1 Gastrostomy:

This is the traditional route for enteral feeding, disadvantages include leakage of gastric contents and infusate around the tube which causes skin excoriation. Migration of the tube can cause duodenal obstruction and vomiting and aspiration can occur.

Indications:
- Patients where a jejunostomy is not technically possible
- Patients cared for in facilities without infusion pump facilities
- uncooperative patients who may periodically displace tubes

Contra-indications:
- patients with severe gastro-esophageal reflux, gastric outlet obstruction or gastric motility disorders
- Patients with documented previous episodes of aspiration
- Patients who have undergone gastric resections[7]

2.4.2.2 Percutaneous Gastrostomy (PEG):

This procedure was developed in 1980 by Gauderer et al as an alternative to operative gastrostomy. This technique avoids laparotomy and can usually be done with local anaesthesia and intravenous sedation.[10] PEG placements can be performed at the patients bedside or in theatre without general anaesthesia required.[9] Catheter related complications associated with operative gastrostomy are still found to be a

factor in PEG but the complications of the laparotomy are avoided. Contra-indications for the use of a peg: - complete esophageal or pharyngeal obstruction, inability to perform an endoscopy, coagulopathy, active peptic ulcer disease, and gastric outlet obstruction. Relative contra-indications include the following: previous gastric surgery, gastric and esophageal varices, ascites, severe gastroesophageal reflux, and gastroenteric fistulas.[10]

2.4.2.3. Jejunostomy:

A jejunostomy is the procedure of choice if the transabdominal route is decided upon. Large bore catheters like the Foley catheter are uncomfortable and subject to problems such as migration and dislodgement. Repetitive movement of the tube in the tract prevents a tight fit and results in leakage around the tube. Over inflation of the balloon can cause obstruction and rupture of the bowel.[7]

2.4.2.4 Microfeeding Jejunostomy:

The procedure entails inserting a small-bore catheter into the jejunum. It is becoming more popular and offers easy access for nutritional support in the postoperative period. The use of a microfeeding jejunosotomy has a disadvantage, as elemental diets must be used. Catheter care must be meticulous to prevent damage or clogging of the catheter.[7] Needle catheter or Witzel jejunostomy placed at the time of a laparotomy allows for early postoperative feeding as the small bowel is less affected by postoperative ileus than the stomach and colon. Jejunal feeding minimises the risk of vomiting and aspiration in comparison to gastric feeding.[10]

2.5. TUBEFEED PRODUCTION METHODS:

2.5.1 MANUAL PRODUCTION:

This is where enteral feeds are individually mixed by hand or by using a blender. Labadarios et al.[2] suggest the following procedure for the manual production of enteral feeds:

Do the following to make a x volume of feed:

a) Weigh all dry ingredients on a scale, place into a round bowl.

b) Add sufficient cold, running tap water to make a paste, using a hand whisk.

c) Transfer paste into a measuring beaker and fill up to the 500ml mark with cold running water.

d) Clean the bowl and then transfer the 500ml back into it.

e) Using a clean measuring beaker add the remaining cold running tap water to the feed to make up the total volume, using the whisk for mixing purposes.

f) Whisk well and pour through a sieve into a clean container

g) Decant the feed into the bottles allocated for that feed, at the volumes prescribed.

h) Refrigerate immediately after sealing the bottle

The procedure currently used at Tygerberg Academic Hospital differs from above in the following way:

a) Weigh all dry ingredients on a scale, place into a round bowl (same as above).

b) Add sufficient cold, running tap water to make a paste, using a hand whisk (same as above).

c) Additional water is then added to the paste which is then returned to the measuring jug where cold running tap water is added until the specific volume required is obtained (for total volumes less than 1000ml).

d) The contents of the above mentioned jug are then poured through a sieve into a clean bucket and the remaining volume required is then measured off using the jug and added to the feed already in the bucket.

e) The feed is then decanted into the bottles allocated for that feed, at the volumes required.

f) All feeds are then refrigerated after being sealed.

2.5.2 READY TO HANG (RTH)

These are industrially produced pre-packed liquid feeds, which are "commercially sterile". No data is available on production methods used. All feeds have expiry dates and date of manufacture printed on them.

2.5.3 MECHANISED PRODUCTION OF TUBEFEEDS

There is a lack of commercial equipment specifically designed for large-scale (bulk) production (including reconstitution) of powdered enteral feeds. Fagerman et al.[1] designed a bulk production technique and equipment that allows for advanced preparation of large quantities of the dietary product and permits freezing in the final container. A 60-litre tank and a heavy-duty mixer were utilised to prepare a ten-day supply of elemental diet. The heavy-duty mixer agitates the solution, which is transferred to individual one-litre bags, by a high volume liquid transfer pump developed from commercially available components, and is then frozen at - 20 °C. The time consuming process of pouring out a specific volume of the solution is therefore eliminated. The product is prepared for patient use by removing a frozen bag from the freezer and quick-thawing it in a warm water bath for approximately 20 minutes. The bags of solution may be thawed in advance or on demand.[1]

2.6 COMPARISON OF TUBEFEED PRODUCTION METHODS:

There is very little data available in the literature with regard to the comparison between different forms of tubefeed production. In this section the following factors, which play a role in the production of tubefeeds, namely; production time, microbiological safety and cost will be discussed. Each factor will first be discussed in general and then include any relevant studies.

2.6.1 PRODUCTION TIME:

In a study by Fagerman et al it was found that mechanised bulk production of enteral feeds resulted in a 56% time saving in comparison to the normal manual production using a blender. The average time taken to prepare a feed using the blender technique was 3.4 minute per litre, in comparison to 1.5 minutes per litre for the bulk preparation method. It was found that mechanised production was practical, convenient and more efficient than traditional blender techniques normally used. Production time in this case included opening of the foil packets, reconstitution of the powder, and transfer of the reconstituted solution to the enteral feeding bag. The methodology does not clarify if production time includes or excludes measuring the volume of water required for reconstitution.[1]

Silkroski et al. did a multidisciplinary audit at 11 teaching hospitals that assessed hidden costs and quality issues related to tube feeding. Dietetic departments were responsible for preparing formulas requiring reconstitution or adding nutrient modulars in 82% of hospitals audited. In 18% of facilities, nursing departments assumed this responsibility. Time spent preparing formulas ranged from seven to thirty minutes per formula, with an average time of 13,4 minutes per formula produced.[11]

2.6.2 MICROBIOLOGICAL SAFETY OF ENTERAL FEEDS:

Contamination of enteral feeds is a product of time, temperature abuse, improper mixing and packaging techniques.[1] Although enteral feeding is a safe and potentially life saving therapy, it has been associated with complications, many of which relate to the possibility of microbial contamination. A variety of guidelines exist for the admixing of parenteral feeding (TPN) but these are not always relevant to enteral tube feeding, it is nevertheless important to exercise similar caution when feeding patients using the enteral route.[12]

Maintenance of the gut barrier is essential to prevent infection, sepsis, and progressive multiple organ failure.[12] The effects of absolute micro-organism colony count and the type of micro-organism present may be modified by the condition (permeability) of the gastro-intestinal tract. Coliform bacteria are usually harmless in their normal habitat (the colon) but can easily migrate into the body though an intestinal wall which is damaged by chemotherapy, radiation, or surgery. Once these bacteria gain entry into the upper small intestine they can place the immune-compromised patient at greater risk of infection and sepsis.

Bacterial contamination of enteral formula is almost inevitable during clinical administration and this could become a source of nosocomial infection. Formula, which is contaminated, has been cited as a potential cause of diarrhoea, sepsis, and pneumonia. Enteral feeding may provide an opportunity for significant reduction in the cost of nutrition therapy, when compared to the cost of TPN. Attention must therefore be focused on viable methods to maintain the quality and safety of services while minimising personnel and equipment costs. Any significant clinical infection, which arises from using a contaminated feed, may obliterate any therapeutic advantage or cost saving achieved by using that TEN feeding method.[13] Complications

such as gastrointestinal symptoms (diarrhoea, vomiting, abdominal distension), colonisation of the GIT, infection and sepsis, pneumonia, prolonged hospital stay, and increased mortality have been cited as a result of patients having received enteral tube feeds which were heavily contaminated with microorganisms.[14] It is important that the significance of these complications be recognised as enteral feeding is being selected more frequently as the primary route of nutritional support in patients, who are immuno-compromised and would have previously received TPN. [15]

It is also important to take note that all infections, even if sub-clinical, decrease nutrient intake and increase nutrient losses. In these cases the intake of contaminated enteral feeds may therefore contribute to, rather than prevent malnutrition.[14] Exogenous contamination of feeds has been implicated frequently in the development of clinically significant infection and sepsis. However, in patients who only receive enteral feeding via the GIT, even the administration of sterile feeds could affect the balance of the intestinal microflora.[14]

Diarrhoea is commonly associated with enteral feeding, occurring in 20% of enterally fed patients in general patient units, and in 40 - 50% of critically ill patients who receive enteral nutrition. Diarrhoea can further compromise the nutritional status of a hospitalised patient by causing dehydration. Diarrhoea may be multifactorial and can be caused by concurrent drug therapies, hypoalbuminemia, general formula intolerance, formula osmolality, and bacterial contamination of the enteral feeding solution.[16]

Schroeder et al. did a study, which estimated the type and amount of contamination that occurred in tinned enteral feeds administered in a community hospital. This study found that several of their patients had diarrhoea but did not have contaminated feeds, and conversely several did not have diarrhoea yet received contaminated feeds.

They also found that at times gross contamination of feeds had been found in patients who were doing well and vice versa.[17] *Clostridium difficile* is the most common infectious cause of nosocomial diarrhoea. Bliss et al. (1998) found that hospitalised, tubefed patients, especially those receiving postpyloric tube feeds, are at greater risk of acquiring *Clostridium difficile* and developing *C. difficile* associated diarrhoea than non-tubefed hospitalised patients.[18]

It is not yet known what level of contamination of enteral feeds will actually cause infectious complications. In most studies which deal with this topic unacceptable contamination was defined as bacterial counts $\geq 10^5$ cfu/ml, (colony forming units) based on milk standards and the Centre for Disease Control standards for food-borne disease (in USA). In South Africa the Department of Agriculture specifies < 50000 total count per ml and coliform < 10/ml. Most patients who receive enteral feeds with this level may not develop complications, but many enterally fed patients are debilitated and may be immuno-suppressed, making them more susceptible. These patients are also at risk of aspiration, and if this were to occur a high inoculum could be introduced and patients could develop aspiration pneumonia.[19] Aspiration pneumonia may be chemical (due to feed components) or can be bacterial due to aspiration of contaminated feeds. Patients who are more susceptible to infection may require sterile commercially prepared feeds and aseptic procedures should then be considered.

Patients who are more susceptible to infection include the following:

a) Cases of acute infection, sepsis and those receiving antibiotic treatment,
b) Oncology patients - specifically those on chemotherapy and those who have leukaemia,

c) Neonates,

d) Patients with burns,

e) Any patients who are receiving long term feeding who have an injury which is associated with recurrent infections - such as a head injury.

f) Patients with reduced gastric acid secretion e.g. achlorhydria, pernicious anaemia, post gastrectomy or receiving gastric inhibitors e.g. Cimetidine

g) Patients being fed via a route which bypasses the stomach,

h) Immune compromised patients e.g. those receiving immuno-suppressive treatment - organ transplants, AIDS. [12]

The composition of enteral feeds is such that if they become contaminated with microorganisms rapid growth may occur. Anderton (1983) reported in a review that contamination of both commercial and hospital-prepared feeds had resulted in counts of up to 10^9 cfu/ml. The administration of contaminated feeds to patients can result in bacterial colonisation and infection by opportunistic pathogens and / or food poisoning due to bacterial endotoxins.[12]

The British Dietetic Association (Anderton et al (1986)) has proposed microbiological limits for the raw materials used as enteral feed ingredients and for the finished product (in the nutrient container prior to administration). Non-sterile feeds (finished product - in nutrient container prior to administration) are acceptable if they have an aerobic plate count cfu/ml of $< 10^1$ and should be rejected if the cfu/ml is greater or equal to a count of 10^2. Organisms not permitted at any level include the following: *E.Coli, Salmonella spp., Clostridum spp. Staph. aureus, B. cereus, Klebsiella spp.* and *Pseudomonas spp.* The presence of any Gram -negative organism is undesirable and is indicative of poor hygiene during preparation. Anderton et al classifies non-sterile feeds as feeds which may contain live bacteria e.g. reconstituted powdered complete feeds, and commercial pre-packed feeds in liquid or powder form

supplemented with nutrients/additives at kitchen, pharmacy or ward level.[12] By definition non-sterile feeds are contaminated at the start of administration; it is for this reason that hanging time for these feeds is limited to 4 hours, to ensure that microbial numbers in the nutrient containers will not exceed 10^3 cfu/ml at the end of feed administration.[14]

Sterile feeds classified by Anderton et al as industrially produced pre-packed liquid feeds, which are "commercially sterile" contain no viable organisms that can normally be detected by the usual microbiological culture methods employed. Recommended microbiological limits for sterile feeds (finished product - in nutrient container prior to administration): an aerobic plate count of 0 cfu/ml is acceptable and no organism are permitted at any level. The maximum recommended hanging time for such a feed is 24 hours.[12] These proposed microbial limits at the start of administration, as well as the recommended hanging times for both sterile and non-sterile feeds, take into account the fact that these feeds will be hanging at ward temperature where rapid multiplication of any contaminants present will occur.[12]

In 1989 the FDA published suggested guidelines for medical foods in their compliance program guidance manual. These guidelines include the following:

1. Aerobic plate count less than 10,000 cfu/g
2. *Salmonella*: absent
3. *Listeria monocytogenes*: absent
4. *Yersinia enterocolitica*: absent
5. *Escherichia coli*: not to exceed 3 organisms per gram
6. *Staphylococcus aureus*: not to exceed 3 organisms per gram
7. *Bacillus cereus:* not to exceed 1000 organism per gram
8. *Clostridium perfringens*: not to exceed 1000 organisms per gram

9. Coliform: not to exceed 3 organisms per gram. [16]

2.6.2.1 Contamination of enteral feeds: sources and principal microorganisms

The potential health hazards to patients who receive microbiologically contaminated enteral feeds should be more widely recognised. The use of contaminated feeds can result in the development of serious infections.[20]

The routes which microorganisms gain access to enteral feeds are both endogenous and exogenous. There is a possibility that retrograde movement of organisms from the patients own GIT may be a clinically significant source of contamination of the enteral feed. Tube placement procedures such as removal of guide wires or aspiration to check tube positioning, or both, can contribute to colonisation of the lumen of the feeding tube and distal end of the giving set with bacteria from the patients own flora. It is important to remember that samples taken from the distal end of the giving set under clinical conditions may reflect endogenous rather than exogenous contamination of the systems. This may help to explain the conflicting results presented in studies evaluating the microbiological safety of prefilled, ready-to-use enteral feeding systems.[15]

Potential sources of contamination include raw material (feed ingredients), inadequately cleaned production equipment, personnel and the patient themselves. The routes by which microorganisms may gain access to the feeds include the procedures involved in the preparation and mixing of ingredients, decanting of both mixed and sterile ready-to-use feeds and assembly and subsequent manipulation of the feeding systems.[21] Bacterial contamination of enteral feeds appears to be cumulative and is related to the many manipulations of the feed and feeding systems

between preparation of the feed and the end of its administration.[22]

a) Feed Ingredients:

Traditional enteral feed ingredients can be a source of tubefeed contamination. The main sources of contamination of enteral feed ingredients and the principal microorganisms causing contamination are as follows:

- Milk or milk-based ingredients - *Staphylococcus aureus*, *B. cereus* and *Escherichia coli*
- Raw eggs - *Salmonella spp.*
- Water (tap or distilled) - May contain gram negative bacilli [23]

All types of feeds may become contaminated if non-sterilised water is used to reconstitute or dilute them. High levels of gram negative bacilli have been found in feeds reconstituted with tap water, due to the fact that although water leaves treatment plants with very low levels of only non-pathogenic bacteria, the range and numbers of microorganisms increase during transit to taps. Distilled water can also be hazardous as it may also contain organisms, which not only remain viable but can also multiply in distilled water. [21] Anderton found that bacteria can survive and may multiply even in feeds with a low pH and high osmolarity, therefore strict hygiene during preparation and handling of all feeds is very important. [22]

b) Feed Preparation:

Handling of enteral feeds during reconstitution or dilution provides many opportunities for microbial contamination to occur. Hospital kitchens are recognised as a potential source of microorganisms that can cross contaminate food prepared in their environment. Microorganisms found in these feeds have also been isolated in

domestic kitchens, which could place home enterally fed patients at risk.[21] Organisms may be transferred to the feed via contact or through the air.

i) Contact:

- Hand, clothes of nurses and other staff - *Staphylococcus aureus* and gram negative bacilli
- Equipment (inadequately sterilised e.g. jugs, liquidisers) - *Staphylococcus aureus* and gram negative bacilli [12]

ii) Airborne

- People - *Staphylococcus aureus* (on skin scales, respiratory pathogens)
- Wound dressing - *Staphylococcus aureus* and Gram negative bacilli e.g. *Pseudomonas aeruginosa*
- Dust from streets, buildings - *Clostridium species* (spp).[12,23]

Blenders provide a major source of contamination of enteral feeds. It is suggested that the use of food blenders be discontinued if there is any doubt in the accuracy of cleaning, especially if immuno-compromised patients are being fed. [21,23] *Clostridium difficile* has frequently been recovered from the hands of personnel caring for patients infected with this pathogen, and this implicates hospital staff as a source of transmission. [18]

Ready-to-use feeds are sterile when produced and are less prone to contamination because no in-hospital mixing is required. However, the presence of bacteria in decanted feeds shows that the procedures involved in the opening and decanting of the feed, from the original container, can lead to contamination of the feed before it reaches the administration container.[21]

c) Feed Administration:

Enteral feeds can become contaminated during the process of administration. Sources of organisms include feeding tubes, the patient receiving the feed as well as the delivery system used.

i) Feeding Tubes

The feeding tube itself can harbour organisms; formula and organisms can adhere to inner surface irregularities of the feeding tube. The feeding tube may therefore be a source of colonisation and could potentially contaminate the distal end of the delivery set tubing with which it is in contact.[19]

ii) Patient:

The patient receiving the feed may be a source of microorganisms; organisms may be transmitted by contact as discussed previously in section b. The main source and type of organisms found are as follows:

- Skin - *Staph. aureus, Staph. epidermidis*
- Nose - *Staph. aureus*
- Intestine - Gram negative bacilli, *Bacteroides spp., Clostridium spp., Staph. aureus*
- Infected lesions - *Staph. aureus, Pseudomonas aeruginosa* [12]

iii) Delivery System:

Sterile enteral feeds have been available as ready-to-hang (ready-to-use) "closed" systems since the mid 1980's. These products are claimed to be associated with reduced labour costs compared with conventional "open systems" in which cans or mixed powders are decanted into larger volume delivery bags by nurses or pharmacists. Studies have documented that contamination can occur during reconstitution and decanting of open-system formulas. "Closed" feeding systems

have been developed to reduce the number of times a tube feed requires manipulation before consumption. In this system, the feeding solution comes pre-packaged in ready-to-use bags with or without attached administration sets. Decanting of the feeding solution from cans and diluting or reconstituting of the formulas is eliminated. The opportunity for contamination to occur is therefore decreased, however poor hygiene techniques and/or contaminated administration sets can contribute to formula contamination.[13] Studies of the sterility of tube feeding systems have reported that manipulation of the systems is a primary cause of bacterial contamination of the systems and formulas. [18]

Wagner et al. compared a closed system, an open system using canned formula (OS can), and an open system using a powder-based formula (OS powder) that required reconstitution before administration. An intensive-care unit setting was used to evaluate preparation time, waste and contamination. Both open systems had significant contamination after infusion namely: 80% of feeds - OS can and 100% of feeds - OS powder, whereas the closed system demonstrated a contamination rate of only 5,7%. Both time and waste were significantly higher when using the open systems. It was found that enteral feeds, infused via a closed system, could be safely provided for up to 48 hours. They were also associated with reduced labour and contamination.[13]

The application of this technology for long-term use has the potential to decrease costs and increase the convenience of providing enteral nutrition both in extended care facilities and at home. The safety of the closed enteral feeding systems when used in this environment has been studied. In a controlled study in a simulated nursing home setting, two hundred and eleven 1500ml containers and administration spike sets were cultured and evaluated following a 36-hour hang time. The

containers were prefilled and then spiked with the administration set prior to administration. No significant contamination was found. [16]

Kohn et al reported that when administration systems were rinsed, refilled and reused in the laboratory for 72 hours, 15 feeds had counts $\geq 10^5$ colony-forming units (cfu) / ml and a further two had to be discarded at 60 hours because they contained visibly spoiled feed which had coagulated and separated.[19] Donius did a study, which compared the contamination of a refillable bag enteral feeding system with a prefilled, ready-to-use system, and the ready-to-use system with a Y-port added - in gastrostomy patients. Results show that, in the clinical setting, the prefilled, ready-to-use system was not less contaminated than the refillable bag system. The addition of the Y-port to the prefilled, ready-to-use distal tubing end did decrease contamination.

These results indicate that the disconnection of the administration set junction (gastrostomy tube) may be a more important factor in contamination than the use of a refillable bag or a prefilled ready-to-use- system.[24] Closed enteral feeding systems appear to offer some advantages over open systems. Decreased levels of bacterial contamination have been shown in the hospital, in the home, and in the extended-care facility setting.[14]

2.6.2.2 Disease potential of microorganisms and possible complications:

It is well documented that contaminated enteral feeds have the potential to cause infections and complications in patients who receive them.[3,13,14,21,24] The following factors can play a role in developing these complications:

- **The integrity of the gut mucosa**

  Microorganisms from the gut lumen can enter the circulation (translocate) as a result of disrupted gut integrity (due to perforation, chemotherapy, and ischemia), gut bacterial overgrowth, and / or loss of systemic and gut immunity.[3] Systemic and gut malnutrition can contribute to translocation.[3] As discussed previously, enteral feeding helps to maintain intestinal tract integrity.[3]

- **Natural enteric microflora**

  Treatment with broad spectrum antibiotics can, and does alter the natural microflora, increasing the risk of infection by opportunistic pathogens. The composition of enteral feeds themselves e.g. pH, and osmolality will affect the rate of growth, and survival of microorganisms. [21]

  The use of antacids and H_2 antagonists, as well as ageing results in an increased pH, and therefore increased bacterial proliferation, which can disturb the normal balance of flora.[21] There is some suggestion that microbes in enteral feeds can colonise the entire GIT, and may therefore be a vector for nosocomial infections.[13]

- **Type of organism and degree of contamination**

The type of organism and degree of contamination can determine whether or not a patient experiences complications. The following table provides information with regard to the different types of microorganisms, which may be found in contaminated enteral feeds, and their potential to cause disease. [12]

Table 1: Disease potential of possible bacterial contaminants of enteral feeds

Principal Division	Genus	Disease potential
Gram Negative Bacteria		
Enterobacteriaceae	*Shigella* e.g. *Shigella Sonnei*	Shigella dysentry
	Escherichia e.g. *E. coli*	Opportunistic pathogen, gastroenteritis
	Salmonella e.g. *S. Typhimurium*	Gastro- enteritis, septicaemia
	Klebsiella e.g. *K. pneumoniae*	Respiratory tract infections, septicaemia
	Enterobacter, Serratia, Proteus	Opportunistic pathogens
Bacteroidaceae	*Bacteroides*	Infections of soft tissues and wounds
Pseudomonaceae	*Pseudomonas* e.g. *Pseudomonas aeruginosa*	Respiratory and wound infections
	Campylobacter	Gastro- enteritis
Gram Positive bacteria		
Micrococcaceae	*Staphylococcus* e.g. *S. aureus*	Toxic food poisoning, wound infections, septicaemia
Bacillaceae	*Bacillus* e.g. *B. cereus*	Toxic food poisoning
	Clostridium e.g. *C. Difficile, C. perfringens*	Antibiotic associated colitis Food poisoning, wound infections
Lactobacillaceae	*Streptococcus* e.g. *S. feacalis*	Gastro-enteritis, septicaemia

2.6.2.3 Prevention /reduction of bacterial contamination of enteral feeds:

The prevention of exogenous microbial contamination of feeds caused by the use of non-sterile ingredients, poorly designed systems, and faulty handling procedures during the assembly and manipulation of enteral feeding systems is an important issue. [15]

Aseptic techniques, the use of ready to hang formulas, and closed delivery systems have been found to reduce contamination of enteral feeds. [18] The speculation that sepsis, diarrhoea, and infection are associated with contaminated enteral feeds has led to the use of methods that decrease the risk of formula contamination. Several studies have shown that enteral formula contamination during the delivery process may cause significant morbidity, as evidenced by the incidence of pneumonia, bacteremia and diarrhoea in the hospitalised and long-term care patient. The type and degree of contamination that is required to cause clinical signs and symptoms of diarrhoea or bacteraemia is unknown. [16]

Kohn (1991) found that the potential cost-effective use of delivery sets for longer than 24 hours is not practical due to progressive contamination. Almost 25% of the delivery sets in this study had unacceptable contamination after 24 hours of clinical use, and contamination continued to increase during extended laboratory usage. It is therefor recommended that delivery sets be used for no longer than 24 hours in the hospital setting, and that examination of contamination after 12 hours of delivery set use is warranted.[19]

Kohn Keeth et al (1996) did a study to investigate whether rinsing enteral delivery sets before addition of further formula, affects formula contamination. Both a simulated and a clinical phase were conducted. In both phases there were no significant differences between the rinse and no-rinse groups with respect to bacteria counts at any time period. This studies finding suggest that rinsing may be unnecessary if delivery sets are used continuously for 24 hours or less. The study sample size was very small so a type II error may be a possibility. [25]

Anderton et al. (1988) found that the assembly of systems done while wearing sterile gloves did not cause feed contamination, but all systems were contaminated

when assembled either with bare unprotected hands or with hands experimentally contaminated with bacterial cells. Delivery of a feed, which was contamination-free, was only found to be possible when sterile gloves were used. [26]

Lee et al. (1999) found that wearing new, non-sterile disposable latex gloves during enteral feeding system assembly prevented contamination of the feeds. The risk of contamination was found to increase for systems, which were assembled with bare hands. Systems assembled with hands experimentally contaminated with bacteria resulted in definite feed contamination. [27]

Fagerman et al (1985) suggest that the addition of a preservative, namely potassium sorbate 0,036%, to reconstituted enteral feeds (open system) in conjunction with stringent aseptic preparation and reduced hang time, can result in a reduction in total bacterial count and final bacterial loads delivered to the patient.[28, 29]

Schroeder et al [17] (1983) did seven related studies, using commercially prepared enteral feeding solutions in a tin, to estimate the type and amount of contamination that occurred in enteral feeding solutions when administered in a community hospital. The initial study was done in a simulated non-clinical setting with select technicians monitoring for gavage systems delivering a commercially prepared enteral feeding solution. The solution tested remained sterile for over 48 hours. In the second study, a number of nurses maintained the enteral feeding simulations unaware of the study objectives. Significant contamination was found, but this decreased when the study was duplicated and the nurses were made aware that the issue of contamination was being studied. The subsequent study had all gavage equipment in clinical use in the hospital on a given day cultured for microbial contamination. Significant contamination was present and it did not decrease when

the study was duplicated following in-service training. In this study rinsing procedures appeared to be helpful in decreasing the number of organisms present.

Patchell et al. did a study in children that examined the effects of the improvement in enteral feeding protocol, coupled with an intensive staff-training programme, on bacterial contamination. The enteral feeding protocol was modified by: priming the enteral feeding set on a metal tray treated with alcohol, using 70% alcohol to spray the bottle opener and top, using disposable non-sterile gloves, and by filling the feeding reservoir with 24 hours worth of feed rather than only 4 hours. Results were as follows: enteral feed contamination rates were significantly reduced from 62% to 6% of feeds given at home, and from 45% to 4 % of feeds provided in the hospital setting. [30]

The role of biofilms must also be considered when discussing the microbiological safety of enteral feeds. The term biofilm is used to denote a polymer -encased community of microbes which accumulates at a surface. They are formed when microorganisms universally attach themselves to surfaces and produce extracellular polysaccharides. Biofilms pose a serious problem because of their intrinsic resistance to antibiotics and host defence systems. Biofilms have the potential to cause infections in patients with indwelling medical devices such as enteral tubes. [31]

It has been shown that a single incidence of exogenous or endogenous contamination may lead to the internal lumen of the enteral feeding tube becoming colonized with bacteria. [15] The presence of the enteral feeding tube itself may play a role in the colonization of the oropharynx, and thereby increase the risk of developing nosocomial pneumonia. [21]

Anderton (1995) suggests that the following methods be used to reduce bacterial contamination of enteral feeds:

a) Assembly of the feeding system:

- Staff should wash, dry and disinfect hands thoroughly and put on clean disposable gloves before preparing feeds, assembling systems and any subsequent systems.
- Staff preparing feeds or handling feeding systems are to wear masks if they have a cold or any type of throat or respiratory infection
- At no time should any part of the feeding system be allowed to touch hands, skin, or clothes of the person assembling the system or the patient
- Feeding systems to be assembled on a clean, dry, disinfected surface. [22]

b) Equipment

- Only use feed preparation equipment that can be adequately cleaned and disinfected before use

c) Feeding system:

- Only handle the system when necessary (each time a connection is touched it increases the risk of introducing bacteria into the system from hands or the environment).
- Avoid administering drugs via enteral feeding tubes if possible. If not possible the following steps should be followed:
  1. Sterile aqueous solutions are preferable to elixirs, emulsions or suspensions (may adhere to the tube causing tube blockage and possibly encourage bacterial growth).
  2. The tube should be flushed with sterile water before and after administration of drugs

3. The luer connector / administration port should be disinfected using a new alcohol impregnated wipe (70% isopropyl alcohol) both before and after giving the drug, and the use of giving sets with ports for giving drugs (mediports, Y- ports) means that the set does not have to be disconnected.

- Visibly dirty bottles, cans or cartons should be washed under clean running water and dried with a disposable towel.
- Before opening, any part of the outside of the surface of bottles, cans or cartons, which is likely to come into contact with the feed when it is decanted should be thoroughly disinfected either using alcohol spray or an alcohol impregnated wipe.
- All bottle openers; scissors, and other equipment used should be cleaned with hot soapy water and disinfected before use.
- Do not attempt to clean / disinfect and reuse any part of the system that is marked for single use only. [22]

Oliviera et al. implemented the HACCP system to help control microbiological contamination of reconstituted enteral feeding formulations. Before the implementation of HACCP, microbiological analyses of feeds showed the presence of indicator organism such as coliforms and *Enterococcus spp.* and unacceptably high levels of mesophilic aerobic organisms (> 10^4 cfu/ml). After the implementation of HACCP the microbial quality of the feeds improved significantly, with counts of < 10^1 cfu/ml. [32]

2.6.3 COST OF ENTERAL FEED PRODUCTION:

Clinicians have traditionally focused on the costs of enteral formulas and delivery devices when evaluating the expense of their tubefeeding programs. The concomitant costs of labour and waste are usually overlooked, and quality assurance is often rarely evaluated. If not recognised and contained, waste, labour costs and

quality risks can escalate the cost of enteral nutrition therapy. [19] It is desirable and possible to deliver enteral feeds, which are not heavily contaminated, to patients who are prone to infections. The question of cost should not be a deciding factor when one decides what type of feed to give a patient. The cost of providing a patient with a contaminated feed may outweigh any money saved.[33]

Moffitt et al. did a study, which used both laboratory, and clinical settings to evaluate whether retrograde bacterial movement under "no flow" conditions results in contamination of closed system feeding containers. The study included an analysis of formula waste and costs using several 24 or 36 hour hanging scenarios. It was found that a potential cost saving of between $67 and $135 per patient per month could be achieved provided the appropriate container size was used and when feeds were provided for a minimum period of 36 hours. [34]

Silkroski et al. did a multidisciplinary audit at 11 teaching hospitals throughout the United States and assessed hidden costs and quality issues related to enteral feeding. Hidden costs were identified: 18% - 62% of formulas were wasted per patient per day. Formula costs contributed to only 43% of mean total tube feeding expenditure and enteral feeding bags and feeding tube sets comprised of 23% of the mean total tube feeding expenditure. Combined costs of formula plus feeding bags and sets constituted 66% of hospital tube feeding expenses. Labour comprised 34% of the total cost of tube feeding in the audited hospitals (this included time spent by nursing staff preparing formulas and managing feeds). Their results indicate that the cost of labour and waste is often not included when purchasing decisions are made. Cost of wages was found to be a significant and reducible expense of hospital tube feeding programs. Tube feed preparation and administrations were found to take up considerable amounts of hospital employee

time. The use of closed feeding systems and minimising the use of powdered and modular formulas can significantly reduce formula waste and labour costs. [11]

Closed enteral feeding systems appear to offer some advantages over open systems. When closed system hang time has been increased (to more than what is recommended for traditional open systems), microbiological safety has not been compromised. [35] Closed system containers are regarded as the safest way to deliver non-contaminated nutrients to patients, ready-to-feed diets supplied in cans are also considered safe when properly handled. However both of these are expensive, and therefore many hospitals still use diets that require major handling, allowing several opportunities for contamination of enteral diets. [36]

All RTH feeds used in South Africa are imported. With the recent decrease in the value of the Rand these feeds are becoming more and more expensive. This is why it is essential to determine not only the true cost of tubefeed production at TBH but also which production method will be most cost-effective when all contributing factors have been taken into consideration.

CHAPTER THREE

METHODOLOGY

3.1 STUDY DESIGN

This study was a descriptive, comparative study, which evaluated and compared three different methods of tubefeed production namely; manual production (present system), mechanised production (using a self-designed bulk production unit) and "Ready to Hang". Data gathered was used to identify the most effective system available for the TBH situation.

3.1.1 DESCRIPTIONS OF DIFFERENT PRODUCTION SYSTEMS / METHODS

3.1.1.1 Present system

At the time of the study the tubefeeds in the tubefeed room were all produced manually. A full-time staff complement of four was required to produce all tubefeeds and supplementary drinks. Orders for tubefeeds were placed via computer and after the dietitian on duty had printed out stickers for the bottles the feeds would be produced. One staff member was responsible for the weighing of polymetric feed powder and this was then placed in a metal bowl. Another staff member then added a small amount of water and mixed, using a whisk, until a smooth paste was obtained. Additional water was then added to the paste and then the entire mixture was transferred to a measuring jug where further water was added until the correct volume was obtained. The correct volume of feed (plus additional water if required) was then transferred to a clean bucket after being poured through a sieve. At times two feeds were reconstituted, in the same bowl, at the same time. All equipment used e.g. whisks, jugs, and buckets were rinsed in biocide water between feeds. Every feed was decanted, using funnels, from the buckets into four marked (with stickers) glass bottles (recycled 1000ml bottles initially used to provide IV rehydration fluid), at the specific volumes required.

Most orders for tubefeeds are made after the dietitians have been on ward rounds resulting in a very busy period from 10h00 - 12h00. The period from 07h00 - 10h00 is utilised for cleaning bottles and making any feeds, which have already been ordered. Feeds are delivered to the wards once all feeds ordered by 12h00 have been made. Random feeds were identified on a daily basis and microbiological samples were collected and sent to the Department of Microbiology for infection control. See Addendum 1 for a diagram indicating the layout of the tubefeed room.

3.1.1.2 Mechanised production (bulk production):

Design of machine for mechanised bulk production of enteral feeds: The researcher used the concept designed by Fagerman et al.[1] as a starting point and drew a basic diagram of the machine she envisaged. She also listed the reconstitution and decanting functions it must be able to fulfil. The researcher then consulted with a number of engineering companies about what was required to manufacture a machine with these specific functions. Small adjustments in the design of the machine were made. All quotes received from the above mentioned companies far exceeded the budget available. It was then decided to consult with a private engineer who would be able to produce the same final product for a much-reduced price. The researcher was involved in every step of the designing process and consulted regularly with the engineer who built the final product (Figure 1,2 and 3 and Addendum 1 and 2).

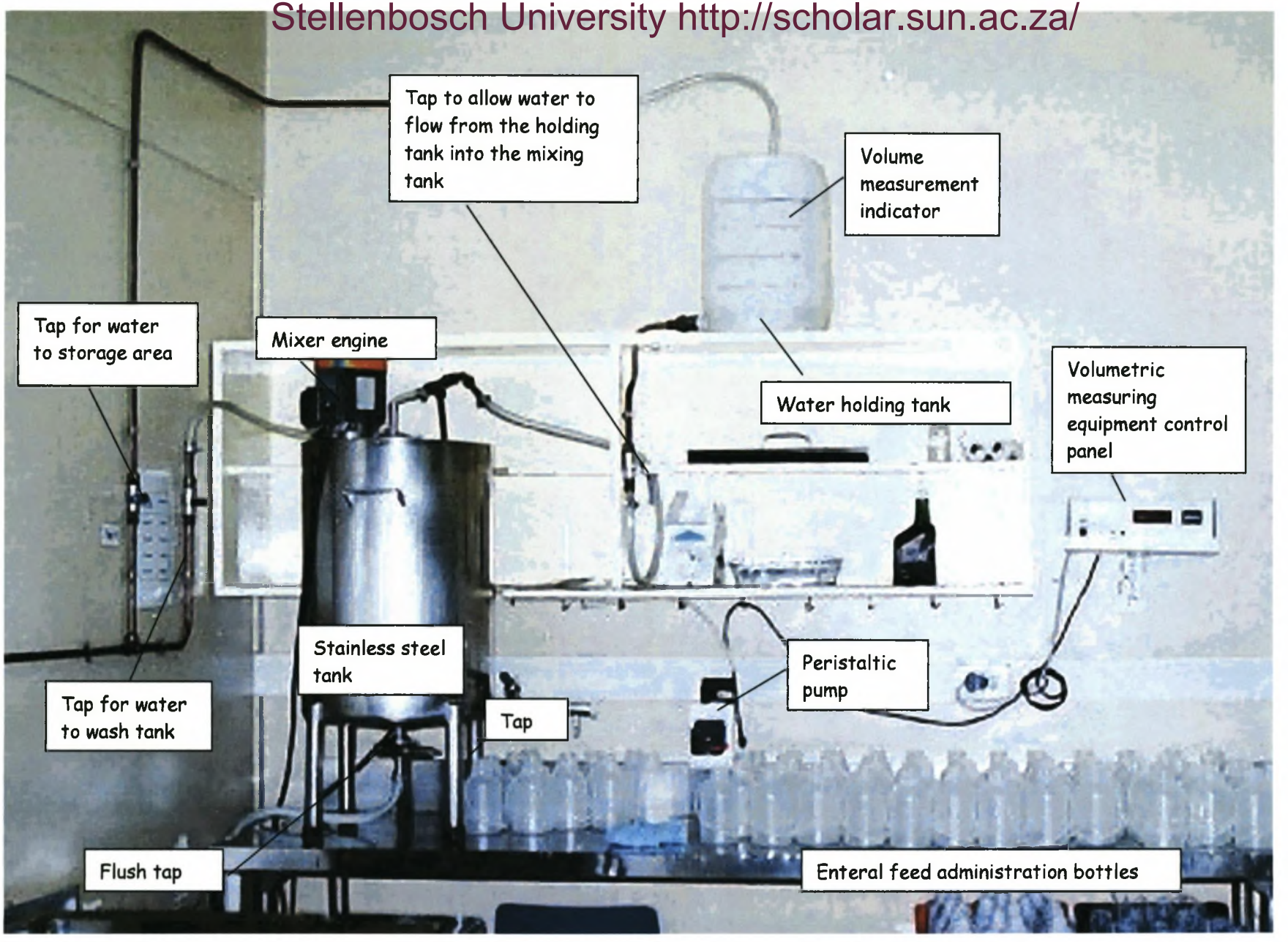


Figure 1: Machine installed in the tubefeed room at TBH

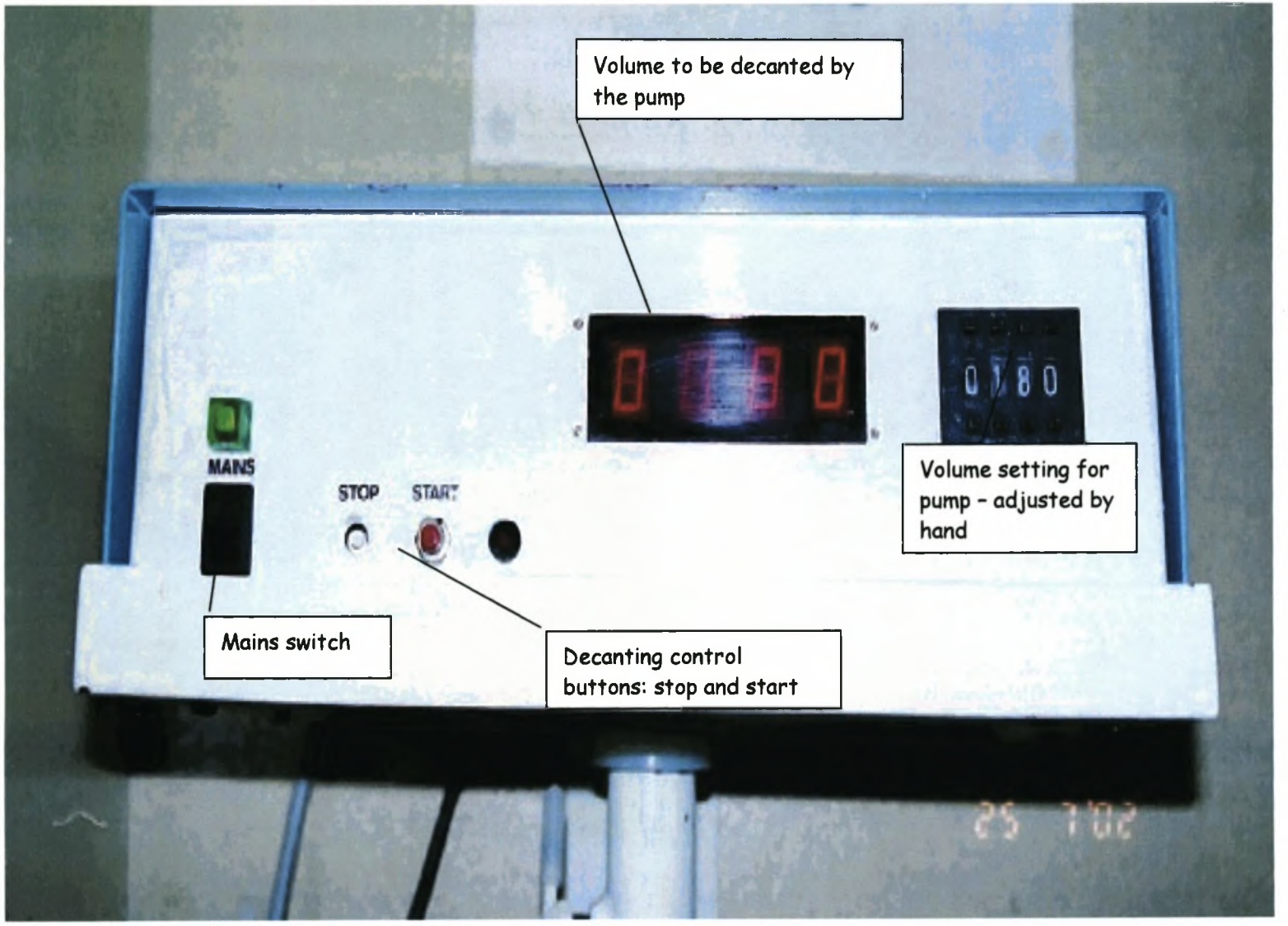


Figure 2: Volumetric measuring equipment control panel

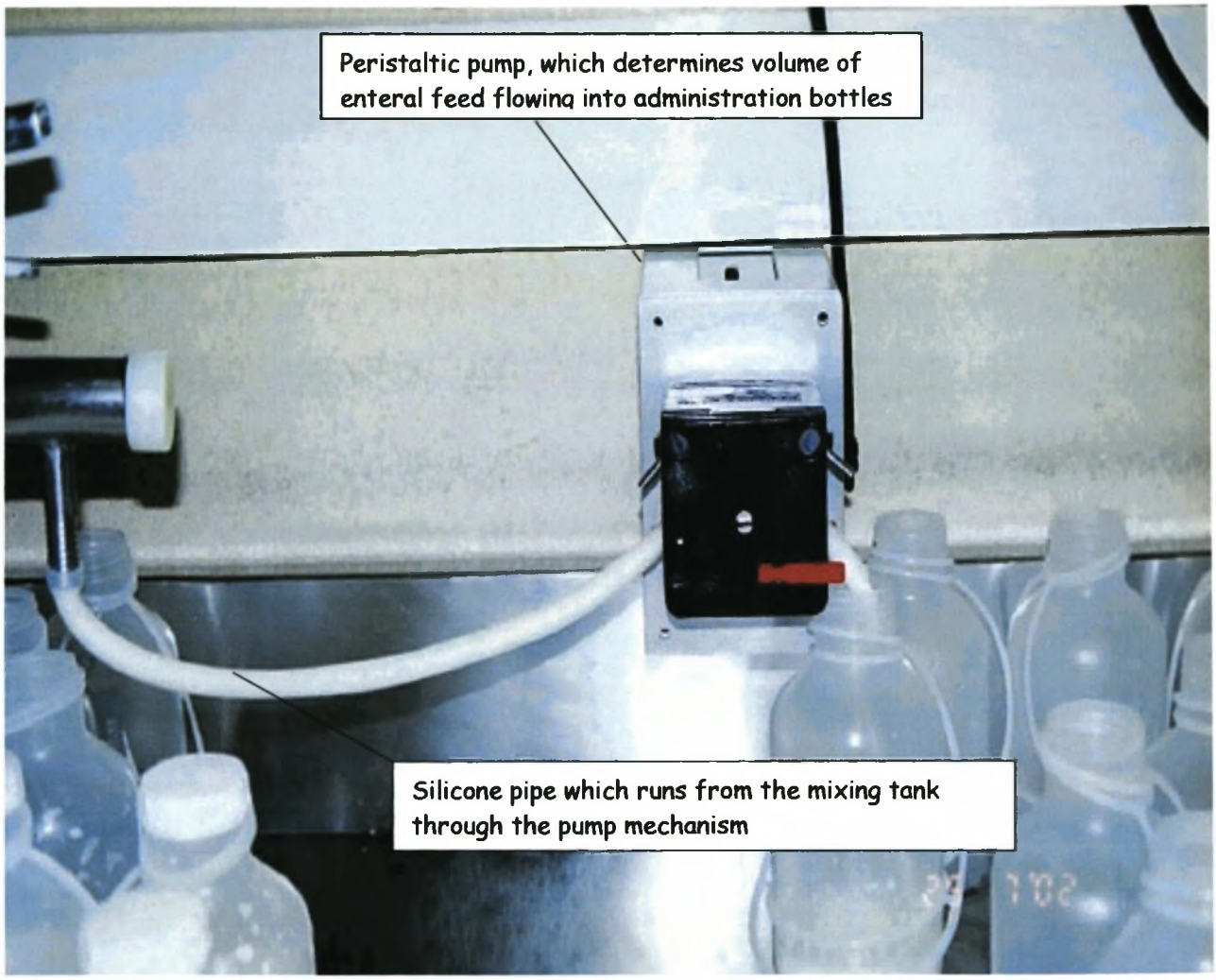


Figure 3: Peristaltic pump mechanism

The machine was designed and built specifically for the TBH situation. Specific factors, which were taken into consideration when producing this machine, included the following:

- Total volume of feed required
- Number of staff required to work the machine
- Funding available for building of the machine
- Methods of mixing required
- Methods of tubefeed administration to be used

The machine designed was built to fulfil the following requirements:

- to produce a large volume of standard concentration tubefeed
- to produce a well mixed, homogenous tubefeed
- to measure various volumes accurately as required
- to be easy to clean, and microbiologically safe
- to be easy to use
- to be compatible to all possible delivery systems that could be used
- to be economical to run
- to be able to be used for training purposes
- to have parts that are easily available and affordable
- to be able to be used in emergency situation

Description of how the bulk production machine functions:

The ordering system used by dietitians to order tubefeeds as described above was not altered in any way. The total volume of tubefeed produced the previous day was calculated, using this information (in conjunction with predetermined charts) the total volume of water and polymeric enteral feed powder required was determined (Addendum 3).

The correct volume of water required is measured and allowed to run into the machine. The machine is turned on and the mixer blades begin to agitate the water. The correct weight of powder is accurately weighed and slowly added to the water to allow for reconstitution. The operator of the machine sets the decanting volume. The volume of polymeric feed required is decanted into 1000ml glass bottles (as used in the description of present method) marked with the patient's name. The volume to be decanted is adjusted as required (Addendum 3).

Validation and Pilot study

The completed machine was installed, cleaned with detergent and all components were rinsed with biocide water. All taps on the machine were numbered and marked. A manual, describing how the machine functions was set up and copies were made available to the staff who work in the tubefeed room (Addendum 3). Two members of the tubefeed room personnel were trained to use the machine. Staff problems at this time made it impossible to train all personnel at the same time.

The two personnel members were given daily training sessions, initially these involved verbal explanations of how the machine functions with reference to the manual provided. The machine was initially run only using water, until the personnel were able to confidently work the machine without having to refer constantly to the manual. They were, however, requested to use the manual as a step-by-step procedure list to prevent any problems from occurring. Expired polymeric feed powder was used for the next practice round to ensure that reconstitution occurred correctly, and to give staff practical experience in weighing off and adding the correct volume of powder to the water in the machine. The reconstituted polymeric tubefeed produced during this trial period was discarded

after production. The machine was then cleaned as described in the manual. This entire process took place over a period of about four weeks. During this time tubefeed production occurred as normal as discussed above under present system.

The pilot study took place, between the 23rd of February 1999 and the 10th of March 1999. During this time small volumes (not more than 20L) of polymeric formula were produced using the machine, but discarded after production and after samples had been delivered to the department of microbiology. It was decided that the machine could only be used to produce tubefeeds for patients in the hospital if could be proved to produce microbiologically safe feeds. The pilot study required the two trained personnel members to be present to work the machine; untrained staffs were not involved at any time. Ten percent of initial samples were contaminated, and personnel were made aware of the need to work very hygienically. It was decided to flush the entire machine and all pipes with biocide solution after tubefeed production and cleaning with disinfectant. The water storage container was filled with a biocide solution each night and this was used to flush out the machine the next day prior to use. Once these adjustments to the cleaning schedule had been made, further samples were taken and checked by the department of microbiology. The machine was tested and used to produce 20L of polymeric formula a further three times and all thirty samples tested (ten taken from each 20L produced) were found to be clear of any bacterial contamination. The machine was then used on a daily basis to produce up to 60L of polymeric formula. Random tubefeed samples were collected during this period for infection control as mentioned previously under present system.

3.1.1.3 RTH (Ready to Hang)

During this section of the study, 500ml glass bottles of RTH polymeric enteral formula were used to replace pre-selected (randomly) powdered polymeric tubefeed which would have been produced in the tubefeed room. All bottles used in this section of the study came from the same batch. A number of samples of these feeds (from the same batch) were collected, and sent to the Department of Microbiology. All samples were found to be free of any bacterial contamination. Powdered polymeric tubefeeds ordered were simply replaced by the correct number of RTH polymeric feed bottles to make up the correct energy and volume required. A record was kept of the number of bottles sent out to each patient.

3.2 METHODS

3.2.1 EVALUATION OF THE THREE METHODS OF TUBEFEED PRODUCTION

In the study each of the three methods of tubefeed production was evaluated for the following:

- The time required for production
- Microbiological contamination levels and safety
- Total cost of the production method used

This was done in order to determine the most appropriate tubefeed production method for TBH.

Methodology

Hand Production	Machine Production	Ready to Hang
Production Time: Reconstitution Decanting	Production Time: Reconstitution Decanting	Production Time: Not required
Microbiological Safety Sample A - after production Sample B - ward, 1st bottle Sample C - ward, last bottle	Microbiological Safety: Sample A - after production Sample B - ward, 1st bottle Sample C - ward, last bottle	Microbiological Safety: Sample B - ward, 1st bottle Sample C - ward, last bottle
Cost: Product, Salaries, Administration sets, cleaning, electricity etc.	Cost: Product, Salaries, Administration sets, cleaning, electricity etc.	Cost: Product, Administration Sets
Student training requirements	Student training requirements	Student training requirements

3.2.1.1 Present system - manual production

The following points were used to evaluate the present system used at TBH:

1. The time required to produce tubefeeds using the present system was determined. Tubefeeds produced were also weighed to determine the accuracy of the decanting method and wastage of tubefeeds at ward level was noted. (Addendum 4 and 5)
2. The microbiological safety of enteral feeds produced using the present system was evaluated
3. True cost of feeds - this included the basic price of ingredients, the cost of labour, the cost of electricity and water used and the cost of cleaning products (Addendum 6) and the cost of administration equipment.

This section of the study took place from Monday 19th October 1998 to Thursday 29th of October 1998

3.2.1.2 Mechanised production and validation of new machine

Once the machine was installed and running, the product and system were evaluated. The following points were investigated and used to evaluate bulk production of tubefeeds:

1. The time required to produce a tubefeed using the machine. Tubefeeds produced were also weighed to determine the accuracy of the decanting method and wastage of tubefeeds at ward level was noted. (Addendum 4 and 5)
2. The microbiological safety of enteral feeds produced using the machine was evaluated
3. True cost of feeds (factors as for manually produced)

This section of the study took place from Monday 12th April 1999 to Thursday 22nd April 1999.

3.2.1.3 Ready to Hang

The available "Ready to Hang" products were evaluated by taking the following points into consideration:

1. Wastage of tubefeeds at ward level was noted.
2. The microbiological safety of the product. (Addendum 5 and 7)
3. The true cost of RTH feeds taking all factors into consideration.

This section of the study took place from Monday 23rd November 1998 to Thursday 3rd December 1998.

2.6.1 SAMPLING

This section refers to how the researcher identified which individual tubefeeds would be included in the evaluation of each method of tubefeed production, namely production time, microbiological safety and cost. The following method was used to evaluate the present system as well as mechanised production:

A total of 160 individual tubefeeds (80 for each method of tubefeed production) were identified for inclusion in the study. Ten tubefeeds were identified on day 1,2,3,6,7,8,9,and 10 (Day 1 = Monday, Day 6 = Saturday) for each production method. The tubefeeds were randomly selected as follows: one of the tubefeed personnel or dietitians was asked to close their eyes and use a pen to randomly mark a point on the tubefeed list which had been printed for that day. The list included all the tubefeeds from all the wards of the hospital. The list was printed on a daily basis, however, feeds were only produced once the dietitian at ward level had sent through the order for that day (via computer).

The researcher had decided in advance to select individual tubefeeds (which fulfilled the criteria below) to be included in the study by marking every 5th feed from the random point identified above. If it was not possible to use the 5th feed

identified (see exclusion list), then the next feed, which fulfilled the criteria below, was included. The 5th feed from this point was taken to be the next sample. The random selection continued through the list until 10 feeds (which fulfilled the criteria) were identified.

Criteria for inclusion were as follows:

- Polymeric feeds normally produced by Tygerberg Academic Hospital tubefeed room.

Criteria for exclusion were as follows:

- all supplementary drinks
- all other types of tubefeeds e.g. semi-elemental, RTH and tinned tubefeeds
- all polymeric feeds with any additions e.g. salt, vitamins
- all tubefeeds ordered for patients in the oncology unit of Tygerberg Academic Hospital as distance from the main hospital building did not allow for tubefeed samples to be collected within the time limits of the study
- any feeds which are not ordered at the standard concentration of 1 kcal/ml
- any feeds which had not been ordered by 12h00 as these would not have had a 24 hour hanging period at ward level (these could only be identified after 12h00 and were therefore not replaced by other feeds)

The individual randomly selected tubefeeds were marked with a highlighter and these feeds were then included in the study (the relevant stickers were marked with a highlighted asterix (*). The randomly identified tubefeeds were allocated project numbers in the order in which they appeared on the tubefeed list.

The method used to identify which feeds would be used in the Ready to Hang component of the study was as follows:

A total of 80 individual tubefeeds were identified for inclusion. Ten tubefeeds were identified on day 1,2,3,6,7,8,9,and 10 (Day 1 = Monday, Day 6 = Saturday). The tubefeeds were randomly selected as follows: one of the tubefeed personnel or dietitians was asked to close their eyes and use a pen to randomly mark a point on the tubefeed list which had been printed for that day. The list included all the tubefeeds from all the wards of the hospital. The list was printed on a daily basis, however feeds were only produced once the dietitian at ward level had sent through the order for that day (via computer).

The researcher had decided in advance to select individual tubefeeds (which fulfilled the criteria below) to be included in the study by marking every 5th feed from the random point identified above. If it was not possible to use the 5th feed identified (see exclusion list), then the next feed, which fulfilled the criteria below, was included. The 5th feed from this point was taken to be the next sample. The random selection continued through the list until 10 feeds (which fulfilled the criteria) were identified. All dietitians were informed that randomly selected polymeric feeds would be replaced with a ready to hang product (provided at 1kcal/ml).

Criteria for inclusion were as follows:

- standard concentration polymeric formula feeds which were replaced with an equivalent energy value of ready to hang product

Criteria for exclusion were as follows:

- all supplementary drinks
- all other types of tubefeeds e.g. semi-elemental, RTH and tinned tubefeeds
- all polymeric feeds with any additions e.g. salt, vitamins
- all tubefeeds ordered for patients in the oncology unit of Tygerberg Academic Hospital as distance from the main hospital building did not allow for tubefeed samples to be collected within the time limits of the study
- any feeds which are not ordered at the standard concentration of 1 kcal/ml
- any feeds which had not been ordered by 12h00 as these would not have had a 24 hour hanging period at ward level (these could only be identified after 12h00 and were therefore not replaced by other feeds)

The individual randomly selected tubefeeds were marked with a highlighter and these feeds were then included in the study (the relevant stickers were marked with a highlighted asterix (*). The randomly identified tubefeeds were allocated project numbers in the order in which they appeared on the tubefeed list. The relevant number of 500ml bottles was sent according to the total volume ordered, using a volume equivalent to what would normally provide 1 kcal per ml. Stickers printed for bottles were adjusted to correctly indicate the contents, and the administration volume.

3.2.3. PRODUCTION TIME

This parameter included the reconstitution time and decanting time for production of tubefeeds. The sum of the two sections is equal to total production time.

The reconstitution time included the following:

- weighing of the powder
- re-constitution of the powder
- measurement of water required for re-constitution (manual production)
- sieving of re-constituted product (manual production)

The decanting time included the following

- transference of the reconstituted product to the administration bottles
- sealing of the bottle after transfer of the reconstituted product

Production time was measured using a stopwatch (recorded in seconds) and the randomly selected feeds were timed as they were mixed. Tubefeed personnel indicated to the researcher, prior to beginning with reconstitution and decanting, which feeds were marked with an asterix (*).

Accuracy of decanting method

The following method (based on weight of the total feed after reconstitution and sealing of the bottles) was used to determine the accuracy of the volume of tubefeed decanted for both manual and mechanised tubefeed production.

Ten, empty 1000 ml glass bottles were weighed so that the average weight for a glass bottle could be determined. Ten bottle lids were weighed so that the average weight of a lid could be determined. An accurate plastic 1000ml measuring jug was used measure 100ml, 200ml, 300ml, 400ml, 500ml, 600ml, 700ml, 800ml, 900ml, and

1000ml of standard concentration polymeric feed (1kcal/ml). This was weighed using a Masskot (10kg x 1 g) digital computing scale (220v/ 50 HD, model 10D, VI.1994) accurate to the nearest gram. These weights were then used to determine the average weight of one ml of standard concentration polymeric feed. This value was then used to determine if feeds had been correctly measured and produced. The four bottles of sealed reconstituted feed were weighed with lids, and the total weight was compared to that of the expected standard weight, for the same total volume (after deducting the total weight of the four lids and bottles - using average weights already determined). Feeds were noted as weighing too little or too much and the volume difference (in ml) was recorded.

Wastage of tubefeeds produced

This was determined for all three methods of tubefeed production. Records were kept of the total volume of tubefeed remaining in the bottle at the time sample C was collected. The researcher calculated what volume of feed would be wasted or not given by the cut off time of 12h00 (taking current ml/hr rate and time till 12h00 into consideration). The ward and kitchen fridge was checked for any remaining bottles and this volume was recorded. The total volume of feed wasted was determined by adding the volume of feed left at ward level (once calculated) to what ever was left over in the fridge. This was then expressed as a percentage of the total volume sent out from the tubefeed room.

3.2.3.1 Present system

A time study was performed to quantitate the production time of tubefeeds using the system presently used at TBH. The staff member was timed whilst preparing a randomly selected tubefeed, whilst using the traditional manual method. The average time value was then expressed as time taken (in seconds) to produce the tubefeed expressed as a final figure of seconds per litre (seconds /L). This was

then be compared to the average time (seconds / L) used to produce tubefeeds using the mechanised production method. Reconstitution time and decanting time were also compared individually.

3.2.3.2 Mechanised production

The average time value was then expressed as time taken (in seconds) to produce the tubefeed expressed as a final figure of seconds per litre (seconds /L). This was determined by dividing the total volume of tubefeed produced (in litres) by the time taken for production. This was then be compared to the average time (seconds / L) used to produce tubefeeds using the manual production method. Reconstitution time and decanting time were also compared individually.

3.2.3.3 Ready to hang (RTH)

No reconstitution or decanting of this product was required and therefore this section was not evaluated. Feeds are already reconstituted and are in a form, which can immediately be administered.

3.2.4 MICROBIOLOGICAL SAFETY

Prior to this study taking place, the tubefeed room staff were responsible for the random daily collection of enteral feed samples for microbiological analysis. These were collected in the tubefeed room (at the time of production) for quality control purposes. The results, when positive for bacteriological contamination, recorded the presence of specific organisms but not precise cfu counts / ml. These statistics were therefore not used in this study.

In this study the bacteriological safety of all three production methods was determined and compared. The evaluation of the bacteriological safety of the three systems included taking samples of each individual randomly selected tubefeed (as discussed under sampling):

- the time of production in the tubefeed room **(Sample A)** - not used for RTH
- initiation of feeding at ward level **(Sample B)**
- completion of administration of the feed at ward level **(Sample C)**

(Addendum 8,9,10)

The specific sampling procedures followed for each production method will be discussed separately.

Microbiology Methodology

In Tubefeed Room (hand and machine production only)

Ward Level (all production methods)

3.2.4.1 Present System:

Tubefeed samples for microbiological analysis were collected as follows:

Week 1:

Monday (day 1)	**Sample A and Sample B**
Tuesday (day 2)	**Sample A, Sample B and Sample C (from Monday)**
Wednesday (day 3)	**Sample A, Sample B and Sample C (from Tuesday)**
Thursday (day 4)	**Sample C (from Wednesday)**
Saturday (day 6)	**Sample A and Sample B**
Sunday (day 7)	**Sample A, Sample B and Sample C (from Saturday)**

Week 2:

Monday (day 8)	**Sample A, Sample B, and Sample C (from Sunday)**
Tuesday (day 9)	**Sample A, Sample B and Sample C (from Monday)**
Wednesday(day 10)	**Sample A, Sample B and Sample C (from Wednesday)**
Thursday (day 11)	**Sample C (from Tuesday)**

Samples were taken on both week and weekend days so as to be fully representative. See Addendum 8 for further details.

The following method was used to collect samples of the feeds:

At time of production (Sample A)

The sample was taken after the bottles had been sealed, once the decanting process had been completed. The researchers hands were washed prior to, and after the sample had been taken. The researchers hands were sprayed with alcohol, and the bottle was shaken well before the sample was taken. The lid of the bottle was removed. A webcol alcohol swab was used to disinfect the lip of the bottle, and 3-5 ml of the contents of the tubefeed bottle was poured out into a

14ml sterile screw closure test tube. The samples were then marked (project number and sample A) and kept refrigerated, on ice, until taken to the Microbiology Department. Samples were delivered to the Microbiology Department within 1 to 2 ½ hours after collection.

When administration of the tubefeed was begun in the ward (Sample B)

These samples were collected once samples A & C (of previous day) had been delivered to the Department of Microbiology. The researchers hands were washed prior to, and after the sample had been collected. The researchers hands were sprayed with alcohol, and once the administration system has been disconnected, the bottle was shaken well and the sample was collected. However, if the bottle had not yet been connected to the administration system, a sample was taken and the source of the sample was noted e.g. ward refrigerator. A webcol alcohol swab was used to disinfect the lip of the bottle, and 3-5 ml of the contents of the tubefeed bottle was poured out into a 14ml sterile screw closure test tube. The samples were then marked (project number and sample B) and kept refrigerated, on ice, until taken to the Microbiology Department. Samples were taken from feeds, stored in refrigerator, if administration had not begun by 14h00. Samples were delivered to the Microbiology Department within an hour of collection.

Completion of administration of the feed (Sample C)

This sample was collected before 12h00, after the administration system had been disconnected. Collection of sample C began from 11h00. The source of the sample was recorded. The researchers hands were washed prior to, and after the sample had been collected. The researchers hands were sprayed with alcohol, and once the administration system has been disconnected, the bottle was shaken well and the sample was collected. A webcol alcohol swab was used to disinfect the lip of the bottle, and 3-5 ml of the contents of the tubefeed bottle was poured out into a

14ml sterile screw closure test tube. The samples were marked (project number and sample C) and kept refrigerated, on ice, until taken to the Microbiology Department. If the feed had been completed before sample C was taken; this was recorded. The total volume of feed remaining was also noted, as well as possible reasons why the feed had not been completed within the 24-hour hanging period. Samples A & C were taken to Department of Microbiology once all A & C samples had been collected. Samples were delivered to the Department of Microbiology within a 2 – 2 ½ hour period after collection (Addendum 8).

3.2.4.2 Mechanised production

Tubefeed samples for microbiological analysis were collected as follows:

Week 1:

Monday (day 1)	**Sample A and Sample B**
Tuesday (day 2)	**Sample A, Sample B and Sample C from Monday**
Wednesday (day 3)	**Sample A, Sample B and Sample C from Tuesday**
Thursday (day 4)	**Sample C from Wednesday**
Saturday (day 6)	**Sample A and Sample B**
Sunday (day 7)	**Sample A, Sample B and Sample C from Saturday**

Week 2:

Monday (day 8)	**Sample A, Sample B, and Sample C from Sunday**
Tuesday (day 9)	**Sample A, Sample B and Sample C from Monday**
Wednesday(day 10)	**Sample A, Sample B and Sample C from Wednesday**
Thursday (day 11)	**Sample C from Tuesday**

Samples were taken on both week and weekend days so as to be fully representative. See Addendum 9 for further details.

The following method was used to collect samples of the feeds:

At time of production (Sample A)

Method as for present system - details can be seen in Addendum 9.

When administration of the tubefeed was begun in the ward (Sample B)

Method as for present system - details can be seen in Addendum 9.

Completion of administration of the feed - Sample (c)

Method as for present system - details can be seen in Addendum 9.

3.2.4.3 Ready to Hang

Samples were taken as follows (there were no A samples):

Week 1:

Monday (day 1)	**Sample B**
Tuesday (day 2)	**Sample B and Sample C from Monday**
Wednesday (day 3)	**Sample B and Sample C from Tuesday**
Thursday (day 4)	**Sample C from Wednesday**
Saturday (day 6)	**Sample B**
Sunday (day 7)	**Sample B and Sample C from Saturday**

Week 2:

Monday (day 8)	**Sample B, and Sample C from Sunday**
Tuesday (day 9)	**Sample B and Sample C from Monday**
Wednesday (day 10)	**Sample B and Sample C from Tuesday**
Thursday (day 11)	**Sample C from Wednesday**

Samples were taken on both week and weekend days so as to be fully representative. See Addendum 10 for further details.

The following method was used to collect samples of the feeds:

When administration of the tubefeed was begun in the ward (Sample B)

The B samples were collected once the C samples of the previous day had been delivered to the Microbiology Department. The sample was taken from first bottle, which was administered to the patient; records were kept of whether the patient was already receiving the feed when the sample was taken. It was also noted whether a new giving set had been used. It is protocol at Tygerberg Academic Hospital to replace the giving set after 24 hours, with the first bottle provided for the day. The researchers hands were washed and sprayed with alcohol prior to, and after the sample was taken. The bottle was shaken well before the sample was collected. A webcol alcohol swab was used to disinfect the lip of the bottle, and 3-5ml of ready to hang feed was poured into a sterile 14 ml screw closure test tube. Samples were marked (project number and sample B) and kept refrigerated, on ice, until taken to the Microbiology Department. Samples were not collected from feeds, which had not been opened by 15h00. Samples were delivered to the Department of Microbiology within a period of 1 - 1 ½ hours after collection.

Completion of administration of the feed – (Sample C)

The C sample had to be obtained before 12h00; and collection began by 11h00. The samples were marked (project number and sample C). The researchers hands were washed prior to, and after the sample had been collected. The researchers hands were sprayed with alcohol and the bottle was shaken well before the sample was taken. A webcol alcohol swab was used to disinfect the lip of the bottle. Three to five ml of the contents of the ready to hang tubefeed bottle was poured out into a sterile 14 ml screw closure test tube after the feeding system has been disconnected. The samples were marked (project number and sample C) and kept

refrigerated, on ice, until taken to the Microbiology Department. Researchers kept records of the volume of feed remaining in the bottle and of how many unopened bottles still remained in the refrigerator. Possible reasons why the feed had not been completed within the 24-hour hanging period were also noted. The samples were kept on ice and were taken to the Microbiology Department after all the C samples had been collected. Samples were delivered to the Department of Microbiology within a 3 - 5 hour period after collection (Addendum 10).

MICROBIOLOGICAL ANALYSES OF SAMPLES

All samples were tested at the Department of Microbiology, Tygerberg Academic Hospital. Tubefeed samples were kept cool in shaved ice until delivered to the Department of Microbiology, where they were stored in the refrigerator (4°C) until tested. Each sample was vortexed and then using a Gilson pipette 0,02 ml aliquots were spread over the surface of three culture plates, two 5% horse blood agar plates, and one Mac Conkey agar plate. Two culture plates (one 5% horse blood agar and one Mac Conkey agar) were incubated with a CO_2 mixture, and one culture plate (5% horse blood agar) anaerobically at 37°C for 18-24 hours, after which identification took place. Culture plates were checked again the next day to determine if any further organisms could be identified. Counts were expressed as colony forming units (cfu) / ml. Isolates were identified by standard techniques. Results were presented as follows: total cfu/ml count for each sample and identification of all organisms present that contributed to the total cfu/ml value. Samples were considered contaminated if one or more organism could be identified, no matter what the cfu/ml value was. Samples were considered free of contamination only if no organisms could be identified.

Prior to the study, it had been decided to group and discuss the microbiology data according to Cfu/ml values e.g. number of samples with a Cfu/ml value of <10 000 Cfu:/ml, number of samples with Cfu/ml value of > 10 000 but < 20 000 Cfu/ml. However the data, in this format, was very difficult to present and it was not easy to draw any meaningful conclusions. The researcher then decided (after consultation with the statistician), rather to present and group the data according to the recognised cut off values found in the literature.[12,14,19] The researcher felt that this data would be more useful and that it would be easier to determine which production method was safest on the basis of accepted international standards.

3.2.5.COST

The cost of electricity and water contribute to the total cost of tubefeed production. However, after discussion with TBH engineers, it was found it was not possible to determine the exact amount of electricity and water utilised by the tubefeed room. The tubefeed room does not have its own electricity or water meter. The electrician consulted, also determined that the electricity used to run the tubefeed room is negligible, and that using the machine would not result in a significant increase in electricity usage. The use of water by the tubefeed room was also considered to be negligible when compared to the volume of water used on a daily basis by the rest of the hospital. On the basis of this advice, in addition to not being able to gather accurate data, it was decided exclude the cost of electricity and water when calculating the cost of tubefeeds produced.

Please note that in all calculations the cost of producing supplementary drinks was not taken into consideration.

3.2.5.1 Present System

The daily cost of tubefeed production (average of 60L) and the cost of producing a standard concentration (1kcal/ml) 2000ml tubefeed using the present manual system was determined by taking the following factors into consideration:

1. Cost of basic tubefeed ingredients - using tender prices available for the time period 1st December 2000 until 30th November 2001.
2. Cost of labour - this was determined in two ways:

a) Daily production cost of feeds using an average volume of 60L produced per day. This was determined by taking the total annual cost of staff salaries (in Rands) and determining how much each staff member would earn on a daily basis. Total income divided by 365 days = amount in Rands earned per day. This amount was then added to the cost of basic ingredients, cleaning products (Addendum 6), and feed administration costs to get the daily production costs.

b) Cost of production of a 2000ml standard concentration (1kcal/ml) feed.

The total daily cost of labour, as determined above, was used to determine the cost of a 2000ml tubefeed. It cost R?? -?? to produce 60L, therefore it will cost R??-?? /30 to produce 2L. The production of supplementary feeds was not taken into consideration when costs were determined.

3. Cost of Electricity

This was excluded after discussion with TBH engineers and electricians.

4. Cost of Water

This was excluded after discussion with TBH engineers and electricians.

5. Feed Administration Costs

The cost of all administration sets and feeding tubes was determined using

tender prices available for the time period 1st December 2000 until 30th November 2001.

6. Cost of cleaning products

   This includes detergents, cloths, hypochlorite solutions, soap, aprons, and disposable caps. It was determined by using the average monthly cost of cleaning products ordered from the main store for tubefeed production purposes. This was then expressed as a daily cost in Rands (monthly value divided by 30 to give a daily value) for the production of 60L of tubefeed.

All the above information was used to determine the exact cost of a tubefeed produced using the present system.

3.2.5.2 Mechanised Production

The daily cost of tubefeed production (average of 60L) and the cost of producing a standard concentration 2000ml tubefeed using mechanised production was determined by taking the following factors into consideration:

1. Cost of basic tubefeed ingredients - using tender prices available for the time period 1st December 2000 until 30th November 2001.

2. Cost of labour -this was determined in two ways:

a) Daily production cost of feeds using an average volume of 60L produced per day. This was determined by taking the total annual cost of staff salaries (in Rands) of all personnel required and determining how much each staff member would earn on a daily basis. Total income divided by 365 days = amount in Rands earned per day.

b) Cost of production of a 2000ml standard concentration (1kcal/ml) feed

The total daily cost of labour as determined above was used to determine the cost of a 2000ml tubefeed. It cost R?? -?? to produce 60L, therefore it will cost R?? -?? / 30 to produce 2L. All costs determined did not take the production of supplementary feeds into consideration.

3. Cost of Electricity

This was excluded after discussion with TBH engineers and electricians

4. Cost of Water

This was excluded after discussion with TBH engineers and electricians

5. Feed Administration Costs

The cost of all administration sets and feeding tubes was determined using tender prices available for the time period 1st December 2000 until 30th November 2001.

6. Cost of cleaning products

This includes detergents, cloths, hypochlorite solutions, soap, aprons, and disposable caps. It was determined by using the average monthly cost of cleaning products ordered from the main store for tubefeed production purposes. This was then expressed as a daily cost in Rands (monthly value divided by 30 to give a daily value) for the production of 60L of tubefeed. (Addendum 6)

3.2.5.3 Ready to Hang

Please not that the cost of producing supplementary drinks or any other additional tubefeeds, or the cost of still having a tubefeed room in addition to using RTH, was not taken into consideration when calculations were done.

Only two factors were taken into consideration when the cost of RTH feeds was determined namely:

1. Cost of basic tubefeed ingredients - using tender prices available for the time period 1st December 2000 until 30th November 2001.
2. Feed Administration Costs - the cost of all administration sets and feeding tubes was determined using tender prices available for the time period 1st December 2000 until 30th November 2001.

3.2.6 STATISTICS AND DATA ANALYSIS

The Statistica statistical analysis package was used for statistical analysis and Excel was used for the graphs. Descriptive statistics were used to evaluate the majority of the data. The two sample t-test for independent samples (with equal or unequal variances) was used as appropriate. All possible combinations of the three production methods were compared to one another, taking account of the effect that the multiple comparisons have on the significance level (Bonferoni inequality). The following variables were compared: production time, waste, percentage waste and the number of organisms in each sample. The Mann-Whitney U test (Wilcoxon rank sum test) based on rank scores of the actual values was used as a non-parametric analogue to the two sample t-test for independent samples. This was used when the cfu/ml count of samples A, B and C (of all production methods) were compared to one another. The Statistica package was also used to test for differences in proportions (based on the t distribution). The following

variables were compared: percentage of feeds contaminated with more than 10^2 and 10^5 cfu/ml organisms, percentage of feeds contaminated with organisms not permitted and percentage of feeds not stored at the correct temperature.[36] The null hypothesis will be rejected for each variable between these groups, if p (after adjustment with Bonferoni) is < 5%.

3.2.7 ETHICAL COMMITTEE PERMISSION

Subcommittee C of the Research committee, University of Stellenbosch, approved the ethical aspects of the research project entitled: Production of Enteral feeds: manual Vs mechanised Vs "Ready to Hang" on the 3rd of January 1998. Issued with project number 98/007.

CHAPTER 4
RESULTS

NUMBER OF TUBEFEED PERSONNEL ON DUTY DURING THE STUDY

The number of personnel on duty during the manual production section of the study ranged from one to four staff members during the week and two over the weekends. This range can be considered to be normal if one takes, days off, and days of sick leave into consideration. There are always only two staff members on duty over weekends. In the mechanised production section of the study only two staff members were involved in the study, both of which were present when data was gathered during the week, as well as over the weekend.

TUBEFEED SAMPLE DISTRIBUTION

The tubefeed samples, which were collected for this study, were distributed throughout the Tygerberg Academic Hospital (Figure 4). The majority of samples tested came from ward A4, 55% (n=65); hand production (HP), 63% (n=63); machine production (MP) and 48% (n=59) when ready to hang products (RTH) were tested. The other samples tested were found distributed through out the other wards. When HP samples were tested, 14% of samples tested came from ward D10 - a trauma ward, and 14% from G5, an ENT ward with laryngectomy patients. When MP samples were tested 13% of samples came from A5E - a respiratory ICU ward, and 13% from ward G5. When RTH samples were tested, 12% of samples tested came from ward A1 - surgical ICU, 15% from ward A2 – a cardiothoracic surgery ward

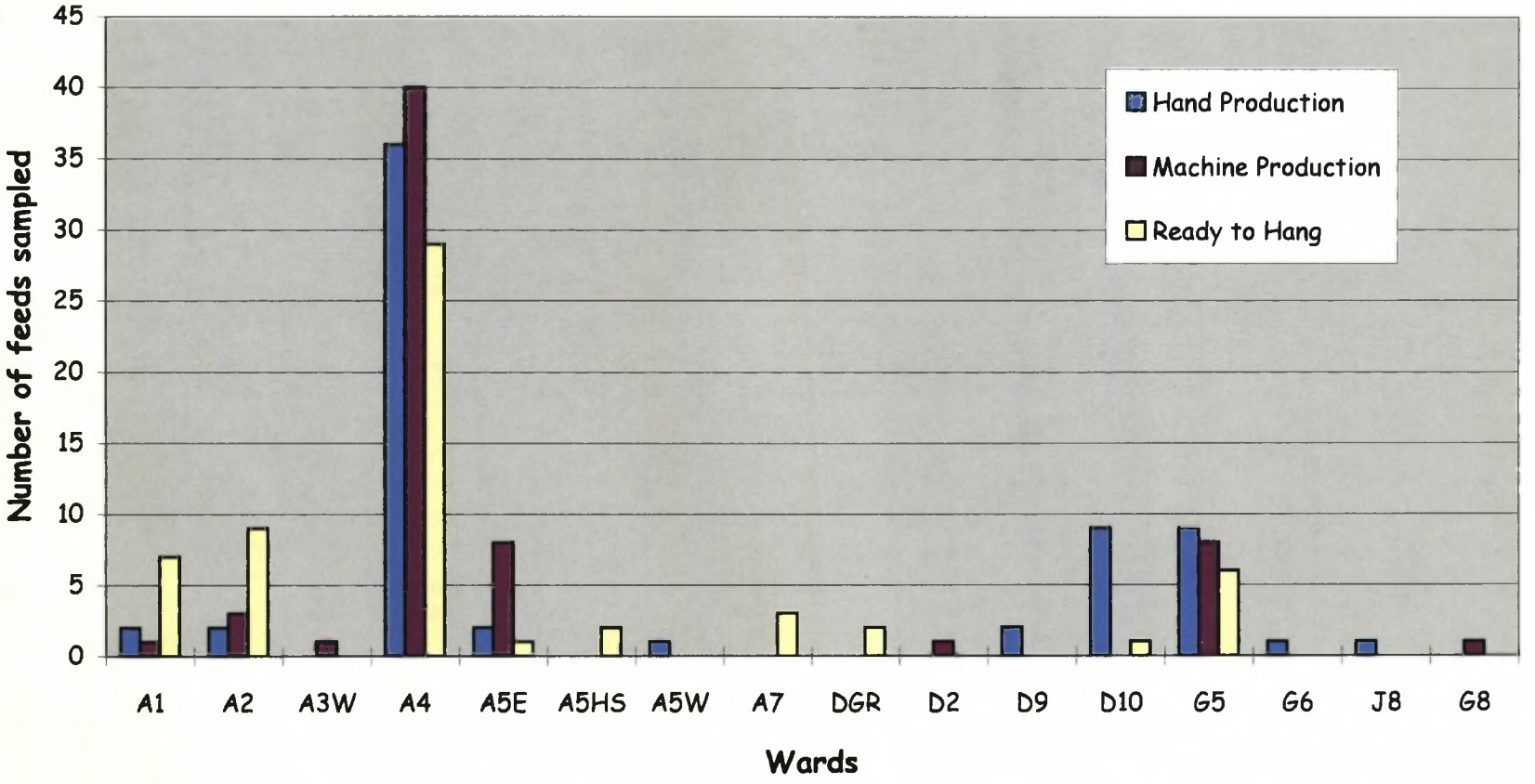


Figure 4: Ward distribution of enteral feed samples collected

WEEK VS. WEEKEND DISTRIBUTION OF SAMPLES

Seventy four percent of HP samples and 73% of MP and RTH samples were collected during the week, whereas 26% of HP and 27% of MP and RTH samples were collected during the weekend (Table2).

Table 2: Tubefeed sample distribution Week vs.Weekend

Week / Weekend	Tubefeed Production Method					
	Hand (n=65)		Machine (n=63)		Ready to Hang (n=59)	
Week	48/65	74%	46/63	73%	44/59	73%
Weekend	17/65	26%	17/63	27%	16/59	27%

TUBEFEED PRODUCTION DATA

The mean volume of tubefeed produced using HP was 2315ml. MP produced a mean volume of 1887ml and the mean of the RTH feeds provided was 1802ml (Table 3).

Table 3: Mean volume (SD) of tubefeed produced

Tubefeed production Data	Method of Tubefeed Production		
	Hand (n=65)	Machine (n=63)	Ready to Hang (n= 60)
Mean Volume (ml)	2315 (699)	1887 (475)	1802 (509)
Range	960 - 3000	220 - 2400	720-2500

A significant difference ($p < 0.001$) was found in the mean reconstitution time, when the different reconstitution methods were compared (Table 4 and Figure 5). HP reconstitution took 72 seconds and MP only 38 seconds. The difference in mean decanting time was found to be significant ($p < 0.001$) when different production methods were compared. HP was 55 seconds, where MP was found to be 152 seconds. The total mean production time is the total production time expressed as seconds per Litre of tubefeed produced. The total mean production time (seconds / Litre) was significantly higher ($p < 0.001$) in the MP tubefeeds (105 seconds/L) when compared to the HP method (59 seconds/L).

When the accuracy of different decanting methods were compared the MP method was found to be significantly ($0.01 \leq p \leq 0.05$) more accurate, when decanting the reconstituted tubefeed, when compared to HP. HP had an average of 62 ml too much/too little compared to 42 ml too much or too little for MP. The decanting methods therefore varied by a significant mean value of 19 ml too much or too little. However when the mean overall error was expressed as a percentage of the mean volume provided to the patient, the difference was far smaller. HP had an overall error of 2,6% compared to one of 2,24% for MP production (Table 4).

Table 4: Reconstitution and decanting data (HP Vs. MP) (SD)

Tubefeed Production data	Method of Tubefeed Production		
	Hand (n=65)	Machine (n=63)	p value
Mean Reconstitution time (seconds)	72 (13)	38 (14)	0 *
Mean Decanting time (seconds)	55 (13)	152 (40)	0 *
Total Mean Production Time (seconds per Litre)	59 (17)	105 (18)	0 *
Mean overall decanting error (% of mean volume provided to patient)	2,6%	2,24%	-
Accuracy of decanting method used (ml) (ml too much or too little after decanting)	61 (0,5)	42 (36)	0,0175 *

* $p < 0.001$ (significant)

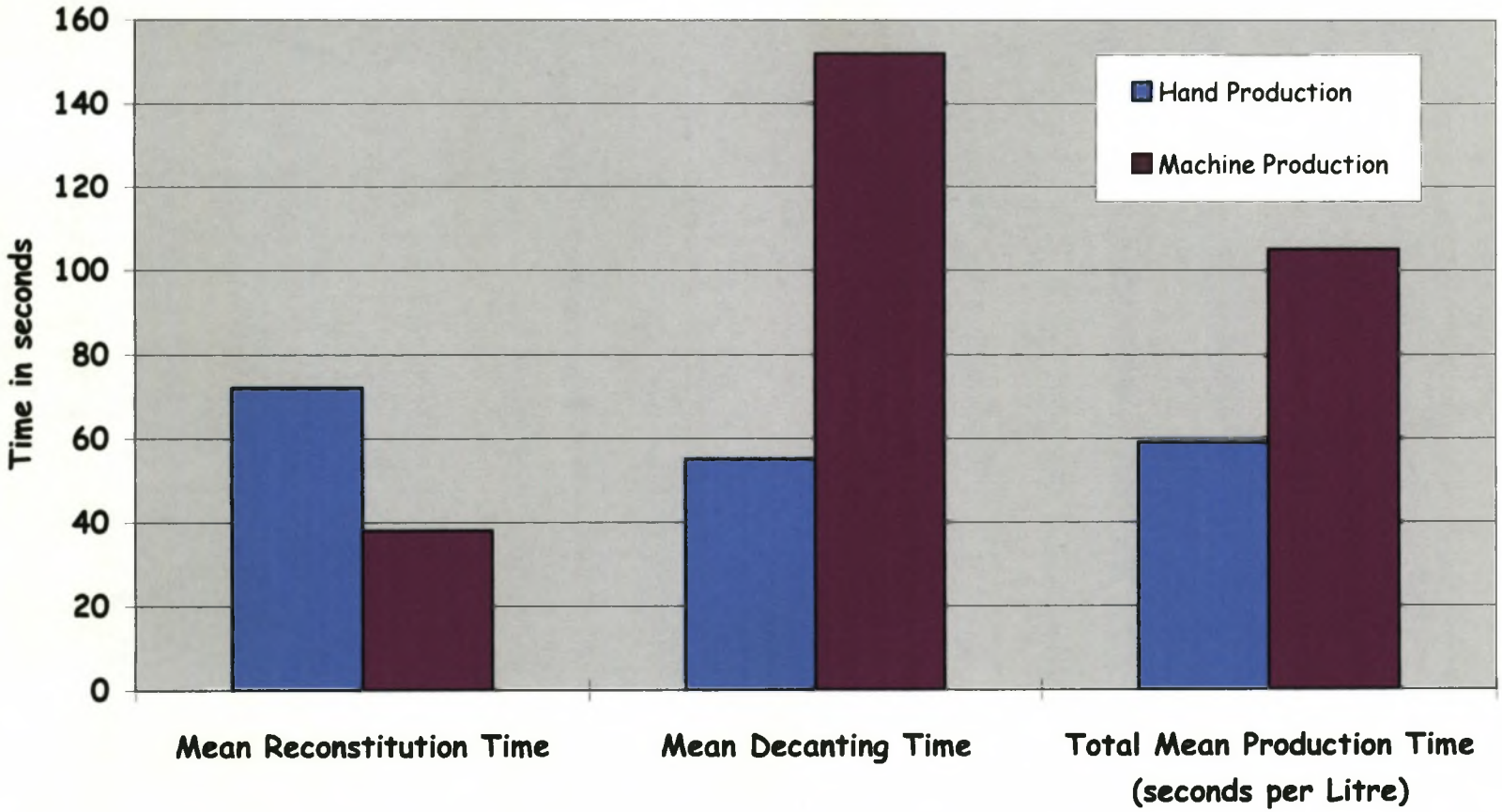


Figure 5: Comparison of tubefeed production times

TUBEFEED ADMINISTRATION DATA

Twenty seven percent of the original volume of tubefeeds produced using HP was wasted in comparison to 19% of the original volume of MP tubefeeds. This difference was not found to be significant (Table 5). However a significant difference ($0.01 \leq p \leq 0.05$) was found when RTH feeds were compared to HP feeds. Only 15% of the original volume of the RTH feeds were wasted in comparison to 27% of the original volume of HP feeds.

Table 5: Wastage of enteral feeds

Tubefeed production data	Method of Tubefeed Production		
	Hand (n=65)	Machine (n=63)	RTH
% of original feed wasted	27%*	19%	15%*

*Significant difference ($0.01 \leq p \leq 0.05$)

PROBLEMS WITH TUBEFEED ADMINISTRATION

The main reasons why tubefeed administration did not take place over a twenty four hour period were as follows: patient complications and problems, problems with tubefeed administration and unknown factors (Table 6 and Graph 6). Patient problems and complications played a role in 9% of HP feeds, 22,5 % of MP feeds and 17% of RTH feeds. Thirty seven percent of HP feeds, 22,5 % of MP feeds and 34% of RTH feeds were not completed over a twenty four hour period due to problems with tubefeed administration. It was also found that large numbers of feeds (all methods of production) had been provided at a rate faster than what had been prescribed. Twenty eight percent of HP feeds had nothing left when sample C (sample taken from feed in last bottle) was collected, in comparison to 16% of MP feeds, and 15% of RTH feeds. Twenty eight percent of HP feeds, 44% of MP feeds, and 29% of RTH feeds were provided as prescribed (administration of total volume prescribed took place over and within a 24-hour period).

Table 6: Main reasons why tubefeed administration was not completed within 24 hours (number of samples)

Reason why tubefeed was not completed within a 24 hour period	Tubefeed Production Method		
	Hand (n=65)	Machine Method (n= 61)	Ready to Hang (n= 59)
	% of total	% of total	% of total
Problems with patient	9% (6)	22,5% (14)	17% (10)
Death	1,5%(1)	5%(3)	2%(1)
Eating	1,5%(1)	1,5%(1)	5%(3)
Nausea /Vomiting	1,5%(1)	-	-
NPO	1,5%(1)	6,5%(4)	3%(2)
Feed Stopped / Acute Abdomen	1,5%(1)	8%(5)	-
Patient Transferred	-	1,5%(1)	3%(2)
Cancelled / Not given	1,5%(1)	-	3%(2)
Problems with feed administration	37% (24)	22,5% (14)	34% (20)
Feed Begun Late	4,5% (3)	6,5%(4)	12%(7)
Tube Out / Tube Blocked	4,5% (3)	-	7%(4)
Feed administered too quickly	28% (18)	16% (10)	15% (9)
Unknown	26%(18)	11% (7)	20%(12)
Feeds administered correctly	28% (18)	44% (27)	29%(17)

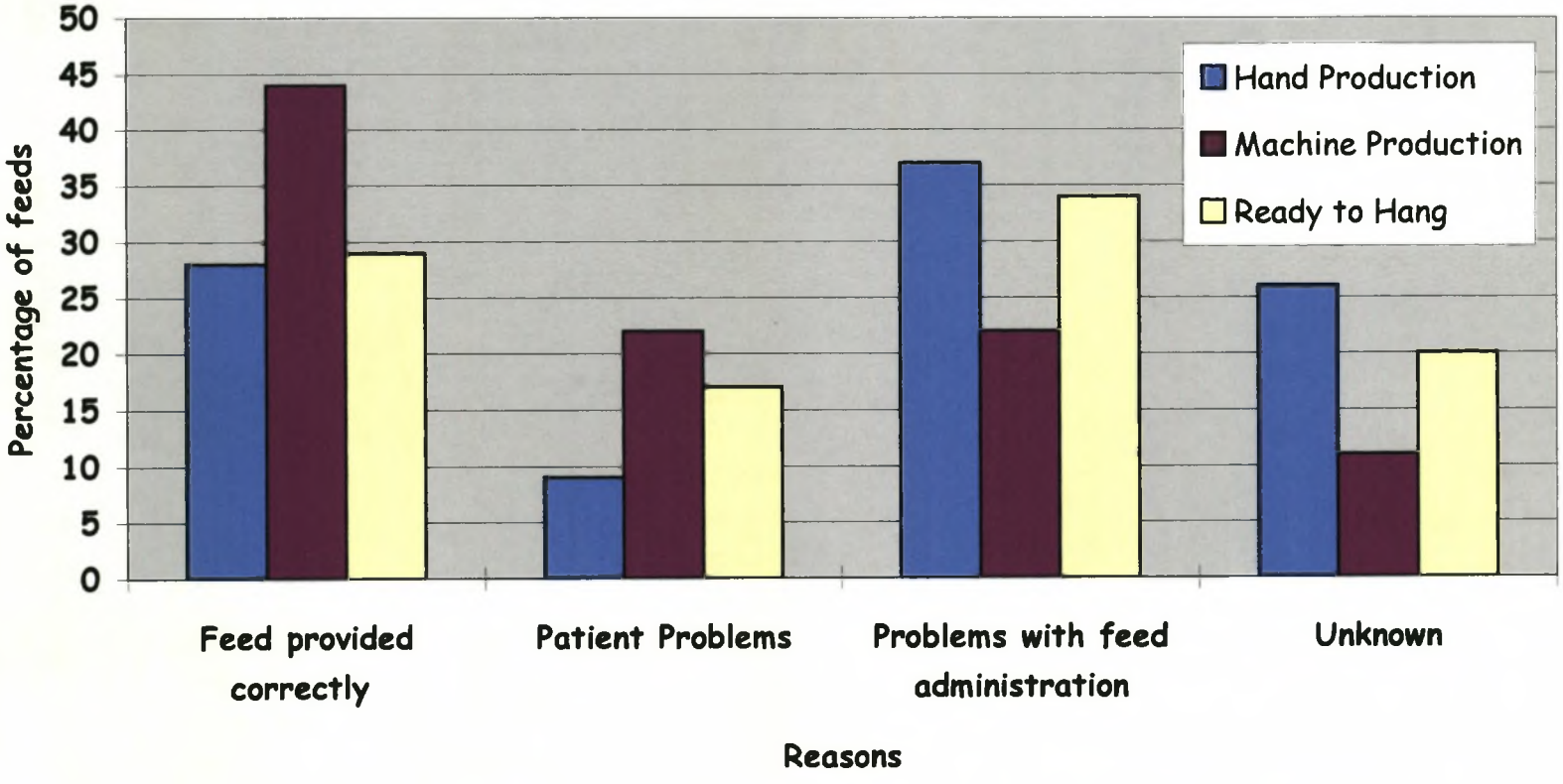


Figure 6: Main reasons why tubefeed administration was not completed within a 24 hour period

SOURCE OF TUBEFEED SAMPLES

The majority of B samples (sample taken at ward level from first bottle by 14h00) taken from feeds produced by HP (40%) and MP (51%) were taken from feeds found in the ward kitchens (not stored in the refrigerator) (Table 7). Thirty two percent of HP B samples were taken from bottles hanging at ward level in comparison to 20% of MP samples. One hundred percent of B samples for RTH were taken from bottles hanging at ward level. Sixty eight percent of HP B samples and 80% of MP B samples were taken from bottles, which were not yet hanging, by the cut off time of 14h00. In many cases the researcher had to request that RTH feed administration be started, so that B samples could be collected by the cut off time of 14h00. Forty five percent of HP B samples, and 66% of MP B samples, which had not been provided by the cut off time, were being stored outside the fridge at incorrect temperatures. No significant difference was found between the number of HP and MP B samples stored incorrectly.

The majority of C samples were taken from bottles hanging at ward level, 75% for HP feeds, 61% for MP and 100% of RTH. Thirty one percent of C samples from MP feeds were collected from bottles stored in the refrigerator at ward level (from bottles not provided within the 24-hour period), in contrast to only 15% in HP feeds. Ten percent of HP C samples and 8% of MP C samples were taken from bottles in the ward kitchen or in the ward (not connected). In the case of RTH, only thirty-seven C samples could be collected, a loss of twenty-two samples. In the case of RTH, samples were only collected from bottles, which were already open at the time the researcher was there. It was not possible to collect C samples for 28% of HP feeds, 16% of MP feeds and 37% of RTH feeds, used for B samples, as feeds were completed prior to the time C samples were to be collected (Table 7 and Figure 7and 8).

Table 7: Source of tubefeed samples collected for microbiological testing

Sample Source	Method of Production							
	Hand			Machine			Ready to hang	
	* Sample A (n=65)	♣ Sample B (n=65)	♦ Sample C (n=47)	* Sample A (n=63)	♣ Sample B (n=61)	♦ Sample C (n=51)	♣ Sample B (n=59)	♦ Sample C (n=37)
Tubefeed Room	100%	-	-	100%	1,5%	-	-	-
Ward kitchen	-	40%	2%	-	51%	4%	-	-
Ward (not hanging)	-	5%	8%	-	16%	4%	-	-
Ward (hanging)	-	32%	75%	-	20%	61%	100%	100%
Refrigerator	-	23%	15%	-	11,5%	31%	-	-
% of feeds not provided by 14h00	-	68%	-	-	80%	-	-	-

* - Sample A taken in the tubefeed room after reconstitution, ♣ - Sample B taken at ward level from first bottle by 14h00,
♦ - Sample C taken from last bottle at ward level

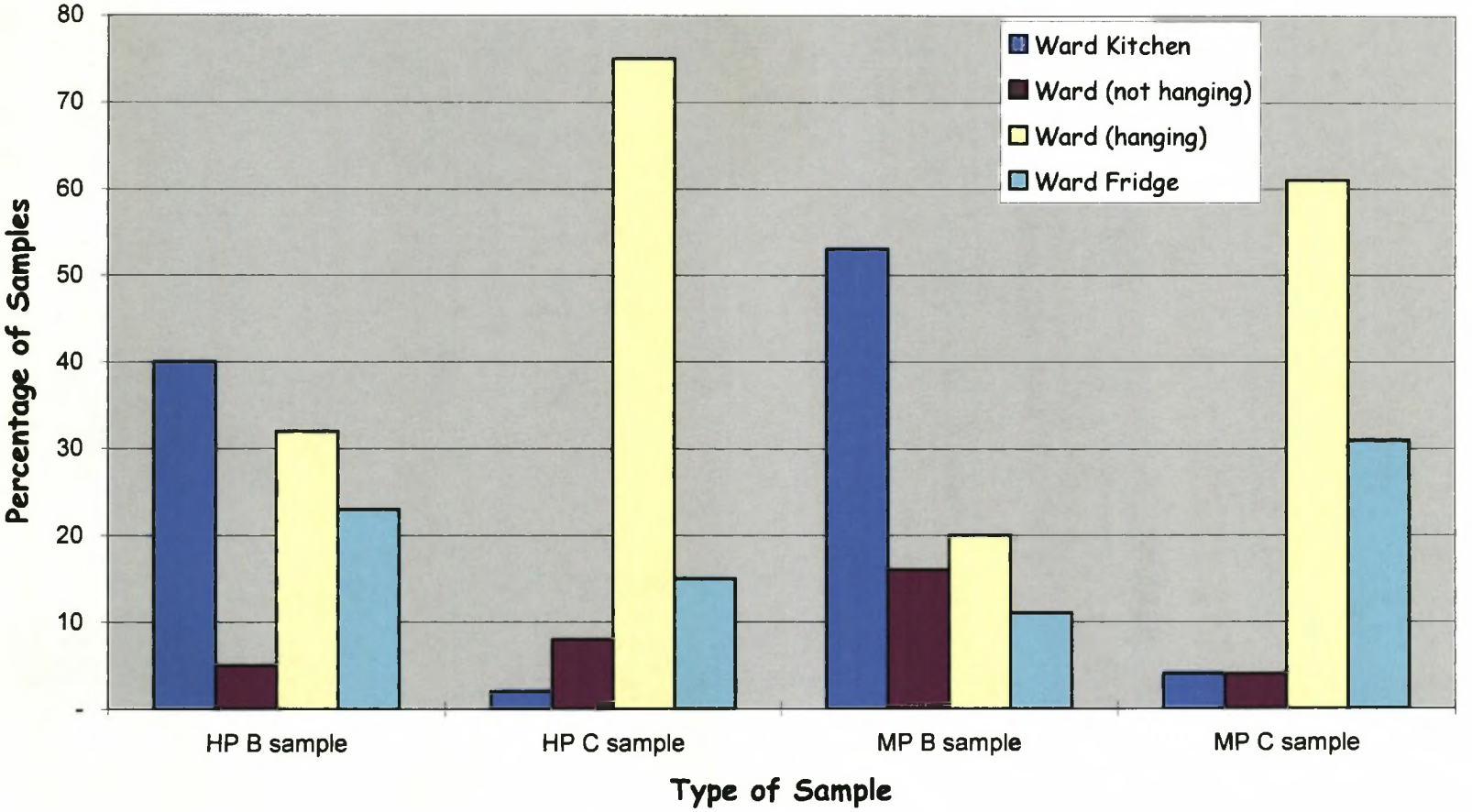


Figure 7: Source of B and C tubefeed samples collected for microbiological testing
(Sample B taken at ward level from first bottle by 14h00, Sample C taken from last bottle at ward level)

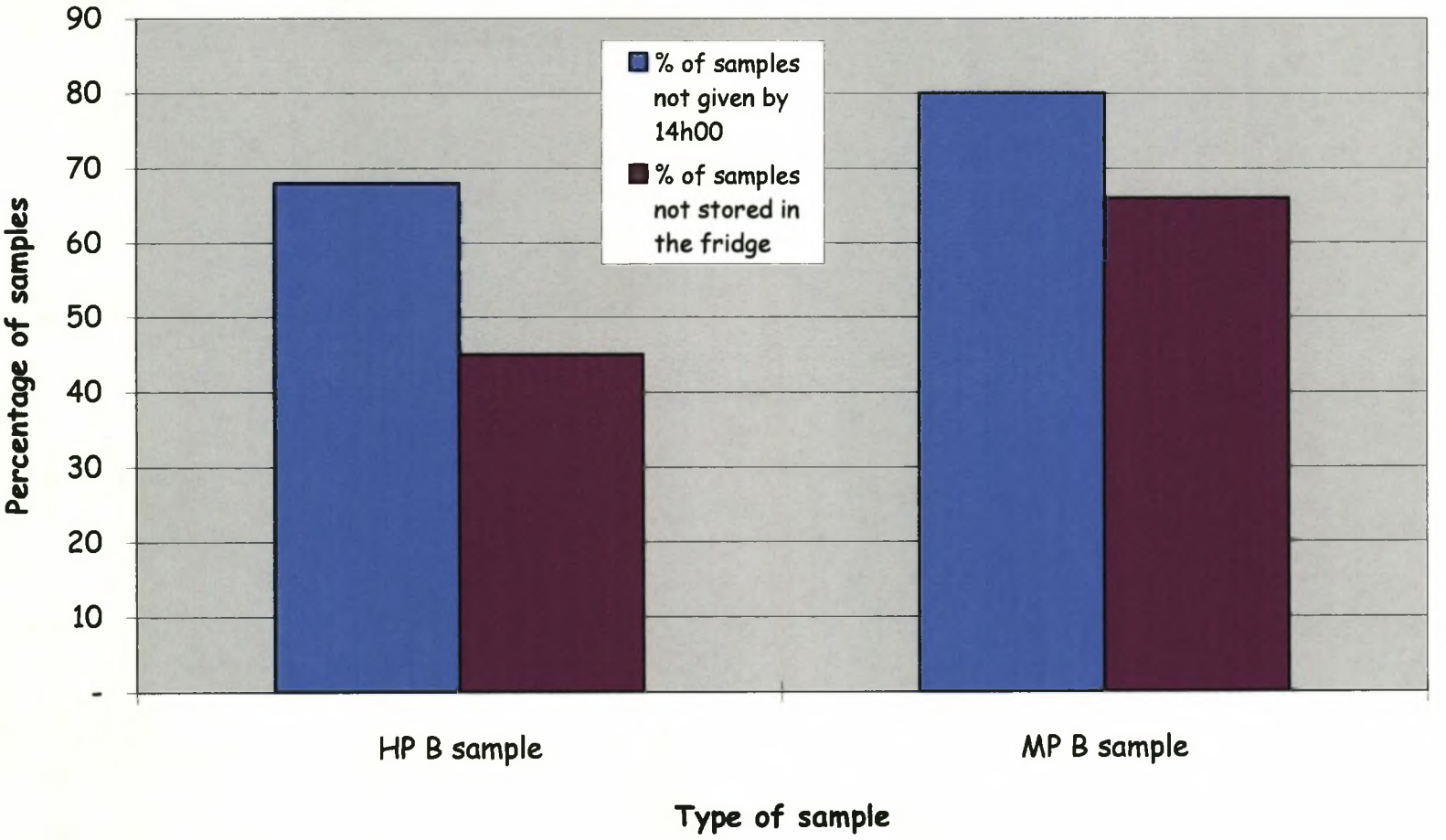


Figure 8: Percentage of samples collected, which had not been provided by 14h00, and which had not been stored in the fridge (Sample B - ward level from first bottle by 14h00)

MICROBIOLOGY RESULTS:

Please take into consideration that once the machine production part of this study had been completed, it was found that a substandard hypochlorite chemical disinfectant had been used in the tubefeed room. The results discussed below are therefore not a true reflection of the safety of the mechanised process. The mechanised section of this study was completed at the end of April 1999. It was the last section of the study to take place. As discussed under methods, the machine was installed and training of staff took place for a month before MP data was collected. During the pilot study, samples of feeds were collected and tested by the Department of Microbiology. The product Biocide (hypochlorite chemical disinfectant) was used to disinfect the machine during the testing period. The MP section of the study took place after all pilot study samples tested were found to be clear of any bacterial contamination. The researcher was not aware that, when the MP data was collected, a substandard hypochlorite solution was being used, in the place of Biocide. This product was used until the end of 1999. Professor Labadarios then addressed a letter to the Department of Finance, TBH complaining about the quality of the product being supplied, after which it was replaced by a more effective disinfectant (Addendum 8). The decline in hygiene standards from the end of 1998 and during 1999, of both tubefeeds and supplementary drinks, can be clearly seen in Addendum 12,13 and 14. One can also see a dramatic improvement in hygiene standards early in 2000, after the substandard hypochlorite solution had been replaced (Addendum 12). The machine has been used to produce all standard

tubefeeds at TBH since the MP section of this study was completed. Addendum 12 and 14 clearly show that the decline in hygiene results during 1999, can be attributed to the substandard hypochlorite disinfectant solution used and not MP. The hygiene standards of both tubefeeds and supplementary drinks were affected negatively during 1999 and both improved during 2000, once the product had been replaced. If MP had been the cause of the decline in hygiene standards then the hygiene results for supplementary drinks should have remained the same. The results of this research work will be presented within the limitations discussed above.

PERCENTAGE OF FEEDS CONTAMINATED

All three methods of tubefeed production were found to have contaminated samples (Table 8 and Figure 9). Twenty three percent of HP A samples were contaminated in comparison to 63% of MP samples. Seventy one percent of HP B samples, 74% of B samples produced by MP and only 34% of RTH were contaminated. Thirteen percent of C samples produced by HP and 15,5% of C samples produced by MP were found to have no bacterial growth, in contrast to 35% of RTH C samples.

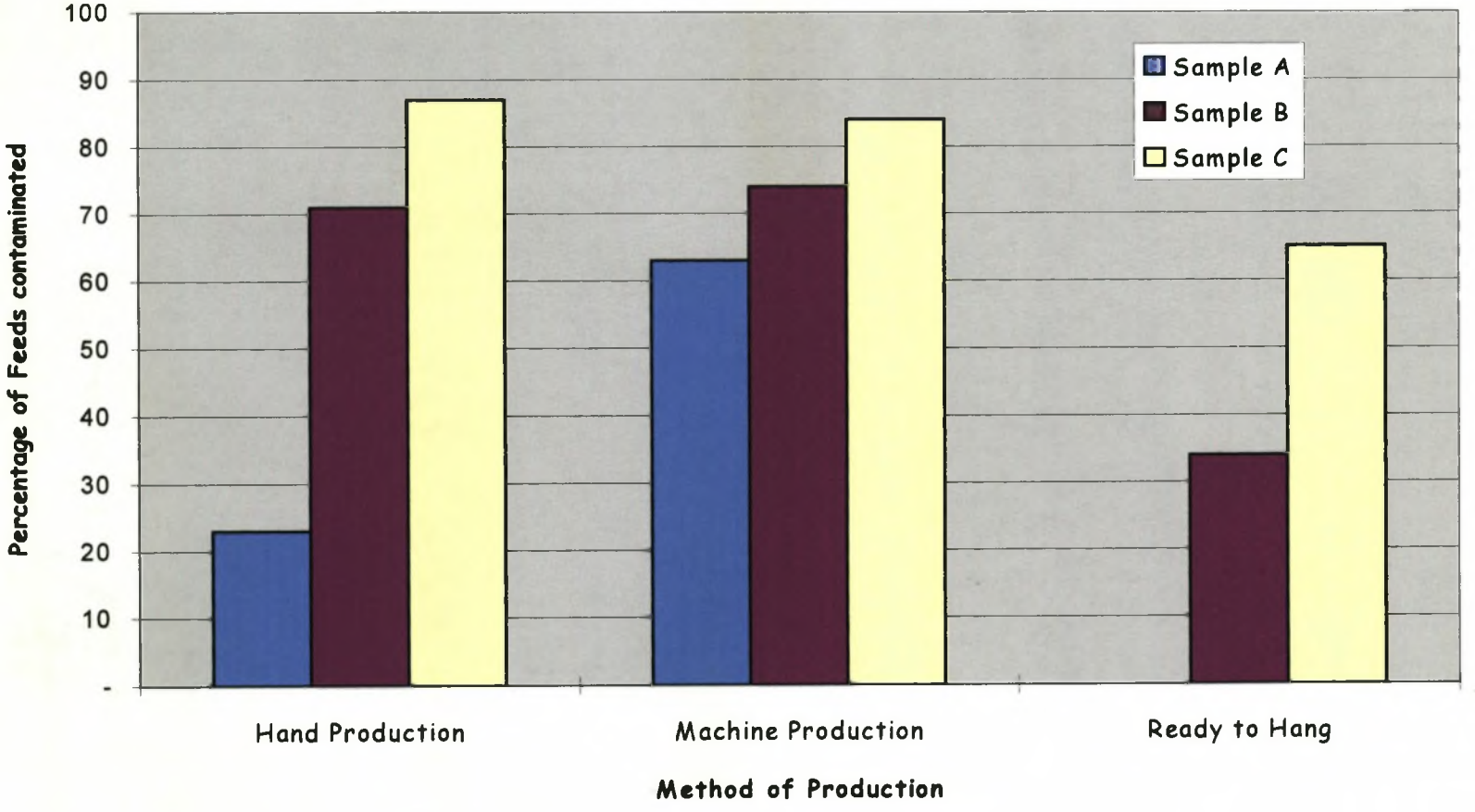


Figure 9: Percentage of tubefeeds contaminated - all methods of production

(Sample A taken in the tubefeed room after reconstitution, Sample B taken at ward level from first bottle by 14h00,Sample C - last bottle at ward level)

PERCENTAGE OF FEEDS CONTAMINATED WEEK VS WEEKENDS

When the contamination rates of samples taken during the week were compared to those taken during the weekend, a difference in the percentage of samples contaminated was noted. When the results of samples (HP & MP) taken during week 1 and week 2 are combined and compared to results obtained for the weekend, both follow the same pattern, namely Sample A is least contaminated and Sample C is most contaminated (Figure 10 &11). RTH samples follow the same pattern with C samples being more contaminated than B samples (Figure 12). However, when one distinguishes between samples taken in week one, week two and during the weekend, different results are obtained. B and C HP samples collected in week one are almost equally contaminated, which is very different to the usual trend seen when the average of week one and week two are compared. HP A samples are less contaminated over the weekend than those tested during the week (Figure 10). Week 1 MP A and B samples are the least contaminated, and the weekend MP C samples are the least contaminated of all production methods. However, all the A, B, and C samples collected during week 2 were found to be contaminated and therefore the average levels of contamination for both weeks are very high (Figure 11). In RTH production during the first week, it was found that B samples were more contaminated than C samples. However, this trend did not continue, and during the weekend less than 20 % of B samples and over 90% of the C samples were contaminated (Figure 12).

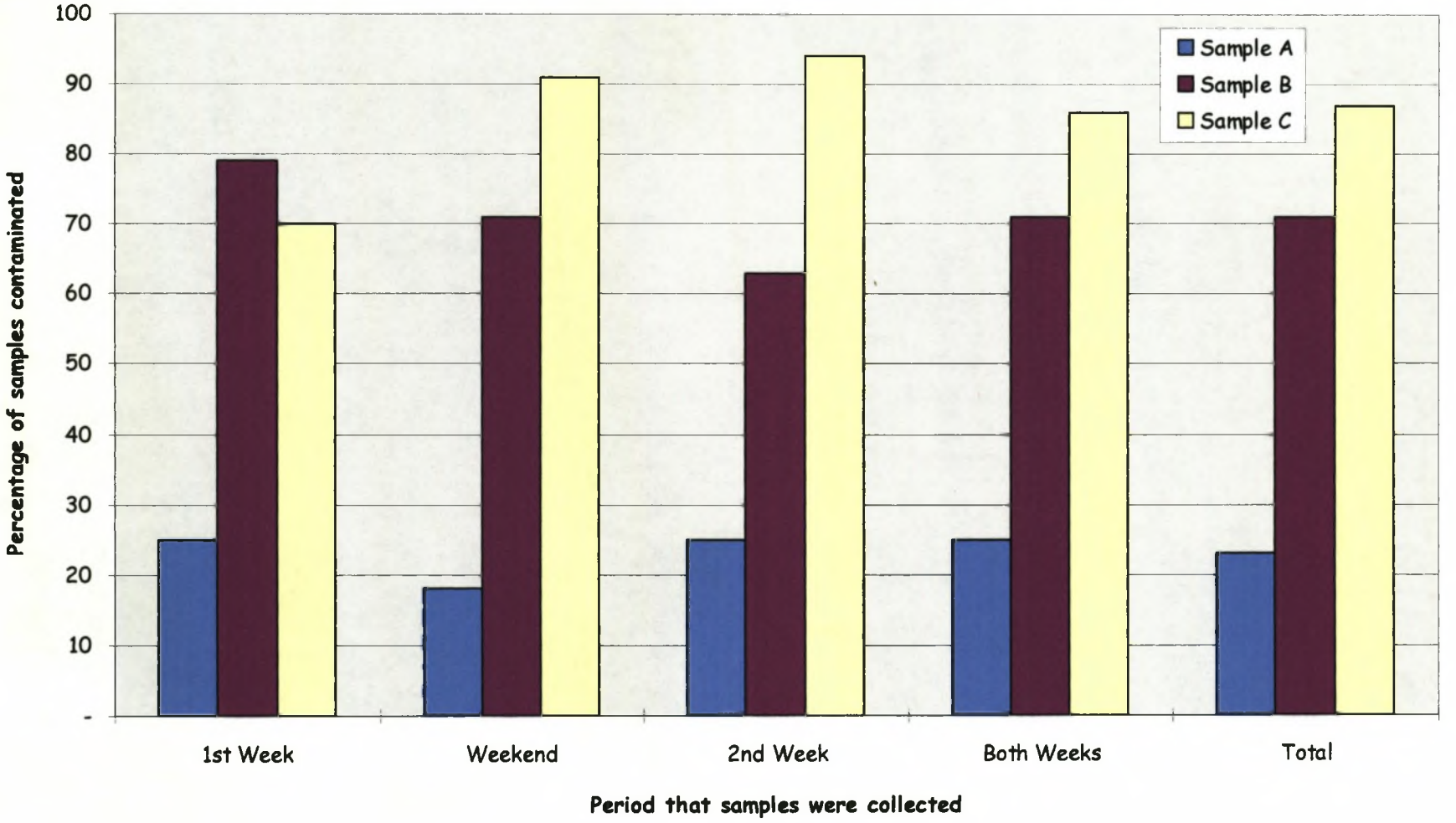


Figure 10: Percentage of feeds contaminated, Week Vs Weekend - Hand Production

(Sample A - tubefeed room after reconstitution, Sample B - ward level from first bottle by 14h00, Sample C taken from last bottle at ward level)

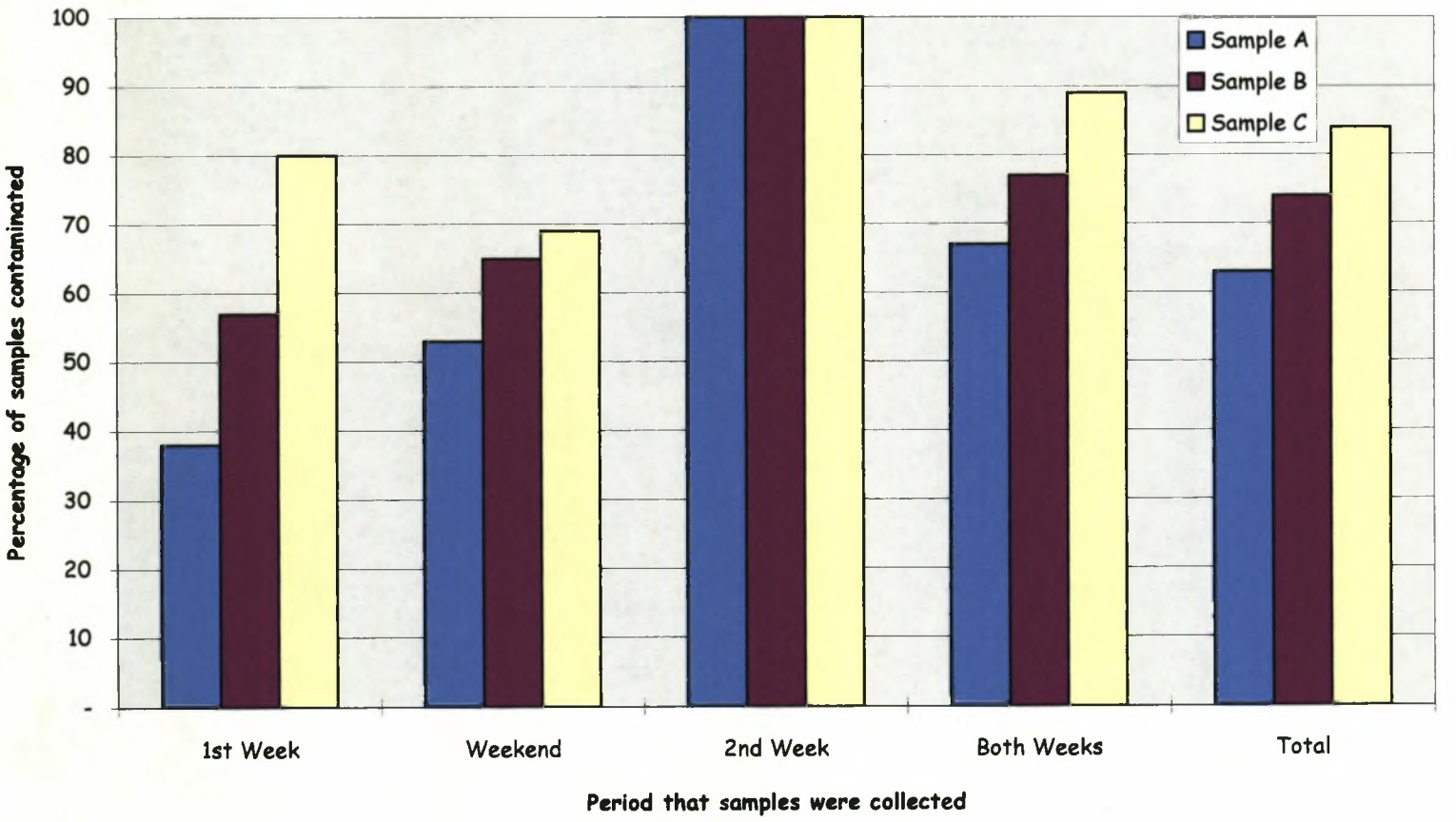


Figure 11: Percentage of feeds contaminated, Week Vs Weekend – Machine Production

(Sample A - tubefeed room after reconstitution, Sample B - ward level from first bottle by 14h00, Sample C taken from last bottle at ward level)

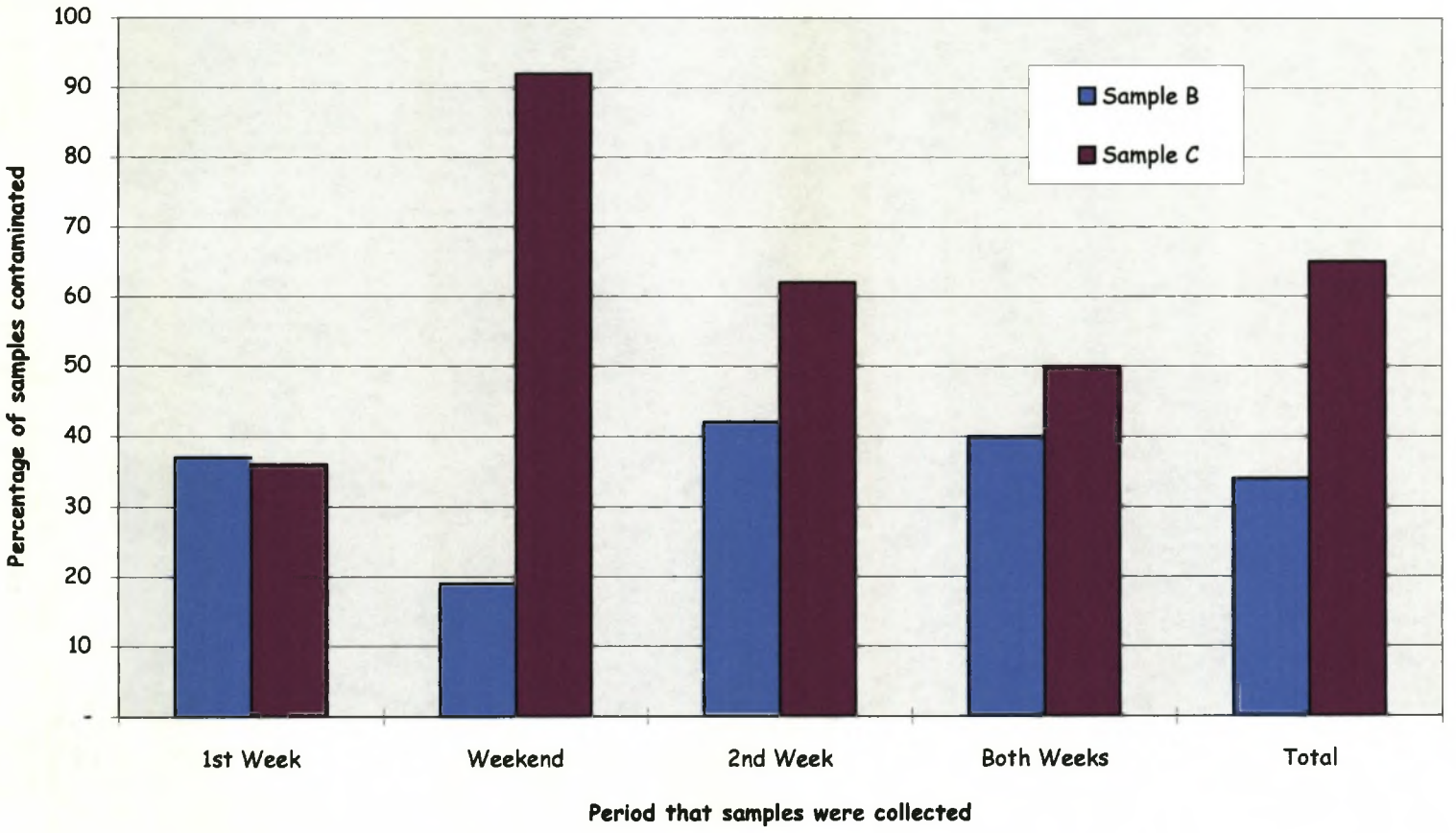


Figure 12: Percentage of feeds contaminated, Week Vs Weekend – Ready to Hang
(Sample B taken at ward level from first bottle by 14h00, Sample C taken from last bottle at ward level)

MEAN NUMBER OF ORGANISMS FOUND IN SAMPLES

There was a significant difference ($p < 0.001$) in the mean number of organisms identified in HP (0,4) and MP (1,2) A samples (Table 8). There was no significant difference found in bacterial contamination levels when the HP and MP B samples were compared. When HP and MP C samples were compared it was found that MP samples had significantly ($0.001 \leq p < 0.01$) fewer organisms that HP samples. A significant difference ($0.001 \leq p < 0.01$) was found in the number of organisms identified in RTH (0,7) and MP (1,5) B samples. Significantly more organisms ($0.001 \leq p < 0.01$) were identified in MP (1,9) C samples when compared to RTH (1,2) C samples. HP B (1,8) and C (2,7) samples were found to be contaminated with significantly ($p < 0.001$) more organisms than RTH B (0,7) and C (1,2) samples.

CFU/ML VALUES OF SAMPLES

When Cfu/ml values were compared between HP and MP samples, significantly more colony forming units ($p < 0.001$) were found in HP A samples when compared to MP A samples. There was no significant difference between the Cfu/ml values of B and C samples. A significant difference ($p < 0.001$) was found in the number of colony forming units, when the B and C samples of MP and HP feeds were compared to RTH feeds. RTH B and C samples had significantly fewer colony forming units than B and C samples of MP and HP feeds. (Table 9, Figure 13)

Cfu/ml values for samples were classified according to the accepted cut off values, which can be found in the literature, namely < 10^2 Cfu/ml and < 10^5 Cfu/ml. Significantly more HP A samples than MP A samples were found be free of contamination or to have contamination levels less than 10^2 Cfu/ml. When B HP and MP samples were compared no significant difference was found the number of samples with contamination levels below 10^2 Cfu/ml. However, when RTH feeds were compared to MP and HP feeds it was found that RTH feeds had significantly more B samples with Cfu/ml values within the acceptable range. When Cfu/ml of C samples (all production methods) were classified according to the cut off point there was no significant difference found. There was no significant difference, found in the number of A,B and C samples contaminated with ≥ 10^5 Cfu/ml. (Table 10)

Table 8: Percentage Contamination and Mean number of Organisms (SD)

	Method of Production							
	Hand			Machine			Ready to hang	
	* Sample A (n=65)	♣ Sample B (n=65)	♦ Sample C (n=47)	* Sample A (n=63)	♣ Sample B (n=61)	♦ Sample C (n=51)	♣ Sample B (n=59)	♦ Sample C (n=37)
Percentage Contaminated	23%	71%	87%	63%	74%	84%	34%	65%
Number of Samples contaminated	15	46	41	40	45	43	20	24
Mean Number of organisms	0,4(0,9)	1,8(1,6)	2,7(1,4)	1,2(1,2)	1,5(1,2)	1,9(1,2)	0,7(1,2)	1,2(1,2)

* - Sample A taken in the tubefeed room after reconstitution,
♣ - Sample B taken at ward level from first bottle by 14h00,
♦ - Sample C taken from last bottle at ward level

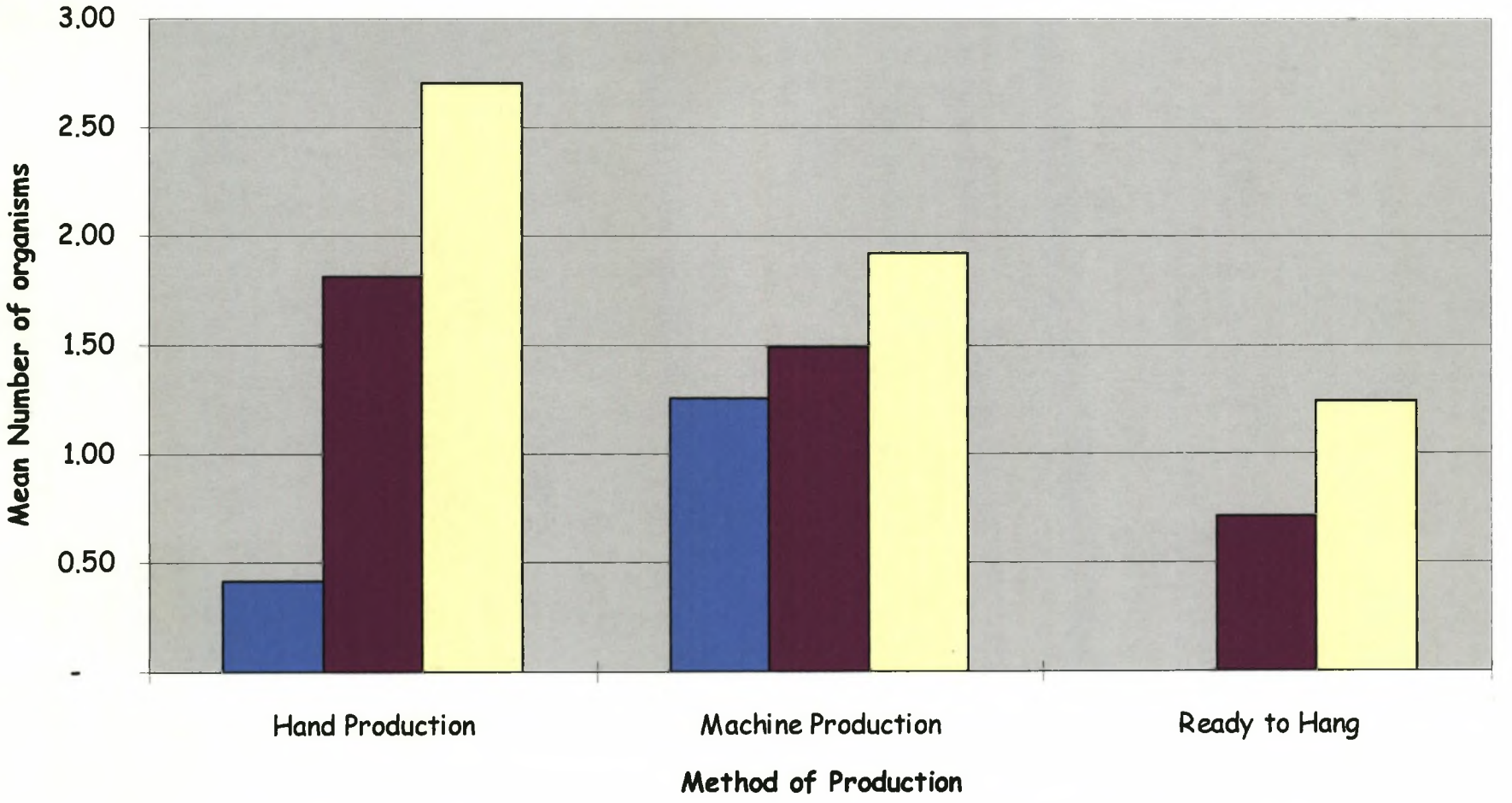


Figure 13: Mean number of organisms causing contamination – all methods of production

Table 9: Microbiology results of different production methods

Microbiological contamination	Production Method		
	Hand (n=65)	Machine (n=63)	p value
Mean number of organisms in Sample A *	0,42	1,23	0*
Mean number of organisms in Sample B ♣	1,8	1,5	0,19
Mean number of organisms in Sample C ♦	2,7	1,9	0,0029 #
Cfu/ml in Sample A* (Rank sum)	-	-	0*
Cfu/ml in Sample B♣(Rank sum)	-	-	0.804
Cfu/ml in Sample C♦(Rank sum)	-	-	0.653

Microbiological contamination	Production Method		
	Ready to Hang (n=59)	Machine (n=63)	p value
Mean number of organisms in Sample B ♣	0,7	1,5	0,001 #
Mean number of organisms in Sample C ♦	1,2	1,9	0,008 #
Cfu/ml in Sample B♣(Rank sum)	-	-	0,002 #
Cfu/ml in Sample C♦(Rank sum)	-	-	0,005 #

Microbiological contamination	Production Method		
	Ready to Hang (n=59)	Hand (n=65)	p value
Mean number of organisms in Sample B ♣	0,7	1,8	0*
Mean number of organisms in Sample C ♦	1,2	2,7	0#
Cfu/ml in Sample B♣(Rank sum)	-	-	0,0015 #
Cfu/ml in Sample C♦(Rank sum)	-	-	0,0049#

I# $0.001 \leq p < 0.01$ (highly significant), * $p < 0.001$ (very highly significant)

* - Sample A taken in the tubefeed room after reconstitution, ♣ - Sample B taken at ward level from first bottle by 14h00,

♦ - Sample C taken from last bottle at ward level

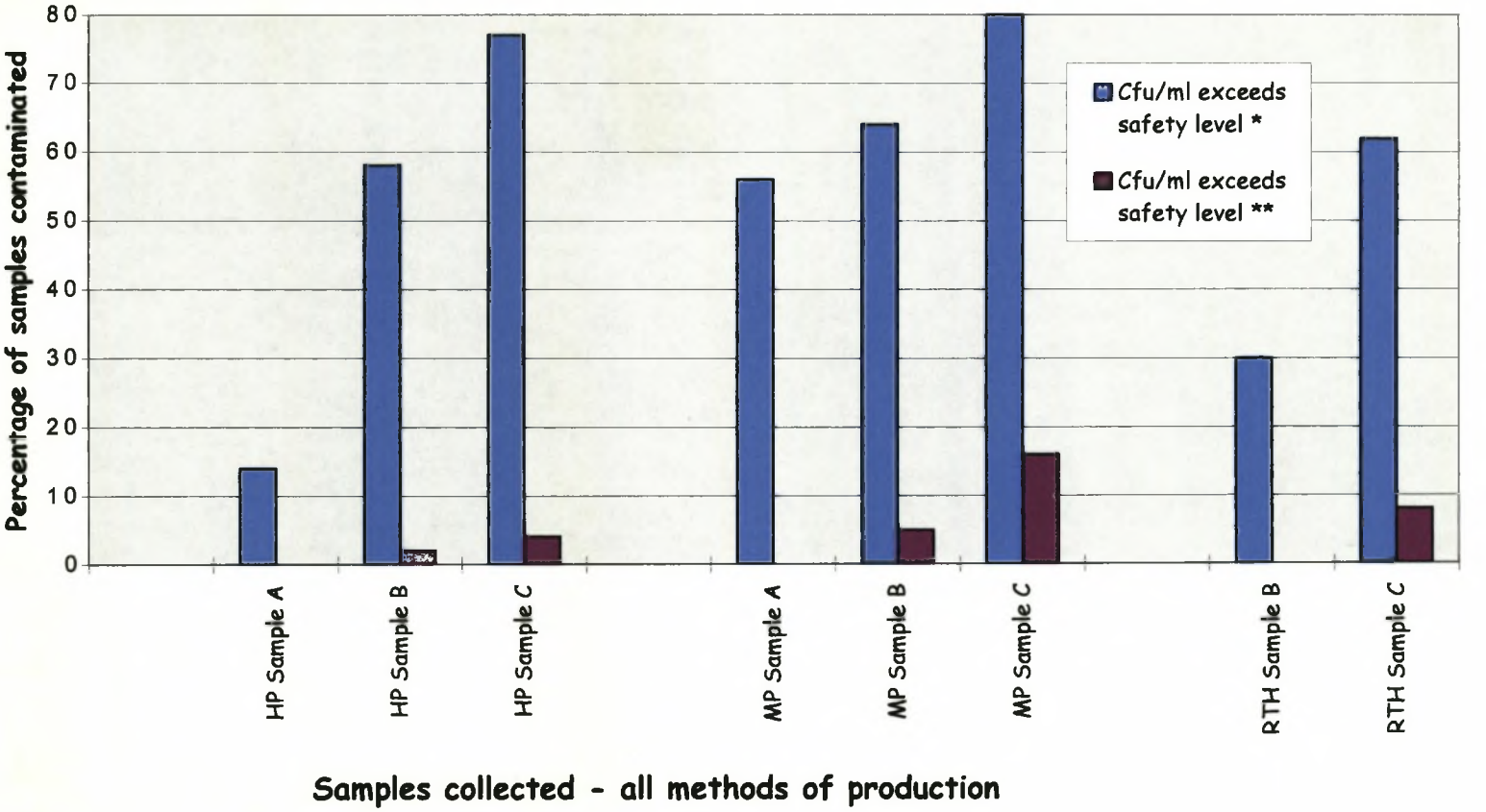


Figure 14: Percentage of samples collected which have contamination levels which exceed accepted cut off points (Sample A - tubefeed room after reconstitution, Sample B - ward level from first bottle by 14h00, Sample C - last bottle at ward level)
(Safety level * = contamination $\geq 10^2$ Cfu/ml, Safety level ** = contamination $\geq 10^5$ Cfu/ml)

Table 10: Samples classified according to accepted Cfu/ml cut off points

Method of Production			
	Hand (no of samples/n)	Machine (no of samples/n)	RTH (no of samples/n)
Percentage of feeds without growth / with acceptable growth < 10^2 cfu/ml *			
Sample A ω	86% (56/65)#	44% (28/63)#	-
Sample B♣	42% (27/65)ξ	36% (22/61) β	70% (41/59)ξβ
Sample C♦	23% (11/47)	20% (10/51)	38% (14/37)
Percentage of feeds with contamination of ≥ 10^5 cfu/ml * *			
Sample Aω	0%	0%	-
Sample B♣	1,5% (1/65)	5% (3/61)	0%
Sample C♦	4% (2/47)	15,5% (8/51)	8% (3/37)

* Accepted cfu/ml according to Anderton et al.

* * < 10^5 threshold cfu/ml according to US Centres for Disease Control and Prevention

ω - Sample A taken in the tubefeed room after reconstitution, ♣ - Sample B taken at ward level from first bottle by 14h00, ♦ - Sample C taken from last bottle at ward level

ξ - Significant difference ($0.01 \leq p \leq 0.05$), β - Significant difference ($0.001 \leq p < 0.01$)

\# - Significant difference ($0.001 \leq p < 0.01$)

TYPE OF ORGANISMS CAUSING CONTAMINATION OF SAMPLES

Samples tested were contaminated with different organisms. The results obtained from the Department of Microbiology indicated total Cfu/ml per sample. Organisms were quantitatively identified. The Cfu/ml value of each sample was therefor a value for any/all organisms identified. Results are therefor presented as descriptive statistics as shown in Table 11, 12,and 13. A total of nine organisms were identified, these included *Citrobacter, Enterobacter cloacae, Non Enterocc GDP Strep, Acinetobacter SP, Klebsiella pneumoniae, Pseudomonas Sp, Escherichia coli, Enterobacter Aerogens,* and *Serratia. Citrobacter* was found in A, B and C HP samples, in C MP samples and in B and C RTH samples (Figure 15,16,17,18). *Non Enterocc GDP Strep* and *Acinetobacter SP* were identified in A, B and C samples produced by all three methods. The following unacceptable gram-negative organisms were identified in some A and B HP and MP samples, namely *Klebsiella pneumoniae* and *Pseudomonas Sp. Klebsiella pneumoniae* was also found in 6 RTH C samples. *Eschericia coli*, an unacceptable gram-negative organism, was also identified in A, B and C MP samples, and in B and C RTH and HP samples. *Enterobacter aerogens*, a gram-negative bacterium, was only found in a single HP B sample and in 3 HP C samples. *Serratia*, a gram-negative bacterium was identified in one MP B sample and in two MP C samples.

Table 11: Percentage of feeds contaminated with organisms not permitted

Percentage of feeds contaminated with organisms not permitted			
Type of sample	Method of Production		
	Hand (no of samples/n)	Machine (no of samples/n)	RTH (no of samples/n)
Sample Aω	3% (2/65) ξ	63% (35/63) ξ	-
Sample B♣	29% (19/65) ξ*	72% (44/71) ξβ	12% (7/59) β*
Sample C♦	51% (24/47) #$	80% (41/51) #ξ	19% (7/37) ξ$

ω - Sample A taken in the tubefeed room after reconstitution, ♣ - Sample B taken at ward level from first bottle by 14h00, ♦ - Sample C taken from last bottle at ward level

ξ - Significant difference (p = 0),
β - Significant difference (p = 0)
- Significant difference ($0.01 \leq p \leq 0.05$),
$ - Significant difference ($0.01 \leq p \leq 0.05$)
* - Would have been significant with ($0.01 \leq p \leq 0.05$), however after taking Bonferoni into consideration it will not be considered significant

Table 12: Summary of the type of organism causing contamination of tubefeed samples, and the percentage which each organism contributes to the level of contamination

Type of organism causing contamination of tubefeed samples (n= total number of organisms identified)	Method of Production							
	Hand			Machine			Ready to hang	
	*Sample A (n= 27)	♣Sample B (n=118)	♦Sample C (n= 127)	*Sample A (n= 79)	♣Sample B (n= 91)	♦Sample C (n=98)	♣ Sample B (n= 42)	♦ Sample C (n= 46)
Citrobacter	18%	17%	16%	-	-	2%	19%	15%
Enterobacter cloacae	4%	7%	10%	-	1%	2%	10%	4%
Non Enterocc GDP Strep	26%	29%	28%	18%	21%	26,5%	19%	22%
Acinetobacter SP	44%	28%	22%	3%	2%	2%	31%	39%
Klebsiella pneumoniae	4%	10%	11%	1%	4%	8%	14%	-
Pseudomonas Spesie	4%	1%	1,5%	49%	42%	25,5%	-	13%
Escherichia coli	-	7%	9%	29%	29%	32%	7%	7%
Enterobacter aerogens	-	1%	2,5%	-	-	-	-	-
Serratia	-	-	-	-	1%	2%	-	-

*- Sample A taken in the tubefeed room after reconstitution, ♣ - Sample B taken at ward level from first bottle by 14h00,
♦ - Sample C taken from last bottle at ward level
Shaded organisms - unacceptable organisms at any level of contamination – not allowed to be present in tubefeeds

Table 13: Type of Organism Found with Cfu/ml > 10^5

Type of organism identified in tubefeed samples	Method of Production							
	Hand			Machine			Ready to hang	
	* Sample A	♣ Sample B	♦ Sample C	* Sample A	♣ Sample B	♦ Sample C	♣ Sample B	♦ Sample C
Citrobacter	-	-	-	-	-	ΦΦ	-	-
Enterobacter cloacae	-	-	-	-	ΦΦ	-	-	-
Non Enterocc GDP Strep	-	-	-	-	-	-	-	-
Acinetobacter SP	-	-	-	-	ΦΦ	-	-	-
Klebsiella pneumoniae	-	ΦΦ	-	-	-	-	-	-
Pseudomonas Spesie	-	ΦΦ	-	-	-	-	-	-
Escherichia coli	-	ΦΦ	-	-	ΦΦ	-	-	-
Enterobacter aerogens	-	ΦΦ	-	-	-	-	-	--
Serratia	-	-	-	-	ΦΦ	-	-	-

ΦΦ - Cfu/ml > 100 000

* - Sample A taken in the tubefeed room after reconstitution, ♣ - Sample B taken at ward level from first bottle by 14h00,

♦ - Sample C taken from last bottle at ward level

Shaded organisms - unacceptable organisms at any level of contamination - not allowed to be present in tubefeeds

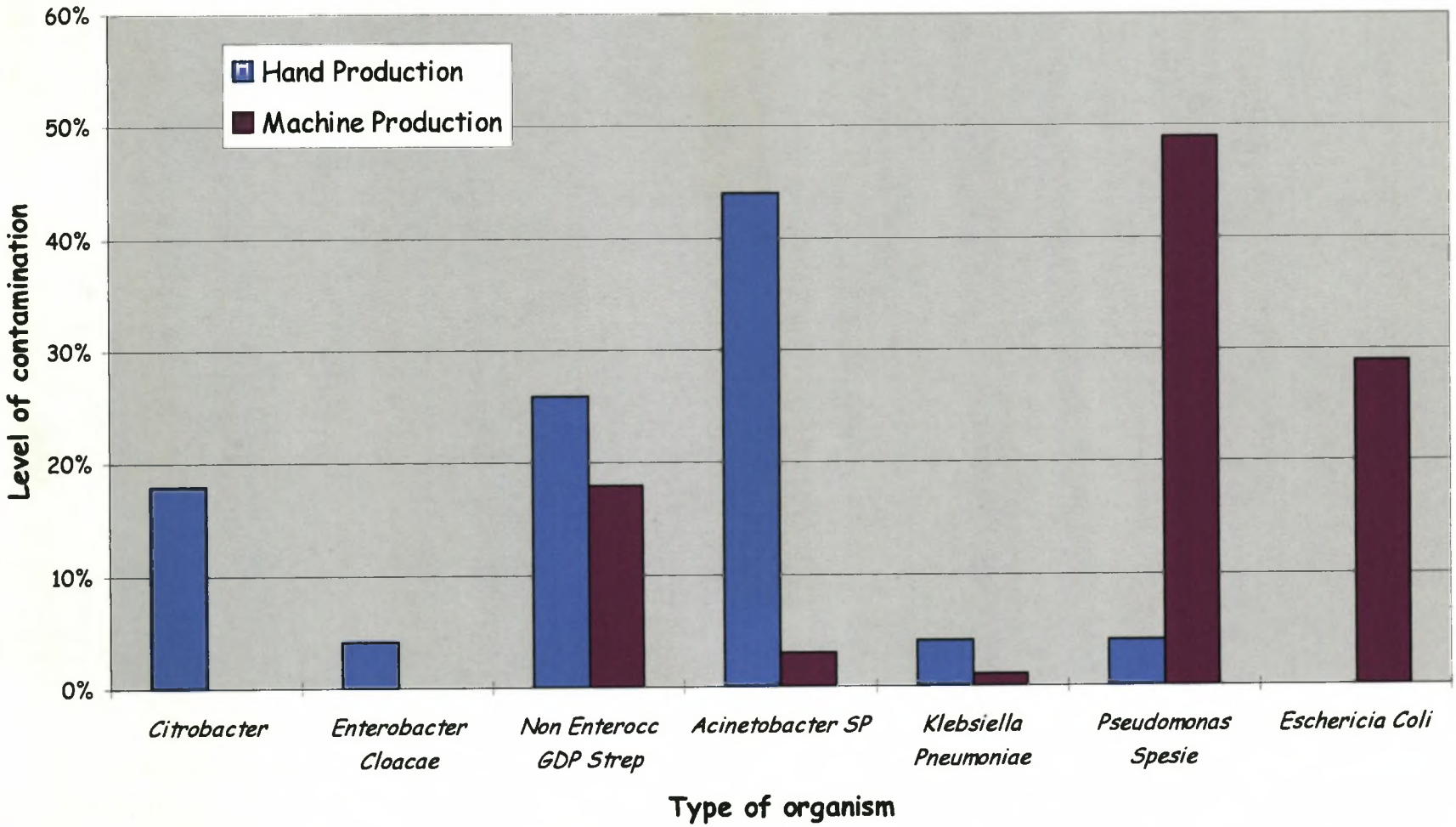


Figure 15: Level of contamination (%) and type of organism causing contamination - Sample A
(taken in the tubefeed room after reconstitution)

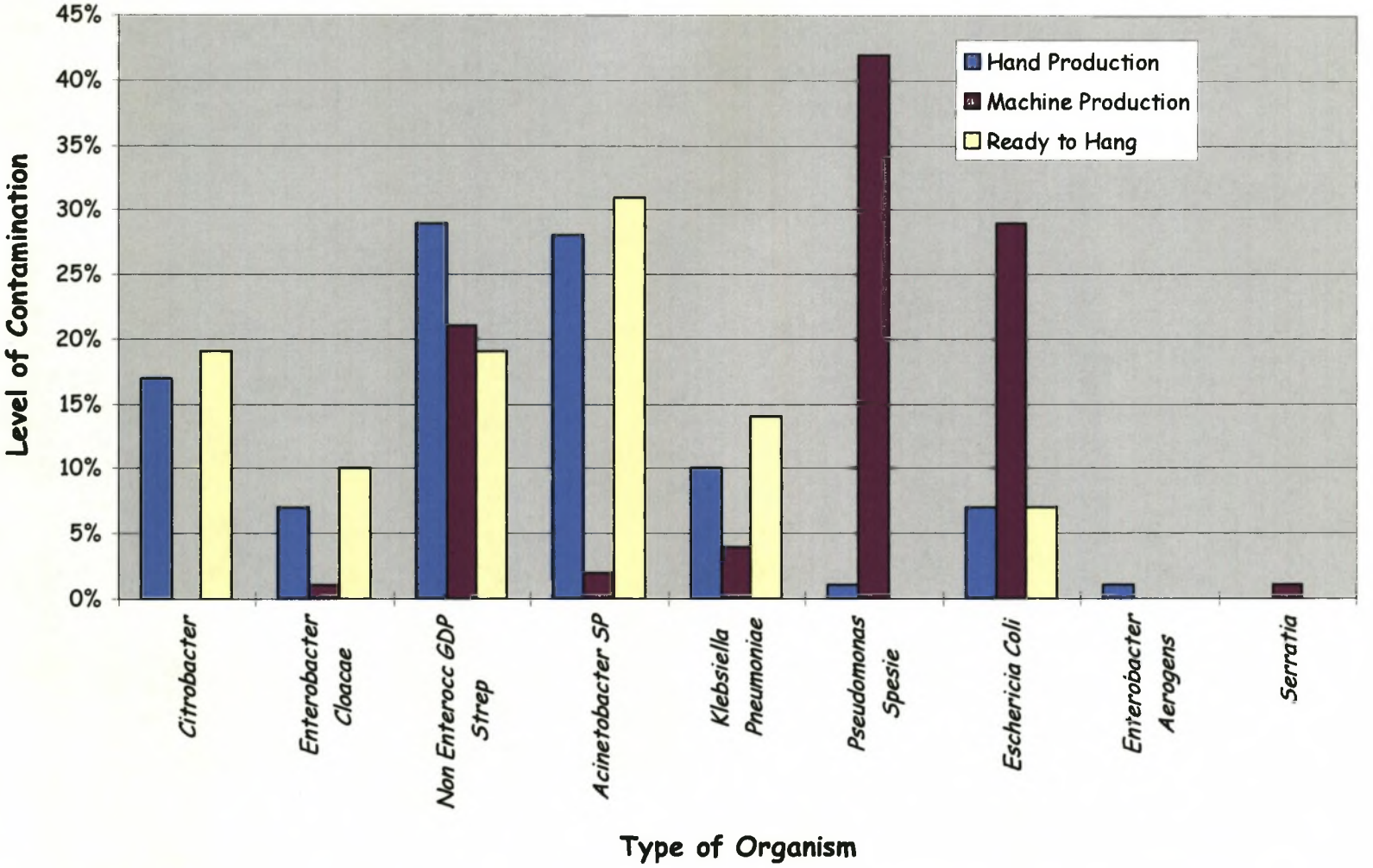


Figure 16: Level of contamination (%) and type of organism causing contamination - Sample B

(Sample B taken at ward level from first bottle by 14h00)

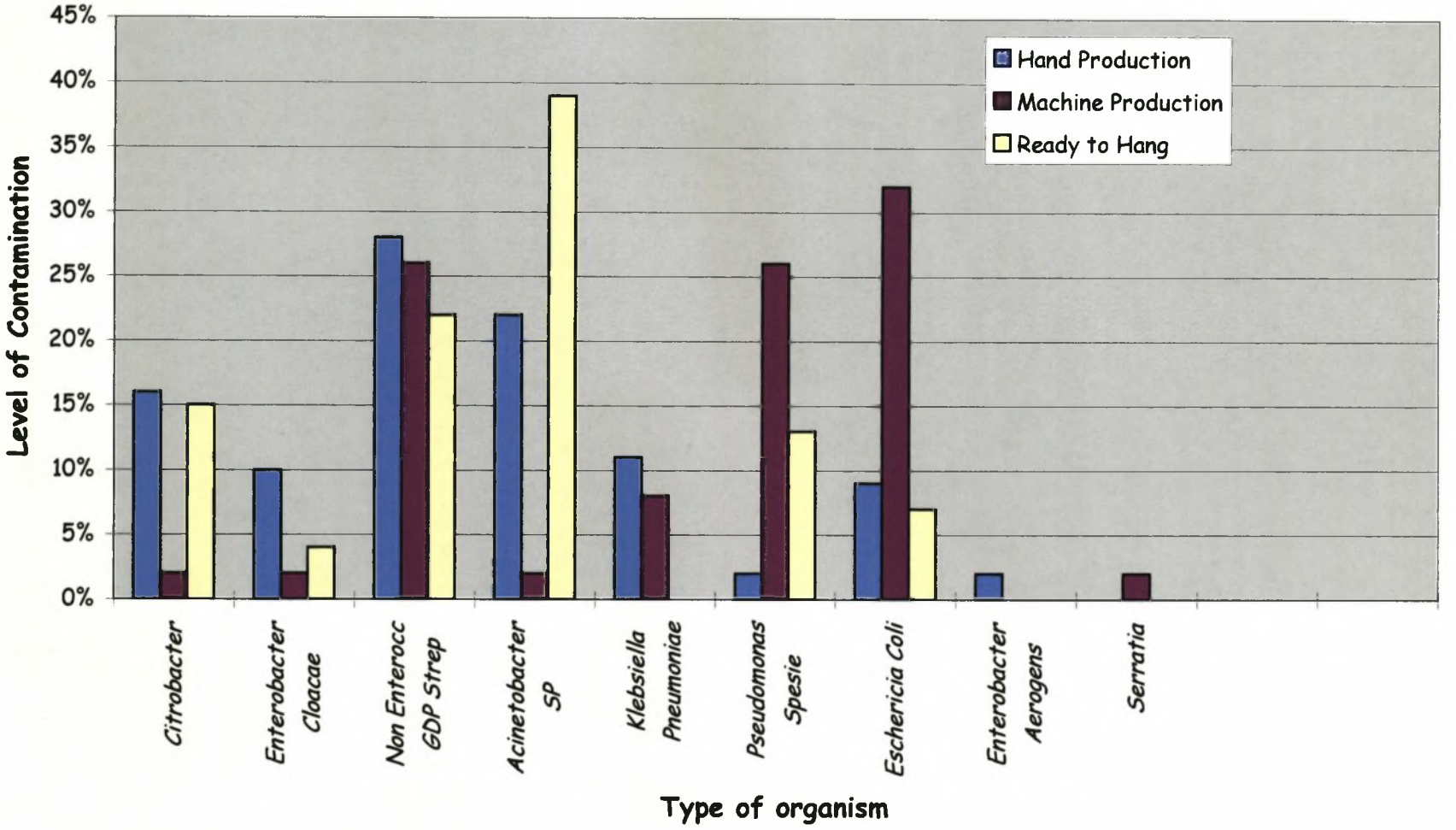


Figure 17: Level of contamination (%) and type of organism causing contamination - Sample C
(taken from last bottle at ward level)

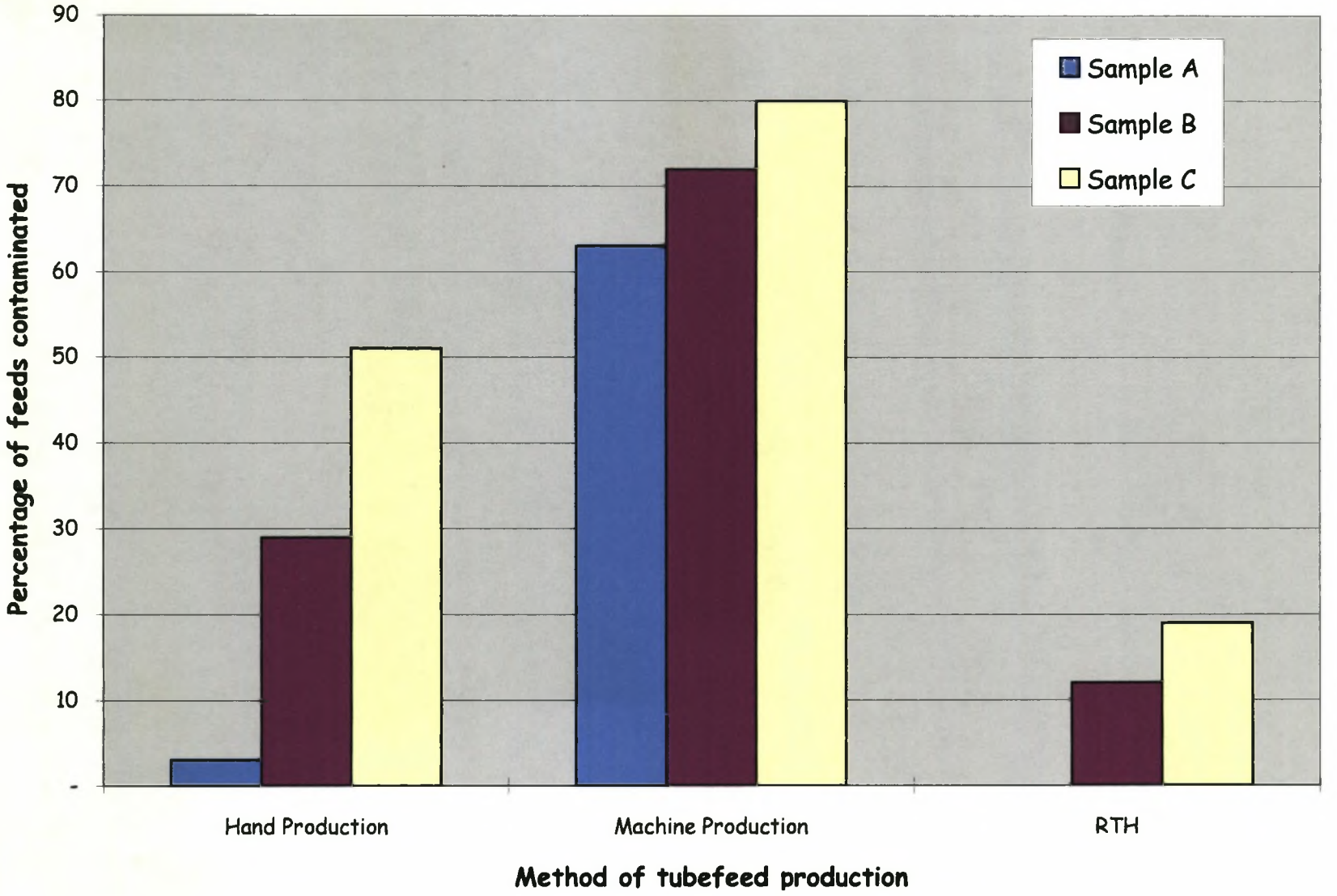


Figure 18: Percentage of feeds contaminated with organisms not permitted

(Sample A taken in the tubefeed room after reconstitution, Sample B taken at ward level from first bottle by 14h00, Sample C taken from last bottle at ward level)

COMPARISON OF COST OF DIFFERENT METHODS OF PRODUCTION

Costs were determined using tender prices for the period 1 December 2000 - 30 November 2001. (Tables 14, 15, and 16 and Figures 19 and 20) Costs have been expressed in a number of ways namely, administration costs (Table 14), daily production cost of feeds (using an average of 60L produced per day) (Table 15), and cost of production of a 2000ml standard feed (Table 16). The following variables were used to determine the total cost of tubefeed production:

- Cost of feed production

  This included the cost of enteral feed powder or enteral feed liquid (RTH), and the cost of cleaning products. The cost of electricity and water were not included as discussed earlier.

- Cost of staff salaries

  This was determined by taking the yearly salary earned per staff member, and then determining how much each staff member would earn per day

The cost of feed administration was determined by taking the cost of administration sets and feeding tubes into consideration. This was not included in the cost comparison calculation as this variable was the same for all production methods (Table 14). The cost of producing the machine was not taken into consideration when these calculations were made. (Addendum 15)

Table 14: Cost of tubefeed administration per day

	Hand Method	Machine	Ready to Hang
Feed Administration			
Pump set (ICU) - (each) changed daily	R27-88	R27-88	R27-88
Gravitation Set (each) changed daily	R19-73	R19-73	R19-73
Feeding tube (each)	R9-12	R9-12	R9-12
Total	R28-85 - R37-00 / patient **		

** Cost varies - depends on which administration set is used, R28-85 (gravitation set and feeding tube), R37-00 (pump set and feeding tube)

COST OF TUBEFEED PRODUCTION PER DAY

Results were expressed as total cost per day, and total cost per month for each method of production. The present method of production, namely hand production (HP), was used as a baseline and the cost of MP and RTH were compared to this. These comparisons are found under the sections difference / month and difference / year. Figures with a minus sign (-) in front of them indicate a saving when compared to HP, and those with a plus sign (+) indicate a value in excess of the cost of HP. MP and RTH are also expressed as a % of the cost of HP with the cost of HP equal to 100%. All costs presented do not take the production of supplementary feeds into consideration. MP requires fewer tubefeed room staff than HP. With MP it is possible for the tubefeed room to function effectively with 3 full time staff members rather than the four required for HP, and this is where the greatest difference in production costs are found. Proposed revised working hours were determined for MP and these can be found in Addendum 13. Ready to

Hang products cost 52% more than the cost of HP feeds, which is an increased cost of R13291-20 per month and R159494-40 per year. It was also found that MP would result in a 10% reduction in the yearly cost of tubefeed production when compared to HP, which is a monthly saving of R 2422-25 and a yearly reduction of R 29067-00. It was found that the provision of MP feeds cost 60% of the cost of providing RTH feeds (Table 15).

COST OF TUBEFEED PRODUCTION PER 2000ML FEED

When the cost of providing a 2000ml standard feed was compared, it was found that MP tubefeeds cost 90% of the cost of HP feeds and RTH tubefeeds cost 52% more than HP feeds. HP feeds cost R28-23 per 2000ml tubefeed whereas MP cost R24-54. RTH feeds cost R42-96 per 2000ml feed (Figure 19). These costs exclude the cost of administration, which is the same for each method of production. The present method of production, namely hand production, was used as a baseline (100%) and the costs of MP and RTH were compared to this, and were expressed as a percentage of the cost of HP. These comparisons are found under the heading of difference per feed when compared to HP, and % of cost of hand produced feeds. Figures with a minus sign (-) in front of them indicate a saving when compared to HP, and those with a plus sign (+) indicate a value in excess of the cost of HP (Table 16).

Table 15: Cost of tubefeed production per day *

(using tender prices 1 December 2000 - 30th November 2001)
Daily price determined using an average of 60L of tubefeed product per day

	Hand production	Machine production	Ready to Hang
Feed Production			
Enteral feed (powder)	R489-02 / day	R489-02 / day	-
Enteral feed (RTH liquid)	-	-	R1288-80 / day
Cleaning products	R266-49 / month R8-88 / day	R266-49 / month R8-88 / day	-
Sub total	R497-90	R497-90	R1288-80 / day

Staff salaries			
AA 1	R75-48 / day	R75-48 / day	-
AA 3	R161-48 / day (for 2 staff members)	R80-74 / day	-
Supervisor	R110-90 / day	R110-90 / day	-
Sub total	R347-86 / day	R267-12 / day	-

Total cost per day	R845-76	R765-02	R1288-80
Total cost per month	R25372-80	R22950-60	R38664-00
Difference / month	-	**- R2422-25$^{\alpha}$**	**+ R13291-20$^{\beta}$**
Difference / year	-	**- R29067-00$^{\alpha}$**	**+R159494-40$^{\beta}$**
% of cost of hand production	100%	**90%**	**152%**

Cost excludes the cost of running the tubefeed room for production of supplementary feeds
α - minus sign (-) indicates a saving when costs are compared to those of HP
β - plus sign (+) indicates a value in excess of the cost of HP

Table 16: Cost of tubefeed production per 2000ml feed

(60L produced per day)

	Hand Method	Machine	Ready to Hang
Feed Production			
Enteral feed (powder)	R16-33	R16-33	-
Enteral feed (RTH liquid)	-	-	R42-96
Cleaning products	R00-30	R00-30	-
Sub total	R16-63	R16-63	R42-96
Staff salaries			
AA 1	R2-52	R2-52	-
AA 3 (x2)	R5-38	R2-69	-
Supervisor	R3-70	R3-70	-
Sub total	R11-60	R8-91	-
Total cost of a standard 2000ml feed / day (excluding cost of administration sets)	R28-23	R25-54	R42-96
Difference per feed when compared to HP	-	**- R2-69$^{\alpha}$**	**+R14-73 $^{\beta}$**
% of cost of hand produced feed	**100%**	**90%**	**152%**

α - minus sign (-) indicates a saving when costs are compared to those of HP

β - plus sign (+) indicates a value in excess of the cost of HP

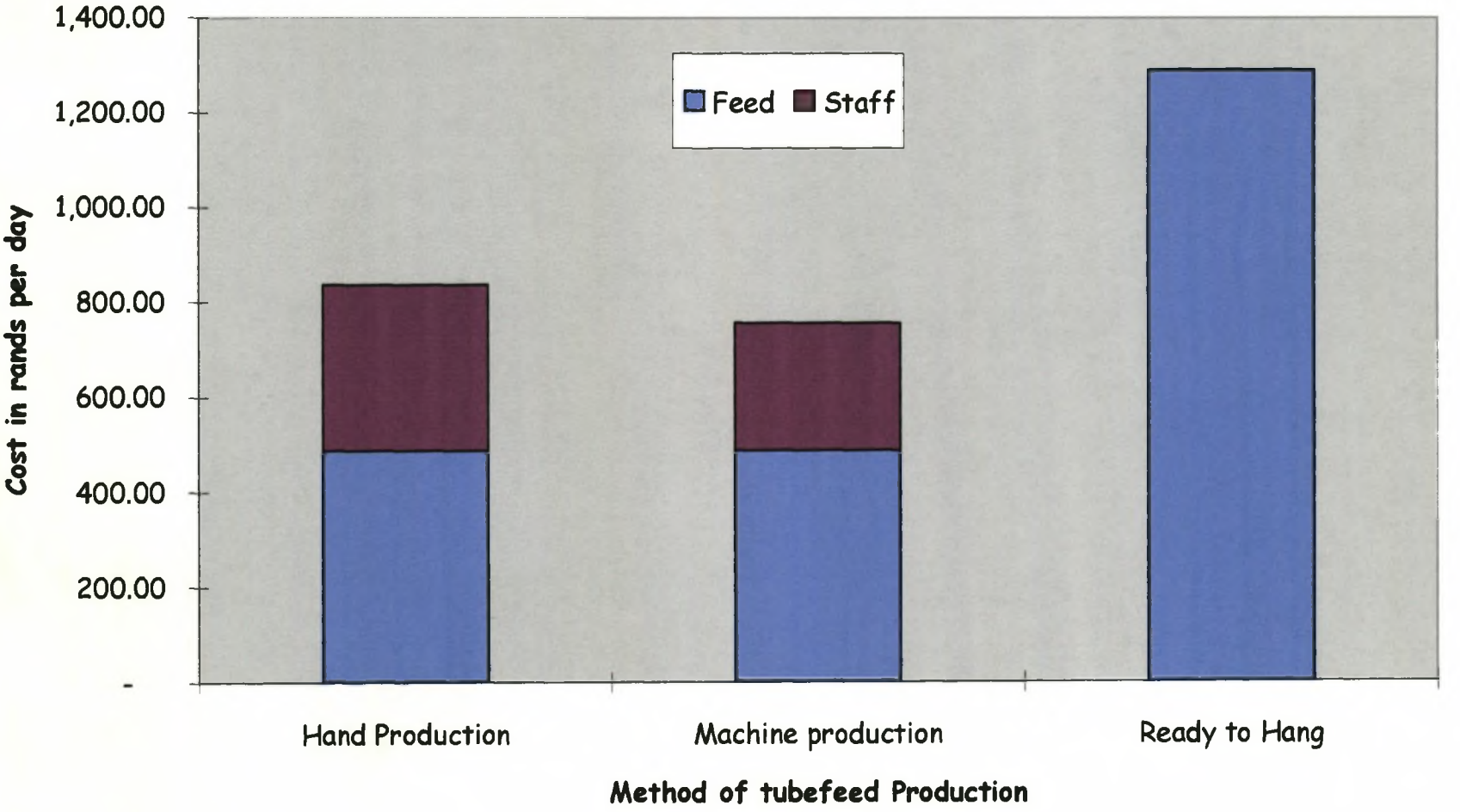


Figure 19: Daily cost of provision of tubefeeds

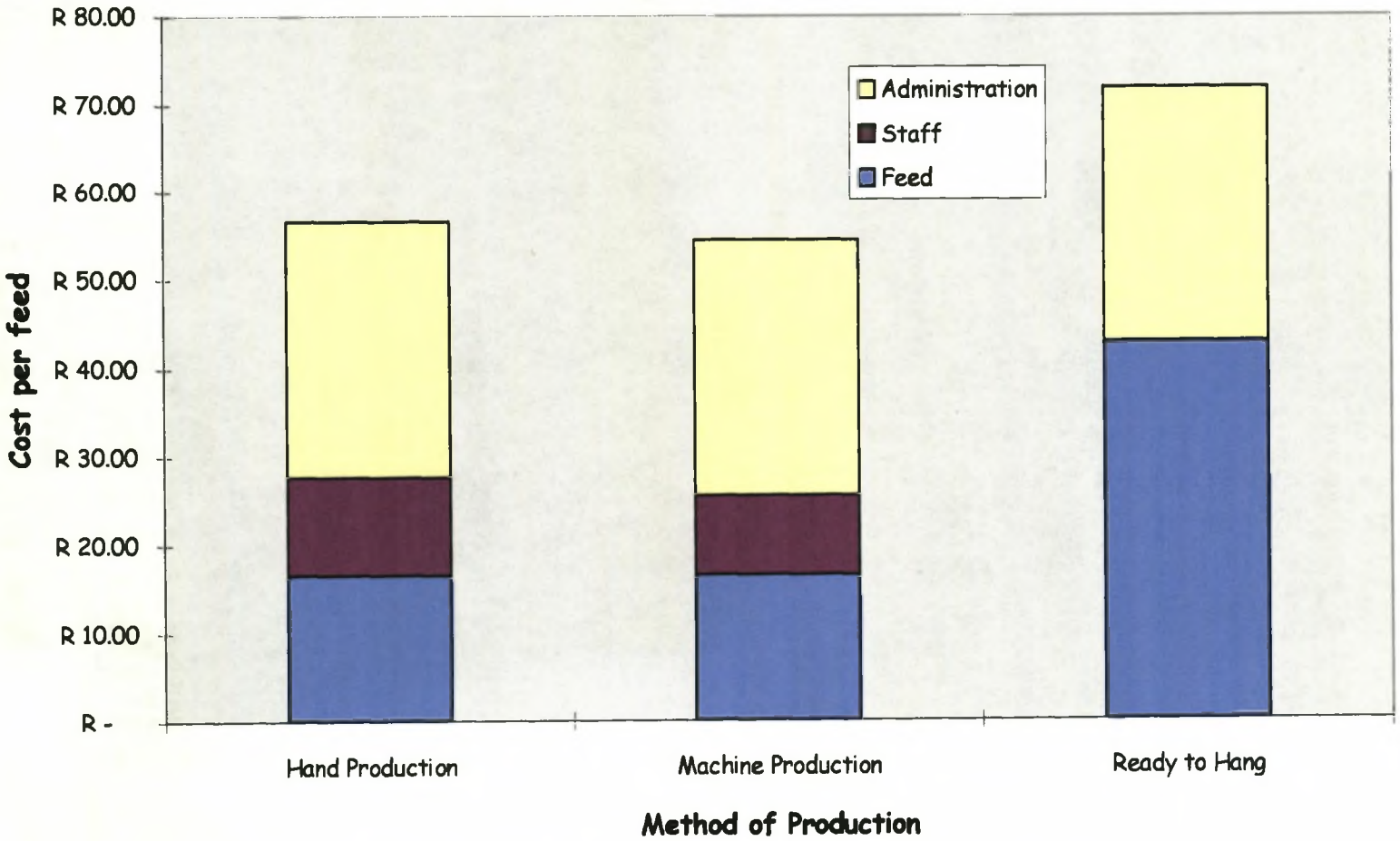


Figure 20: Cost of producing a standard 2000ml tubefeed

CHAPTER 5
DISCUSSION

TUBEFEED SAMPLE DISTRIBUTION

Total enteral nutrition (TEN) is the preferred method of feeding patients who are unable to ingest adequate nutrients by mouth, but who have a functioning gastrointestinal tract (GIT) e.g. coma, head and neck malignancies, GIT dysfunction.[5] Tubefed patients are common in intensive care units. It is to be expected that the majority of samples, which were included in this study, would be collected from these types of wards. In this study tubefeed samples of all production methods were found to be randomly distributed throughout the wards of Tygerberg Academic Hospital, with most samples of feeds coming from ICU's and wards specialising in head and neck surgery or trauma to the GIT. The highest percentage of samples in all production methods came from A4 - a neurology ICU and general ward. This ward also has a large number of comatose patients at all times. The specialised wards and ICU wards e.g. A1 - surgical ICU, A2 - cardiothoracic surgery and A5E - respiratory ICU, also had a higher percentage of samples, which is representative of the more specialised type of patient found in these wards. Other wards which also are generally found to have a large number of patients fed using TEN, such as ward D10 - trauma surgical ward, and G5 - an ENT ward with a lot of laryngectomy patients, were also well represented in the samples tested.

WEEK VS WEEKEND

Samples were collected as indicated in the methodology chapter. It was therefore expected that most samples tested would have been collected on weekdays. This was clearly found. Any differences in microbiology results will be commented on in detail later in the discussion.

TUBEFEED PRODUCTION DATA

The development of an efficient, reliable and microbiologically safe method for preparing large quantities of enteral feeds was one of the main aims of this study. Up till this time there has only been one attempt to produce commercial equipment specifically designed for bulk compounding of enteral solutions. Fagerman et al. made a 60L tank, mixer and transfer pump system which was found to decrease preparation time and increase the efficiency of preparation of 1 L bags of elemental diet. A significant time saving of 56% over individual blender preparation was also found.[1] The microbiological safety of products produced was not investigated.

The reconstitution and decanting of hand produced enteral feeds is very labour intensive, and at the time of this study, four full time employees were required to run the tubefeed room. They work shifts and are on weekend duties twice a month, taking days off in the week. There are therefore at times only three staff members on duty. Their tasks at this time also included the making of supplementary drinks, the washing of all bottles used for enteral feeds, and delivery of tubefeeds to wards after production. These functions were not investigated, as they are impractical to determine, and time taken for these was not taken into consideration.

The mechanised process of reconstitution was significantly faster (38 seconds) than the hand method of production (72 seconds), but the decanting process was significantly slower (55 seconds (HP) versus 152 seconds (MP)) (Table 4). This meant that the total mean production time (seconds per litre) of MP was found to be significantly slower (152 seconds) than that of HP (59 seconds). These findings make it difficult to determine which method of production is most effective. The traditional hand method of production requires weighing of the powder for each feed individually, as well as measuring of the volume of water required. This is the

main reason why the mechanised process is faster, as a bulk volume of powder (weighed once) is mixed with a bulk volume of water. Decanting using a jug and funnel is relatively fast as the diameter of the funnel allows a quick flow of feed. This is why the HP method is faster than the MP method, which uses a calibrated pump with a small diameter to measure the exact amount of feed required. Accuracy is, however, compromised when the two methods are compared. The overall average error of HP is significantly higher (61 ml) than that of MP (42ml) (Table 4).

Fagerman et al, after incorporating an overfill of 3 - 5%, had an overall decanting error of within 5%, which was determined on a standard volume of 1000ml.[1] Accuracy of decanting for both HP and MP were far more accurate than this, with HP having an average overall error of 2,6 % and MP one of 2,24%. The total volume decanted for HP and MP was not standard as in the Fagerman study, and varied according to the individual patient requirements. However, when feeds are not provided as prescribed, the need for accuracy during decanting is nullified.

It is also important to take into consideration that only one member of staff is required to both reconstitute and decant all feeds when the MP method is used. This allows other members of staff to make supplementary feeds, other specialised feeds and to fulfil other functions. The HP method looks quicker on paper, but the study did not take into consideration the washing of bowls and other equipment between feeds, and the time wasted moving from area to area whilst feeds are mixed and decanted. It would have been useful to have an indication of true staff preference when comparing different methods of tubefeed production. However this was not one of the aims of this study and it would have entailed a separate study on its own. Practical experience indicates that factors such as washing of bowls and other equipment, and moving around within the tubefeed room adds considerably to overall production time of HP feeds. These factors do not play a

role in MP feeds. The final product produced by the machine can also be used for supplementary feeds, which will also help to decrease the staff workload. The amount of feed wasted varied between different methods of production. A detailed summary of the advantages and disadvantages of each method of tubefeed production can be seen in Table 17.

SOURCE OF TUBEFEED SAMPLES

Feeds are reconstituted and decanted in the tubefeed room and delivered to wards from 12h00. Feeds are placed in refrigerators in ward kitchens when possible or otherwise, in the ward kitchen on the counter closest to the refrigerator. Ward refrigerator space is limited, and at times refrigerators still contain feeds which, for some reason, were not administered the previous day. The researcher had expected to collect all B and C samples from tubefeeds already hanging at ward level. However, this did not happen as planned, as the majority of B HP (68%) and MP (80%) samples collected were taken from feeds that were not hanging by the cut off time of 14h00. The TEN Policy at Tygerberg Academic Hospital recommends that feeds (total volume divided into four bottles) should run over a 24 hour period from 12h00 - 18h00, 18h00 - 24h00, 24h00 - 06h00, and 06h00 - 12h00. Each bottle hangs for a period of 6 hours. All feeds older than 24 hours are to be discarded. This is why a cut off time of 14h00 had been established. Feeds not provided immediately should be stored in the refrigerator. It is then to be expected that any feeds not administered by 14h00 should be kept refrigerated until administration begins. This was not found to be the case and a large number of both HP and MP feeds were stored incorrectly. This factor will be discussed further under the microbiology section. Fagerman et al. found that bacterial growth is virtually arrested at recommended refrigerator temperature (7°C), and due to the logarithmic growth of bacteria at room temperature, the importance of proper refrigeration cannot be overemphasised. [29] The majority of wards in Tygerberg Academic Hospital do not have air conditioning and therefore the

temperature within ward kitchens is very similar to the temperature outside the building. The average temperature outside the hospital during the period of this study exceeded 20°C at all times. (Addendum 16) A large number of tubefeeds were therefore exposed to temperatures in excess of the recommended storage temperature of ≤ 10°C.[12] Poor storage conditions of feeds, prior to administration, must have contributed to the fact that the initial Cfu/ml counts of Sample A rose once the feeds had left the tubefeed room.

C samples should have come from the remainder of the feed in the last bottle or from the refrigerator (when feeds had not been provided for some reason). In most cases this was found to be true. RTH C samples were taken from bottles hanging at ward level. It was worrying to see that so many feeds were completed far quicker than they should have been. At times C samples were collected as early as 09h30 to ensure that adequate feed remained, this however did not prevent twenty two HP, and 10 MP feeds from finishing before C samples could be collected. The TEN Policy at Tygerberg Academic Hospital states that feeds, including those administered using gravity administration sets should be administered over a six-hour period. Flow rate should be controlled to allow this to be possible.

MAIN PROBLEMS ASSOCIATED WITH TUBEFEED DELIVERY

According to the TEN protocol of Tygerberg Academic Hospital, feeds are provided at a specific hourly rate (not exceeding 120ml/hr) over a 24-hour period. Feeds should be provided at ward level as prescribed by the dietitian, with details of total volume, rate of delivery, energy and protein content indicated on the sticker stuck on to each individual bottle. The total volume of the feed to be provided over the 24-hour period is divided into 4 bottles; each hung at ward level for a period of 6 hours. There should have been more than adequate time to collect C samples from the last bottle of feed, which should hang for a period of 6

hours from 06h00. In practice feeds are not always delivered timeously (due to staff shortages, and excessive numbers of new tubefeed patients') and therefore feed administration begins later than the recommended 12h00. It would therefore be expected that, if feeds were provided at the correct volume, feeds would run for a longer period of time the next day. It was not possible to collect C samples for 28% of HP feeds, 16% of MP feeds and 38% of RTH feeds, used for B samples, as feeds were completed prior to the time C samples were to be collected. This indicates that feeds are being provided at a rate, which far exceeds that prescribed by the dietitian. This is worrying as TEN complications such as diarrhoea, can occur when feeds are not administered at the correct rate required for each specific patient. [2] In the ICU situation all feeds are provided using a pump which should ensure that feeds are delivered at the correct volume. However, the majority of feeds in general wards are administered using the gravity feeding set (due to financial constraints and lack of pumps), feeds can therefore not be delivered as accurately. If the flow rate is monitored there should be no reason why patients receive more than the required volume of feed per hour. This would ensure that feeds run over a period of 24 hours. Close monitoring does not seem to happen at ward level as many feeds were completed far quicker that they should have been, and nursing records were incomplete.

In this study no distinction was made between feeds administered using pump administration sets and those administered using gravity administration sets.

This study identified two main reasons why feeds were not correctly delivered namely:

a) Administration errors

TEN protocols are not being implemented correctly, less than 45% of feeds identified in this study were provided correctly.

b) Problems with patients

These include GIT problems and do play a big role, and this is to be expected as patients who receive TEN generally have more complications than those who are fed orally.

Patient problems, however, are not generally factors that can be avoided, and therefore wastage in these situations is inevitable. Feed administration problems are a different matter, as these should be able to be avoided if the TEN protocols are adhered to. TEN protocols exist to prevent TEN complications such as tube blockages from occurring. Wastage due to these reasons is preventable in the majority of cases. The RTH samples were not collected in the same way and HP and MP. The B sample was taken from the first bottle provided to the patient and the C sample was to be taken from the bottle hanging at the patient's bedside the following morning. In 38% of cases the bottle at the bedside was either empty or not yet connected. C samples were not collected from bottles opened at this time as they would not have been connected to the giving set for any period of time. In these cases only B samples were evaluated.

At times researchers would return slightly later to see whether administration of the last bottle of feed had begun, and in these cases C samples were collected.

MICROBIOLOGICAL SAFETY OF TUBEFEED PRODUCTION METHODS

Please take into consideration that the results discussed below are not a true reflection of the safety of the mechanised process (as discussed previously in the result section).

Enteral feeding solutions represent an ideal medium for the growth of various microorganisms, and several of them have been isolated in previous studies: *Escherichia coli, Klebsiella sp, Proteus sp, Salmonella enteritidis, Pseudomonas*

aeruginosa, Bacillus cereus, Staphylococcus aureus, and yeasts.[23,37] Studies have shown that both handling procedures and the design of enteral feeding systems are important in limiting the risk of microbial contamination.[21] The more the system is manipulated during preparation and delivery, the higher the rate of contamination. The contamination rate of TEN has been found to be as high as 61%.[16] Contamination of enteral feeds may originate from inadequately cleaned and disinfected equipment, utensils, and surfaces used during formula preparation, ingredients or other supplements used in the preparation or modification of the formula; improper conditions of storage and transportation; inadequate hygiene of the handlers; or the improper use of administration sets.[37] The risk of microbial contamination of enteral feeds is related to the type and number of manipulations of the feeds and feeding systems between preparation of the feed and the end of administration. [21] Microorganisms can multiply rapidly in most enteral feeds and studies have shown that even one bacterial cell in the nutrient container can multiply to yield 10 000 organisms/ml in the patient within 16 hours.[34] According to Anderton et al., a non-sterile feed is contaminated at the start of administration and should have a bacterial count of $< 10^2$ cfu/ml (< 10 microorganisms / mL is ideal) prior to administration beginning. This will prevent microbial numbers in the nutrient containers from exceeding $10^3 ml^{-1}$ at the end of administration.[12] The US Centres for Disease Control and Prevention cite a count of 10^5 micro-organism / ml as a threshold for food-borne disease outbreaks. A number of adverse clinical outcomes have been linked with specific threshold counts.

Anderson et al., found that the incidence of diarrhoea, in tube-fed hospitalised patients receiving a feeding solution with a microbial count less than 10^5 cfu /ml, was significantly less than when compared to a solution where the microbial count was greater than 10^5 cfu /ml. [38] In another study, an outbreak of infectious enterocolitis in an intensive care unit was found to be associated with feeds contaminated with 10^5 - 10^6 cfu/ml. [21]

TUBEFEED ROOM - A SAMPLES

Results from the present study found unacceptable levels (using guidelines from Anderton et al.) of organisms in HP feeds and MP feeds immediately after preparation (sample A). When the guidelines of the US Centres for Disease control and Prevention are used as a bench mark, all HP and MP A samples, which were contaminated, had acceptable cfu/ml counts. Many studies have documented the fact that enteral feeds can contain bacteria including *Enterobacter spp., Klebsiella spp., E. coli., S. enteritidis, Ps. aeruginosa, Staphylococcus spp.,* and *Bacillus spp.,* before leaving the preparation area.[21] The results of this study are therefore not unexpected, what is however disturbing, is the number of feeds which contained greater than recommended levels of organisms immediately after reconstitution and decanting.

In the case of MP feeds substandard disinfectant solutions were later found to be the main reason why such a high rate of contamination was experienced. Previous studies have found that mixers, blenders, plastic jugs, sink surfaces, work surfaces, dish cloths and detergent dispensers can be reservoirs of gram negative bacilli in both hospital and domestic kitchens. [14,22] It is therefore understandable that substandard disinfectants could result in enteral feeds becoming more easily contaminated with these organisms. Anderton & Aidoo [26] found that inadequate cleaning and disinfecting of blenders played an important role in enteral feed contamination. Blenders were experimentally contaminated with feed containing either 10^2 or 10^5 cfu *K. aerogenes* / ml, and were rinsed with water and/ or immersed in hypochlorite solution (125ppm available chlorine). The residual organisms provided an innoculum, for the sterile feed used to refill the blender, giving counts $\leq 10^3$ cfu /ml immediately after refilling with sterile feed. They suggest that only blenders, which can be dismantled and autoclaved, should be used.

The HP method of feed production does not use a blender, however plastic jugs are used to decant feeds, and metal bowls are simply rinsed between mixing feeds. Inadequate cleaning and disinfecting could therefore have led to contamination in this case. In the case of MP feeds (when substandard disinfectant was available), the machine does use a blade to reconstitute the feed, however, it is easy to get to and can be cleaned well without a problem. If correct cleaning procedures are adhered to, the blade should not increase the risk of feeds becoming contaminated. The final number of bacteria delivered to the patient during administration of enteral feeds depends on the size of the initial inoculum and the amount of time the product is held at room temperature.[29] Enteral feeds need to be kept at adequate temperatures in order to keep growth of organisms within reasonable limits.

A study by Bastow et al found counts ranging from 10^2 to 10^3 cfu/ml just after feed preparation and from 10^8 to 10^9 cfu/ml after 24 hour exposure to room temperature.[36] Other studies have demonstrated that bacterial growth in enteral feeds is exponential at room temperature.[29] Closed system containers are regarded as the safest way to deliver non-contaminated feeds to patients. RTH diets supplied in cans (which still require pouring out) are also considered safe if properly handled. [37]

WARD LEVEL - B SAMPLES

When the microbiological results of all B samples were analysed, RTH samples, as expected, were far less contaminated than both HP and MP samples. However, the levels of contamination were found to greatly exceed recommendations (Anderton et al.), and feeds were contaminated with organisms which should not be permitted at any level (Anderton et al.). When the guidelines for the US Centres for Disease control and Prevention are used as a bench mark, a few MP and HP B samples were

found to have cfu/ml counts exceeding those recommended, however these results did not differ significantly.

These results indicate that sterile feeds can easily become contaminated very quickly if not correctly handled at ward level. Previous studies have shown that "closed" feeding systems, where the feeding solution comes pre-packaged in ready-to-use bags or bottles with or without attached administration sets, are less likely to become contaminated when compared to traditional methods of reconstitution.[16] Wager et al. compared (in an intensive-care unit) a closed system, an open system using canned formula, and an open system using a powder-based formula that required mixing before administration. Significant contamination occurred with both open systems, whereas the closed system demonstrated a contamination rate of only 2%. [13] In contrast Patchell et al. found that levels of contamination rose to as high as 100% in children given modular feeds at home, and only a slight advantage was seen with a ready to hang formula, where 62% of feeds became contaminated.[30] In a study by Dentinger et al., large volume (1500ml), closed system containers with pierceable caps and piercing spikes were studied to determine their ability to reduce the incidence of microbiological contamination due to their design and ability to decrease handling requirements. Feeds were not administered to patients, and contamination was found to be virtually non-detectable. [35]

These results support Donius, who suggested that the disconnection of the gastrostomy tube-formula administration set junction, may be a critical factor in contamination. [24] Kohn-Keeth et al. found that bacterial contamination of delivery sets may be reduced when sterile rather than tap water is used to reconstitute enteral feeds and contamination tends to increase over time.[25] In all three stages of this study normal tap water was used to reconstitute enteral feeds and to clean

all equipment. The microbiological quality of the water was not tested, and it could therefore have played a role in contamination of feeds.

WARD LEVEL - C SAMPLES

By the time C samples were tested there was a very small difference (not significant) between the number of C samples contaminated (using Anderton et al. as a reference) when all three production methods were compared. HP feeds were initially far less contaminated than MP feeds, but by the time C samples were collected the number of samples contaminated with greater than 10^2 cfu/ml was almost the same. This may be because the plato phase of logarithmic bacterial growth was reached by the time C samples were collected, resulting in similar organism counts.

It is not easy to explain the different results obtained when samples taken during the week were compared to those taken during the weekend. When one looks at the average levels of contamination, it seems that all production methods follow the same trend with A and B samples being least contaminated and C samples being most contaminated. However, when one looks at the results obtained for week one, separately from those obtained during week two, a different picture is obtained. B and C HP samples taken in week one were found to be equally contaminated, and reasons for this are unclear, as B samples were equally distributed between the ward kitchen, the ward refrigerator, and those being administered to the patient. The majority of C samples (84%) were obtained from enteral feeds being administered to the patient, one would have expected C samples to be more contaminated than B samples, due to a longer time having elapsed since production, however, this was not found. Week one and weekend MP samples followed the expected trend, however, all week two A, B, and C samples were contaminated. This is most probably due to cross contamination from contaminated bottles, which may not have been washed effectively during the weekend, and the substandard

hypochlorite solution which was being used as a disinfectant during this time period. This may have resulted in cross contamination from the bottle to the newly decanted feed. The excessively high levels of contamination during week two caused the average level of contamination for MP production to be far higher than it would have been. One could have expected it to be very similar to that of Hand production, as week one and weekend results obtained compared very favourably to HP results. Contamination of week one and weekend RTH feeds was unusual. In week one B samples were found to be slightly more contaminated than C samples, however, this is not statistically significant. These samples from week one are however less contaminated than those from week two. Weekend samples followed the same trend as HP and MP samples with B samples being far less contaminated than C samples. However, B RTH weekend samples were found to be far less contaminated than week one and week two B samples, and C RTH weekend samples were far more contaminated than week one and week two C samples. Possible reasons for this may be the fact that giving sets were not always replaced as recommended and as stated in the TBH TEN protocol. This was despite the fact that new giving sets were provided on a daily basis with any RTH bottles sent to wards. Giving sets may have become colonised with bacteria from contaminated feeds resulting in the new bottle (from which C samples are collected) becoming contaminated. Reasons for this variation in results are not clear, but the literature has found that incorrect handling techniques of sterile RTH feeds can cause contamination levels similar to those found in this study. [30]

TYPE OF ORGANISM CAUSING CONTAMINATION

The organisms identified in this study have all previously been identified in studies as contaminants of enteral feeds.[12,14,20,23] Gram Negative Bacteria identified included: *Escherichia coli, Klebsiella pneumoniae, Enterobacter cloacae* and *aerogens, Serratia, Citrobacter, Pseudomonas Sp.* and *Acinetobacter Sp.* The coliform group includes well-established pathogens such as *Salmonella spp.,*

emerging pathogens of global significance (*E coli*), and opportunistic pathogens such as *Klebsiella and Citrobacter* species.[32] Coliform organisms are organisms which are normally found in the gastrointestinal tract, specifically the colon area. The following organisms are classified as coliforms: *Escherichia coli* (specific indicator of faecal contamination), *Klebsiella pneumoniae* (respiratory pathogen), *Enterobacter cloacae* and *Enterobacter aerogens, Serratia*, and *Citrobacter*. They are usually harmless in their normal habitat, but can become pathogenic if they come into contact with tissues outside the GIT.[12,38] It is possible for coliforms to migrate into the body through an intestinal wall damaged by radiation, chemotherapy, or surgery.[38] *Enterobacter* and *Serratia* are also found free living in soil and water. The presence of these coliform organisms is undesirable and is usually indicative of poor hygiene standards during enteral feed preparation.[12] *Pseudomonas Sp.* and *Acinetobacter Sp.* are free living, wide-spread bacteria and are found on the skin, in water and in other moist areas e.g. soil. Only one gram positive bacteria was identified, namely *Non enterococc GDP Strep.* This is an opportunistic bacterium normally found in the gut and can be pathogenic if it comes into contact with tissues outside the GIT. The presence of these organisms indicates faecal contamination or poor hygiene standards. Patchell et al. found viable counts of up to 10^8 cfu/ml organisms in sterile ready to hang and modular enteral feeds in both the hospital and home setting. They identified commonly isolated organisms such as coagulase negative *Staphylococci*, *Streptococci (faecal and viridans*), and Gram negative bacilli.

Most organisms identified in this study are gram negative bacteria of faecal origin, suggesting that inadequate hand washing techniques within the tubefeed room and at ward level may have played a role in contamination of enteral feeds. An observation of hand washing at ward level showed that hand washing was not done at all before setting up the RTH enteral feeding system. Hand washing practices were not monitored specifically when HP and MP samples were collected. However,

one can assume that nursing staff would behave in the same way. In a number of instances, RTH feeds were hung immediately after nursing staff had washed patients, without hands being washed between procedures. It was also noted that administration sets were not always changed according to protocol, and at times when bottles were being exchanged administration sets came into contact with surfaces which had not been disinfected. In general from observations (made by the researcher whilst collecting data - this was not officially recorded or documented) made during data collections, it was noted that in most cases enteral feeds where administered without any specific hygiene protocols being adhered to. Previous studies have shown that hands are a major source of contamination, because of poor hand washing techniques. [26]

The staff in the tubefeed room, however, are very aware of the importance of hand washing, and hands are washed prior to staff entering the working area of the tubefeed room. In this instance poor hand washing techniques may play a role, however staff, when preparing feeds using HP, are constantly busy with their hands in the chlorine solution whilst rinsing feed administration bottles and equipment used for reconstitution. Therefore contamination of HP A samples is most likely not due to inadequate hand washing practices. The number and type of microorganism present also affect the action of disinfectants. The concentration of the disinfectant solution, the contact time, the temperature (higher temperature increase the effectiveness) and the presence of protein materials (e.g. enteral feed residue) all affect the activity of disinfectants. Washing of all equipment prior to exposure with a chemical disinfectant will increase its effectiveness. Even the best chemical disinfectants, under the best working conditions will rarely kill 100% of the bacteria present. Where refilling of wet containers continues day after day there will be a carry over of bacteria with increasing resistance to the disinfectant being used. [12]

The enteral feeding administration bottles used at Tygerberg Academic Hospital are made from glass and are reused after washing and disinfecting. Once tubefeeds have been administered, the administration bottles are supposed to be washed at ward level prior to being returned to the tubefeed room. This does not always take place, so it is possible that feed residues remain before bottles are washed in the tubefeed room. In the tubefeed room bottles are washed by hand using a soap solution and bottle brushes, this ensures that all feed residues are removed. They are then rinsed in a hypochlorite solution. The bottles are, however, not dry inside when reconstituted feeds are decanted into them. This may be a source of microbiological contamination, as the bottle may have had a high innoculum of bacteria, due to incorrect washing at ward level, which may not have been 100% killed by the chlorine solution. The carry over of bacteria from the water remaining in the bottle (bottles are not dried before being filled) could have been the cause of the majority of contamination of all HP and MP A samples. Therefore it is possible that enteral feeds which become contaminated at ward level, result in the re-contamination of enteral feeds produced the following day. Anderton et al., noted that micro-organism may survive and multiply in the film of water retained after food preparation equipment is cleaned. If the film is dried, many, but not all, of the microorganisms will be inhibited.

The number of organism will depend on a number of factors, which include the type of organism, the composition of the dried film and the rate of drying. The more rapidly and thoroughly the surfaces are dried after cleaning, the fewer organism will remain. It is suggested that any food preparation equipment, which remains wet for longer than four hours following cleaning, should be re-cleaned, disinfected and thoroughly rinsed prior to it being used again.[12] The bottle opener and feed bottle are other known sources of contamination, and studies have shown that disinfecting of the bottle opener and feed container can eliminate feed contamination.[30]

As mentioned previously all enteral feeds reconstituted in this study were done so by using normal tap water. The quality of water used to reconstitute the feeds is also important as gram negative bacteria, which may be present in water, may contaminate feeds, therefore it is suggested that sterile or boiled water is used. [32] The microbiological safety of the water was not tested during the study period and therefore the possibility that the tap water could have could have been contaminated with *Acinetobacter Sp.* cannot be excluded. In a number of HP and MP samples new organisms were identified in B and C samples which had not previously been found in A samples. This indicates that contamination of these samples must have occurred at ward level, due to incorrect handling procedures. In the case of the HP samples *Escherichia coli* and *Enterobacter aerogens* were identified in both B and C samples, but not any A samples, indicating contamination at ward level. In MP samples, *Enterobacter Cloacae, Serratia and Citrobacter* were found in B and C samples but not in A samples.

These results would seem to indicate that the tubefeed room is the main source of contaminants, however, RTH feeds, which had no contact with the tubefeed room, were also contaminated with all organisms mentioned, with the exception of *Pseudomonas Sp.* and *Enterobacter aerogens*. This indicates that contamination may have occurred when bottles were being opened and whilst administration sets were being attached, due to poor hand hygiene. It is therefore possible that the wards are the main source of organisms, which contaminate the feeds at ward level but only cause contamination of feeds produced in the future due to bacterial multiplication in dirty bottles, which are not destroyed by disinfecting and washing procedures. Skin contaminants from touch are also not uncommon considering the steps required to administer feeds.

A study by Lee et al. found that it is possible to set up systems, which administer contaminant -free feeds even when using hands with a high bacterial load if meticulous attention is given to avoid hand contact with any potential routes of bacterial entry. They highlight the importance of hygiene and handling procedures when assembling delivery systems since patients can only receive contaminated feeds if microbes are able to invade the reservoir during the assembly process. It was also found that wearing new non-sterile surgical gloves during the assembly of feeding systems could achieve the delivery of a feed free of contamination, if correct handling procedures were followed. [27]

Microbial quality of enteral feeds can be improved if certain measures are taken, these include the development of protocols for clean techniques in the preparation, handling and storage of feeds and cleaning of preparation equipment. Personnel must adhere to proper administration techniques, including meticulous hand washing and limitations on administration times. [39]

The following variables affected the results of this study:

- the quality of hypochlorite solution used
- the fact that normal tap water was used to reconstitute feeds
- poor storage conditions and incorrect storage temperatures at ward level
- poor nursing techniques and poor hygiene standards at ward level
- handlers were multiple nurses unaware of the purpose of the study.

COST OF TUBEFEED PRODUCTION

When reading this discussion please take into consideration that TBH has an existing tubefeed room with four permanent staff. The TBH situation is therefore different to a hospital where feeds are reconstituted at ward level by professional nursing staff. The use of professional nursing staff to fulfil this function immediately makes the reconstitution of powdered feeds, at ward level, a far more

costly undertaking. In these situations the use of RTH feeds is often found to be more cost effective. [11]

Please note that the cost of producing supplementary feeds was not taken into consideration in this study. The protocol also included taking the cost of electricity and water use into consideration. However, after consulting with TBH engineers, it was found that it was not possible to determine the exact amount of electricity utilised by the tubefeed room, as the tubefeed room does not have a separate meter to record this. The electrician consulted determined that the electricity used to run the tubefeed room is negligible, and that using the machine would not result in a significant increase in total electricity used. It was also not possible to determine the total volume of water used specifically by the tubefeed room, as this is not recorded separately from the total volume used by the hospital. However, a meter was placed within the water pipe leading to the work area of the tubefeed room (Addendum 1) and average daily volumes of water used were obtained. MP used an average of 179 litres of water less per day than HP. This is most probably due to the fact that water is saved whilst using MP, as bowls and other equipment used do not require washing, and during HP taps run constantly. MP does save a small volume of water, however, the cost of it is negligible when looking at the total water bill for TBH. Therefore this cost was not factored into the calculations used to determine the true cost of tubefeed production.

Cost containment is key to survival in today's health care arena. In previous studies, the cost of tube feed formulas, enteral feeding bags, and delivery sets have been the focus of attention. Large volume purchasing has reduced the cost of enteral formula acquisition, but it does little to cut the cost of other contributing factors to the total equation. Labour and waste are less obvious variables, which can be expensive constituents of enteral nutrition. The total cost, inclusive of

labour and waste is often not considered when purchasing decisions are made, but it provides a tremendous opportunity from which to take economic advantage. [11]

Closed system containers and RTH feeds which require pouring out are expensive and this is one of the main reasons why many hospitals still use enteral feeds which require major handling, allowing several opportunities for contamination.[36] Sterile enteral diets have been available as RTH "closed" systems since the mid-1980's. These products are associated with reduced labour costs when compared to the conventional "open" systems. [13] Silkroski et al. found that the cost of wages stood out as a significant and reducible expense of hospital tube feeding programs as the preparation of tubefeeds and their administration used considerable amounts of hospital employee time. They found that where facilities used minimal amounts of powdered and modular feeds that less money was spent on labour than when hospitals relied on mixed or manipulated formulas.[11] Technical advances permit enteral feeding in patients once supported exclusively with TPN, TEN may provide an opportunity for significant reduction in the cost of nutrition therapy. This plays an important role as attention focuses on viable methods to maintain the quality of services while minimising personnel and equipment costs.

The clinical consequences of contaminated enteral feeding may be under appreciated. Any significant clinical infection arising from a contaminated feed may obliterate any therapeutic advantage or cost saving achieved by using that feeding method. Wagner et al. compared a closed system, an open system using canned formula, and an open system using a powder-based formula that required mixing before administration. Preparation time, waste, and contamination were evaluated, in a intensive care unit setting. It was found that both time and waste were significantly higher when using the open systems. Enteral nutrition in the closed system was safely infused for up to 48 hours and was associated with reduced labour and contamination. In one institution, using a closed enteral feeding

system resulted in an annual cost saving of $23 000 - $ 35 000.[13] Moffitt et al. found that a potential cost saving of between $67 and $ 135 per month could be achieved, by increasing hanging times up till 36 hours (by using a reservoir with an appropriate size). This did not result in increased bacterial contamination. [34]

These savings were not found in this study, in contrast it was found that RTH feeds were far more expensive than powdered feeds, which require reconstitution. This is perhaps due to the high purchase price of RTH feeds which are not presently produced in South Africa and which need to be imported from America and Europe. The present administration system used in Tygerberg Academic Hospital reuses glass IV bottles (from IV's given at ward level) and therefore the cost of enteral feeding bags is excluded. This results in considerable cost savings and is one of the reasons why the cost of HP and MP feeds is so much less than that of RTH.

The TEN protocol used at Tygerberg Academic Hospital allows for the same type of giving set to be used for both HP and RTH feeds, therefore the cost of administering these feeds is exactly the same. In this study it was found that MP would cost less than HP, as the mechanised process requires fewer staff. All other costs are the same for both methods of tubefeed production. See Addendum 17 for revised working hours for MP, for three full time staff.

COMPARISON OF TUBEFEED PRODUCTION METHODS

The researcher used the findings of this study to compile a summary of the advantages and disadvantages of different methods of tubefeed production (Table 17).

Table 17: Advantages and disadvantages of different methods of tubefeed production

Methods of Tubefeed Production		
Hand Production	Ready to Hang	Machine Production
Advantages ■ decanting significantly faster than MP ■ total mean production time (seconds per litre) significantly faster than MP ■ utilises present staff available ■ average overall error during decanting - 2,6% ■ provides an opportunity for student training, including management of staff ■ additives required can be added without any problems ■ cost saving - costs less than RTH even with four members of staff employed	Advantages ■ no staff members required to mix and decant feeds ■ less wastage, as bottles not opened can be re-issued ■ number of staff employed could be decreased or deployed elsewhere ■ bottles can be stored at room temperature - no refrigeration required ■ not affected by staff shortages or strikes ■ if correctly handled at ward level feeds should be significantly less contaminated than reconstituted feeds ■ no problems with late delivery of tubefeeds to wards should ensure that feeds are administered more correctly	Advantages ■ reconstitution significantly faster than HP, time is not affected by the volume produced ■ final product can be used for supplementary feeds ■ can make up bulk volume based on the previous days volume in advance - no waiting required (storage not a problem) ■ only one staff member required to mix and decant feeds ■ other staff members free to do other jobs ■ less cleaning as less equipment is used - better time management ■ able to manage time more effectively as total volume to be made is always known ■ volume decanted significantly more accurately than HP ■ tubefeed room functions more effectively as there is less movement from work station to work station ■ workload is more consistent -the work is better distributed throughout the day ■ pump can be calibrated for any volume of feed, can be adjusted at any time ■ concentration of feed is constant for all feeds produced that day ■ average overall error during decanting - 2,4% ■ uses less water than HP

Advantages and disadvantages of different methods of tubefeed production (cont'd)

Methods of Tubefeed Production		
Hand Production	Ready to Hang	Machine Production
Advantages continued:	Advantages continued:	Advantages continued: ■ provides an opportunity for student training which is not found anywhere else within South Africa ■ total number of staff required to manage the tubefeed room can be decreased or redeployed elsewhere ■ less disruption when there are staff shortages or strikes ■ feeds produced are administered using the same system of bottles and tubes as for hand production ■ implementation requires no training at ward level as present administration system is used ■ additives can still be added to individual tubefeeds after decanting has occurred ■ machine can be used to reconstitute any powdered form of enteral feed ■ cost saving - costs 95% of the cost of HP

Advantages and disadvantages of different methods of tubefeed production (cont'd)

Methods of Tubefeed Production		
Hand Production	Ready to Hang	Machine Production
Disadvantages ■ very labour intensive - requires four staff members to be available, requires two staff on duty over weekends ■ difficult to manage time effectively as feeds are produced as the orders come through - work load is inconsistent ■ more washing of bowls to be done ■ decanting not as accurate as MP ■ all supplementary feeds have to be reconstituted individually ■ inadequate storage space at ward level may result in feeds being exposed to incorrect temperatures causing an increase in bacterial growth ■ correct volume not always administered - needs control of volume administered per hour	Disadvantages ■ all supplementary drinks have to be reconstituted individually, unless replaced by ready made products ■ cost influenced by exchange rates ■ become contaminated at ward level if correct procedures are not followed - additional training required ■ may require additional tubes and pumps for administration ■ not possible to adapt the feed e.g. add salt without greatly increasing the risk of contamination ■ correct volume not always administered - needs control of volume administered per hour	Disadvantages ■ decanting is time consuming ■ training required to use machine ■ specialised equipment used - breakdowns can cause delays ■ costly to replace machine ■ inconclusive results obtained for the microbiological safety of machine production ■ inadequate storage space at ward level may result in feeds being exposed to incorrect temperatures causing an increase in bacterial growth ■ correct volume not always administered - needs control of volume administered per hour

CHAPTER 6

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSION

The null hypothesis in each case was found to be invalid. There were a number of differences found between the different methods of tubefeed production and the various parameters measured. When we look at the list of advantages and disadvantages of each method of tubefeed production, (Table 17) it is clear that all methods of production have both positive and negative aspects in them. However on the basis of the findings of this specific study MP has many more advantages than the other methods of tubefeed production evaluated.

The questions posed at the beginning, before this study was implemented, now need to be answered.

We are able to say that mechanisation of tubefeed production was found to be less labour intensive than HP. Fewer members of staff are required to produce the same volume of feeds.

When the costs of different production methods are considered, it is clear that the process of mechanisation can result in cost savings. Fewer members of staff are required, and this results in more cost-effective feeds being produced. In South Africa, at TBH, RTH feeds were found to be considerably more expensive than both HP and MP feeds.

The inconclusive microbiological data results make it impossible to say with conviction, exactly which method of tubefeed production is best suited to the TBH situation. It would be preferable to have been able to redo this section of the study, however this could not be considered at the time due to time constraints and the financial implications of doing so. The Department of Microbiology was paid on an hourly basis from funds provided by sponsors as sample analysis, cfu/ml determinations and organism identification are very time consuming processes.

However, when one looks at the microbiology statistics, which are kept by the Department of Human Nutrition, of random samples collected on a daily basis, one gets a fairly good idea of how the machine functions. The machine has been used to produce large volumes of reconstituted tubefeed since this study was concluded. Although not scientific, the statistics kept by the department indicate that, once the substandard hypochlorite solution was replaced, the standard of hygiene within the tubefeed room and for both tubefeeds and supplementary drinks has improved considerably. (Addendum 9,10,11 and 12)

Although the randomly selected microbiological samples, collected by the staff in the tubefeed room and analysed by the Department of Microbiology, do not provide exact cfu/ml counts, or identify organisms present, they do indicate the presence of contamination. Tubefeeds are either recorded as having no contamination or as being contaminated. Hygiene percentages are determined by working out what percentage of samples collected were contaminated and this is reflected by the total of 80% for hygiene if 1/5 of samples were found to be contaminated. The graphs in the addendum, which reflect this information, clearly show that the substandard hypochlorite product also affected the hygiene standards of supplementary drinks. The hygiene standards of the supplementary drinks improve at the same time as the improvement in hygiene standards of the tubefeeds. This indicates that the substandard hypochlorite product, and not the machine, is responsible for the increased rate of contamination of samples found in the study.

If the present financial situation was to be resolved and the budget was to be increased dramatically, then RTH feeds could be considered. However, at the present time, their cost and the ease with which they can become contaminated (when correct hygiene protocols are not adhered to - at ward level), does not warrant their use, unless in an emergency situation. Training of nursing personnel, with emphasis that enteral feeds should be treated as if they were TPN, would

help to decrease this rate of contamination dramatically. Correct hand washing procedures would also help to decrease coliform contamination.

The machine provides an opportunity for student training which is not possible anywhere else in the world. This is an additional benefit.

In conclusion the machine is in place and produces tubefeeds on a daily basis. The hygiene standards are acceptable and no further problems have been experienced. Only supplementary feeds are still produced by hand. The RTH option is simply too expensive, and it can therefore not be considered if a viable alternative is available.

RECOMMENDATIONS OF HOW TO IMPROVE THIS STUDY

- A more comprehensive environmental pilot study could have helped to decrease the number of confounding variables, which were identified, after the study had been completed.
- A more comprehensive pilot study may have foreseen the specimen collection problems encountered at ward level during the study.
- Patient monitoring could have helped to determine complications specific to the ingestion of contaminated feeds. Patients receiving tubefeeds could have been assessed for a period of time, after feed administration, to ensure that possible complications (due to intake of contaminated feeds) could have been identified. Patients with recorded TEN complications (such as diarrhoea and vomiting) could have then been assessed more closely so that other reasons for complications e.g. medication could have been excluded.
- An attempt to identify possible sites / routes of infection/ procedures relating to contamination of enteral feeds would be of benefit to the study.

- It would have been beneficial to have checked water quality on a daily basis so as to be able to exclude this as source of contamination - however this would have resulted in increased costs of the study.
- It would have been beneficial to have checked the quality of dry enteral feed powder from each tin opened, to be able to exclude this as source of contamination - however this would have resulted in increased costs of the study.
- In future studies the researcher must ensure that the same quality of cleaning products are used throughout the study to prevent inconclusive microbiology results.
- Future studies, based on this study, could distinguish between feeds administered by gravity and those administered by pumps to be able to determine if this plays any role in levels of contamination.
- Future studies, based on this study, could look in more detail at hygiene protocols and administration techniques used at ward level to determine sources of organisms identified.

RECOMMEDATIONS TO TBH WITH REGARD TO TEN ADMINISTRATION

(Based of the findings from this study)

The TEN protocol (which has been updated since this study took place) must be adhered to at all times. Special emphasis must be placed on the following:

- correct storage of TEN prior to administration, correct temperatures to be maintained
- correct hygiene at ward level, especially hand hygiene, staff must be trained to treat TEN administration as they would treat TPN administration
- accurate records of administration volumes must be kept and the flow rate must be monitored to ensure accurate administration

- administration (giving) sets must be replaced on a daily basis as stated in the TEN protocol
- comprehensive training of all nursing staff at TBH required to ensure that the TEN protocol is understood and applied correctly

Please note that the Department of Human Nutrition has, since this study took place, employed a dedicated nutrition nursing sister who is responsible for the monitoring both TEN and TPN at ward level. Many of the recommendations mentioned above are now receiving attention.

CHAPTER 7

BIBLIOGRAPHY

1. Fagerman KE, Flaska L, McCamish MA, Dean RE. Mechanised bulk production of enteral diet: a comparison with manual methods of preparation. Hosp Pharm 1982;17:374-379
2. Labadarios D, Haffejee A. A pocket Manual of Clinical Nutrition. Volume 1. Cape Town: Saspen, 1990: 129
3. Zaloga GP, Macgregor DA. What to consider when choosing enteral or parenteral nutrition. J Crit Illness 1990;5(11):1180-1200
4. Randall, H.T. Enteral Nutrition: Tube Feeding in Acute and Chronic illness JPEN 1984; 8:113-136
5. Guidelines for the use of enteral nutrition in the adult patient JPEN, 1987;11:5:435 - 439
6. Guidelines for the scientific review of enteral food products for special medical purposes. JPEN 1991: 15(3) S104-S106
7. Kaminski MV. Hyperalimentation a guide for Clinicians. New York: Marcel Dekker, Inc. 1985.
8. McArdle AH, Palmason C, Morency I, et al: A rationale for enteral feeding as the preferable route for hyperalimentation. Surgery 1981; 90:616-623
9. A.S.P.E.N Board of Directors. Guidelines for the use of parenteral and enteral nutrition in adult and paediatric patients JPEN 1993; 17(suppl)
10. Skipper A. Dietitians Handbook of Enteral and Parenteral Nutrition. Maryland: Aspen Publishers, Inc. 1992;18
11. Silkroski M, Allen F, and Storm H. Tube Feeding audit reveals hidden costs and risks of current practice. NCP 1998; 13(6):283-290
12. Anderton A, Howard JP, Scott EW. Microbiological control in enteral feeding. A guidance document. The Parenteral and Enteral Nutrition Group. London: The British Dietetic Association, 1986.
13. Wager DR, Elmer MF, Knoll DM. Evaluation of "Closed" vs. "Open" Systems for the delivery of Peptide-Based Enteral Diets. JPEN 1994, 18:453-457

14. Anderton, A. Growth of bacteria in enteral feeding solutions. J Med. Microbiology 1985;20:63-68.

15. Anderton, A. Enteral Tube Feeds as a Source of Infection: Can we reduce the Risk? Nutrition 1999; 15(1):55-56

16. Curtas, S. Closed Enteral Nutrition Delivery Systems: Fine tuning a Safe Therapy. Nutrition 2000; 16:307-310.

17. Schroeder P., Fisher D, Volz M and Paloucek J. Microbial Contamination of Enteral Feeding Solutions in a Community Hospital. JPEN 1983; 7:364-368

18. Bliss D.Z., Johnson S., Savik K., Clabots C.R., Willard K., and Gerding D.N. Acquisition of Clostridium difficile and Clostridium difficile associated diarrhoea in hospitalised patients receiving tube feeding. Ann Intern Med. 1998;129:1012-1019

19. Kohn C. The Relationship Between Enteral Formula Contamination and Length of Enteral Delivery Set Usage. JPEN 1991; 15:567-571

20. Casewell, M.W., Cooper, J.E. and Webster, M. Enteral feeds contaminated with Enterobacter Cloacae as a cause of septicaemia. Br Med Jr 1981; 282:973

21. Anderton, A. Bacterial contamination of enteral feeds and feeding systems. Clinical Nutrition 1993; 12 (S1) S16-S32

22. Anderton A. Reducing bacterial contamination in enteral tube feeds. B J Nurs 1995;4:368-76

23. De Leeuw I.H., and Vandewoude M.F. Bacterial contamination of enteral diets. Gut 1986; 27(S1):56-57

24. Donius M.A. Contamination of a prefilled ready-to-use enteral feeding system compared with a refillable bag. JPEN 1993;17:461

25. Kohn-Keeth C, Shott S, Olree K. The Effects of Rinsing Enteral Delivery Sets on Formula Contamination. NCP 1996, 11:269-273

26. Anderton A, Aidoo K.E. The effect of handling procedures on microbial contamination of enteral feeds. J Hosp Infect 1988;11:364-72

27. Lee C.H. and Hodgkiss I.J. The effect of poor handling procedures on enteral feeding systems in Hong Kong. J Hosp Infect. 1999;42(2):119-23

28. Fagerman K.E., Paauw J.D., Dean R.E., Bacterial contamination of Enteral solutions JPEN 1985;9:378

29. Fagerman K.E., Paauw J.D., McCamish M.A. and Dean R.E., Effects of time, temperature, and preservative on bacterial growth in enteral nutrient solutions. Am J Hosp Pharm. 1984;41:1122-1126

30. Patchell C.J., Anderton A., Holden C., MacDonald A., George R., & Booth I.W. Reducing bacterial contamination of enteral feeds. Arch Dis Child. 1998; 78(2):166-168

31. Wilson M. Bacterial biofilms and human disease. Sci Prog. 2001;84(Pt 3):235-54

32. Oliviera MH, Bonelli R, Aidoo KE, et al. Microbiological quality of reconstituted enteral formulations used in hospitals. Nutrition 2000; 16(9):729-733

33. Casewell MW. Bacteriological hazards of contaminated enteral feeds. J Hosp Infect. 1982;3:329-331

34. Moffitt SK, Gohman SM, Sass KM, et al. Clinical and laboratory evaluation of a closed enteral feeding system under cyclic feeding conditions: a microbial and cost evaluation. Nutrition 1997;13(7-8): 622-628

35. Dentinger, B., Faucher K.J., Ostrom S.M., and Schmidl M.K. Controlling bacterial contamination of enteral formulas through the use of a unique closed system: contamination, enteral formulas, closed system. Nutrition 1995; 11:747

36. Carvalho MLR, Morias TB, Amaral DF, et al. Hazard Analysis and Critical Control Point System Approach in the Evaluation of Environmental and Procedural Sources of Contamination of Enteral Feedings in Three Hospitals. JPEN 2000;24:296-303

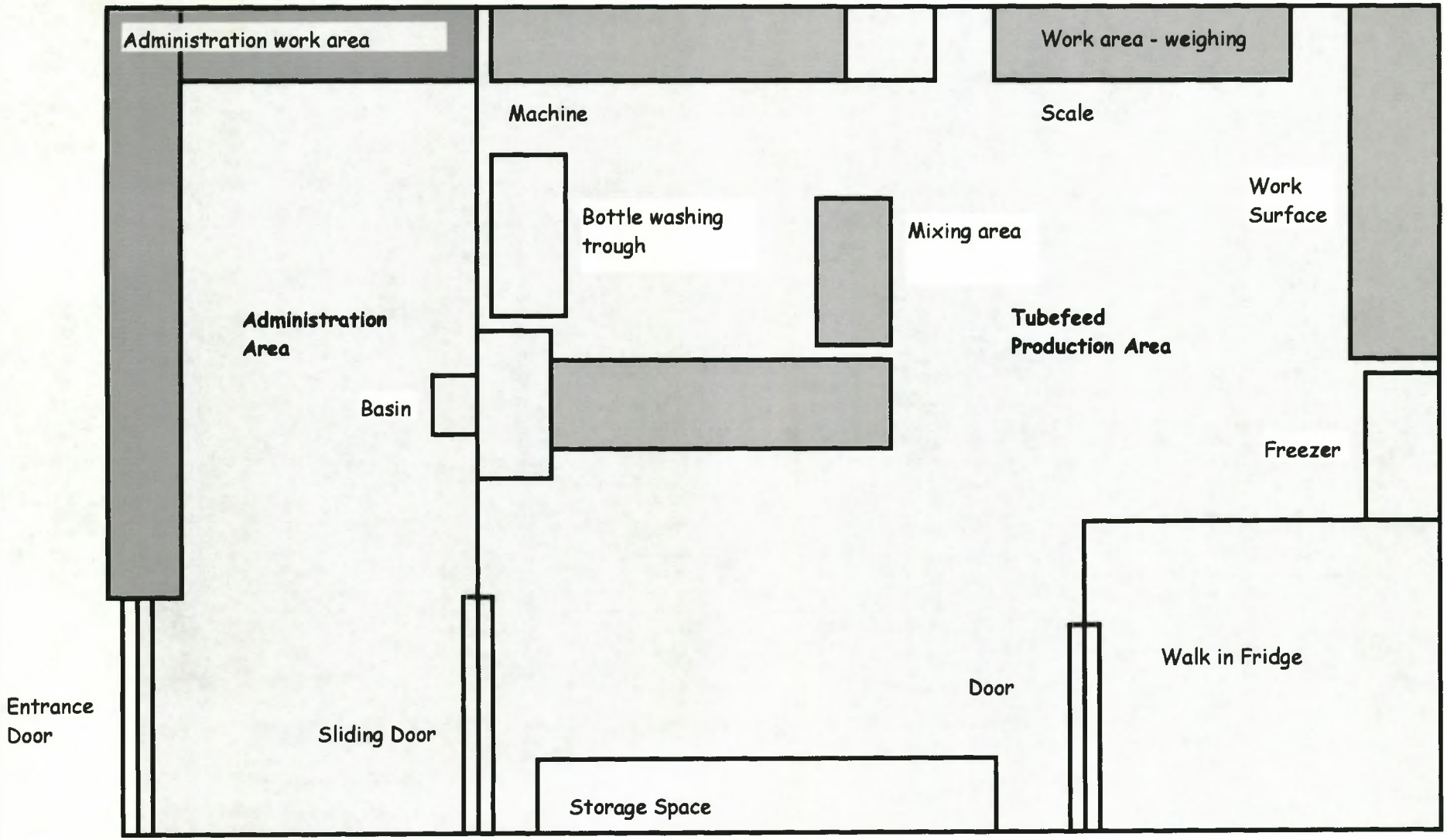
37. Rosner B. Fundamentals of Biostatistics. 4th ed. London: Duxbury Press, 1995; 8:251, 9:315, 12:551

38. Anderson K.R., Norris D.J., Godfrey M.S., Kirk Avent C., and Butterworth C.E. Bacterial Contamination of Tube-feeding formulas. JPEN 1984;8:673-678,

39. Sullivan MM, Sorreda-Esguerra P, Santos EE, et al. Bacterial contamination of blenderized whole food and commercial enteral tube feedings in the Philippines. J Hosp Infect. 2001; 49:268-273

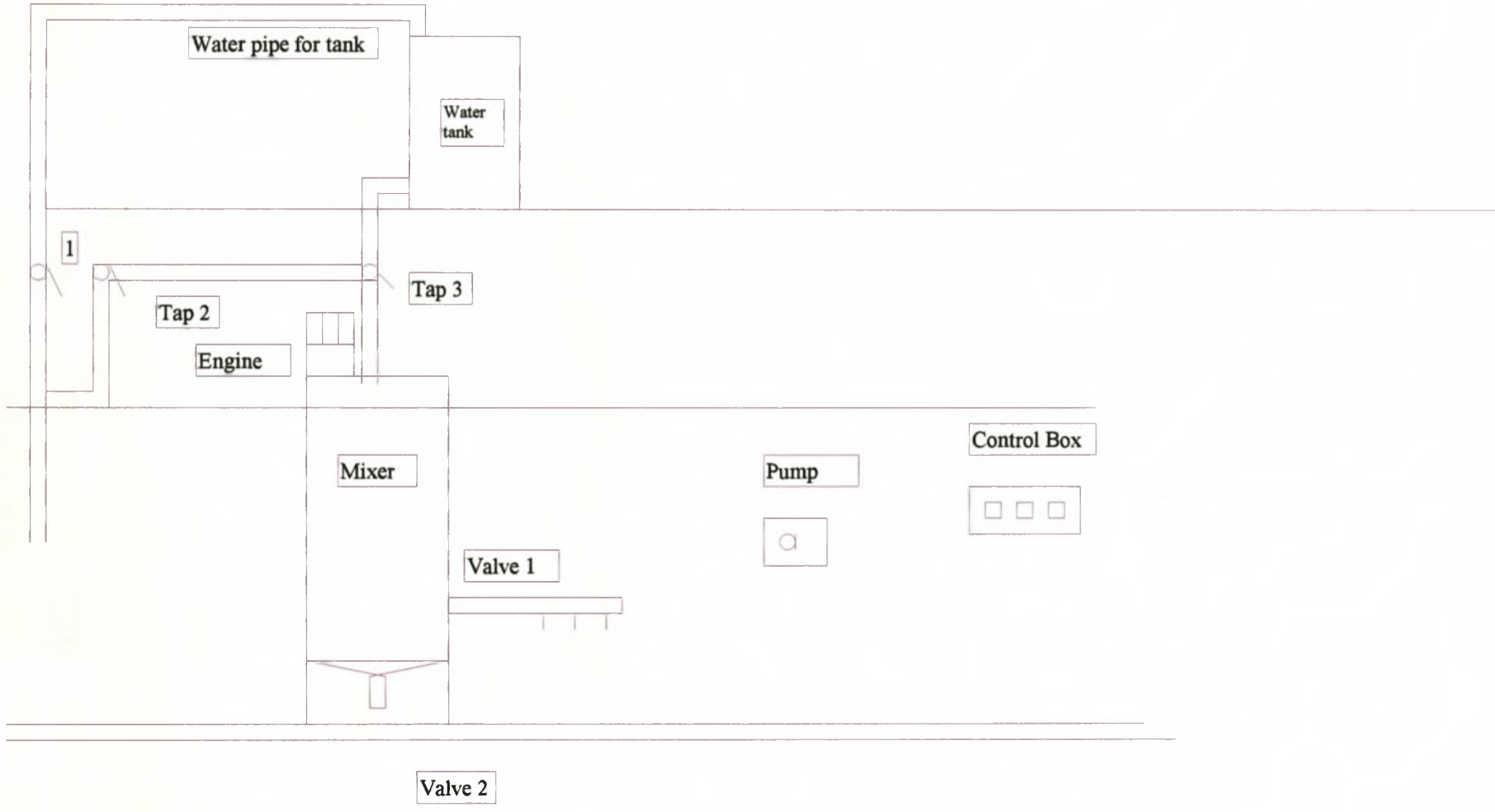
ADDENDUM

ADDENDUM INDEX



ADDENDUM 1: TUBEFEED ROOM LAYOUT

LARGE SCALE ENTERAL FEED PRODUCTION UNIT



ADDENDUM 2: SCHEMATIC DRAWING OF MACHINE, INDICATING TAPS AND VALVES

ADDENDUM 3:

MANUAL FOR THE BULK PRODUCTION OF TUBEFEEDS

1. The role of the dietitian when the large scale tubefeed production unit is in use

2. Total reconstituted formula produced from specific volumes of water

3. Use of the mixer and volume control system

4. Biocide mixing instructions

5. Powder formulae volumes - hourly administration

1. ROLE OF THE DIETITIAN WHEN LARGE SCALE TUBEFEED PRODUCTION MACHINE IS IN USE:

The machine functions by using a pre-measured volume of water to which the powder formulae powder is added - once the powder is added the total volume produced increases - see table below.

TOTAL POWDER FORMULAE PRODUCED FROM SPECIFIC VOLUMES

Volume of water (L)	Tins of Powder formulae	Powder formulae in grams	Total litres obtained
20	**2 tins + 1650g**	5900	25,00
25	**3 tins + 1000g**	7375	31,25
30	**4 tins + 350g**	8850	37,50
35	**4 tins + 1825g**	10325	43,75
40	**5 tins + 1175g**	11800	50,00
45	**6 tins + 525g**	13275	56,25
50	**6 tins + 2000g**	14750	62,50
55	**7 tins + 125g**	16225	68,75
60	**8 tins + 700g**	17700	75,00

Determine the total volume of powder formulae to be produced using the previous days total volume as a guideline (volume of powder formulae produced - not extra water added). Round off the volume to the total litres closest to what you require (use bigger volume rather than smaller). E.g. 53 L of powder formulae were produced yesterday, today use the recipe for 56,25 L. Let the tubefeed room personnel know which recipe to use, by indicating the final volume required.

2. TOTAL POWDER FORMULAE PRODUCED FROM SPECIFIC VOLUMES

Volume of water (L)	Powder formulae in grams	Total litres obtained
20	5900	25,00
25	7375	31,25
30	8850	37,50
35	10325	43,75
40	11800	50,00
45	13275	56,25
50	14750	62,50
55	16225	68,75
60	17700	75,00

3. USE OF THE MIXER AND VOLUME CONTROL SYSTEM

PREPARATION

- Turn on the control box when you come on duty, - let it heat up for about an hour

- Wash hands. Use D germ / alcohol to disinfect hands before completing any of the following actions

- To ensure that the mixer tank is clean and drained of all cleaning solution, rinse out the tank as follows: close valve 1, open valve 2, open tap 2 to rinse out the tank

- Once rinsing is completed, ensure that valves 1 and 2 are closed
  - valve 1 (beside the tank) is used to pump out the contents of the tank
  - valve 2 (below the tank) is used only to drain the tank after use and during cleaning

MIXING OF POWDER FORMULAE

- Ensure that valves 1 and 2 are closed

- Wash hands. Use D germ / alcohol to disinfect hands before completing any of the following actions

- Use tap 1 to add the required amount of water to the water tank - be careful to measure accurately

- Once the correct volume is measured open tap 3 to fill up the mixer (the mixer blade must always be beneath the water)

- Weigh formulae powder or pack bottles until the total volume has flowed into the mixer (there will always be a small amount of water left in the tank)

- Turn on the motor

- Remove the mixer lid

- When the water is churning well, begin to add the pre-weighed powder formulae very slowly - do not allow lumps to form
- Allow the mixer to run for a period of 10 minutes
- Once the mixing is complete, turn off the motor

DECANTING OF POWDER FORMULAE

- Wash hands. Use D germ / alcohol to disinfect hands before completing any of the following actions
- Attach the silicon pipe to Valve 1 (beside the tank)
- Place the silicon pipe in the control pump and secure the lid of the pump carefully
- Valve 1 can now be opened
- Place a bottle under the silicon pipe which passes through the control pump
- Adjust the control box mechanism to 100ml - the required volume shown in millilitres, which must be pumped from the tank into that specific bottle - initially to remove any air or water in the pipe. Throw away the contents of this first bottle
- Push the "start" button on the control panel
- Push the "stop" button if the process needs to be stopped at any time
- The pump will automatically stop once the required volume in the bottle has been reached
- Once the contents of the first bottle has been discarded - adjust the control box mechanism as the volumes required change
- Use D germ / alcohol to disinfect hands regularly whilst filling bottles

CLEANING OF THE MIXER TANK AND COMPLETE SYSTEM

- Wash hands. Use D germ / alcohol to disinfect hands before completing any of the following actions
- Once all Powder formulae has been decanted close Valve 1 and 2
- Disengage the silicon pipe from Valve 1 (on the side of the tank) – place it in a biocide (cleaning) solution
- Open tap 2 to begin cleaning the tank
- Open valve 2 and allow the contents of the tank to flow freely into the drain - this process should continue for a period of five minutes or until all water draining from the tank is clear
- Turn off tap 2, close valve 2
- Open tap 2 - fill the tank to almost full, and remove the lid
- Add the disinfectant / biocide solution to the tank
- Turn on the motor and allow the mixer to run for a few minutes
- Once the detergent / disinfectant is well mixed, turn off the motor. Scrub the inside of the tank and then allow the contents of the mixer tank to drain from both valve 1 and 2
- Repeat if necessary
- Allow all water to drain from the tank (using valve 2)
- Fill both the mixer tank and water tank with biocide water (use correct dilution) and let stand overnight. Drain and rinse both tanks before using the next day
- **KEEP HANDS OUTSIDE MIXING TANK WHENEVER THE MIXER IS ON**

4: BIOCIDE MIXING INSTRUCTIONS

WATER VOLUME	BIOCIDE
20 Litres	15 grams
30 Litres	20 grams
40 Litres	25 grams
50 Litres	30 grams
55 Litres	35 grams
60 Litres	40 grams

5: POWDER FORMULAE VOLUMES

ml / Hour	Total Volume (in ml)	Volume per bottle
20	480	120 ml
30	720	180 ml
40	960	240 ml
50	1200	300 ml
60	1440	360 ml
70	1680	420 ml
80	1920	480 ml
90	2160	540 ml
100	2400	600 ml
110	2640	660 ml
120	2880	720 ml
125	3000	750ml

ADDENDUM 4: DATA COLLECTION FORM - MICROBIOLOGICAL SAFETY AND PRODUCTION TIME

1. Project Number ☐☐☐ (1 2 3)

2. Patient Name:..... (1 2 3)

3. Ward:..... ☐☐ (4 5)

4. Date:..... ☐☐ (6 7)

5. Total volume of feed..... ☐☐☐☐ (8 9 10 11)

6. Sample Type

Present	1
Mechanised	2

☐ (12)

7. Day

Week	1
Weekend	2

☐ (13)

8. Number of staff on duty ☐ (14)

9. Production Time
(Reconstitution).....seconds ☐☐☐ (15 16 17)

(Decanting).....seconds ☐☐☐ (18 19 20)

Production Time (total).....seconds ☐☐☐ (21 22 23)

10. Accuracy of initial volume mixed: ☐ (24)

Weight of 4 bottles (+ lids).....g (Bottle + lid = 578,5g)
1 ml standard Powder formulae = 1,05g (Br bottle =209,5g)

Amount (in ml)..... ☐☐☐ (25 26 27)

11. Total volume left in the bottle at time of last sample being taken.....ml
    % of total volume wasted

□□□
28 29 30

12. Reason why feed was not completed:
    .....

□□
31 32

ADDENDUM 5: CODES USED TO ANALISE DATA

Codes for organisms causing contamination

1. *Citrobacter*	33. 3 + 10
2. *Enterobacter Cloacae*	34. 3 + 4 + 5
3. *Non Enterocc GP D Strep*	35. 3 + 4 + 6
4. *Acinetobacter SP*	36. 3 + 5 + 6
5. *Klebsiella Pneumoniae*	37. 3 + 4 + 5 + 6
6. *Eschericia Coli*	38. 3 + 4 + 5 + 8
7. *Moraxella Catarrhalis*	39. 3 + 4 + 5 + 7
8. *Enterobacter Aerogens*	40. 4 + 9
9. *Pseudomonas Spesie*	41. 1 + 4 + 5
10.	42. 1 + 3 + 8 + 9
11. 1 + 2	43. *Actinomyces SP*
12. 1 + 3	44. *Actinomyces* + 3
13. 1 + 4	45. 1 +4 + 5
14. 1 + 2 + 3	46. 5 + 6
15. 1 + 2 + 4	47. 1 + 5
16. 1 + 3 + 4	48. 3 + 5 + 9
17. 1 + 3 + 5	49. 2 + 3 + 6 + 9
18. 1 + 3 + 6	50.
19. 1 + 2 + 3 + 4	51. 3 + 50
20. 1 + 2 + 3 + 5	52. 3 + 6 + 9
21. 1 + 2 + 4 + 5	53. 1 + 5 + 9
22. 1 + 3 + 4 + 5	54. 3 + 5 + 6 + 9
23. 1 + 3 + 5 + 9	55. 3 + 9
24. 1 + 2 + 3 + 4 + 5	56. 50 + 3 + 9
25. 1 + 3 + 9 + 10	57. 6 + 9
26. 2 + 3	58. 4 + 6 + 9
27. 2 + 3 + 4	59. 4 + 6
28. 2 + 3 + 6	
29. 2 + 3 + 4 + 6	
30. 2 + 3 + 6 + 8	
31. 3 + 4	
32. 3 + 6	

CODES FOR ORGANISMS

Organisms	Code	Organisms	Code
No growth	1	< 7000	8
< 1000	2	< 8000	9
< 2000	3	< 9000	10
< 3000	4	10 000	11
< 4000	5	> 10 000	12
< 5000	6	100 000	13
< 6000	7	> 100 000	14

SAMPLE SOURCE

1	Tube feed room
2	Kitchen
3	Ward - not hanging
4	Ward - hanging
5	Fridge
6	Ward, hanging no tube connected
7	Ward, not hanging, giving set attached

REASONS WHY FEED NOT COMPLETED

1	Feed begun late
2	unknown
3	death
4	eating
5	nausea / vomiting
6	cancelled
7	patient transferred
8	NPO
9	Nothing left
10	Feed stopped / acute abdomen
11	Tube out
12	Not given to patient
13	500ml bottle
14	tube blocked

CODES FOR WARDS

Ward	Code	Ward	Code	Ward	Code
A1	1	D10	8	A5HS	15
A2	2	G5	9	A3W	16
A4	3	G6	10	D2	17
A5E	4	G8	11		
A5W	5	J8	12		
D6	6	A7	13		
D9	7	DGr	14		

ADDENDUM 6 : COST OF CLEANING PRODUCTS ON A MONTHLY BASIS

Breakdown of cost of cleaning products used in the tubefeed room on a monthly basis:	
Caps (100)	R 24-40
Sponges (6 packs)	R 16-98
Paragon 85 Soap (15L)	R 25-17
Disinfectant (15kg)	R 94-05
Blue daily wipes	R 34-22
Hand Soap (5L)	R 21-56
Aprons (100)	R 33-00
Total	R 266-49

ADDENDUM 7: DATA COLLECTION FORM - MICROBIOLOGICAL SAFETY AND PRODUCTION TIME

1. Project Number ☐☐☐ (1 2 3)

2. Patient Name:..... (1 2 3)

3. Ward:..... ☐☐ (4 5)

4. Date:..... ☐☐ (6 7)

5. Total volume of feed..... ☐☐☐☐ (8 9 10 11)

6. Sample Type

RTH	3

☐ (12)

7. Day

Week	1
Weekend	2

☐ (13)

8. Total volume left in the bottle at time of last sample being taken.....ml ☐☐☐ (14 15 16)
   % of total volume wasted

9. Reason why feed was not completed:
   ..... ☐☐☐ (17 18 19)

Bottle Batch Number: 1
2
3
4
5
6

ADDENDUM 8: DAILY ORDER OF PROCEDURES FOR COLLECTION OF SAMPLES FOR PRESENT METHOD OF TUBEFEED PRODUCTION

8h00	Ice (to keep test tubes cold during collection of samples) and the stopwatch were collected from A10 lab
8h30	Random selection of tubefeed patients from list - by tubefeed personnel or dietitian on duty * mark stickers for bottles (all 4 bottles) Write out sample Collection forms (name, ward, file number, project number), data collection forms (all information as above , total volume) and stickers (project number) for test tubes
8h30 - 10h00	Time reconstitution / decanting of identified feeds Take Sample A (record time sample is taken) Wash hands prior and after samples are taken Tubefeed personnel to make feeds after informing the researchers that they have a feed marked with an *
10h00 - 10h30	Collect sample C from wards
10h30 - 11h00	Time reconstitution / decanting of identified feeds Take Sample A (record time) Wash hands prior and after samples are taken If quiet - begin to collect Sample C after informing the ward sister.
11h30 - 12h00	Time reconstitution / decanting of identified feeds Take Sample A. Wash hands prior and after samples are taken Finish collecting Sample C
12h00-12h30	Take Samples A & C to the Department of Microbiology
13h30- 14h00	Collect Sample B. Wash hands prior and after samples are taken
14h00 - 14h30	Take Sample B to Department of Microbiology

ADDENDUM 9: DAILY ORDER OF PROCEDURES - BULK PRODUCTION

8h00	Ice (to keep test tubes cold during collection of samples) and the stopwatch were collected from A10 lab
8h30	Random selection of tubefeed patients from list *mark stickers for bottles (all 4 bottles) Write out sample Collection forms (name, ward, file number, project number), data collection forms (all information as above , total volume) and mark test tubes with the relevant project number
9h30 - 10h30	Time reconstitution of total volume of feeds (keep a record of the total litres produced). Time decanting of identified feeds Take Sample A (record time sample is taken) Wash hands and spray with alcohol prior and after samples are taken Tubefeed personnel to begin bulk mixing of feeds and decanting of relevant feeds marked with *after informing the researchers
10h30 - 11h30	Time decanting of identified feeds with *- Take Sample A (record time) Wash hands and spray alcohol prior and after samples are taken If quiet -begin to collect Sample C at ward level after informing the ward sister
11h30 - 12h00	Time decanting of identified feeds with *- Take Sample A. Wash hands and spray alcohol prior and after samples are taken Finish collecting Sample C at ward level * Feeds ordered after 12h00 were not included in the study
12h00-12h30	Take Samples A & C to the Department of Microbiology
13h30- 14h00	Collect Sample B. Wash hands prior and spray alcohol after samples are taken
14h00 - 14h30	Take Sample B to Department of Microbiology

ADDENDUM 10 : DAILY ORDER OF PROCEDURES FOR THE COLLECTION OF READY TO HANG SAMPLES

8h00	Ice was collected from the A10 lab - for transport of test tubes during data collection
8h30	Tubefeed patients were randomly selected from the list (as mentioned above in the methods above. The stickers on the bottles were changed to indicate the ready to hang product being used. The number of bottles required to be sent out was determined by using 1kcal / ml to determine the total volume required. Researchers recorded the batch number of all bottles sent out. Researchers wrote out sample Collection forms (name, ward, file number, project number), data collection forms (all information as above , total volume) and marked test tubes. Researchers marked giving sets with the relevant ward and patient name - Each randomly selected patient received a new giving set
10h00 - 11h30	The researchers hands were washed and sprayed with alcohol prior to and after samples were taken Collection of sample C was begun after informing the ward sister The following were noted: volume of feed left in bottle being administered and the number of unopened bottles in the refrigerator
11h30 - 12h00	Collection of sample C was completed New giving sets were delivered to identified wards and discussed with the Sister in charge
13h45- 15h00	Collection of Sample B began - using the method described above. The researchers hands were washed and sprayed with alcohol prior to and after samples were taken
After 15h00	Sample B and c were taken to the Department of Microbiology

ADDENDUM 11

UNIVERSITEIT VAN STELLENBOSCH
UNIVERSITY OF STELLENBOSCH

21 November 1999

Mrs L Lahner
Assistant Director: Finance
TYGERBERG HOSPITAL

Dear Mrs Lahner

TUBEFEED ROOM (TFR): DISINFECTANT

The hygiene profile of the enteral feeds and supplementation drinks in the TFR has recently deteriorated to such an extent that I can no longer guarantee the safety of the feeds or for that matter be held responsible for any adverse patient outcomes.

Apart from the chronic and continuing problems in the TFR which are well known to you and the Management, it now appears that a recent change, to my knowledge without any prior consultation, to a cheaper disinfectant has compounded the problems we encountered. The new disinfectant, of which we apparently use more of in order to compensate for its poor quality (so it is not cheaper), does not adequately dissolve in water. Complaints to the supplier apparently led to the product being replaced with a less inferior product, which is also inadequate.

Our current statistics show:

Score	1998	1999
Average hygiene score	92%	80%
Average for tubefeeds	89%	63%
Average for suppl.drinks	96%	77%

This alarming decrease in hygiene needs to be addressed immediately and I do hope we can revert to Biocide forthwith at least for the TFR.

I look forward to your help and suggestions. I would also strongly recommend that, as appropriate, any changes in purchases likely to affect hospital practices are discussed with the relevant roleplayers and are tested thoroughly before a decision is made to change a product. In this case, it does appear that a cheaper product is costing us much more in the end due to wastage, apart from patient safety considerations.

Yours sincerely

Demetre Labadarios

PROF. D LABADARIOS
HEAD: DEPARTMENT OF HUMAN NUTRITION
dl/ys s/pam96/thtubefeedroom.doc

Copy: DR WASSERMAN

Committed to Excellence in Professional Training, Patient and Community Care and Research

Fakulteit Geneeskunde • Faculty of Medicine
Departement Menslike Voeding • Department of Human Nutrition
Posbus / P O Box 19063, 7505 Tygerberg, Suid-Afrika / South Africa
Tel. (27) 021 - 9389259, Fax. (27) 021 - 9332991

ADDENDUM 12

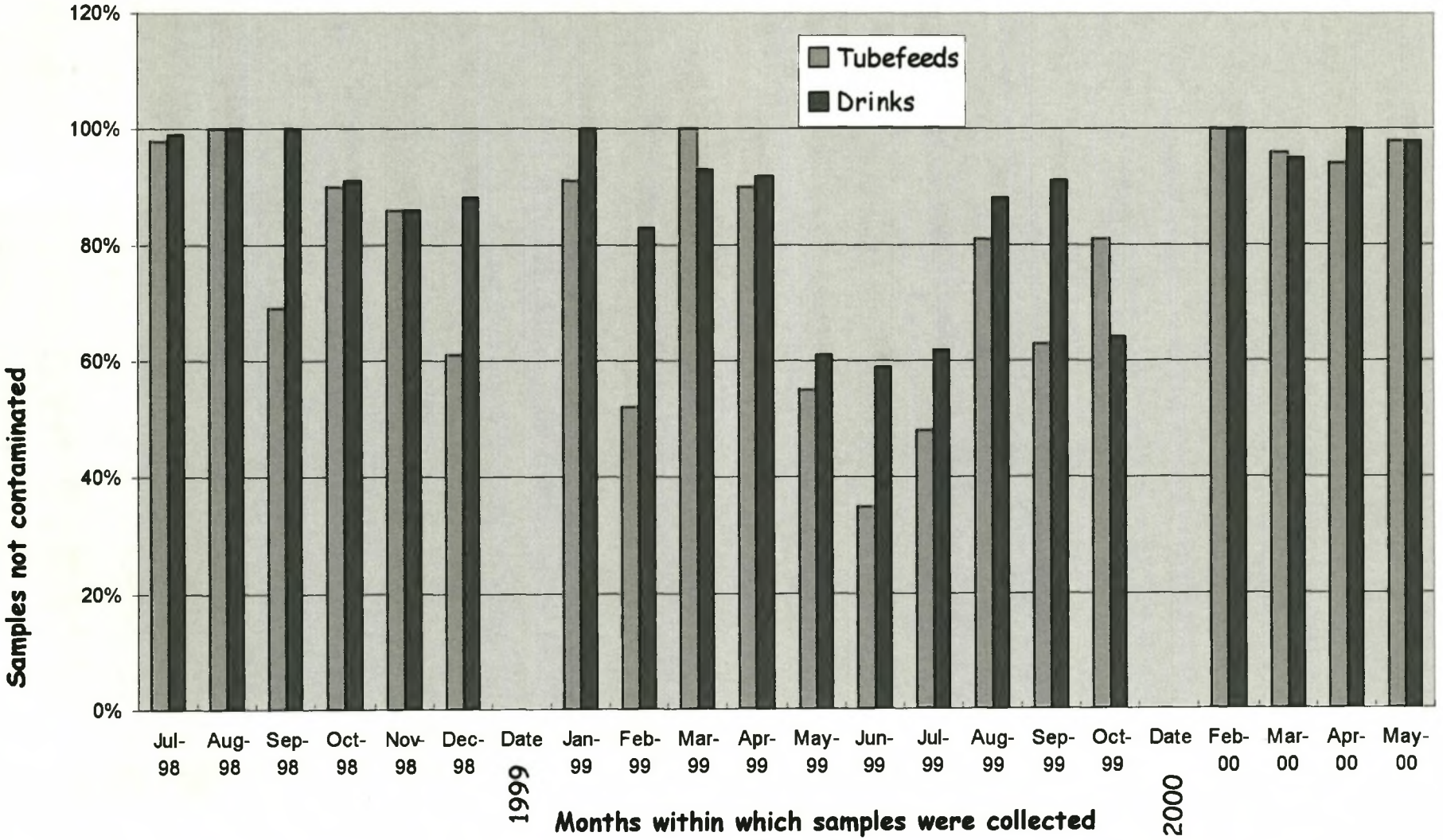


Figure a: Summary of random tubefeed and supplementary drink samples

ADDENDUM 13

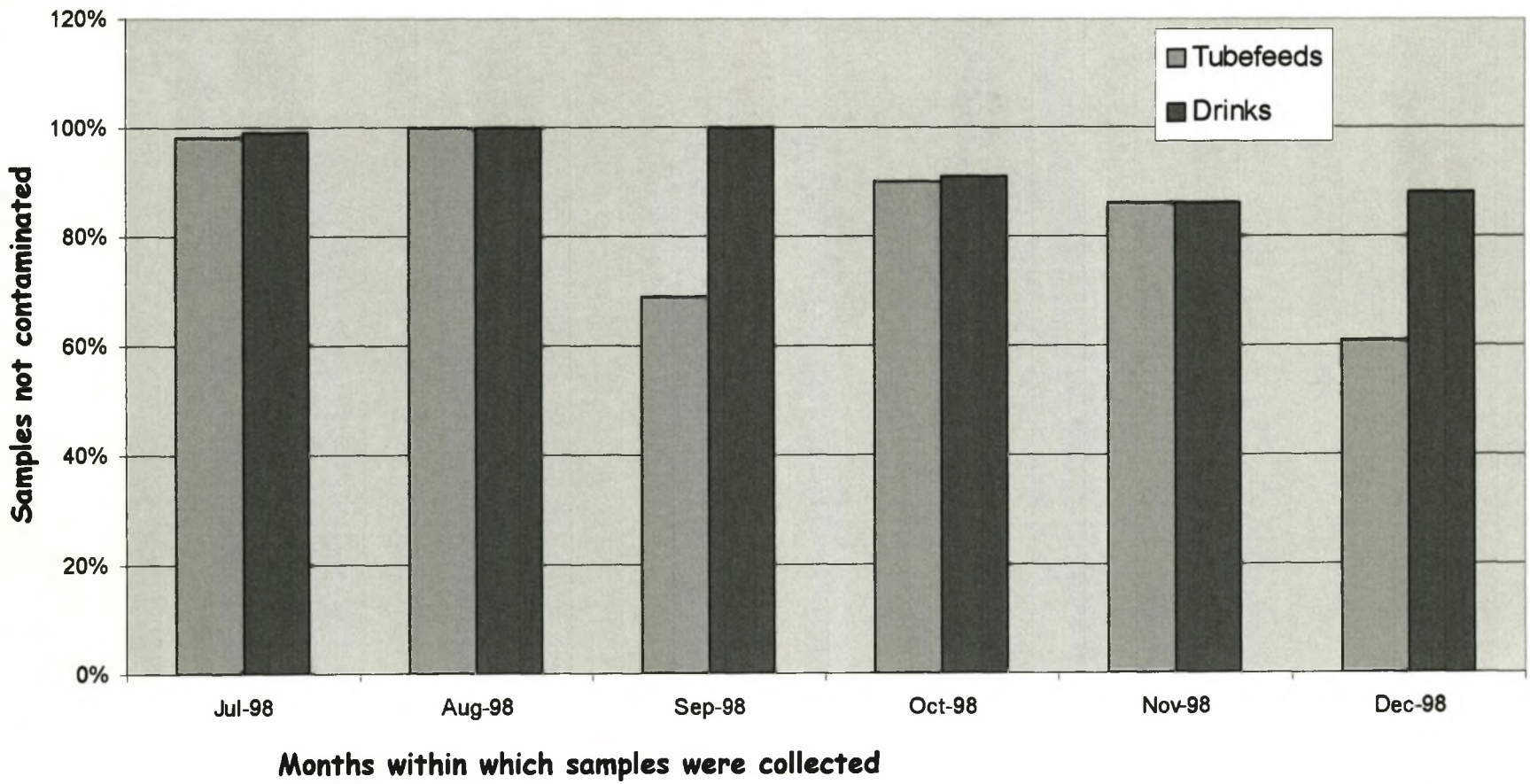


Figure b: Summary of random tubefeed and supplementary drink samples, 1998

ADDENDUM 14

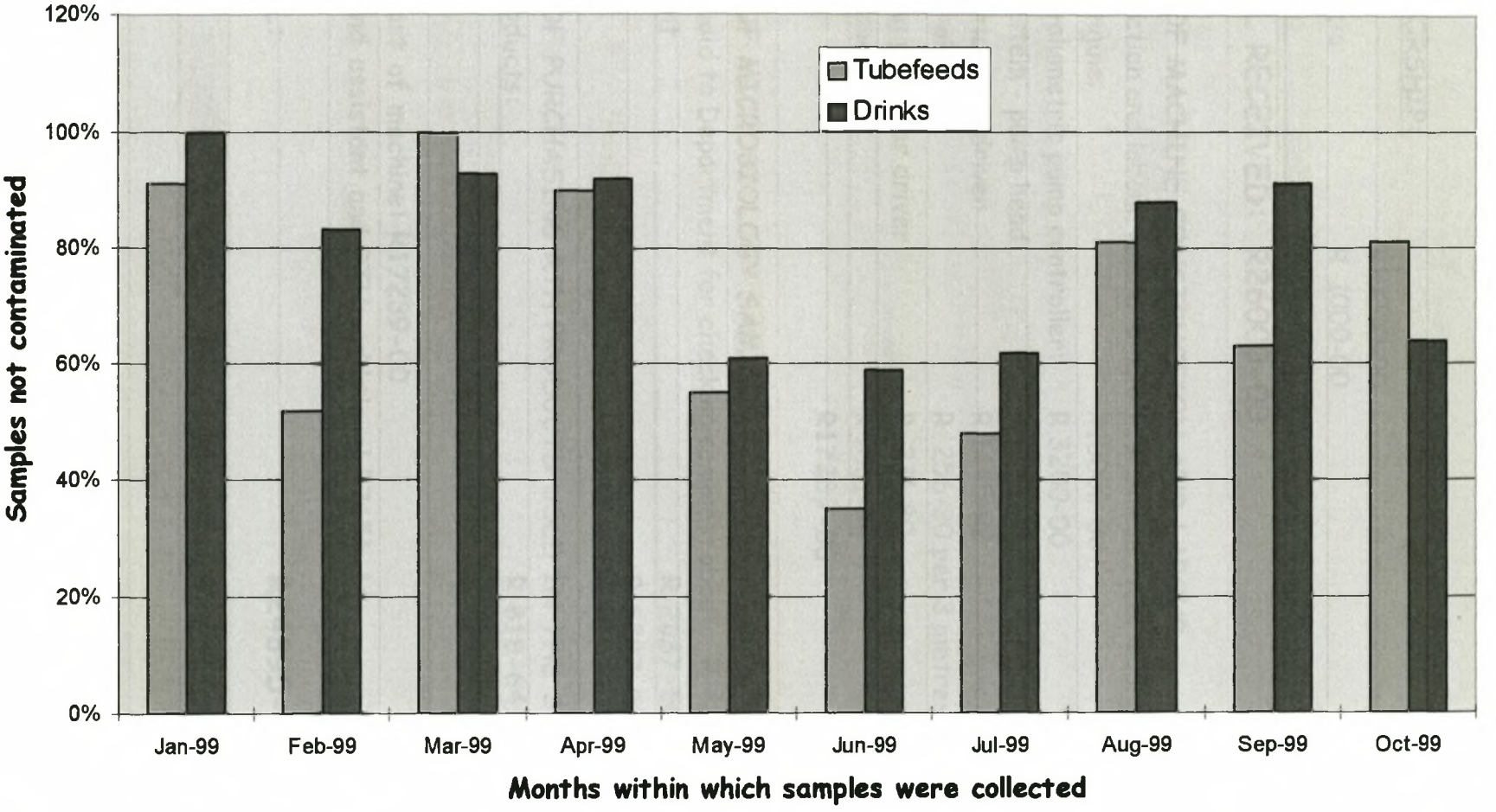


Figure c: Summary of random tubefeed and supplementary drink samples, 1999

ADDENDUM 15: COST OF MACHINE PRODUCTION

Initial quotes from engineering firms between R20000-00 - R25000-00 (only construction of machine)

SPONSORSHIP:

Abbott:	R15000-00
Pharmacia:	R 1000-00
PAWC :	R10000-00 (for machine construction and RTH)
TOTAL RECEIVED:	**R26000-00**

COST OF MACHINE CONSTRUCTION AND LABOUR

Construction and labour for building 60L stainless steel mixing bowl and mixer engine: R10000-00

Digital volumetric pump controller:	R 3200-00
Pump system - pump head	R 1043-10
Peristaltic pump driver	R 1445-92
Silicone pipe	R 256-20 per 3 metres
Mounting plate for driver	R 231-80
Labour costs	R 1061-98
TOTAL	**R17239-00**

COST OF MICROBIOLOGY SAMPLES AND ASSISTANT

Micro (paid to Department for checking samples) about	R 4000-00
Assistant	R 2837-50
TOTAL	**R 6837-50**

COST OF PURCHASING RTH PRODUCTS USED IN THE STUDY

RTH products:	R 818-64
TOTAL	**R 818-64**

Total cost of machine: R17239-00
Micro and assistant and RTH: additional R7656-14

TOTAL: R24895-14

ADDENDUM 16: TEMPERATURE OUTSIDE DURING STUDY PERIOD

Date	Temp °C	Date	Temp°C	Date	Temp°C
19/10/98	23.9	23/11/98	26.3	12/4/99	37
20/10/98	19.8	24/11/98	20.3	13/4/99	23.5
21/10/98	23.3	25/11/98	22.4	14/4/99	24.2
24/10/98	21.7	28/11/98	28.4	17/4/99	19.7
25/10/98	22.4	29/11/98	24.3	18/4/99	16.2
26/10/98	28.8	30/11/98	24.1	19/4/99	19.7
27/10/98	21.2	1/12/98	28.1	20/4/99	19.3
28/10/98	20.2	2/12/98	30.1	21/4/99	19.5
Average Temperature	20.1		25.5		22.4

ADDENDUM 17: PROPOSED WORKING HOURS WHEN MACHINE IS IN USE (3 STAFF MEMBERS)

	Day	Supervisor	AA 1	AA3	Number of staff on duty
31 /12/01	Monday	8	Day Off	8	2
01/01/02	Tuesday	Day Off	8	8	2
2	Wednesday	8	8	8	3
3	Thursday	8	8	Day Off	2
4	Friday	8	8	8	3
5	Saturday	Day Off	Day Off	8	1
6	Sunday	Day Off	Day Off	8	1
7	Monday	8	8	Day Off	2
8	Tuesday	8	8	8	3
9	Wednesday	8	8	8	3
10	Thursday	8	Day Off	8	2
11	Friday	8	8	8	3
12	Saturday	Day Off	8	Day Off	1
13	Sunday	Day Off	8	Day Off	1
14	Monday	8	Day Off	8	2
15	Tuesday	8	8	8	3
16	Wednesday	8	8	8	3
17	Thursday	8	8	Day Off	2
18	Friday	8	8	8	3
19	Saturday	Day Off	Day Off	8	1
20	Sunday	Day Off	Day Off	8	1
21	Monday	8	8	Day Off	2
22	Tuesday	8	8	8	3
23	Wednesday	8	8	8	3
24	Thursday	8	Day Off	8	2
25	Friday	8	8	8	3
26	Saturday	Day Off	8	Day Off	1
27	Sunday	Day Off	8	Day Off	1
28	Monday	8	Day Off	8	2
29	Tuesday	8	8	8	3
30	Wednesday	8	8	8	3
31	Thursday	8	8	Day Off	2
1	Friday	8	8	8	3
2	Saturday	Day Off	Day Off	8	1
3	Sunday	Day Off	Day Off	8	1

L 07h00 - 16h00 (8 hours), E 07h00-13h00 (6 hours), WE 07h00 -12h00 (5 Hours)