The Hyperbaric Incident Monitoring Study (HIMS): An International Study of Incidents Occurring in Hyperbaric Medicine Units

Christy Joan Pirone
BSN, RN

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CONTENTS

Abstract Summary of Thesis

This thesis analyses incidents that occurred in Hyperbaric Medicine Units or as a consequence of hyperbaric oxygen exposure with the aim of developing recommendations for safety improvement in hyperbaric medical practice. Analysis of the health care literature demonstrates that medical error is of significant concern and that investigation into its causes through the use of "near miss" anonymous voluntary incident reporting is an effective method for safety improvement. Review of the hyperbaric literature demonstrated that the systematic collection of incidents was limited to retrospective anecdotal reports, mainly those involving morbidity or mortality and that a comprehensive review of hyperbaric safety issues has not previously been conducted. This study presents a comprehensive review of incidents that have been reported in the hyperbaric literature and data from 200 reports of incidents collected from a convenience sample of 45 Hyperbaric Medicine Units representing 17 countries for a 20 month period. The reports provided information on factors that contributed to and minimised the incident and allowed the reporter to give a narrative description of the incident. An integral feature of the study design was a structured education and data feedback system for the study participants.

The data was analysed by classifying the incidents, statistically reviewing the associations between incidents and contributing factors, reviewing the narratives and minimising factors and relating them to clinical experience and the hyperbaric literature. Consistent with current hyperbaric literature, this study showed that ear barotrauma is the most frequently reported patient complication of hyperbaric treatment. The second most frequently reported complication is oxygen toxicity. Complications not previously identified in the hyperbaric literature included, stress reactions in patients having witnessed an oxygen toxicity seizure, oxygen hood deflation, aggressive patient in the chamber, risks associated with training exercises in the chamber, the forceful ejection of a monoplace chamber plug, vision loss in the form of hyperopia, and pulmonary oxygen toxicity in staff. From the data, the study presents recommendations for quality improvement, research, policy and procedure development, education, and equipment design modification. The continuation of the HIMS research is recommended with suggestions for improving the study.

Declaration

This work contains no material which has been accepted for the award of any other degree or diploma in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text.

I give consent to this copy of my thesis, when deposited in the University Library, being available for loan and photocopying.

Signed: _ **Date:** 11/05/01

Dedication

This research thesis is dedicated to fellow hyperbaric colleagues who have suffered injury or have died as a consequence of their work in hyperbaric medicine, and especially to Ben, my friend who has shown great courage to overcome his injury and continue to work in hyperbaric nursing. Joyce Vause (deceased as a result of attendant decompression illness), Mary Ann, and the nurses who perished in the Galeazzi chamber fire have inspired me to strive for the improvement of occupational health and safety for hyperbaric attendants.

Tribute is extended to those patients who have suffered or died as a result of hyperbaric treatment.

Remembered too are hyperbaric clinicians who have been involved in these incidents and live with the consequences of them, many of whom were "the last link" in the chain of events or system errors that culminated in an incident on a particular day.

The tragedy encountered by these people should not be forgotten but branded in our minds and inspire us to put safety first in the special work that we do.

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This study has evolved as a result of several influences. First, my parents who have supported me, promoted the advancement of my education and instilled in me the ethics "to always do your best whatever you set out to do" and "you can lose your possessions but no one can ever take away what you have learnt".

Second is my professional duty of care to provide safe care and a safe environment to my patients. My role as a nurse and supervisor has put me in a position to have myself caused medical err, counselled others who have erred, and cared for those who are the victims of medical error.

Third, is the promotion of nursing research from the Department of Clinical Nursing. Particularly, I would like thank Professor Alan Pearson who suggested that I formalise my research into Masters Degree study and Mary Fitzgerald, my supervisor, who has demonstrated enduring patience and compassion as I humbly learn to research and write.

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Since launching HIMS internationally, there are many people that have contributed to the study. The individuals that have submitted reports of incidents have contributed the most, as they have shared an experience in their work that will lead them to improving safety for others.

My sincere gratitude goes to the "Persons On The Spot" (POS) in the study, who logistically make the study happen from their location. The HIMS International Coordinators have invested great effort to make this study a truly international effort through their promotion, presentations, and translations. Dick Clarke, Peter Mueller, Cuauhtemoc Sanchez, Ann Charlotte Grönqvist, Folke Lind, Lief Aanderud, Aud Jorunn Thorsen, Michael Michael, Ole Hyldegaard, Jordi DeSola, and Jurg Wendling have been especially helpful. These individuals are genuinely committed to the continual improvement of safety in hyperbaric internationally.

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The staff of the Royal Adelaide Hyperbaric Medicine Unit have all contributed to HIMS, each in their own uniquely talented way. The level of support and dedication from my colleagues at the Hyperbaric Medicine Unit has been tremendous. The contributions made in recent years by Piers Robertson is very much appreciated. The staff of the Unit will be thrilled at the completion of this thesis, as by now, I am certain they are weary of me even mentioning it.

Mostly, I would like to thank my husband, Ralf. Many days and nights over the past four years, he has been left to deal with caring for our young girls, all the domestic duties of a family, and sacrificed his leisure time and our time together so I could study. His selfless commitment to my ideals has tested and demonstrated a most powerful bond for which I am forever grateful and humbled.

I would like to thank my three beautiful girls, Amanda, Jessica, and Sophie. They too have sacrificed much time with me. While I can't make up for those valuable moments of their youth, I hope that some day, they too will grow to understand the value of education.

Hopefully, this small contribution from my research will serve to improve safety in hyperbaric practice.

List of tables

List of Figures

Abbreviations

ABPM	American Board of Preventative Medicine
ACGME	Accreditation Council on Graduate Medical Education
AICD	Automatic Implantable Cardioverter Difibrillators
AIMS	Australian Incident Monitoring Study
ANZHMG	Australian and New Zealand Hyperbaric Medicine Group
APSF	Australian Patient Safety Foundation
ASRS	Aviation Safety Reporting Systems
ASME	American Society of Mechanical Engineers
ASTM	American Society for Testing and Materials
ASNZ	Australian New Zealand Standard
ATA	Atmospheres Absolute
BIBS	Built-in-breathing system
BHA	British Hyperbaric Association
BNA	Baromedical Nurses Association
CAQ	Certificate of Added Qualification
CDRH	Center for Devices and Radiological Health
CNS	Central nervous system
CPI	Cardiac Pacemakers Incorporated
DAN	Divers Alert Network
DCI	Decompression Illness
DipDHM	Diploma in Diving and Hyperbaric Medicine
ECG	Electrocardiograph
FAA	Federation Aviation Administration
FDH	Food and Drug Administration
GAIN	Global Aviation Information Network
HIMS	Hyperbaric Incident Monitoring Study
HTNA	Hyperbaric Technicians and Nurses Association
ICU	Intensive Care Unit
ISMP	Institute for Safe Medication Practices
IV	Intravenous
JCAHO	Joint Commission of Accreditation of Healthcare Organisations
MDR	Medical Device Reporting
NBDHMT	National Board of Diving and Hyperbaric Medical Technology
NFPA	National Fire Protection Association
OBD	Overboard dump
PA	Pulmonary artery
POS	Person on the spot
PRP	Product Reporting Program
PVHO	Pressure Vessels for Human Occupancy
SPUMS	South Pacific Underwater Medical Society

UHMS	Undersea and Hyperbaric Medical Society
UMS	Undersea Medical Society
USA	United States of America
USAF	United States Air Force
USN	U.S. Navy or United States Navy
USP	United States Pharmacopeial

Introduction

Hyperbaric nursing is a relatively new speciality in nursing. It has evolved over the past three decades in the USA and for the past two decades in Australia. It involves the care of patients breathing 100% oxygen in a recompression chamber. The role of the hyperbaric nurse was first defined by the Baromedical Nurses Association (BNA) as "the diagnosis and treatment of human responses to actual or potential health problems in an altered environment" (Baromedical Nurses Association 1987, p. 3). The nurse may be required to attend to the patient inside a multiplace (more than one occupant) chamber or may supervise patient care and/or operate a monoplace (one occupant) chamber (Appendix A). This nursing speciality requires training in physics relating to gas and pressure changes as well as the effects of these changes on the human body and the physical environment.

There are particular health requirements for nurses that work inside hyperbaric chambers. They must pass a medical examination that satisfies the physical criteria for working in a compressed gas environment. Additionally, there are restrictions to the physical activities surrounding the time of exposure to the hyperbaric environment and the state of health at the time of exposure.

The features of this speciality introduce distinctive challenges for nurses in terms of the delivery of nursing care and management of nursing staff. Hyperbaric nursing has occupational and patient hazards that are not common to other nursing environments. The potential hazards are well documented (Kindwall 1994a, Desola 1996) but the actual incidents occurring in this work environment have been reported infrequently and feature those that have produced significant morbidity or mortality.

The researcher's interest in this study topic began in 1989 after working in a variety of Hyperbaric Medicine Units in the USA and in Australia. There were many similar incidents occurring to both patients and staff in all the Units. There were also unique incidents occurring as a result of different hospital system designs and structure. No formalised multi-centred incident reporting systems specific to hyperbaric had ever been instituted. It was apparent that incidents could be prevented if clinicians were aware of what types of incidents

occur and that there may be common solutions to the similar problems among hyperbaric clinicians worldwide.

The Research Questions

The central questions are:

> *What incidents occur involving patients, staff, and or equipment, in Hyperbaric Medicine Units, or as a consequence of hyperbaric exposure.*
>
> *What factors minimised or contributed to these hyperbaric related incidents?*

Definition: The incident may be any event that caused harm or could have caused harm if no intervention to stop it occurred. It may be an event involving a patient, staff member, or equipment.

Aims

The study aims to identify and analyse incidents occurring in a sample of international hyperbaric medicine units in order to make recommendations for safety improvement.

This study, through its aim, intends to contribute to the improvement of patient and staff safety in the speciality of hyperbaric medicine practice.

Objectives

- Evaluate contributing and minimising factors to the incidents
- Develop recommendations for the prevention of similar incidents
- Establish a culture in hyperbaric that is safety conscious
- Further refine and improve the incident reporting tool

It is hoped that the study will lead to an on-going incident reporting system that will evaluate the effectiveness of the strategies developed from it.

Overview of the thesis structure

This study attempts to introduce the reader to a method of safety improvement, demonstrate how this method of incident reporting is used on an international and local level, and describe and analyse the data from the reporting system to make recommendations for safety improvement.

The literature review is divided into three parts. Chapter One describes the scope of medical error in hospitals and reviews the literature relating to incident reporting with discussions on the evolution, use, and analysis of incident monitoring. This review describes the concept of using anonymous, voluntary incident reporting in health care.

Chapter Two reviews safety in hyperbaric practice. The origins of safety practices in clinical hyperbaric medicine practice have been and continue to be influenced by commercial and military diving and undersea and space exploration. This unique association is described to contextualise discussions relating to the safety issues contained in this thesis and provides a history of safety in hyperbaric practice.

The final section of the literature review (Chapter Three) may be disturbing to the reader. It contains a concentrated collection of reports and anecdotes of incidents reported in hyperbaric over the last century, from the English language literature. The reader is cautioned to put this literature into context as similar reviews of other specialties in medicine could yield equally unsettling accounts. A comprehensive recording of this type in hyperbaric medicine has not previously been done. Such a review is necessary for this study to relate the past to the incidents reported in the study.

Chapter Four describes the research methods used to enlist participants into the study and the design, strengths and limitations of the research tool.

Chapter Five presents the data collected in the study. The interpretation and discussion of the data is reserved for Chapter Six in which analysis of the data, and its relationship to the literature, current practice, and safety implications are discussed.

Finally, Chapter Seven summarises the thesis, highlighting the main features of the data, strengths and limitations of the study, and makes recommendations based on the data in the context of the literature, and for the continuation of the study.

It is anticipated that the material presented in this thesis will heighten awareness of safety issues in hyperbaric and provide a framework for the continuation of safety improvement initiatives.

CHAPTER 1

Incident Monitoring In Health Care

'It may seem a strange principle to enunciate as the very first requirement in a Hospital that it should do no harm.' Florence Nightingale (1820-1910)

Notes on Hospitals, Preface (Daintith & Isaacs 1989, p. 94)

1.1 Scope and Significance of the Clinical Problem

There is no shortage of data to show that hospitalisation can cause harm. A seminal study, the Harvard Medical Practice Study (Brennan et al. 1991), has been central in disclosing the magnitude of adverse events occurring in hospitals. This retrospective review of 30,195 randomly selected records from fifty-one hospitals in the state of New York found a 3.7 percent incidence rate of adverse events during hospitalisations in 1984. By extrapolating this data to the United States population, Leape and colleagues estimated that approximately 100,000 preventable deaths a year, were caused by adverse events occurring in health care institutions in the United States in 1984 (Leape et al. 1993, p. 147). This is twice the annual highway death toll for the United States.

Studies following the Harvard review suggest that the rate of adverse events in hospitals may be even higher. James (1997) compared methods of traditional and enhanced incident reporting to a computer-automated system for the review of adverse drug reactions in hospitals. The automated review system detected an *eighty times* higher rate of adverse drug reactions than the traditional nursing incident reporting system.

The Quality in Australian Health Care Study by the Commonwealth Department of Human Services and Health (Wilson et al. 1995) reviewed medical records of over 14,000 admissions

in twenty-eight hospitals in Australia in 1992. The study was modeled on the methodology of the Harvard Medical Practice Study, and reported an adverse event rate which resulted in disability or a longer hospital stay of 16.6 percent in hospitalised patients. All of these events were caused by health care mismanagement. Fifty-one percent of the adverse events were judged as preventable.

Although the two studies utilised similar rigorous methodologies, the Australian study demonstrated a higher incidence of adverse events. Brennan (1995) proposed several explanations for the differences between the studies. First, the severity of illness may have been higher in the Australian hospitals. Second, the nurse reviewers in the Australian study referred a higher rate of possible adverse events for medical review. Third, the Australian physicians may have made determinations of adverse events at a higher rate than the American physicians. Brennan also suggested that the educational differences of the reviewers might have influenced this pattern. Finally, more adverse events may have occurred in Australian hospitals.

Leape (1994) reported that the Harvard Medical Practice Study found two-thirds of the adverse events were preventable. Leape et al. (1993) suggested that error identification and reporting methods should be expanded. He speculated that too much emphasis is placed on identifying the error, rather than examining why the error occurred and how it can be prevented in the future. Furthermore, Brennan argued that until the epidemiological science of error detection is refined, calculating medical error rates and determining the impact of error reduction programs may be unreliable (Brennan 2000).

The problem of adverse events in health care is not limited to harm incurred by the patient, but also extends to the effect on the patient's family and the community in which they live. There are medico-legal issues and a huge cost to society (Runciman 1995, p. 3). An adverse event can also have a significant psychological impact on the clinician (Newman 1996).

The impact of adverse events in health care is not always readily apparent, as they occur in complex systems, and tend to be opaque and non-transparent to the observer. Modern health care systems, technology, and human physiology are complex and subject to constant change. For example, the change in a patient's condition may be quite easily thought to be a consequence of the natural course of their illness, when in fact it is due the side effect of a drug. The situation can be so complex that a harmful adverse event may go unrecognised by the clinician.

Adverse events will never be totally eliminated in health care, but by identification of the types of incidents and the investigation of their causes, many of them can be reduced and safer systems for delivering care can be developed.

1.2 Incident Reporting in Health care: Review of the Literature

A thorough literature review of incident reporting was conducted. The methodology of the review is followed by discussions on the evolution and use of incident reporting in health care, and incident analysis.

1.2.a Overview and Methodology of the Review

CINAHL and MEDLINE databases were used to search for bibliographic citations under the index category of "Risk Management" with the keywords: incident reports, incident monitoring, accidents, adverse events, and errors. There were 1,777 references under these headings. The titles and abstracts were screened for content, particularly relating to incident reporting methodologies and monitoring of adverse events in health care. A total of 233 articles were reviewed. A summary of the type of journals in which the articles were published is listed in Table 1.1.

Type of Journal	Total Number of Articles (N=233)
Medical – total	97
Anaesthesia (60)*	
Other (37)	
Nursing	74
Hospital Administration	27
Other Health care Journals	35

* Australian Incident Monitoring Study (31)

Table 1.1 Type of Journals

Papers relating to incident monitoring are published most frequently in medical journals, with Anaesthesia journals containing the majority. Thirty-one of the references come from the Australian Incident Monitoring Study (Webb et al. 1993) of the Australian Patient Safety Foundation in the Symposium Issue of *Anaesthesia and Intensive Care* in 1993. Papers published on incident reporting are common in nursing journals. Incident reporting, being one of the quality assurance functions of hospitals, has often been the responsibility of nursing staff. The involvement of medical practitioners in hospital incident reporting, with the exception of anaesthetists, has traditionally been to assess the patient for harm incurred as a result of the incident. This traditional practice pattern is reflected in the type of papers most often represented in the literature.

Pharmacists have also had a long standing commitment to incident monitoring, as evident in the literature review by their publications on medication error in their own professional journals and in the nursing literature.

1.2.b Evolution and methods of incident reporting

The evolution of incident monitoring began with the concept of the "critical incident technique", credited to John Flanagan (1954). The technique is a "...procedure for gathering certain important facts concerning behaviour in defined situations"(Flanagan 1954, p. 335). The critical incident technique was developed through studies on the performance of pilots in the Second World War and subsequently used to define the critical requirements for work as a commercial airline pilot and a number of other occupations (Runciman 1996). The original use of the critical incident technique was to look for critical behaviours or actions and their relationship to outcomes. It had no negative or positive connotations. Although the technique remains principally the same, it has been adapted for a variety of uses, one of which is described by Burnett,

> ...asks people who work in a particular environment to report equipment, practices, or other people that cause, or almost cause, accidents. The technique can be implemented as either a written or oral process i.e., we can ask people to supply their reports in writing or in face-to-face interviews. (Burnett, 1996)

Burnett (1996) emphasised that the critical incident technique recognises that the person most familiar with unsafe elements of their work is the person in that working environment. While the person may not recognise all the factors that contribute to an error, they are aware of common errors that produce no harm. This information is rich with data and can be used to determine the factors that may lead to harmful events.

The critical incident technique was first introduced into medical practice in 1960 to examine drug administration errors made by nursing staff (Safren & Chapanis 1960a,b). It was subsequently used to improve the examination process for measuring competency in graduate medical training programs (Hubbard et al. 1965, Miller 1968). In 1970, Sanzarro and Williamson studied the effects of physician performance on patients using the critical incident technique. It was introduced into anaesthesia in the late 1970's by Cooper and colleagues (1978).

Williamson (1988) and Morgan (1988) introduced a modified form of the critical incident technique in Australian anaesthesia by expanding the definition of a reportable incident. Reportable incidents included incidents that were not necessarily caused by anaesthetist error or equipment malfunction. The error may or may not have been preventable, and it need not have been a deviation from normal procedure or caused any harm to the patient. This broader definition expanded the scope of incident reporting to allow for reporting of "near misses". Some may criticise this type of incident reporting for including too much "trivia". It collects information that is different from traditional studies that focus only on medico-legal risk and outcomes resulting in harm.

The collection of "near misses" provides rich information for causative factor analysis. In some adverse event or morbidity/mortality studies, this information would not exist. Barach and Small (2000, p. 5) compared the advantages of "near misses" with adverse outcome studies and concluded:

> ...*(a)* near misses occur 3-3000 times more often than adverse events, enabling quantitative analysis; *(b)* fewer barriers to data collection exist, allowing analysis of interrelations of small failures; *(c)* recovery strategies can be studied to enhance proactive interventions and to de-humanise the culture of blame; and *(d)* hindsight bias is more effectively reduced.

Changes in the speciality of anaesthesia such as training, improved drugs, better equipment and monitoring, the introduction of standards, and the formation of the Anaesthesia Patient

Safety Foundation in the United States and the Australian Patient Safety Foundation in Australia have contributed to the improvement of safety in anaesthesia. The use of malpractice claims reviews (Domino et al. 1999) and incident monitoring studies particularly have unveiled previously undiscovered causes of incidents (Cooper 1994).

Incident reporting was traditionally used by hospitals to identify mishaps involving patients or visitors that resulted from non-physician employee actions (Freedman & Gerring 1993, Fiesta 1994). The rise of malpractice litigation in the mid-1970's prompted hospital risk management programmes to be established (Robbins 1987). Risk management as defined by the Medical Defense Union is:

> ...an approach designed to identify, assess, and reduce risks to patients, staff, and visitors. Its aim is to prevent the expenditure of health authority funds on litigation to enable them to be used instead for the improvement of patient care (Tingle 1994, p.17).

The result of the surge in litigation led health care systems to review methods of measuring quality of care. The customary use of incident reporting as a tool to detect and monitor adverse events in hospitals expanded, and in many institutions became a mandatory requirement for all events that led to patient harm. In New York State, reporting certain types of incidents became a legal requirement (Braff et al. 1986, Kirtland 1991). The Safe Medical Devices Act of 1990 is a Federal Drug Administration regulation for the mandatory reporting of serious adverse events that suggest a medical device caused, or may have caused harm to, a patient or employee (Furst 1994).

More recently, hospitals and the public, through an inquisitive press, have become more aware of the numerous adverse events in the health care system, such as wrong-sided surgery, adverse drug events, and misdiagnosis. Health care institutions have focused attention on hospital risk management, with the aim of reducing medico-legal compensation payments. Hospital accreditation agencies now emphasise compliance with total quality improvement systems to improve patient safety.

A variety of methods are used to measure quality in health care. Some of these methods include; professional credentialling, mortality and morbidity reviews, audits, autopsy, utilisation review, patient satisfaction, coroners reports, patient complaints, hospital

accreditation, practice guidelines, occurrence screenings, total quality management, and incident reporting (Wolff 1994).

Attempts to reliably compare adverse event rates between health care institutions, regardless of the method, have been hampered by differences in definitions, terminology and methodologies. Some groups have designed national incident reporting systems, in a bid to gain a better understanding of the problem types and causes of adverse events n health care.

The Food and Drug Administration, USA, instituted the National Medical Device Reporting (MDR) System in 1984 (Hepplewhite 1986). The mandatory reporting system required manufacturers and distributors to report deaths or serious injuries that were associated with the use of their medical devices. In 1990, this system was extended to health care facilities on a voluntary basis and named the Product Reporting Program (PRP).

Pharmacists were one of the first groups to undertake a national, voluntary, incident reporting scheme in health care. The medication error reporting system was administered in the United States in 1991 by the United States Pharmacopeial Convention (USP) and the Institute for Safe Medication Practices (ISMP) (Edgar, Lee, & Cousins 1994). The programme extended to all health care settings, could be reported by telephone or standard report form, and accepted anonymous reports. The aim was to encourage increased reporting by allaying fear of punitive repercussions. Another feature of the programme was that the results were readily accessible. In a twenty month period, 568 reports were received. They found the causes of medication errors were multi-factorial. Product labeling and packaging were common problems. Errors that resulted in fatalities were much fewer and most commonly involved cognitive errors by the clinician. Under-reporting occurred in this study, as in all incident reporting programmes, and pharmacists were most often the reporters.

In the USA, the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry (1998) recommended a national voluntary, legally immune system for reporting adverse events in health care. They advise a programme similar to the Aviation Safety Reporting System (ASRS) developed by the Federal Aviation Administration (FAA) used in aviation. This system is based upon the principals of blame-free, voluntary, reporting of "near misses", adverse events, and accidents. It focuses on determining the "root" causes of the

incidents and uses human factor and systems analysis techniques to interpret and establish safety improvement recommendations.

The aviation industry has extended the breadth of their reporting system with the establishment of the Global Aviation Information Network (GAIN). GAIN is an aviation industry initiated system designed for the international collection, analysis and dissemination of aviation safety information (U.S. Federal Aviation Administration Office of Safety Control 1998). It builds on existing national aviation safety data gathering systems and allows the sharing of incident data internationally, for the purposes of improving safety in aviation.

A trial of a "near miss" reporting system for the analysis of error in transfusion medicine was undertaken at the University of Texas Southwestern Medical Center at Dallas in 1998 (Battles et al. 1998). This confidential reporting system incorporated Rasmussen's taxonomy for identification of human behaviour types and human error (Rasmussen 1987), Reason's theories on accident causation analysis (Reason 1990a), and Van der Schaaf's rationale for "near miss" reporting systems (Battles et al. 1998). In their study, an interdisciplinary consensus development approach was used to design and implement the reporting system. Using Nadler's IDEALS concept of design, the reporting system was developed and trialed at three blood centres and three hospital transfusion services in the USA. The study effectively demonstrated the use of a confidential "near miss" reporting system that was coordinated with the agencies' quality assurance and risk management programmes to address weaknesses in systems that could lead to adverse events.

National voluntary, anonymous incident reporting schemes are operational in Australia including:

1. The Australian Patient Safety Foundation administers the Australian Incident Monitoring Study (AIMS) in Australia, an international voluntary, anonymous reporting system that analyses and classifies incidents in anaesthesia, and on a national basis from hospital wide specialities.
2. The Therapeutic Devices Evaluation Committee involves the anonymous reporting of negative incidents nationwide, which involve equipment and machines.
3. The Australian Drug Evaluation Committee and one of its subcommittees, the Adverse Drug Reactions Advisory Committee, operates a national, anonymous adverse drug reaction reporting system.

There are other national reporting systems in the United Kingdom, the United States, Italy, France, and Spain, that monitor occupational exposure to blood and bodily fluids (MacDonald et al. 1995). While this list is not conclusive, it provides examples of operational anonymous, voluntary reporting systems that are used on at least a national level in health care for the purpose of obtaining information to prevent incidents in health care.

1.2.c Incident Analysis

Once incidents are reported they require analysis. Synchronous with the medico-legal boom of the mid-1970s to late-1980s, there were a number of notable accidents that had an effect on the public at a global level. The Three Mile Island and Chernobyl nuclear disasters, King's Cross tube station fire, the Exxon Valdez oil spill, and the Piper Alpha oil platform explosion to name a few, generated public concern for community safety (Reason 1990b) and initiated a re-look at accident analysis and disaster control.

Valeri Legasov, an investigator of the Chernobyl nuclear power station disaster, left a series of tapes before his suicide death, describing his thoughts on the nuclear plant accident. Legasov is credited by Reason (1994) to aptly sum up the causation of accidents in complex systems. Reason made the point, after listening to Legasov's tapes, that the causation of accidents is the:

> ...product of many different failures, distributed widely in both space and time...the errors and violations of the operators simply added the finishing touches to a disaster [Chernobyl] that had been in the making for years. (Reason 1994, p. xi).

Studies repeatedly show that human error is the main contributor to serious incidents that involve the interaction of humans and machines in complex systems (Runciman et al. 1993, Van Cott 1994). In anaesthesia, human error was a factor in eighty percent of incidents reported (Short et al. 1992, p. 3).

Reason defines error as:

> ...a generic term to encompass all those occasions in which a planned sequence of mental or physical activities fails to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some degree of chance agency.
>
> (Reason 1990b, p.9)

An error does not necessarily incur harm. An error may be detected and corrected so as not to induce harm. Allnutt (1987, p. 857) eloquently describes error in humans, '...all human beings, without any exception whatsoever, make errors and that such errors are a completely normal and necessary part of human cognitive function.'

Senders described the theory of error and accidents in medicine. He defines an accident as, '...an unplanned, unexpected, and undesired event, usually with an adverse consequence.' (Senders 1994, p. 166).

Human error in the causation of adverse events in medicine should not imply that blame be placed on the clinician performing when the event took place. The incident most likely had "been brewing" for quite some time. The clinician is the one at "the sharp end", the last link in the accident chain (Reason 1990b). Blame has little remedial value and blaming the person does not necessarily solve the problem. The error will occur again, but with a different clinician unless the conditions in which the error occurred are identified and altered (Bogner 1994). An accident is the result of a chain of events and we will only profit by analysing all the links in the chain, not just the person at the end.

One dominant theory on accident analysis utilises the systems approach. The systems approach does not place blame on the individual. It looks at components of the system, such as design problems, procedures, administrative decisions, working conditions, and patterns of behaviour, as possible causes for "setting up" the right environment for humans to commit an error (Moray 1994). This "systems approach" to investigating the underlying causes of medical error has been adopted by many of those leading the way in medical error analysis (Galletly & Mushet 1991, Eagle & Davies 1992, Runciman et al. 1993, Leape et al. 1995).

Blameless, voluntary reporting with an emphasis on a systems approach to the analysis of medical error is quite the opposite of traditional incident reporting methods used by hospitals. Some authors suggest that nurses were using incident reports as instruments of punishment rather than tools of correction (Curtin 1981, Fuqua & Stevens 1988). It was standard procedure for incident reports involving drug administration errors to be used as a tool in assessing nurse performance with punitive repercussions for multiple errors. Copies of the report were put into the employee file (Wrenn 1981) and incident reports have been summoned as evidence for malpractice litigation (Creighton 1979a,b, Sklar 1981, Dwyer 1982, Creighton 1983, Tammelleo 1987, Fiesta 1994). Varying mechanisms of reporting occurred. Some institutions required reports in duplicate, with one copy sent to administration and one filed in the medical record. Other institutions had one type of form to be sent to administration and a different form to document the event in the medical record. Confusion on what to report, how to report it without incriminating oneself, and fear of disciplinary action were strong disincentives to report incidents (Ludwig-Beymeret al. 1990, Camac et al. 1994).

In recent studies it has been shown that as many as thirty-five percent of incidents go unreported (Sutton, Standon & Wallace 1994a, p. 65). In another study using computerised anaesthesia information management systems for the detection of intraoperative incidents, only 4.1 percent of incidents detected were voluntarily reported (Sanbornet al. 1996, p. 977). Cullen et al. (1995, p. 545) compared incident reporting patterns by nursing staff for adverse drug events to daily nurse investigator visits to the wards, coupled with an adverse drug event log, and daily chart review. The review found that only seven percent of the adverse drug events were detected by incident reports. They propose the following reasons for the low rate of voluntary reporting by nurses: Fear of disciplinary or legal action, not seeing the value of it or being too busy to fill out the form, lack of understanding as to what constitutes an incident, and failure to recognise the incident. The researchers caution that such underreporting could be misleading when used exclusively to study drug related complications.

Others have also described causes for underreporting. Fear of medico-legal risk (Perper 1994) and stigma associated with making a medication error (Bechtel, Vertres, & Swartzberg 1993) are two factors. Discrepancies in who is responsible for completing the form (Hackel, Butt, & Banister 1996), and in perceptions of what constitutes an incident (Sutton et al. 1994b) also impede the reporting process. Fear of disciplinary measures (Fuqua & Stevens 1988, Gladstone 1995), having to leave the patients (and leaving them at risk) to fill in the form,

nurse educational level, and poor form design were also identified as causes for under-reporting (Elnitsky, Nichols & Palmer 1997).

In a study designed to examine the causes and consequences of nursing errors (Meurier, Vincent & Parmar 1997), it was found that nurses are least likely to report errors if senior staff are perceived to be insensitive, unsupportive, and if unsafe practices were unchallenged. Nurses may react emotionally to error and they may respond by feeling guilty, angry, and inadequate. They may feel less confident and anxious at work. Alternately, nurses who take responsibility for their error assume a more constructive approach and make changes to their practice (Meurier et al. 1997).

The traditional approach to incident reporting in hospitals requires a dramatic shift in order to become an instrument for improving practice rather than one of censure. A systems-based method of analysis, coupled with a blame-free, non-punitive method of collecting information on medical error is needed. Prevention of adverse events in health care will benefit from a variety of quality improvement review techniques, which include an effective multi-institutional, system-wide and united approach to incident reporting.

CHAPTER 2

History of Safety in Clinical Hyperbaric Medicine

An overview of the history of hyperbaric safety and training will be described in chronological order in this chapter. Intertwined in the history of hyperbaric are developments in diving and compressed air work. Many of the principles relating to these areas have been adapted for use in therapeutic clinical hyperbaric facilities.

From the late 1870's, compressed air work, and later diving work have existed to support civil engineering projects such as building tunnels and bridges, undersea and space exploration, and military operations. With advances in these areas, came morbidity and mortality. Elliott (1994) and Leitch & Hallenbeck (1985), describe a report by Moir and Smith in the 1880's in which there were twenty-six deaths in men from the newly recognised "caisson disease" or "the bends" [decompression illness] resulting from major tunnelling work in St. Louis and New York. As the hazards associated with this work became apparent, advances in safety followed. Paul Bert made the first significant advance in 1898. Bert first demonstrated the cause of decompression illness (DCI) to be dissolved nitrogen becoming gaseous during decompression (Elliott 1994, p.312). Following on from Bert's discovery, Professor J. S. Haldane, a British scientist, developed the first scientifically based decompression procedures and formed many of the basic safety principles for compressed air and diving procedures (Construction Industry Research and Information Association, 1991).

The first regulatory document for the control of compressed air workers, *Work in Compressed Air Special Regulations* was written in England in 1958 (Construction Industry Research and Information Association, 1991). In the 1970s and 1980s, formal standards and codes of practice were written for workers in compressed air (Canadian Standards Association Occupational Safety Code for Construction Work in Compressed Air CSA - Z275.3, 1986; American National Standards Institute Inc., 1977; American National Standard for Construction and Demolition - Tunnels, Shafts, and Caissons - Safety Requirements ANSI

A10-1977; and Medical Code of Practice for Work in Compressed Air, Construction Industry Research And Information Association, 1973). While these codes were not targeted for hospital based hyperbaric chambers, many of the principles behind them have relevance to clinical hyperbaric operation. The 1970s and 1980s also marked the years of rapid growth in underwater exploration. Again, as new boundaries were crossed, workers died or were injured, resulting in safety research and the evolution of new standards.

The largest database of health information ever to be collected on compressed air workers was commenced in England in 1956. The Medical Research Council formed a Decompression Sickness Panel and for twenty years, ran the Decompression Sickness Registry. This registry, with over 15,000 records, provided data for the analysis that commenced in 1989 supported by the Construction Industry Research and Information Association and the Health and Safety Executive. The report, published in 1991, was the largest study ever undertaken to assess the health effects of compressed air work. The final report discussed risk factors for decompression sickness, made associations between compressed air exposure patterns and decompression sickness and aseptic bone necrosis, compared two different decompression procedures, and suggested further studies (Construction Industry Research and Information Association, 1991)

The practice of clinical hyperbaric medicine has been active from the late 1960's. Since then, most hyperbaric clinicians have respected the inherent risks associated with the administration of oxygen in pressurised environments. There have been relatively few catastrophic events in the history of hyperbaric medicine, but those that have occurred have been tragic and are a constant reminder of the need for diligence and respect of safety principles. A recent Italian hyperbaric chamber fire killing eleven people has prompted further action by hyperbaric clinicians to review existing fire procedures and re-emphasize regard for safety.

The first professional society for specialists in diving and undersea medicine was the Undersea Medical Society (UMS), founded in 1967. The UMS, in 1976, developed an *ad hoc* Committee on Hyperbaric Oxygenation (Kindwall, 1994e). This was the start of hyperbaric medicine growing into a professional society. The membership of hyperbaric specialists in that organisation grew over the next ten years, prompting the name change of the UMS to the Undersea and Hyperbaric Medical Society (UHMS). The UHMS has throughout the years been intertwined with other societies and organisations to promote and research safety and training guidelines for the practice of hyperbaric medicine. The historical origins of diving

and undersea medicine and the involvement of aerospace physiologists and medical specialists in hyperbaric medicine are reflected in the development of hyperbaric safety standards. The involvement of these groups continues to support safety initiatives of the specialty.

Two organisations, the National Fire Protection Association (NFPA) and the American Society of Mechanical Engineers (ASME) have contributed significantly to the development of practical guidelines and compilation of scientific data for the operational safety of hyperbaric chambers. Representation on the NFPA Technical Subcommittee on Hypobaric/Hyperbaric Facilities is composed of chamber manufacturers, hyperbaric chamber users, fire service personnel, and others interested in hyperbaric chamber safety. This subcommittee has had UHMS members' involvement since its inception.

Two key events in 1967 prompted development of hyperbaric/hypobaric safety codes by the NFPA. Three astronauts perished in the Apollo I Command Module from a fire in hyperbaric conditions and a few days later a pure oxygen hypobaric chamber fire killed two United States Air Force Airmen. The NFPA tentative standard 56D was approved in 1968 and has since been revised regularly, to reflect current technological and clinical advances. The current standard is the NFPA 99, Chapter 19 - Hyperbaric Facilities, 1999 Edition. The standard is revised every three years (Workman 1992). The NFPA-99 Standard is the most comprehensive hyperbaric fire safety document written and should be utilised by all hyperbaric clinicians.

The rapid development of commercial diving operations in the early 1970's prompted the need for hyperbaric chamber safety codes. In response to this need, the American Society of Mechanical Engineers (ASME) began its involvement in hyperbaric safety. In 1974, the ASME Safety Code Committee on Pressure Vessels for Human Occupancy (PVHO) was formed. The PVHO Committee, a consensus standards committee, is chartered to establish minimum requirements for the design and construction of safe and affordable hyperbaric and hypobaric facilities. Representation of the committee includes those who are classed as general interest, insurance/inspection, manufacturers, regulators, users and window fabricators (Reimers 1992). The standard is revised every three years. The AMSE - PVHO code is a key document for safety guidelines in clinical hyperbaric facilities, as it addresses chamber design specifications that prevent dangerous pressure related mishaps (Gorman 1984, Grundstrom 1984).

Other organisations have assisted in the foundation of hyperbaric safety guidelines, standards, training and regulations. The American Society for Testing and Materials (ASTM), an international, non-profit, voluntary standards organisation founded in 1898, made significant contributions to the recognition of hazards in oxygen systems through fire testing. The data derived from these tests have been utilised to develop standards for oxygen systems. These standards have daily practical value in the hyperbaric setting. (Larrymore 1992).

The USA Center for Devices and Radiological Health (CDRH) in the Food and Drug Administration (FDA) promotes hyperbaric safety through regulation. The CDRH has designated hyperbaric chambers as "class II, medium risk, general controls". Manufacturers of new hyperbaric chambers must submit a pre-market notification application and the CDRH decides whether the chamber is "substantially equivalent" to a legally marketed chamber. Manufacturers generally follow ASME-PVHO and NFPA standards. This process relates only to manufacturers of chambers in the USA.

Established in 1913, the Compressed Gas Association creates technical specifications, safety standards, and training and educational materials. It cooperates with government agencies in formulating responsible regulations and standards and promotes compliance with these regulations and standards in the workplace. The memberships of the committees are composed of experts in related specialty areas from around the globe, and are voluntary appointments. Their mission is to provide information about accidents and incidents involving industrial gases and cryogenic liquids to prevent their recurrence. Their standards form the foundation of many internationally equivalent standards. The standards have important applications in daily clinical hyperbaric operations that address gas purity, the safe handling of gases, and the safety of gas distribution systems (Compressed Gas Association 1998).

Some of the first guidelines for hyperbaric safety were written by Dr. Eric Kindwall in 1977 for adoption by the Joint Commission of Accreditation of Healthcare Organizations (JCAHO) in the USA (Kindwall 1994e). While the guidelines were not at that time adopted by the JCAHO, some of the JCAHO inspectors referred to those guidelines when inspecting hospital based hyperbaric facilities. Of greater significance are the current UHMS Guidelines for Hospital Accreditation in the UHMS Hyperbaric Oxygen Therapy 1999 Committee Report (Hampson 1999).

In 1984, the UHMS formed the first Hyperbaric Chamber Safety *ad hoc* Committee. The Committee was chaired by Dr. George Hart, Hyperbaric Medical Director and surgeon at Long Beach Memorial Medical Center. Membership of the committee included those also representing the UHMS on the NFPA and ASME Committees, and members involved in the advancement of hyperbaric safety. A historical account of the actions of this committee has been made difficult due to years of Safety Committee Meeting minutes being unavailable and, regrettably, the illness of a key informant, causing further difficulties in accounting for the historical contributions of the UHMS Safety Committee.

Furthermore, in 1989, the Baromedical Nurses Association (BNA) sent out a questionnaire to all hyperbaric units in the USA with the intention of developing a national databank of safety issues in hyperbaric (Pressure 1989). No publications resulted from this effort.

There was a strong enthusiasm for the establishment of a UHMS administered accident reporting network in the late 1980s. Justifiably, the climate of the time introduced legal liability issues for such programs, so measures to introduce such a system were thwarted. This is described in greater detail in a review of incident monitoring in hyperbaric in Chapter Three.

Important safety publications made by the committee include regular safety information submissions to *Pressure* (the UHMS Newsletter), Monoplace Hyperbaric Chamber Safety Guidelines first published in 1991, and Multiplace Chamber Safety Guidelines, published in 1994. These publications, along with the previously described accreditation guidelines, are the key safety documents available from the UHMS.

From 1993, UHMS Safety Committee meeting minutes described Committee activities including a review of the United States Air Force Safety Survey of Mishaps in Hyperbaric Chambers, review of United States Navy testing of acrylic viewports, continued involvement in ASME and NFPA Committees, the development of a UHMS Mishap Database, commencement of an equipment database, and a UHMS Safety Committee internet web site. Monoplace Hyperbaric Chamber Guidelines were revised by Weaver in 1997. Sheffield and Desautels (1997) published a review of hypobaric and hyperbaric chamber fires from data obtained in the UHMS Safety Committee Mishap Database. Moves are now underway to revise safety documents and write guidelines for the safe decompression of hyperbaric attendants.

2.1 Hyperbaric Specific National Standards/Guidelines

In 1993, Canada was one of the first countries to develop a national standard to address the needs of therapeutic hospital based hyperbaric chambers. The Canadian Standard for Hyperbaric Facilities Z275.1 - 93 details technical specifications and operational procedures for hyperbaric facilities and it generally addresses administration and personnel requirements. One year later, in 1994, the Faculty of Occupational Medicine of the Royal College of Physicians of London published, *'A Code of Good Working Practice for the Operation and Staffing of Hyperbaric Chambers for Therapeutic Purposes'*. This code of practice designates general technical information, training and staffing requirements, documentation, medical fitness to dive, and other relevant legislative issues (Faculty of Occupational Medicine, 1994).

Germany has extensive written standards that relate to hyperbaric and diving medicine, and is the only country in which a certifying body inspects and accredits hyperbaric facilities for safe operation. Once certified, the facility becomes a member of the Association of German Hyperbaric Centers.

German publications that relate to safe hyperbaric practice are listed in Appendix B and other German standards will be listed with the international listing of hyperbaric standards in Appendix D.

Internationally, standards and guidelines have been written in order to promote safe hyperbaric and diving operations. The current international hyperbaric standards and guidelines may be divided into three types: hyperbaric system, operational, and personnel. As with any written standards, in order to be effective, they need to be strictly adhered to, easily accessible, and reinforced through education programmes. A list of the current international standards/guidelines is provided in Appendix D.

2.2 Training

In the USA, regularly occurring hyperbaric training courses for civilian physicians began in 1976 by Dr. Eric Kindwall in Milwaukee, Wisconsin. Since that time numerous courses are

run every year in the USA (Kindwall 1994e). In 1974, the first Australian diving medicine courses were taught by the Royal Australian Navy at the School of Underwater Medicine in Balmoral, New South Wales. Available to civilians and Navy personnel, this course focuses on diving related illness and does not incorporate subjects on the use of hyperbaric for non-diving related illnesses. In response to this need, Medical Officer, Diver Medical Technician, and Hyperbaric Nurse Courses were commenced at the Royal Adelaide Hospital in South Australia in 1985 by Dr. Des Gorman. Since then, the Royal Adelaide Hospital has become a leading training centre for Hyperbaric Medicine in Australia, New Zealand, and South-East Asia.

Training requirements for hyperbaric staff vary widely. In 1972, the UHMS made the first attempt to standardise training programs in hyperbaric medicine. It would, upon request, review hyperbaric courses and give official "UHMS Approval" for those courses delivering a sufficiently high standard of hyperbaric educational content (Kindwall 1994e). Continuing education units were offered for approved courses. Further standardisation occurred in 1998 when the UHMS established the minimum criteria for a UHMS Designated Introductory course in Hyperbaric Medicine.

The British Hyperbaric Association (BHA) recently published a basic curriculum for the training and education of hyperbaric unit personnel. Currently, they have also established a working party on medical education, which is constructing a syllabus for hyperbaric medicine subspecialty training.

In 1991, several other steps were taken to improve the quality of hyperbaric education and to standardise course curricula. Clarke (1991) developed a certification program for the hyperbaric medicine team. The National Board of Diving and Hyperbaric Medical Technology (NBDHMT) was introduced in an effort to assure uniform minimum training requirements for technicians and nurses in hyperbaric medicine practice. It is well recognised as a reputable credential in the USA and is often required as a prerequisite for employment in hyperbaric medicine units.

Additionally, the NBDHMT accredits civilian introductory hyperbaric medicine courses. The courses are designed to teach all groups such as, nurses, technicians, doctors, and respiratory technicians that work in the hyperbaric field. It is based on the premise that everyone entering into clinical hyperbaric medicine should receive the same basic training. The curriculum has

been established by the NBDHMT and consists of 40 hours of training time. The responsibility of teaching more than the basic introductory subjects is left to the individual hyperbaric unit.

The only training courses approved by the NBDHMT that are specifically for nurses or technicians are run by the US Air Force and the US Navy. However, those courses all teach the same basic 40 hours that is approved by NBDHMT. They add further training hours to the courses that are specific to the group being taught.

Budziszewski, Fabus, and Raleigh (1991) developed a competency based orientation programme for hyperbaric chamber nursing and technical staff. The aims of the orientation programme were to provide consistency in training as well as evaluating all levels of staff on hyperbaric skills. In 1991, the Royal Adelaide Hospital Hyperbaric Nurses Course also became competency based. Nurses working in the Unit are required to pass annual competency checks. Medical, technical and nursing staff undergo annual reviews and drills in emergency protocols.

In order to standardise training qualifications for hyperbaric nurses in the USA, the Baromedical Nurses Association (BNA) in 1996 developed (with the assistance of the NBDHMT) and administered a Hyperbaric Nursing Certification Examination. There are three levels of certification awarded (Josefsen 1996). This award is offered internationally, and although the award is not affiliated with a tertiary institution, it is often cited as a requirement in USA hyperbaric nursing employment specifications.

In Australia, hyperbaric nursing is well developed, with ten hyperbaric medicine centres offering hyperbaric nurse training courses in accordance with the Hyperbaric Technicians and Nurses Association (HTNA) Hyperbaric Nurses Course Standard of 1995. The first Graduate Certificate in Hyperbaric Nursing was offered at the University of Adelaide in 1997. This is the only University based Hyperbaric Nurse Training established in the world at the time of this publication.

A process for certification of doctors in Hyperbaric Medicine is in its infancy. The American Board of Preventative Medicine (ABPM) developed an exam for those with an ABPM diploma for a certificate of Added Qualification (CAQ). The exam was given in 1972 to 12 individuals, but was never repeated due to the enormous expense of administration for so few applicants (Thalmann 1997). In 1999, the ABPM approved the offering of a certifying

examination in Undersea and Hyperbaric Medicine. The examination is offered to those who have completed an approved fellowship in Undersea and Hyperbaric Medicine following primary board certification or to those who meet the requirements through a combination of basic training and practical experience and have primary board certification through the American Board of Medical Specialties (Fife 1999). There are established residency and fellowship programmes for hyperbaric medicine in the USA but these are not yet accredited programmes. The Accreditation Council on Graduate Medical Education (ACGME) accredits universities who offer graduate medical education programs. Thus far, they have rejected the UHMS proposal for Residency in Hyperbaric Medicine.

In Australia, certification for hyperbaric medicine as a subspecialty is being sought through the Australian & New Zealand College of Anaesthetists Australian and New Zealand Hyperbaric Medicine Group (ANZHMG). Fellowships in Hyperbaric Medicine are also offered in Australia. The South Pacific Underwater Medical Society (SPUMS) awards a Diploma in Diving and Hyperbaric Medicine (DipDHM). This requires the candidate to have appropriate experience and training in hyperbaric medicine as well as to submit a formal thesis accepted by the SPUMS Board of Censors.

A position statement regarding the minimum training requirements for Hyperbaric Medical Practitioners was written by the ANZHMG in 1995. The opinion of the ANZHMG is that the prescription of hyperbaric oxygen treatment must be made by a physician with appropriate training in hyperbaric (Bennett 1995). Training standards for hyperbaric technicians in Australia are in accordance with the HTNA Standards for Hyperbaric Technician's Training. The HTNA formed a training board in August 1999 that will formalise training programmes and provide guidelines for certification.

Other hyperbaric staff minimum training standards/guidelines have been developed for the European Community (Desola 1996), Germany, Latin America, Japan, Canada, South Africa, the USA, Australia / New Zealand and the United Kingdom. Currently, the National Fire Protection Association (NFPA) Technical Committee for Hyperbaric/Hypobaric Facilities is writing staffing and training requirements for the USA. Additionally, the UHMS Operations Committee recently published a report describing the roles, responsibilities, and training required for staff working in hyperbaric facilities (Kimbrell 2000). This document is an important resource for setting individual hyperbaric medicine unit staffing policies and national training standards.

Hyperbaric Safety Training Symposia are held annually in the USA by International ATMO, a hyperbaric training institution. The entire focus of these symposia is on providing current information on hyperbaric safety for those employed in this specialty.

In the field of hyperbaric medicine there are many resources for the safe operation of hyperbaric chambers. Some useful safety references are listed in Appendix C.

Hyperbaric textbooks have included chapters on hyperbaric safety issues. Hamilton and Sheffield (1977) discussed medical support, supplies and equipment, and personnel recommendations for multiplace hyperbaric facilities in their chapter: 'Hyperbaric chamber safety' in *Hyperbaric Oxygen Therapy.* In 1981, Sheffield and Heimbach described the physician's role in hyperbaric chamber safety in their chapter 'The physician and chamber safety' in *Hyperbaric and Undersea Medicine* (1981). These authors outlined the hyperbaric physician's responsibility for the management of safety issues of equipment, gas supply, fire prevention, safety procedures, maintenance, and staff training and qualifications. Jain, in 'Hyperbaric chambers, equipment, technique, and safety' in *Textbook of Hyperbaric Medicine* (1990) included basic principles for safe hyperbaric operation. Hart (1994) and Kindwall (1994a) focused on equipment and fire safety in their chapters 'The monoplace chamber' and 'The multiplace chamber' in *Hyperbaric Medicine Practice.* Nistrio (1996) and Desola (1996), in their chapters 'Medical Oxygen Characteristics, Use, and Safety Guidelines' and 'Personal, Professional, and Educational Requirements for the Staff of a Hyperbaric Medical Centre', gave guidelines for safety and training in medical hyperbaric facilities.

From the origins of compressed air and diving work, hyperbaric medicine has made significant improvements in hyperbaric safety over the past thirty years through the cooperation of hyperbaric professional associations, associated organisations and the commitment of the clinicians, designers, manufacturers, and researchers in hyperbaric medicine. Nevertheless, much work remains to be done. There is a lack of information on the occupational health of hyperbaric attendants, a need for the collection of international hyperbaric safety standards for comparison, and to develop staffing guidelines and training requirements for various classes of chambers, medical fitness standards and decompression guidelines for hyperbaric attendants, and to improve patient safety. It is a tribute to those who died or were injured in the initial caisson, diving and space exploration, that hyperbaric medicine has reaped the benefit of safety improvements from their pioneering work.

CHAPTER 3

Review of the Literature: Incidents and Safety in Hyperbaric Medical Practice

'Le prisent ne contient rien de plus que le passé, et ce qu' on trouve dans l' effet e'tait déjá dans la cause'

'The present contains nothing more than the past, and what is found in the effect was already in the cause.' French Philosopher Henri Ferson 1859-1941
Evolution créatrice (1907) chapter 2

This chapter begins with the methodology of the review process followed by a review of incident monitoring in hyperbaric clinical practice. A comprehensive summary of fire and pressure incidents is subsequently followed by an overview of occupational safety risks, which sets the background for a review of staff incidents occurring in hyperbaric clinical practice. Staff related incidents are categorised as decompression illness, barotrauma, pressure, oxygen toxicity, musculoskeletal effects, and other.

The next section examines patient incidents. As common side effects of barotrauma, visual effects, oxygen toxicity, hypoglycaemia, and confinement anxiety have already been well described in the literature, an overview of the literature is presented on these topics, thereby setting the background for reviewing patient side effects that are reported in the Results Chapter. Equipment and chamber type incidents are the remaining incidents reported in the literature that do not fall into the previously described categories.

3.1 Methodology of the review

There is a large body of literature regarding safety in hyperbaric but the information is difficult to find. Safety information for hyperbaric has been reported as case reports, contained in classified government documents, unpublished reports, Undersea and Hyperbaric Medicine Society (UHMS) guidelines, and chapters of hyperbaric texts. It has been a painstaking process to uncover the sources for this review, much of which was aided by correspondence with individuals personally involved in the development of hyperbaric safety principles. The librarians from the UHMS and the Royal Australian Navy School of Underwater Medicine collated a complete set of *Pressure* Newsletters to assist this review.

Limitations of the review are associated with hyperbaric medicine's history in the military, where documents are not readily available for civilian review and the incomplete process of cataloguing hyperbaric literature onto a library database. This resulted in many hours of manual review of the resources and a coordinated effort with many persons from several countries in locating sources. Where there were missing copies of *Pressure* newsletters at the UHMS, the researcher located them through the Royal Australian Navy School of Underwater Medicine in Balmoral, Australia and through personal associations with members of the UHMS.

This literature review includes all incidents reported in hyperbaric textbooks, those found in a manual review of all *Pressure* newsletters, a review of UHMS hyperbaric journals, Medline, Cinhal, and Occupational Health and Safety Database (OshRom) reviews, unpublished UHMS reports, UHMS Safety Committee Meeting Minutes, internet reports, and many found by emailing individuals involved in the development of safety standards who had unpublished reports on file (Table 3.1). A large contribution to this review includes data from the UHMS Experience and Mishap Database (Desautels, unpub. 1997).

1.	Unpublished UHMS Reports
2.	Internet reports
3.	Hyperbaric texts
4.	Medline review
5.	UHMS Hyperbaric Journals
6.	Cinhal review
7.	Communication with UHMS members involved in hyperbaric safety standard development
8.	UHMS Safety Committee Meeting Minutes

Table 3.1 Literature Review Sources

3.2 Review of Incident Monitoring in Hyperbaric

Incidents in hyperbaric are normally presented as case reports, in *Pressure,* an official Undersea and Hyperbaric Medical Society (UHMS) publication, and in safety chapters in hyperbaric texts. The incidents that are reported are mainly those that involved morbidity and mortality.

Several attempts to collect reports of hyperbaric incidents have been conducted. The first began in 1980 as a request for Undersea Medical Society members to submit their "best" case histories of hyperbaric accidents. It was specified that no identifying details of those involved in the accident be disclosed and that the focus of the case history was the circumstances of the accident. After acquiring funding support from three sources, 'Case Histories Of Diving And Hyperbaric Accidents' was published by the UHMS in 1988.

UHMS Safety Committee Chairman, Dr. Keith Van Meter, was committed to setting up an informal accident reporting service for hyperbaric in 1987 (UHMS). After deliberation, the concept was accepted by the UHMS Executive Committee as long as the incidents that were to be published were first screened by an editorial review panel of the UHMS and, if equipment was involved, manufactures would have an opportunity to reply to the UHMS prior to publication (Van Meter 1988). The concept was developed further to include the publishing of recommendations for the prevention of similar incidents. Fear of liability issues

reduced the effectiveness of this reporting process by requiring that the accident report contain only verifiable details of an incident and undergo review by UHMS legal counsel and Executive Committee (Undersea & Hyperbaric Medical Society 1987).

With the persistence of members of the UHMS Associates, the Safety and Technical Network was instituted in 1990. This system utilised a telephone tree, for the telephone exchange of safety, technical, and equipment information between hyperbaric units in the USA. Any incidents reported to regional coordinators of the network were reviewed for their technical correctness and then screened by the UHMS prior to their publication in *Pressure* (Rugh 1991). Valuable safety reports from the Safety and Technical Network contained incidents in hyperbaric, design innovations, and training and staffing policies affecting safety were published in *Pressure* until 1993.

In 1991, Reimers Engineering Incorporated set up an electronic bulletin board for hyperbaric medicine unit personnel, UHMS members, and affiliates to communicate safety, equipment, and operational procedure information with each other (Undersea & Hyperbaric Medical Society 1991). No reports of information from this system were published.

Also in 1991, the United States Airforce sent a survey to 700 hyperbaric facilities in the UHMS Hyperbaric Chamber Registry. This retrospective survey of mishaps attempted to collect, analyse and report incidents in hyperbaric. It used the principles previously used in the airforce to look for common trends, and contributing factors to incidents. The survey concluded in 1992 and the results are described later in this chapter.

In 1992, the Hyperbaric Incident Monitoring Study (HIMS) was commenced in Australia to report incidents and "near misses" in hyperbaric. The mishap survey conducted by Brown, Dart and Workman of the United States Air Force (USAF) Davis Hyperbaric Laboratory and the commencement in Australia of HIMS data collection started the systematic review of incidents that occur in hyperbaric medicine practice.

The UHMS Safety Committee, Chaired by David Desautels, appealed for UHMS members to post in any accounts of mishaps in hyperbaric to the central database. This "Experience and Mishap Database" commenced in the mid 1990's, and continues today. The database includes historical and contemporary experiences and mishaps in hyperbaric, hypobaric and diving systems. Only details of incidents that have been previously published or those with written consent of the parties involved in the incident are included in the database. Report forms for

the database include identifying features and details of injuries or fatalities. A sample of the report form is included in Appendix E.

Demand for the collection and analysis of incidents in hyperbaric is demonstrated by the persistence of attempts to establish an effective reporting system over the past thirteen years. The main limiting factors to these systems are legal liability, anonymity, and maintenance of the reporting system. Furthermore, the process of reporting recollections of past incidents and basing future recommendations on these will suffer from selectivity of the reporter's memory of the event. Without the reporter identifying the contributing factors of the event, there is danger of strong influences of hindsight bias. In this respect, the person analysing the data can not judge how much influence the knowledge of the outcome affects their perception of what could have or should have happened and hence may exaggerate what others should have been able to anticipate in foresight. This effect, proven by Fischoff (1975), and its effect in event reporting systems is summarised by Billings (1998), who has extensive experience in aviation incident reporting systems.

None of the reporting systems, except for the Hyperbaric Incident Monitoring Study (HIMS), allow for anonymous reporting and a structure that incorporates a systematic process of detecting and analysing contributing and minimising factors of the incident. Hindsight bias in HIMS is lessened by the analysis of the reporter's determination of the factors that contributed to and minimised the incident.

3.2.a Findings of Incident Reporting in Hyperbaric

The UHMS published the first report of accidents in hyperbaric. A historical collection of accidents occurring in diving and hyperbaric chambers is presented by Waite (1988) in *Case Histories Of Diving And Hyperbaric Accidents*. The accounts of the accidents were solicited by calls for submission in *Pressure*. A wide variety of incidents from gas contamination of the chamber atmosphere to barotrauma in divers are described. Few of the accidents involve clinical hyperbaric medicine chambers, and these incidents are discussed individually in the literature review.

Brown, Dart, and Workman (1992) published a survey of mishaps that occurred in hyperbaric facilities. Seven hundred surveys were sent out internationally and eighty-seven reports from

both the survey and those found in reviewed literature were included in their analysis. There were fifty-seven non-fire reports and thirty fire incidents. Incidents included clinical and non-clinical hyperbaric facilities as well as hypobaric environments. There were sixty-three occurrences inside the chamber and twenty-four occurrences outside the chamber. Fire caused twenty-eight deaths; improper ascent caused six deaths. The non-fire mishaps were attributed to human error, equipment failure, design flaws, and high pressure.

Hyperbaric Incident Monitoring Study data collected previously by the author have been presented at Hyperbaric Medicine Scientific Meetings. In 1993, an eighteen-month analysis reported on twenty-two incidents. Eleven incidents were equipment related, five were patient complications to treatment, four were staff complications to hyperbaric chamber exposure, and two were drug related incidents (Pirone 1993).

In another review of forty-nine incidents over a period of eighteen months, Pirone and Williamson (1995) reported the most common incident as being barotrauma. Patient incidents also included oxygen toxicity, claustrophobia, physical injury, falls, intravenous and pressure line problems, drug over dosage and under dosage, and inadequate ventilation. Staff incidents were barotrauma, decompression illness, and physical injuries and complaints. The explosive decompression of a medical lock was also reported. Factors that contributed to and factors that minimised incidents were included in the report. Recommendations to improve equipment design and introduce protocols for checking equipment were made.

Another HIMS report (Pirone and Williamson 1996) provided data from a ten month period involving sixty-eight incidents. Thirty incidents (forty-four percent) involved equipment, both design problems and misuse. Sixteen (twenty-three percent) involved barotrauma, equally in patients and staff. Other incidents included patient complications (fourteen reports/twenty-one percent), fire hazards, minor physical injuries to staff, and technical problems. Recommendations from this review were again to improve equipment design and training in its use, and equipment checking discipline. Assessment of attendants' ear equalisation abilities prior to compression along with ensuring experienced supervision, alert staff and close teamwork during treatments was also suggested.

The unpublished report of the 'UHMS Experience and Mishap Database' (Desautels 1997) described ninety-one accounts of incidents that occurred over seventy-four years (1923-1996). Data was extracted from a previous review by Brown et al. (1992), literature review, and from

reports submitted by a request published in *Pressure*. The data included reports involving diving, hyperbaric, and hypobaric facilities. It is further classified into monoplace, multiplace, diving bell, hypobaric and system (an incident which occurred in the support system of a chamber). Causes of mishaps were grouped under the headings of "pressure", "fire", and "other".

Of the total ninety-one incidents, fifty-seven (sixty-one percent) occurred in hyperbaric facilities, thirty (thirty-two percent) in diving chambers, four (four percent) in hypobaric chambers, and three (three percent) unknown. In the hyperbaric group, the causes of the mishaps were fire in thirty-five (fifty-nine percent), pressure in fourteen (twenty-four percent), other causes in ten (seventeen percent). There were twenty-two (fifty-eight percent) injuries and sixty-six (sixty-eight percent) fatalities in the hyperbaric group out of the database total of thirty-eight injuries and ninety-seven fatalities. Fire and pressure incidents featured in this morbidity and mortality study.

Examining the prevalence of mortality and morbidity by type of system, multiplace chambers have resulted in eighteen incidents involving fifty-one fatalities and seven injuries, while monoplace chambers have had nineteen incidents with fifteen fatalities and eleven injuries. Nineteen system incidents (those involving support equipment to chambers or oxygen supplies) were responsible for four injuries but no fatalities. Most of the fatalities (ninety-one percent) were caused by fire (forty-five in multiplace and fifteen in monoplace).

These data show fire to be the main cause of mortality in clinical hyperbaric chambers. These fires were all preventable by adhering to proper engineering and fire safety codes, protocols, and training standards for hyperbaric personnel.

The remaining data from the UHMS Experience and Mishap Database will be presented with the remaining literature review.

3.3 Incident literature review by type of incident

To structure this review, similar types of incidents are classed together and discussed under the main headings of: fire, pressure, hyperbaric staff safety, patient problems, and chamber/ equipment problems.

3.4 Fire Incidents

Fire accounts for the most devastating incidents in hyperbaric chambers. The risk of fire in hyperbaric chambers is increased due to the higher partial pressure of oxygen in the pressurised chamber. The oxygen percentage may also be elevated, resulting in an increased burning rate and ease of ignition. The properties of increased flammability coupled with the barrier to escape, and the rapid rise in pressure associated with increased temperature, demand respect for the inherent dangers of fire in hyperbaric facilities (Hamilton & Sheffield 1977).

Fire safety is one of the most well researched and published aspects of hyperbaric safety (Sheffield & Desautels 1997). The most comprehensive review of hyperbaric and hypobaric fires was published by Sheffield and Desautels in 1997. Their analysis was from literature review and the UHMS Experience and Mishap Database. In the years from 1923-1996 in three continents, there were thirty-five hyperbaric chamber fires, a fire in a pressurised space module, and three hypobaric chamber fires. These fires resulted in eighty-two fatalities. Twenty-five of the fires occurred in clinical hyperbaric chambers, resulting in sixty fatalities. Only four of the clinical chamber fires involved no fatalities, and of those, two had no occupants at the time of the fire. The only survivor of an occupied chamber fire was in an air environment with oxygen percentage less than 23.5%. The data also revealed that seventy-six percent of the clinical chamber fires and ninety-eight percent of the fatalities occurred in Asia. The primary causes of the fatal fires were faulty electrical components and ignition sources that were carried into the chamber. Each fire was characterised by an abundance of burnable materials, elevated oxygen concentrations, and inadequate extinguishing facilities. Since the introduction of the National Fire Protection Association (NFPA) Tentative Standard 56D-T in 1968, the final Standard for Hyperbaric Facilities NFPA 56 in 1970, and the subsequent upgrading to NFPA 99, Standard for Health Care Facilities, Chapter 19, Hyperbaric Facilities, there has been a dramatic reduction in chamber fires involving electrical ignition as a source (NFPA 1968, NFPA 1970, NFPA 1999).

Until 1986, China suffered eighty-three percent of chamber fires originating from an electric or static electricity source. Fires in clinical chambers since 1980 that did not have any electrical source were those in which the occupant carried prohibited items into the chamber (Sheffield & Desautels 1997).

In 1989, Youn and colleagues reported a fire in a clinical multiplace hyperbaric chamber. The fire resulted from a blanket being externally heated in a microwave oven and then passed into the chamber via the medical lock. The central deluge system was activated and the fire was extinguished with no personal injury.

An account by Kindwall (1992) of an oxygen fire in a U.S. Naval submarine base in 1968 resulted from the use of a ball valve in a high pressure oxygen line that had a small accumulation of dirt or hydrocarbons in the high pressure oxygen manifold. A hospital corpsman sustained severe burns from the explosion. The report states that three more incidents of this type have occurred more recently with two resulting in personal injury. Desautels, Reimers, and Butler described an oxygen fire at a hospital in 1990. The Teflon component of a ball valve in the breathing system of a multiplace chamber ignited when a technician activated a ball valve of a high pressure oxygen line. The three-way Teflon ball valve was designed to select either the low pressure hospital oxygen supply or a high pressure oxygen cylinder bank. The Teflon seat material ignited when the technician turned the valve 90 degrees. At once the technician heard a sizzling sound and retreated and activated the fire alarm. The valve failed spraying her with molten Teflon and stainless steel. The technician suffered burns to her face, arm and back. The burning valve continued blowing fire and burned an adjacent filing cabinet and papers inside. An investigation into this incident showed that particulate matter lodged in the oxygen cylinder valve may have occurred during shipment, and when coupled with the ball valve system caused auto-ignition of Teflon. It was recommended that ball valve systems should not be used for oxygen service at pressures greater than 125 pounds per square inch gauge (PSIG). It is necessary to use slow opening type valves and large diameter piping to reduce oxygen velocities and lessen the heat of compression.

Alger and Nichols (1971) described eleven chamber fires, seven of which occurred in hyperbaric chambers. Of the eleven fires he reports, ten were due to electrical ignition and all were characterised by an increased oxygen concentration (Sheffield & Heimbach 1981).

A flash fire in a hyperbaric unit occurred outside a chamber when a battery charger shorted out. The nurse extinguished the fire with her hands and sustained minor burns (Sullivan 1996).

Fires in monoplace chambers have included a fibreglass patient trolley tray bursting into flames outside the chamber with no personal injury. In Japan over the past twenty years three monoplace chambers have caught on fire and exploded killing the occupants and one family member outside the chamber (Hart 1994, Bush 1996). Recently reported by Borisova (1996) from the St Petersburg Press in Russia (via the Internet) was an account of a twelve year old boy who burned to death during treatment in a chamber at the St. Petersburg Pediatric Academy.

In 1997, a child died in a monoplace chamber in Cuba. As the boy was playing with a toy gun in the oxygen filled chamber, the doctor noticed the toy and asked the chamber operator how much longer until the end of the treatment. There was only ten minutes remaining, so the decision to continue the treatment was made. In those remaining minutes the toy sparked a fire and the boy burned to death.

3.5 Pressure Incidents

Captain Klaus Seeman (1979) described the first known report of a fatal accident of decompression illness in humans associated with a hyperbaric air therapy. The incident occurred in Hanover, Germany in 1976. A homeopath, a medical practitioner and three technical assistants ran the Unit. They were treating four groups of twenty patients per day at a treatment depth of thirty metres (4.0 ATA). There were no staff members in the chamber with the patients. One patient had difficulty breathing and was paralysed on one side. The technical assistant notified the doctor who asserted that he was only responsible for pre and post compression physicals. The homeopath was called in and he ordered an immediate decompression [the chamber was on a six metre (1.6 ATA) decompression stop]. The rapid reduction of pressure resulted in five deaths from decompression illness.

Desautels (1995) reported five people injured when a chamber underwent explosive decompression resulting from a failed acrylic chamber door. The patient suffered a seizure after missing her anti-convulsant medication, and the patient's wife, also an inside occupant of the chamber, suffered chest pain. Other victims were outside the chamber. One was struck in the head by shrapnel and required surgery and the other two had cuts and bruises. Acrylic fragments were reported to have projected down a seventy-five foot hallway, piercing a chair and pieces were also found in a parking lot three hundred feet away.

In another pressure related incident, a hospital hyperbaric chamber was pressurised to six ATA. The air pressure became greater than the hospital oxygen pressure and caused air to be introduced into the hospital oxygen system. This reportedly resulted in the oxygen levels dropping to as low as eight percent in patients on anaesthesia machines undergoing surgery (Desautels 1997).

In an account from an off shore commercial diving chamber, Carter and Goldsmith (1970) recounted the occurrence of a diver eviscerated while sitting on a toilet in a recompression chamber. This incident involved the untimely opening of a valve that controlled the evacuation of the chamber toilet contents. The diver survived by heroic surgical intervention. While this incident occurred off shore, it has relevance to the design of toilets in all hyperbaric chambers.

High pressure storage cylinders can also fail. In one such incident, cylinders filled to 16,547 kilopascals ripped the piping from two other cylinders. A pressure reduction regulator in an air compression system failed allowing a pressure surge in a chamber from 2.0 ATA to over 3.0 ATA before the control valve could be closed. Pressure was then reduced to 2.0 ATA and the chamber occupant was put on oxygen for one hour before being decompressed. The occupant sustained ear barotrauma.

In a pressure test of a man-lock section of a multiplace chamber, over-pressurisation caused the lugs to be blown off the door and spun around in the main chamber compartment. Since the chamber was unoccupied at the time, no one was injured (Sheffield 1999, personal communication).

In the USA, in the 1960's, an acrylic hull of a monoplace chamber exploded causing severe lacerations to a nearby radiotherapist and in Mexico a metal collapsible monoplace chamber exploded resulting in the death of the occupant (Hart, 1994).

Computerised chamber systems have unique hazards. In one incident, an incorrect input caused a rapid decompression of a multiplace chamber. The computerised chamber control had been accidentally programmed to rapidly decompress rather than shift to manual operations after a power failure. After a twenty minute power outage from a lightening strike, normal power returned causing the computer to decompress from 2.8 ATA to 1.0 ATA in one minute. The four patients and physician were unharmed.

3.6 *Hyperbaric Staff Safety*

The occupational health risks associated with working in hyperbaric chambers are different from other working environments in hospitals. The particular risks include decompression illness (DCI), barotrauma, oxygen toxicity, injury related to explosive decompression, and increased risk of mortality should a fire occur. Although these risks are unique to hyperbaric chamber work, they proportionately do not constitute a greater risk than those resulting from other forms of hospital work such as back injuries, needle stick injuries, radiation exposure, or exposure to radiation or toxic agents. Hyperbaric employee compensation claims are not proportionally greater than any other work injuries in hospitals.

There are several variables that affect the level of risk involved in attendants working in hyperbaric chambers. These include the fitness of the attendant to work in compressed air environments, technical and operational safety of the chamber, level of hyperbaric training of the hyperbaric staff, adherence of the Hyperbaric Unit to safe operating procedures, activities surrounding hyperbaric exposure, and decompression profiles. Of these, fitness to dive requires specific attention as hyperbaric exposure has direct consequences on the health of staff that may be unfit to work in such environments.

3.6.a Fitness to dive

Fitness to "dive" or work in hyperbaric environments is an issue that generates much discussion at hyperbaric scientific forums (Van Meter 1988, Hill 1990, Scoggins 1991 & Wilson 1996). The UHMS and several countries have fitness to dive standards or guidelines for occupational and recreational diving. While there are differences in the nature of hyperbaric chamber work and in-water diving, the specific differences have not been previously described and their significance in relation to medical fitness has not been determined. Hyperbaric units generally dictate their own policy on fitness to work in hyperbaric chambers and these practices may vary considerably (Hill 1990). Most Units have a policy requiring hyperbaric attendants to undergo an annual diving medical examination (Persels 1989).

Australia is the only country in which a national fitness to dive standard is required for acceptance into the nationally recognised minimum standard for hyperbaric multiplace nurse

attendant training. The Hyperbaric Technicians and Nurses Association (HTNA) requires that nurses must be fit to dive (according to a modified Australian New Zealand Standard (ASNZ) 2299.1: 1999) to be accepted into a HTNA Hyperbaric Nurses Course Standard approved course, provided they are being trained in a multiplace facility.

The United Kingdom, Canada, Europe, Australia, and New Zealand all require attendants in hyperbaric chambers to undergo medical examination according to written standards or guidelines (McIver 1995). Although the frequency of repeating the occupational dive medical for chamber attendants must also be considered, there is no consensus in the literature on this subject. Furthermore, fitness to dive may alter for an individual on a daily basis. Individual hyperbaric facilities may have their own policies, but nothing in the literature could be found that addresses daily fitness to dive criteria.

In both commercial and navy diving, male divers form the majority. Conversely, in hospital hyperbaric units, nurses are frequently attendants, resulting in a predominance of females in dry chamber diving. The occupational health issues of working in a hyperbaric chamber have not been studied for hyperbaric medicine unit attendants as an occupational group. It is not known if there are any differences between this group and members of other forms of diving with respect to their predisposition to diving related injuries.

The use of oxygen breathing and prohibiting repetitive diving are methods used by many centres as safety precautions for staff. Careful selection of attendants by thorough health screening will increase safety of staff attendants. The use of appropriate decompression tables, proper attendant training, annual diving medicals, and adherence to written occupational safety policies will minimise the risk of injury to the hyperbaric attendant. Even following these guidelines, there is still potential for barotrauma and decompression illness. Kindwall (1995) described guidelines for hyperbaric attendant selection and attendant safety precautions. He recommended no repetitive diving, the use of oxygen breathing on decompression, no strenuous physical work before, during or immediately after diving in the chamber and no flying for twenty-four hours after diving. The long-term health effects of daily exposures to the hyperbaric environment are still unknown (Kindwall 1994a).

Gender and diving has introduced issues such as the risk of DCI in women, safety of diving during pregnancy, the interaction of diving and the menstrual cycle. It is believed that gender is an important issue for hyperbaric work in Italy, as hyperbaric chamber work is prohibited to

women. Some of the issues related to women diving are as much historical and cultural, as they are physiological (Edmonds, Lowry & Pennefather 1992a). The male domination in occupational and to a lesser extent in recent years, recreational diving, influence the reception of women into diving and hyperbaric occupations. Cultural attitudes that assume women do not understand the mechanical aspects or physics related to diving work still exist.

Bangasser (1978) described some of the concerns that women have about diving. These include thermal comfort, diving while menstruating, the effect of diving while using birth control pills, and diving while pregnant. Resultant from her publications and presentation on this topic, advances were made to highlight previously unaddressed concerns for women entering into diving as an occupation or for recreation.

It is known that nitrogen is four and a half times more soluble in fat than in other non-fatty body tissues (Edmonds, Lowry & Pennefather, 1992c). It has been argued that women, having a greater percentage of subcutaneous fat than men, have a greater risk of nitrogen loading, and hence an increased susceptibility to decompression illness. Obesity has regularly been included as a risk factor of decompression illness because of this notion. Hart et al. (1981) demonstrated an increased nitrogen load in females versus males by mass spectrometry of probes inserted directly into the tissues of subjects in a recompression chamber. Although the hypothesis of increased subcutaneous tissue as a risk factor for decompression illness is widely accepted, data have not yet conclusively demonstrated a higher incidence of decompression illness in obese individuals. This is reflected in the leniency that has been granted for weight in diving medicals for hyperbaric attendants by diving medicine and hyperbaric doctors.

The first documented study on female divers in mixed gas diving occurred in the early 1970's at the Hyperbaric Physiology Department of the Virginia Mason Research Center, for Sub Sea International, Incorporated. "Two women, Diane Norkool and Mary S. Keller, were pressurised along with Dr. Brian D'Aoust, senior investigator, for thirty minutes at 600 feet of sea water. No significant limitations due to sex were noted" (Undersea & Hyperbaric Medical Society 1975, p. 8.). This limited trial of women exposed to significant pressure did not demonstrate overt gender differences.

St. Leger Dowse et al. (1997) postulated that scuba diving might alter the menstrual cycle in some women. This was based on a retrospective study gathering data from 1050 women on

the effects of the menstrual cycle and scuba diving. Soon to be completed is a three year prospective study on the same topic that includes data on female hyperbaric attendants.

In a review of all women scuba divers treated for DCI in the Divers Alert Network database from 1989-1995, it was found that women taking oral contraceptives are significantly more likely to experience DCI if they scuba dive while menstruating (Doyle et al. 1997).

Dunford and Hampson (1992) reviewed DCI in hyperbaric attendants. Although there was no gender related risk of DCI, they stated that there was a significant risk of DCI in menstruating female attendants. This was based on data from twenty-six inside attendants, nine of them female, of which five were menstruating when they developed DCI.

Bangasser (1979, 1980), in a retrospective survey, found decompression illness to be three times greater in women compared to men diving the same profiles. She found no relationship between the use of the contraceptive pill, or menstruation, and decompression illness in this review.

In a retrospective study of Navy training dives performed over a six year period, no gender difference in the incidence of DCI was found in a US Navy Diver Training Center (Zwiegelberg and Knight 1987). The dive characteristics were well matched for both male and female groups.

Studies of the incidence of decompression illness in women from altitude exposure may have significance to hyperbaric attendants. Bassett (1973) showed that female US Air Force altitude chamber trainees had a higher incidence of decompression illness than males. Similarly, Weien and Baumgartner (1990) found females suffered a four times greater incidence rate of decompression illness from altitude exposure than males. Rudge, in 1990, reported an eleven year review of the relationship of menstrual cycle and decompression illness in US Air Force Personnel. This finding showed a linear relationship between decompression illness and onset of menses. As the days post-menstrual increased, the incidence of decompression illness in females decreased and became similar to the incidence rate in males. In a prospective survey, Workman and Schrimer (1992) reviewed the menstrual history of women completing altitude chamber training who did not develop DCI. Approximately thirty-three percent (541) of all female United States Air Force altitude chamber trainees voluntarily completed the survey over a one year period. Results showed the women who did not develop DCI were evenly distributed throughout their menstrual cycle,

suggesting that the groups in other studies may not be reflective of the whole population of women undergoing altitude exposure in relation to their stage in the menstrual cycle.

These studies do not give sufficiently definitive results to make conclusions on gender as a risk factor in decompression illness. More research is needed to determine if there is an increased susceptibility of women to decompression illness. A study nearing completion led by Marguerite St. Leger Dowse will hopefully contribute to the resolution of this long standing concern.

Walker (1996) reviewed the literature on the fitness of females to dive and concluded that there is no difference in fitness to dive for women, provided the woman is not pregnant. This author warned of the precautions to be taken if diving during pregnancy and the possibility of tissue trauma from deep saturation diving in women with mammary implants.

When Edmonds, Lowry, and Pennefather (1992b) reviewed the literature on women and diving, they concluded that there is substantial evidence to suggest that diving in pregnancy may cause harm to the foetus, but there was insufficient data to prove this hypothesis.

From a review of all available data on pregnancy and diving, Fife and Fife (1996) found that no cases of abnormal foetal development could be conclusively related to diving. They recommended that women who know or believe that they may be pregnant should not dive. Women who find that "they are pregnant after diving should not be counselled to terminate the pregnancy solely on the basis of diving exposure" (Fife & Fife, p. 165).

In order to protect the unborn child, it can be concluded that hyperbaric attendants should not work in hyperbaric chambers if there is any suspicion that they are pregnant.

Fitness to dive standards have been adopted for occupational and recreational in-water diving and caisson work. Much can be borrowed from pre-existing standards of fitness to dive, but due to the nature of the work in a clinical hyperbaric chamber (a duty of care to the patients inside the chamber) and the occupational group that are attendants in these chambers, specific fitness to dive standards should be written for clinical hyperbaric chamber attendants.

In a presentation at the Undersea and Hyperbaric Medical Society (UHMS) Annual Scientific Meeting in Bethesda, Maryland in 1992, the current author, reviewed a history of incidents occurring in hyperbaric staff (Pirone 1992). Chamber attendants were encouraged to educate

themselves to safe chamber exposure practices and to take responsibility for their own health instead of expecting others to be responsible.

The task of proceeding with the development of fitness to dive standards for hyperbaric chamber attendants requires the commitment of hyperbaric attendants and the assistance of their professional organisations.

3.6.b Incidents Affecting Staff Safety

The effects of hyperbaric exposure on personnel in clinical hyperbaric facilities is poorly researched and published. The first known accidental death in a pressurised chamber was Fontaine, a French surgeon. He began the first scientific studies in compressed air. His "pneumatic institute" was described as a mobile chamber used as an operating room (Persels 1989). No details about his death were found in the hyperbaric literature.

Decompression Illness (DCI)

In three decades, there have been few reports of injuries to staff attendants working in clinical hyperbaric chambers. It has only been in the past five years that more Units are keeping statistics of their staff DCI incidence and reporting their findings. This may be a result of much discussion on the topic at hyperbaric meetings and the emphasis on quality improvement and improved occupational health and safety guidelines in hospitals. The incidence of attendant DCI will now be reviewed.

Anderson, Whalen, and Saltzman (1964) were the first to report on the health effects of working in a medical hyperbaric chamber. They surveyed the effects of hyperbaric exposure on sixty-two medical personnel exposed to 1516 compressions. The most serious symptoms were three cases of transient homonymous hemianopsia. Decompression illness symptoms "occurred only rarely, and were so mild or so fleeting as to require no treatment" (Anderson et al. 1964, p. 89).

In the USA, in 1990, an attendant nurse for a routine treatment in a multiplace facility in the morning was called back to be an attendant for a diver later that day. The nurse and patient

were compressed to 165 feet (6.0 ATA) for a Treatment Table 6A*. In error, air was delivered instead of nitrox. The nurse complained of chest pain on ascent to two ATA so was brought to the surface and sent home. She died from cardiopulmonary decompression illness a few hours later (Desautels 1997). This is the only reported death of a nurse attendant, not related to fire in a clinical hyperbaric facility.

Dunford and Hampson (1992) reviewed fourteen years of clinical hyperbaric treatments with 8424 pressure exposures of inside attendants. The rate of decompression illness was 0.31% with the incidence related to the depth of exposure to pressure.

Dietz and Myers (1995) examined twenty-three years of exposures in hyperbaric personnel. A total of 439 tenders had 25,164 exposures. Nineteen cases of DCI occurred in thirteen tenders. The overall incidence rate was 0.076%. The study did not show a correlation of DCI and gender of the tender. There was a linear correlation with increasing depth and incidence of DCI.

Kindwall (1994a) stated that standard hyperbaric treatments to ten metres (2.0 ATA) are tolerated well in hyperbaric attendants, even when two exposures to this pressure are made in the same day. He reported problems with the use of the common treatment profile of fifteen metres (2.5 ATA) for 100 minutes exposure, finding "several" cases of DCI using this profile. Although this is equivalent to the standard U.S. Navy no- decompression dive of fifteen metres (2.5 ATA), he warned that it is not adequate for civilian hyperbaric attendant use. Kindwall added that, officially, there is no requirement for attendant oxygen breathing in the US Navy Table 6A, but he highly recommended that oxygen be breathed for the last thirty minutes of the Table regardless of extensions to the Table. Kindwall (1994a) stressed the importance of calibrating pressure gauges and checking for gauge line leaks every six months to prevent false gauge readings being the cause of DCI in attendants.

Geiger, Crouch, Mezistrano-Boer (1995) describe their experience of utilising the USN standard air decompression table 50/140 for a ninety minute oxygen breathing treatment table (with air breaks resulting in a 117 -127 minute total bottom time). After eight cases of DCI during a sequential introduction of reducing total bottom time, reviewing the physical status of staff attendants pre-dive, and introducing oxygen breathing for ten minutes prior to

* Treatment Table 6A is a US Navy prescribed recompression table for the treatment of decompression illness that requires the patients and attendant to be pressurised to six ATA, followed by a series of lower pressures for prescribed periods.

decompression, they reported four more incidents, none over the past year. These authors highlighted the significance of attendant fitness to dive, in addition to the total bottom time and oxygen breathing. Specifically, variables such as rest, adequate hydration, a febrile state, and fatigue of attendants were considered important.

Klossner et al. (1996) found little in the literature to guide them in establishing a policy for safe decompression of inside nurse attendants. They considered decompression tables developed for Finnish amateur scuba divers with the inclusion of breathing 100% oxygen for the entire decompression to be safe for chamber attendants. Their incidence of DCI using this profile was 1.3%. They lengthened their decompression protocol considerably and reduced the treatment depth from 2.8 ATA to 2.5 ATA. Nurses also breathe 100% oxygen at 2.5 ATA for the first ten minutes of the treatment. Their DCI incidence of 0.14% after these changes was much lower and more in line with other studies. They report no adverse effects from the added oxygen breathing.

In a retrospective review, Huggins and Catalano (1997) found a 0.26% incidence of DCI in 3068 people exposed to 165 feet of seawater pressure for the purpose of training and orientation in a hyperbaric chamber.

Brattebe and colleagues (1997) presented their DCI incidence rate in nurse attendants for a fourteen metre (2.4 ATA), ninety minute treatment. Eighteen nurses were attendants for 1,534 compressions with a DCI incidence rate of 7.6 per 1000 compressions. Their protocol was for the attendant to breathe oxygen on decompression for seven minutes. After the introduction of additional oxygen breathing for five-ten minutes preceding their standard decompression protocol they have had no more cases of DCI after 1139 subsequent compressions.

The first documented account of lymphodema resulting from DCI in a hyperbaric attendant was described in 1998. The nurse was an attendant on a fifteen metre (2.5 ATA) dive with a bottom time of 104 minutes. Oxygen was breathed for fifteen minutes preceding and throughout the fifteen minute ascent. Symptoms of DCI following this exposure included tingling and rash. She responded well to recompression, but later developed lymphodema involving the face and arm which resolved four days later with lymphatic drainage and compression drainage. Her last hyperbaric exposure was two weeks prior and required significant physical exertion. It was followed by extreme fatigue but no other DCI symptoms (Kulikovsky et al. 1998)

The probability of DCI based on the United States Navy (USN) air or oxygen treatment tables vary from zero to 19.7% depending on the table used. These predictions were based on a model developed by P.K.Weathersby in 1985. The applicability of these statistics to the civilian clinical hyperbaric experience has not been demonstrated.

An attempt to monitor attendant DCI was undertaken by the Baromedical Nurses Association (BNA) in 1992. The BNA hyperbaric employee incident trending form, based on the design of the Divers Alert Network (DAN) accident and decompression illness incident form, was introduced (Vincent 1994). It is intended to be used for the reporting of any injuries occurring to staff of hyperbaric facilities. Its main focus is reporting of inside tender DCI. Since its introduction six years ago, no data have been reported from the forms. One suggestion for the lack of reporting could be that the form requires identifying information. This could lead to medico-legal risk. Additionally, individuals may be reluctant to identify themselves as having DCI as this information may be used against them in future employment prospects.

The literature reports the incidence of DCI reported ranged from 0.076 to 1.3%. These few reports show a generally low incidence rate of DCI in civilian hyperbaric chamber attendants. Even so, several of the reporters found their incidence rates unacceptably high, reviewed their practice and altered their profiles to decrease their staff incidence of DCI. Extending attendant oxygen breathing time, more conservative decompression rates than U.S. Navy Tables for civilian hyperbaric chamber attendants, and attention to attendant fitness were actions taken to reduce DCI incidence in this small group of reports.

Overtly apparent is the lack of suitable published guidelines for hyperbaric chamber attendants. Clearly, decompression profiles for civilian hyperbaric chamber attendants and the effects of attendant exposure in hyperbaric chambers have not been studied. More research is required to determine the actual DCI incidence rate of currently practised treatment profiles. Once "safe" profiles are determined, they should be incorporated into international hyperbaric safety guidelines.

Barotrauma

Ear barotrauma is probably the most common malady of hyperbaric exposure in hyperbaric attendants and the most infrequently documented. Anderson, Whalen, and Saltzman (1964)

described pain in the ears and sinuses as the most common complaint in hyperbaric attendants. This is consistent with the HIMS data reported by in 1995 by Pirone and Williamson.

This malady is often not reported because it is usually mild and requires conservative or no medical treatment. When it does require treatment, the attendant may be referred to other medical specialists. This is in contrast to decompression illness that is treated in hyperbaric and consequently must be documented in the hyperbaric records. Additionally, because it is a well known complication, hyperbaric staff often treat themselves or "accept" its occurrence without complaint until it becomes debilitating. Middle ear barotrauma can be quite painful and inner ear barotrauma may cause permanent disabling injury. Currently, there are only three documented cases of permanent ear barotrauma in hyperbaric attendants in the literature (Pirone 1998).

Sinus and dental barotrauma also occur in hyperbaric attendants (Robertson, Pirone, & Bullock 1999). Similarly, these forms of barotrauma are rarely reported in the literature.

Pulmonary barotrauma in attendants has never been published. The author has heard of no cases of this until recently, when it occurred in a prospective chamber attendant at the Royal Adelaide Hospital in her first training dive. She had been passed medically fit to dive and her pre-dive chest x-ray was unremarkable. The training dive was uneventful and an experienced staff member accompanied the attendant in the chamber. The detection of a pneumothorax in the upper lobe of fifteen percent was made several days later, after the nurse attributed the mild pain and "clicking" sound to other causes. It was brought to the attention of the hyperbaric staff at that time and the attendant was declared permanently unfit to dive.

Facial barotrauma was reported in a staff member by Hildreth (1997). In a training dive in a multiplace chamber, a trainee attempted to inhale through a Scott® mask. No gas supply was turned on and the chamber was at 4.0 ATA. When no gas flow occurred, the trainee exhaled, which opened the valve to the exhaust of the breathing system, causing a significant negative pressure to the trainee's face from the mask. Facial barotrauma included deem and bruising of the lips and mouth, and petichiae of the oral mucosa. It was proposed that hyperbaric facilities using Scott® masks be aware of this hazard (Hildreth 1997).

Pressure related injuries

In 1986, a nurse was seriously injured when a medical lock door was blown open. The nurse had passed the patient's chart through the medical lock, but either he did not secure the exterior lock door, or the door locking lugs failed as the inside door was opened. There was a sudden decompression that was halted when the medical lock door blew shut. Fortunately the decompression was only three feet of seawater pressure and the inside occupants were unharmed. Flying debris caused extensive damage outside the chamber and the nurse suffered a dislocated knee and degloving injury to the sole of the left foot, as well as multiple lacerations and contusions (Desautels 1997).

Incidents that affect staff health are not limited to attendant and medical staff. Injuries to chamber technicians are also reported. A low pressure reservoir was being charged from high pressure air cylinders. The reducing valve between the two systems failed, allowing 3000 psi into copper piping. As the pipe disintegrated, a section of hot copper pipe wrapped around the operator's face and head. A quarter turn valve and section of copper piping was expelled through the ceiling and roof before exiting the room.

In another incident, a technician sustained injuries to his feet when a high pressure air line ruptured. Details of the incident were not recorded (Desautels 1997).

Oxygen toxicity

Sheffield in 1981 reported the first central nervous system (CNS) oxygen toxicity reaction at thirty feet of seawater in a dry chamber. A grand mal seizure occurred in a medical attendant after breathing oxygen for thirty minutes at thirty feet of seawater pressure (approximately 2.0 ATA) just prior to ascending from a US Navy treatment Table 6A. The attendant had been working hard administering life support measures during the treatment of a diver with decompression illness. Later, the attendant was given an oxygen tolerance test (sixty feet of seawater pressure, 2.8 ATA, for thirty minutes) and demonstrated the same symptoms, so was disqualified from chamber diving. No further reports of oxygen toxicity in attendants have been reported in the literature until 1993 when an attendant reported anonymously in the HIMS Study oxygen toxicity symptoms of nausea, light-headedness, and aura while breathing oxygen on decompression (Pirone 1993).

Musculoskeletal Effects

"Popping" or "cracking" of the joints, compression arthralgia, has been reported to occur in patients, staff, or divers. It is noticed more often in hyperbaric chambers than in water diving. One theory proposed is a gas-induced osmosis that disrupts joint lubrication producing cavitation (Edmonds et al. 1992d). There is no evidence of long term health problems due to this phenomenon but if the pain continues throughout decompression, the attendant should be disqualified from hyperbaric work, as the arthralgia would be difficult to distinguish from decompression illness.

Dysbaric osteonecrosis is a potential long term effect of diving and is more evident in divers that have sustained decompression illness and have repeated exposures greater than thirty metres (4.0 ATA). It is well documented in caisson workers and occupational divers (McCallum & Harrrison 1997). It may occur in chamber attendants but the probability of this is remote. There are no documented cases of dysbaric osteonecrosis in hyperbaric attendants in medical facilities. The disease may be latent in onset and once it develops is painful, debilitating, and difficult to treat. One difficulty in prevention and early recognition of dysbaric osteoradionecrosis is that there may be no correlation between joint pain from decompression illness and bone lesions (Ohta and Matsunaga 1974). Another difficulty is radiological screening procedures do not consistently identify those whom will develop the disease. Baseline long bone x-rays and repeat long bone x-rays are required to monitor for this condition. A radiographer experienced in the technique of this bone survey and a radiologist experienced in interpreting it is required, and not readily available to most hyperbaric facilities. Additionally, performing this baseline bone survey does subject the attendant to the effects of radiation. While this may not seem to be significant, many attendants begin hyperbaric work in their early to mid twenties and many of those do not continue hyperbaric work for more than a year or two. Exposing them all to the radiological risk of long bone surveys is unwarranted for the low pressure of compressed air they are exposed to in the absence of reported attendant dysbaric osteonecrosis. Selecting which attendants may need surveillance for dysbaric necrosis may be difficult. Bone scintigraphy (bone scans) have also been used to attempt to detect for early stages of dysbaric osteonecrosis. Bone scans are very sensitive and non-specific and are believed by some hyperbaric specialists to be an unreliable tool for prediction of dysbaric osteonecrosis. Magnetic resonance imaging may prove to be the most reliable, but practicalities in scanning all the joints that may be affected and expense are limitations. A comprehensive review of the vast literature on dysbaric necrosis by

McCallum and Harrison (1997) highlighted this subject as being one of the most investigated health effects of diving.

Other

Other problems have been reported in hyperbaric attendants. Davis and Roberts (1993) reported a 37.5% incidence of nurse attendant fatigue post hyperbaric exposure. They interviewed nurses from three Canadian Hyperbaric Units for a two month period. It was the most frequently mentioned troublesome change from hyperbaric exposure. No other details of the study were given. This is the only report of its type but warrants further investigation.

Another reported injury described an incident in which a chamber door fell from its mounting due to faulty manufacturing causing several fractured bones in the attendant's foot (Desautels 1997).

3.7 Patient Problems

3.7.a Barotrauma

Ear

Middle ear barotrauma is the most frequent patient complication of hyperbaric treatment. An incidence of five to sixty-eight percent of middle ear barotrauma in hyperbaric patients has been reported in both retrospective and prospective studies (Youngberg & Myers 1990, Fernau et al. 1992, Igarashi, Watansbe, & Mizukoshi 1993, Presswood et al. 1994, Beuerlein, Nelson, & Welling 1997). As shown in a prospective study by Blanshard et al. in 1996 involving eighty-two patients, twenty-nine percent required pressure equalisation tubes for hyperbaric treatment, and eight percent of those without pressure equalisation tubes developed significant middle ear barotrauma.

Persons at most risk are those with artificial airways (Farmer 1998, Tweedley, Reeves, & Gow 1997, Farmer 1998). In a retrospective review of 267 patients treated in hyperbaric, ninety-four percent developed middle ear barotrauma and sixty-one percent required insertion of pressure equalisation tubes (Presswood et al. 1994). Others at risk of developing middle ear barotrauma in

hyperbaric are persons with eustachian tube dysfunction (Fernau et al. 1992, Beuerlein et al. 1997, Spronken & Lehm 1997), specifically those with radionecrosis of the head and neck region (Blanshard et al. 1996).

Other risk factors include patients with abnormal rhinoscopic findings or altered state of consciousness (Igarashi et al. 1993), children, and those with limited comprehension of the spoken language in the treating facility. The rate of compression is also associated with the risk of barotrauma. In a study conducted by Minkiewitz (1985) in a monoplace hyperbaric facility, compression rates for hyperbaric treatment were studied for their effect on the incidence of ear barotrauma. A linear progression of compression rate to the incidence of barotrauma was found, with barotrauma rates starting at sixty percent at one psi/minute, seventy percent at 13.8 (two pounds per square inch/minute, and ninety percent at 20.1 kilopascals per minute (three pounds per square inch/minute).

Prevention of ear barotrauma has been the focus of research. The search for a reliable test of eustachian tube function is still being researched. The most promising technique for determining eustachian tube function is impedance audiometry using a nine-step autoinflation technique described by Bluestone (1975). Unfortunately, it is most predictive after the patient has already had one hyperbaric treatment (Fernau et al 1992), requires a person experienced for the administration of the test, and may need repeated application on separate visits to achieve sensitivity (McBride et al. 1988). Another limitation of this type of assessment is the requirement for the patient to be alert and cooperative to perform the test. Patients presenting for hyperbaric treatment may present acutely at any hour; be unconscious, sedated, a child or a group of persons; have limited understanding of the English language; or have an altered mental status. Bluestone technique tympanometry could not be used in most of these patients. Spronken and Lehm (1997), found abnormal tympanometry was highly predictive of patients who developed middle ear barotrauma in hyperbaric, but half of the patients in their study sample developed barotrauma despite a normal tympanometry.

Clinical assessment of the patient by otoscopic confirmation of tympanic membrane motion simultaneous with the patient demonstrating autoinflation techniques has also been used as a method of determining eustachian tube function (Beurlein et al. 1997). However, this technique has also been shown to be an unreliable predictor of barotrauma (Igarashi et al. 1993), being compromised by the same factors limiting the use of tympanometry.

Moreover, as poor eustachian tube function is a good predictor of middle ear barotrauma, good eustachian tube function is not a sensitive indicator of those patients who will not develop middle ear barotrauma (Beuerlein et al 1997).

Prophylaxis of ear barotrauma may include the use of oral or topical decongestants as described by Fernau et al. (1992). Capes and Tomaszewski (1996) reported that one third of USA Hyperbaric Centers surveyed in 1996 routinely used decongestants in the prophylaxis of ear barotrauma with the preferred agent being topically versus orally administered. While anecdotal, the practice of administering topical decongestants has been regarded as useful in middle ear pressure equalisation, but no controlled trial has demonstrated its efficacy. Carlson et al. (1992), in a prospective, parallel, double-blind, randomised trial of patients undergoing hyperbaric treatment found no statistically significant difference in the incidence of middle ear barotrauma in those given topical decongestants compared to those who received a placebo.

Oral decongestants are commonly used in hyperbaric centres, although less frequently than topical decongestants (Capes & Tomaszewski 1996). While the use of oral decongestants is supported anecdotally for the prevention and management of middle ear barotrauma, this has yet to be validated in the hyperbaric setting. In a controlled trial, Brown, Jones, and Krohner (1997) showed that pseudoephedrine sixty milligrams administered thirty minutes preceding a dive in recreational scuba divers reduced the incidence of middle ear barotrauma. This finding could be the basis for establishing a similar study in patients commencing hyperbaric treatment with no contraindications to the medication.

Prophylactic placement of pressure equalisation tubes or performing myringotomies prior to hyperbaric will prevent ear barotrauma. Again, it is difficult to select which patients are at most risk of developing ear barotrauma and if they should have prophylactic myringotomies. All medical procedures have risks, and myringotomy and ear pressure equalisation tube placement procedures are no exception.

In a retrospective study of forty-five patients requiring myringotomy and pressure equalisation tube placement for hyperbaric treatment, Clements, Vrabec, & Mader (1998) reported a thirty-eight percent complication rate to the procedure. Most of the patients had more than one complication and it developed, on average, at nine months post completion of hyperbaric

treatment. Furthermore, the investigators found the incidence of otorrhea and persistent perforations to be significantly higher than most other studies of myringotomy and tube placement complications for non-hyperbaric indications. They concluded that allowing the pressure equalisation tubes to extrude spontaneously over time might have resulted in the high complication rate.

In response to the above findings, Clements et al. compared two tympanostomy techniques for use in the management of ear barotrauma in patients undergoing hyperbaric. Carbon dioxide laser myringotomy was perfomed on one ear of the subjects and pressure equalisation tube placement was performed on their other ear. Tubes were extracted at the completion of their course of hyperbaric treatments. Both methods showed a reduced incidence of complications compared to their original retrospective study. Ears treated with carbon dioxide laser myringotomy had a lower rate of associated persistent perforations and a trend toward less otorrhea than the ear treated with pressure equalisation tubes. Patients, who had both techniques performed, rated the carbon dioxide laser myringotomy as being less painful with a higher overall satisfaction grade.

In these studies, otolaryngologists performed the myringotomy procedures. Skill is required in the conducting myringotomies. Although this is a specialised technique, to date, no review has been conducted to determine the effect of myringotomies conducted as an early intervention by non-otolaryngologists on ear barotrauma in the hyperbaric setting. Likewise, the incidence of complications in patients receiving myringotomies by hyperbaric physicians compared to otolaryngologists has not been explored.

Some may argue that medical management of ear barotrauma in the hyperbaric setting should be more conservative. It is not standard practice in many hyperbaric centers to perform myringotomies in patients with artificial airways. Capes et al. (1996) reported that less than half of the hyperbaric centers surveyed in the USA routinely performed prophylactic myringotomies on intubated patients despite it being recommended by otolaryngologists (Presswood et al. 1994, Farmer 1998). Anecdotally, no increased incidence of ear problems or loss of hearing have been reported in follow-up of patients not having myringotomies performed prophylactically for intubation (Weaver 1998).

There is a view that if an effusion occurs in the middle ear space and the patient does not experience pain or is paralysed and or sedated, no intervention is warranted. Theoretically, once the middle ear space is filled with fluid, increased atmospheric pressure from hyperbaric exposure should not cause further injury. Contrary to this view, some argue that further pressure could cause the transmission of excessive pressure on the inner ear structures and cause the inner ear barotrauma with significant long term morbidity. This risk could be exacerbated by attempts to equalise the pressure, which could increase the intracranial pressure, resulting in excessive perilymph fluid pressures and inner ear barotrauma. Inner ear barotrauma is well described in the diving literature (Money et al (1985), Farmer 1990, Shupak, Doweck, & Greenberg 1991, Talmi, Finkelstein, & Zohar 1991, and Nakashima, Kaida, & Yanagita 1992) but has not been reported in hyperbaric patients. Two cases of inner ear barotrauma have been reported in nurses working in hyperbaric chambers (Pirone 1992) and several anecdotal reports of permanent severe hearing loss were elicited in the telephone survey conducted by Cape et al. in 1996.

Other complications, although rare, can arise from the use of autoinflation techniques for ear equalisation. Performing the Valsalva on decompression can result in gas embolism (Bond 1977). Significant hypotension can result from the use of Valsalva manoeuvre on pressurisation (Kluger 1996) or breath holding on decompression (Radermacher et al. 1993).

To date, no recognised standard guideline for the prophylaxis or management of ear barotrauma in hyperbaric patients has been established.

Sinus

Sinus barotrauma is well described as a potential complication in the hyperbaric literature but is rarely reported. Management usually includes decongestants but if ineffective, the treatment must be aborted.

Pulmonary

Patients with untreated pneumothorax must not be exposed to hyperbaric pressure. If decompressed with an untreated pneumothorax, the gas in the pleural space will expand on decompression causing respiratory distress and may progress very quickly to cardiac arrest.

Once ventilation of the pleural cavity has been made and a one way valve is in situ, the patient may be treated with skilled supervision. There are reported incidents of patients developing pneumothoracies in hyperbaric. The management of this problem in multiplace chambers is the insertion of a needle or pleural drainage tube into the pleural space. In a monoplace chamber, a team of doctors and nurses must be assembled prior to decompression to decompress the pleural cavity once the patient has reached atmospheric pressure. This event is a life threatening emergency. Measures can be taken to prevent this event from occurring by careful screening of the patient and chest x-ray examination when clinically indicated.

Pulmonary barotrauma may also occur in patients that hold their breath while decompressing. No reports of barotrauma have been recorded in hyperbaric chambers from this occurring. Also at risk of pulmonary barotrauma are patients having a grand mal seizure. No attempt to decompress the patients during the tonic stage of the seizure should be made. During this stage, the patient will block their airway and if decompression is attempted, gas expansion in the closed space of the lung and upper airway will occur, resulting in potentially serious pulmonary barotrauma. There are no reported incidents of barotrauma occurring from this scenario.

There is one report of a patient developing a moderate degree of chest pain after her first hyperbaric treatment. Except for the symptom of pain, clinical examination findings and chest x-ray were unremarkable. Computed tomography, prior to any further pressure exposure, revealed a right-sided pneumothorax and a large emphysematous bulla. Despite chest drain insertion, the patient required thoracoscopic surgery of the bulla and closure of the pleura (Mueller et al. 1998). Another report described three cases of tension pneumothorax occurring in critically ill patients with carbon monoxide poisoning during hyperbaric treatment. All three patients having received cardiopulmonary resuscitation and had normal supine portable chest x-rays prior to hyperbaric exposure and all subsequently died after the diagnosis of brain death was made. The same researchers reported 297 cases of carbon monoxide poisoned patients at their centre, with one percent had tension pneumathoracies over a ten year period. Of that group, those that had received cardiopulmonary resuscitation had a twelve percent incidence rate of tension pneumothorax (Sloan, Murphy & Hart 1989). There are other case reports in the literature (Unsworth 1973) but the incidence rate is not reported.

Other forms of barotrauma may include dental pain when there is a gas space in between a filling and the tooth, requiring dental replacement of the filling. Patients should be advised to

defer routine dental work such as fillings until after the course of hyperbaric to avoid introducing the risk of developing dental barotrauma.

3.7.b Oxygen toxicity

Central nervous system

Central nervous system (CNS) oxygen toxicity is well researched. The incidence rate of oxygen toxicity seizures in hyperbaric treatment pressures of 2.4 ATA is reported as 0.013% (Davis, Dunn & Heimbach 1988) and 0.21% in a population of 891 patients receiving a total of 14, 966 treatments at varying pressures (Rettenmaier, Gresham, and Myers 1985). Rettenmaier and colleagues also reported the incidence of CNS oxygen toxicity symptoms other than seizure. In the same patient population over a six year period the reported incidence rates of these symptoms are shown in Table 3.2.

Symptom	Incidence
nausea and vomiting	0.43%
Muscular twitching	0.12%,
Anxiety	0.11%
Respiratory changes	0.06%
Vertigo	0.06%
Behaviour change	0.05 %
visual change	0.04%
Sweating	0.03%
Auditory change	0.03%
altered consciousness	0.02%

Table 3.2 Incidence of Symptoms of Oxygen Toxicity (non- seizure)

Kindwall (1994b) speculated that some oxygen toxicity seizures are due to hypoglycaemia versus oxygen and estimated the incidence of oxygen seizures at 2.4 ATA to be 0.007%.

The incidence of hyperbaric oxygen therapy induced central nervous oxygen toxicity remains unclear due to under-reporting, differing definitions of what symptoms of oxygen toxicity to report, and hesitancy to report adverse events.

Pulmonary oxygen toxicity

The effects of oxygen on the lung are well researched (Clark & Lambertson 1971, Clark et al. 1991). While breathing oxygen is well tolerated in the adult lung at pressures less 0.5 ATA, breathing oxygen at higher pressures or prolonged duration may cause '...intratracheal and bronchial irritation, such as substernal burning, chest tightness, cough, and dyspnoea' (Clark & Whelan 1999, p. 72). Early symptoms of pulmonary oxygen toxicity are reversed with the withdrawal of oxygen but if allowed to progress may develop into adult respiratory distress syndrome (Clark & Whelan 1999).

Although the pulmonary toxic effects are well described in the literature, there are few anecdotal reports of pulmonary oxygen toxicity, mostly in patients treated on treatment tables reserved for the treatment of decompression illness and severe gas embolus (Clark & Whelan 1999, p.74).

Thorsen, Aanderud & Aasen (1998), in order to quantify the effect of a standard course of hyperbaric treatment on the lung, found a reduction in the conduction of small airway flow, but the amount of change was not considered to be significant.

Although the effects of oxygen on the lung are tolerated well in standard hyperbaric therapy, caution should be used in critically ill, ventilated patients who are receiving continuous oxygen pressures, patients that have conditions or take drugs that are known to hasten the onset of oxygen toxicity, and in neonates (Kindwall 1994b).

Visual side effects

Prospective studies have demonstrated that myopia may progressively develop in patients undergoing a series of hyperbaric treatments (Anderson & Farmer 1978, Lyne 1978; Palmquist, Philipson, & Barr 1984). In a prospective review of ten patients, Anderson and Farmer (1978) found an average of 1.61 diopters of myopia in patients treated at 2.4 ATA for 120 minutes, six days per week for a total of forty treatments. Lyne (1978) showed that eighteen of twenty-six patients (sixty-nine percent) developed myopic changes after hyperbaric treatments at 2.5 ATA for a range of four to fifty-two weeks. The degree of myopia that developed in this series ranged from 0.5 to 5.5 diopters, usually at a rate of 0.5 diopters per month. In another prospective review, twenty-five patients received twice daily,

one hour 2.0 -2.5 ATA hyperbaric treatments, with a range of 150 -850 treatments (Palmquist et al. 1984)

In these studies, the myopia reversed in the weeks to months following hyperbaric exposure. Between the three studies, sixty-one patients were reviewed for myopic change. At one year follow-up, the patients all had nearly complete reversal of their hyperbaric induced myopia (within one diopter).

The incidence rate of hyperbaric induced myopia has been approximated at twenty to forty percent with higher rates in diabetics and the elderly (Clark 1994). In a retrospective study by Dedi et al. (1998), 596 charts were reviewed, and eighty-eight had complete data for evaluation. There was no statistically significant difference in pre and one month post hyperbaric visual acuity in patients treated at 2.0 ATA. The authors suggested that 2.0 ATA may have a decreased incidence of myopia compared to 2.4 ATA treatment pressures. No prospective studies have been done to compare the incidence of hyperbaric induced myopia at different commonly used treatment pressures.

Although the effect of oxygen on the eye has been well researched, the mechanism by which hyperbaric induces myopia remains unknown. It is suggested that the shape of the lens is altered (Anderson & Farmer 1978, Lyne 1978, Hammerlund 1994,).

Clark (1994) reviewed the literature of the relationship of nuclear cataracts and hyperbaric treatments. He found that the progression of pre-existing and the formation of new nuclear cataracts may occur in patients having prolonged hyperbaric treatment series (greater than fifty treatments) as evidenced in studies by Palmquist et al.1984, Anderson & Farmer (1978), Anderson & Shelton (1987), and Lyne (1978). Furthermore, the formation of new cataracts in patients having less than fifty standard hyperbaric treatments was not reported.

Kobayashi & Murakami (1972) reported what was probably the first case of blindness in an adult due to excessive oxygen breathing. This occurred in a myasthenia gravis patient requiring treatment with an iron lung. Due to mechanical limitations of the ventilator, oxygen could not be reduced from eighty percent. This occurred for 150 days prior to the patient developing blindness in both eyes. Retinal constriction was observed using ophthalmoscopic examination.

There are anecdotal reports of temporary and permanent blindness related to treating patients in hyperbaric with a history of optic neuritis (Nichols & Lambertson 1969, Kindwall 1994c, Davis et al.1988). Optic neuritis is classed as a relative contra-indication for hyperbaric treatment. A thorough history should be taken prior to commencing a series of hyperbaric treatments to screen for this disease.

There was one anecdotal report from a Medical Defense Union Report of blindness in a patient treated in hyperbaric for scrotal gangrene in 1971. Although hyperbaric was not proven to be the cause of the blindness, it occurred during the last hyperbaric treatment. The plaintiff was approved compensation because he had in his sometimes confused state complained of visual disturbance, yet the treatment was continued (Walker 1980).

Another visual problem related to hyperbaric is the concern for the development of retrolental fibroplasia in premature infants. It is rare that premature infants are treated in hyperbaric, hence there are no clinical reports of retrolental fibroplasia as a complication of hyperbaric.

A report by Herbstein & Murchland (1984) of a man developing a "cotton wool" spot on his retina two weeks after two, one hour, 2.0 ATA hyperbaric treatments, was recounted by Davis et al. (1988). These authors viewed the cause of this man's retinal changes to be unrelated to hyperbaric as he had a history that could be linked to this retinal change, and there have been no reports in animal or human data of this type of retinal change with this level of exposure.

3.7.c Hypoglycaemia

Diabetic patients are often treated in hyperbaric for diabetic foot ulcers. This group of patients require special care as their blood glucose levels can drop when exposed to hyperbaric conditions (Springer 1991, Rudell 1993).

Capelli-Schellpfeffer et al. (1996) reported an incidence of hypoglycaemic events in diabetics undergoing hyperbaric to be 1.3 per 100 treatments compared to a 0.01 per 100 incidence of oxygen toxicity seizures during hyperbaric treatment. These authors demonstrated an average decrease in blood glucose of twenty-one milligram/decilitre. Although the mechanism for hyperbaric induced hypoglycaemia is not established, they suggested that hyperbaric induces a change in glucose metabolism that leads to hypoglycaemia. This may be attributed to the

supersaturation of the plasma in hyperbaric conditions that causes increased metabolic function, hence glucose consumption.

Blood glucose testing and clinical assessment for hypoglycaemia in the diabetic patient must be carried out prior to hyperbaric treatment. O'Malley et al. (1998) emphasise that low blood glucose levels or symptoms of hypoglycaemia should be managed before hyperbaric treatment commences. They utilised a pre-treatment feeding protocol for diabetic patients with low blood glucose levels. Additionally, they reported an incident of an outpatient developing post-hyperbaric treatment hypoglycaemia while awaiting transport outside the hospital, and recommended blood glucose testing for diabetic patients post-hyperbaric treatment to prevent discharge of a patient with hyperbaric induced hypoglycaemia.

Glucose measuring devices in hyperbaric chambers or blood that is highly oxygenated from hyperbaric treatment may not be deliver accurate readings (Zel 1987, Price et al. 1995, Vote et al. 1999). Some of the glucose measuring devices rely on a glucose oxidase reaction to calculate the blood glucose level. Oxygen drives this reaction and high levels of oxygen interfere with the accuracy of most of these type systems. Glucose measuring devices that do not use the glucose oxidase reaction may have mechanical faults or electrical fire risks when exposed to the hyperbaric environment.

3.7.d Confinement Anxiety

Confinement anxiety occurs in approximately one in fifty patients in a multiplace chamber (Davis et al. 1988) and one in ten in a monoplace chamber (Kindwall 1994c). Anti-anxiety drugs and nursing interventions to distract and calm the patient are useful.

Hillard (1990) cited a case report of a patient who developed severe claustrophobia while being treated in a hyperbaric chamber. In the report, the patient received two hundred hyperbaric treatments in a monoplace chamber and tolerated the treatments despite claustrophobic symptoms. During one of the treatments, the chamber operator walked out of view of the patient causing the patient considerable anxiety. Ten years later, when she required ten more hyperbaric treatments, the patient requested to see the chamber and upon seeing it, developed a panic attack. After two weeks of psychiatric intervention including desipramine, systematic relaxation and visualisation techniques, the patient was able to tolerate the ten treatments.

3. 7.e Mortality

Two reports of cardiac arrest in patients undergoing hyperbaric treatment have been reported in the literature. In one case a patient had thirty cardiac arrests, twenty-eight while breathing air at 1.0 ATA and two arrests while having hyperbaric. Two-hourly cycles of hyperbaric and air breathing continued for two days, after which the patient recovered and was able to return to work (Kindwall 1994f). In one report, a patient was treated in hyperbaric following a suicide attempt with carbon monoxide poisoning. Besides the patient having a history of depression, he also had severe chest pain and intense fear of doctors, which precipitated the suicide attempt. Despite observation in the coronary care unit and a number of investigations prior to hyperbaric, the patient had a grand mal seizure followed by respiratory and cardiac arrest and electromechanical dissociation. This patient could not be resuscitated. Post mortem findings included haemopericardium secondary to rupture and dissection of a thoracic aortic aneurysm (Hamilton-Farrell & May 1997).

3.8 Chamber/Equipment Problems

Chamber and equipment problems other than pressure or fire incidents are poorly described in the literature. Reports in this category are presented below.

Chamber environmental control and gas supply may account for some chamber incidents. Four divers during a saturation dive in a research chamber, recovered from a hypoxic episode after the chamber environment at 1.0 ATA contained an oxygen content of only five percent (Sheffield and Heimbach 1981).

In 1991, Rugh described the importance of carbon monoxide gas monitoring of chamber gas supply. Following structural additions to the hospital located around the air intake, construction equipment introduced exhaust fumes directly into the air intake for the chamber air supply. Carbon monoxide gas levels increased dramatically causing the changeover to an alternate gas supply of oxygen for the inside occupants. Injury was prevented in this incident (Rugh 1991).

Rugh (1992) also reported the potential for suction regulator failure in hyperbaric chambers and provided technical advice on how to prevent such a hazard. Suction apparatus are a

necessary patient safety item in clinical hyperbaric chambers, and variance in atmospheric pressure will introduce alterations in suction performance.

Obstructions to the delivery of oxygen may also occur although this is not unique to hyperbaric. An incident of patient hypoxia during hyperbaric occurred when a patient had a right mainstem intubation and left basilar atelectasis. The hypoxia was first detected by P_aO_2 measurement (Larson-Lohr 1993).

New medical equipment should be tested for pressure and fire safety before introducing it into the hyperbaric environment. In the 1960s, a patient with an internal pacemaker developed a run-away pacemaker and went into a shock-like state from a heart rate of 240 per minute. The patient survived and the manufacturers of the implantable pacemakers now produce pressure tested pacemakers (Hart 1994).

No incidents have yet occurred in hyperbaric with the Automatic Implantable Cardioverter Defibrillators (AICD). Cardiac Pacemakers, Inc. (CPI), a subsidiary of Eli Lilly, issued a statement that the company's AICD models 1550, 1555 and 1600 have been tested to function to a depth of 2.36 ATA. The company states these models are safe to use in hyperbaric and will not cause an arching electrical charge. They are not easily recognisable unless a visual examination of the abdominal area is performed. Few patients have been treated in hyperbaric with these devices. Precautions before treatment include contacting the manufacturer for device specific pressure testing, monitoring of patients' ECG, and all inappropriate firings and non-firings should be reported (Durand 1992).

Implantable infusion pumps are also potentially unsafe in a hyperbaric environment. One model made by Medtronic Corporation utilises positive pressure to deliver the drug from the reservoir. Once external pressure exceeds 8 psi, the pressure inside the pump becomes negative and bodily fluid can then be forced into the pump until the pressures equilibrate. Upon decompression, the high pressure in the pump may force boluses of drugs into the patient. These devices should not be used in hyperbaric environments (Meyer, Hart &Strauss 1990).

Akman et al. (1994) reported an event demonstrating the danger of using implantable infusion pumps in the hyperbaric environment. In this case report, a spinal cord injured patient was receiving medication via the Medtronic Synchriomed® Model 8611H implantable infusion pump. The patient had daily treatment in the hyperbaric chamber and at the conclusion of the

treatments, when the infusion pump was scheduled to be checked, it was found that cerebral spinal fluid had leaked back into the implanted infusion pump. The elevated pressure exposure in the hyperbaric chamber was found to be the cause of this anomaly. The patient displayed no symptoms as a result of the incident.

Although there has been much attention to safety in the practice of hyperbaric over the years, the need for reporting adverse occurrences in hyperbaric practice is obvious. Occasional accounts scattered through the literature are certainly of value but significantly more information could be gathered to improve the safety for both patients and staff in hyperbaric facilities.

The UHMS and other hyperbaric professional associations have addressed safety issues by supporting on-going safety committee activities, the development of fire, pressure and electrical standards, staff training guidelines, certification programs of staff, the publication of chamber safety guidelines, and safety education forums. Studies have identified the main side effects of hyperbaric treatment in patients, but more work is required to understand these problems and improve the prevention and management of complications. The occupational effects of diving have been studied in in-water divers, but little attention has been given to studies of the occupational health of the hyperbaric attendants. Equipment problems (both chamber equipment and medical) are not well documented in the literature. The emphasis of the whole of the literature has been on incidents that result in morbidity and mortality rather than "near misses".

An anonymous, structured, ongoing study of "near misses" and the causes of incidents in hyperbaric on an international level might better inform health professionals, chamber and equipment designers and manufacturers, and hyperbaric technical and safety officers to improve safety for all concerned.

CHAPTER 4

Research Design and Method

4.1 Research Design

The Hyperbaric Incident Monitoring Study (HIMS) is a descriptive study using qualitative data collected through survey. The design of the study is modelled on the Australian Incident Monitoring Study (AIMS) (Webb et al. 1993). Runciman (1993, p. 503) explains that incident monitoring is '...classical qualitative research, with attributes and limitations which are familiar to social scientists'.

Taking a naturalistic approach, that is, studying the incidents as they occurred during routine work, provides data that reveal the broad spectrum of the challenging and complex nature of safety maintenance associated with all aspects of the delivery of hyperbaric treatments. In this study descriptive accounts of errors, incidents, or adverse events from the field in narrative form are categorised and reported by frequency and interpreted and used for discussion. Hypotheses for further testing/research and recommendations for change are developed from the analysis of the incidents.

Incident monitoring was pioneered in aviation safety (Billings & Reynard 1984) and has prompted safety improvements in anaesthesia since the introduction of the Australian Incident Monitoring Study (AIMS) (Hains 1993). The current author adopted the AIMS methodology for specific use in hyperbaric medicine after gaining the permission of the Royal Adelaide Hospital Department of Anaesthesia. The title Hyperbaric Incident Monitoring Study (HIMS) has been adapted from AIMS to indicate the change.

Both AIMS and HIMS use anonymous, blameless reporting to avoid high underreporting rates in traditional incident reporting systems where the possibility of being exposed to either local or public censure or even legal action acts as a deterrent to reporting (Perper 1994, Fuqua & Stevens 1988). This anonymous incident reporting technique lends itself particularly well to the relatively small specialty group of Hyperbaric Medicine in which many members know each other. It is contended that when anonymity is valued and secure, clinicians feel more at liberty to disclose incidents without a concern that their "neighbour might find out". This sense of security, therefore, should result in a higher number of reports than conventional systems of mandatory reporting of adverse incidents (Barach & Small 2000). There is no interest in culpability in this study, and the purpose is to determine the causative factors, such as personal, team, cognitive, and system conditions that can predispose the practitioner to make errors.

The focus of this research is not only the incident *per se*, but the factors that contribute to the incident. Incidents are commonly complex chains of events and detecting the combinations that lead to the incidents can be more valuable than investigating the incident in isolation (Reason 1990a). Most incidents are detected, corrected and cause no harm and these episodes contain a great deal of information that may be used as feedback to staff. The narrative descriptions of incidents in this study are analysed in order to provide precautionary information for hyperbaric staff. It is considered that incidents that result in harm are just the 'tip of the iceberg' and that the harm-free incidents in the "body of the iceberg" are of greatest relevance to this study. This metaphor, coined by Harrison (1983) in this context, is one of the most significant differences in this study from traditional methods of incident reporting in hospitals. HIMS analyses the 'near misses' in a bid to uncover risks and prevent a similar set of circumstances in the future proceeding to a harmful event.

4.2 Research Sample

The voluntary nature of the participants in this study makes the sampling one of convenience. It comprises clinical hyperbaric medicine units, civilian or military, that:

- treat patients in hyperbaric chambers in a hospital or a clinic based setting;

- were aware of the study; and
- agreed to participate in HIMS.

The anonymous reporting system in this study means there is no denominator from which to calculate the prevalence of incidents. However, as Runciman et al. (1993) claims it is extremely difficult and expensive to determine the absolute incidence of any event. The more reports generated in HIMS, the more likely benchmarks can be set on which to compare units and impact changes in practice. Rather than predicting events in a given population, researchers using this method develop a retrospective snapshot view of the types of problems that are occurring in hyperbaric practice.

The number of Australian Hyperbaric Units reporting to HIMS at the commencement of the study was approximately fifty per year. In order to increase the number of reports in the study and to include the range of hyperbaric chamber designs, a multi-centred, international sample was recruited to generate more data from which to develop strategies to reduce incidents.

A number of strategies were utilised to recruit and retain participants in the study and it was promoted in several ways The researcher presented information about the study at display booths, when space was donated from the associations hosting the scientific meetings. Educational and recruitment material included a video produced with the resources of the Australian Patient Safety Foundation (APSF) and the Royal Adelaide Hospital Hyperbaric Medicine Unit Fund. The video was produced in English, Italian and French languages and in PAL, NTSC, and SECAM video formats. A poster display translated into three languages was also produced and presented at two international and one national meeting. These materials were developed with the assistance of the Medical Director of the Hyperbaric Medicine Unit, Staff of the Hyperbaric Medicine Unit, Staff of the APSF, The Royal Adelaide Hospital Medical Illustrations Unit, The Adelaide University Audiovisual Department, and translators.

"Key" coordinators (senior nurses, technicians or doctors) in several countries volunteered to promote the study. They assisted by helping at the booth displays, presenting the study to colleagues at regional scientific meetings, facilitating the introduction of HIMS to newly participating hyperbaric units, and by sharing in meetings to coordinate and discuss logistical issues in data collection and language translation. The study required promotion as such a scheme for reporting hyperbaric incidents was novel and there was a natural reluctance to

divulge incidents due to medico-legal threat and fear of negative exposure for either individuals or institutions.

Staff representing their hyperbaric unit could register to participate in the study by lodging a form at the booth display or by contacting the author by facsimile, letter, or electronic mail. This method of obtaining participants and of voluntary anonymous reporting represents a self-selection sample. Hyperbaric medicine units voluntarily chose to participate in the study, and the individuals from that Unit chose to report the incident.

4.3 Research Tools

The Hyperbaric Incident Report is the survey instrument modelled on the Australian Incident Monitoring Study (AIMS) Report Form used by the Australian Patient Safety Foundation (Webb et al. 1993). It is based on the "critical incident technique", but modified to be a voluntary, anonymous reporting system which invites participants to report "near misses". The definition of an incident for reporting in this study is any incident, no matter how seemingly trivial, which affected or could have affected the safety of the patient, or hyperbaric chamber staff. The incident may be preventable or unpreventable.

The form was trialed in Australia in 1992 in eight hyperbaric medicine units. With minor changes, it was utilised for data collection in eleven hyperbaric medicine units in Australia and New Zealand from 1993. After an 18 month trial of the form in the United States and Europe, final revision of the form was completed. The design changes included modifications of the "narrative" and "contributing factor" pages to concur with changes made to the AIMS Forms. The HIMS Form was introduced for international use in 1996. A sample of the instrument is located in Appendix F. Data was collected from January 1996 to September 1997 inclusive.

The research instrument is entitled 'Hyperbaric Incident Report'. There are four pages in the report, and on the first page there is an invitation to the participant to use the form to report incidents occurring in hyperbaric practice. It includes the definition of an incident, anonymity assurance, information regarding medico-legal risk and indemnity clauses, instructions on how to complete the from, where the form will be sent, and advises the reporter to direct

questions regarding the form or the study to their local coordinator. There is an empty box at the top right hand corner of the form for the researcher to assign a number to the incident.

The second page of the Incident Report form is the "specialty page". Data specific to hyperbaric is requested in a multiple choice format. This page was designed and modified after the international trial of the form to accommodate various chamber designs, allow for standard information regarding types, location and what/whom was involved in incidents, and to allow for standard categories for classifying outcomes. There are a number of clinical areas that have adapted the AIMS form in this way, for example ICU (Beckman et al. 1996). The respondents categorise their experience into groups of problems relating to patients, equipment, chamber system, staff, ventilation, intravenous (IV) / invasive pressure lines / patient drainage tubes, and drug administration. The group to which the incident is assigned is determined the by the reporter ticking the two letter code adjacent to the descriptive words under general categories on the HIMS Incident Report Form. Where more than one descriptive word is ticked, the incident is categorised into more than one group. This allows a later review of possible associations between descriptors in different groups. If patterns emerge with the association, then useful information in the prevention of these types of incidents may be discovered.

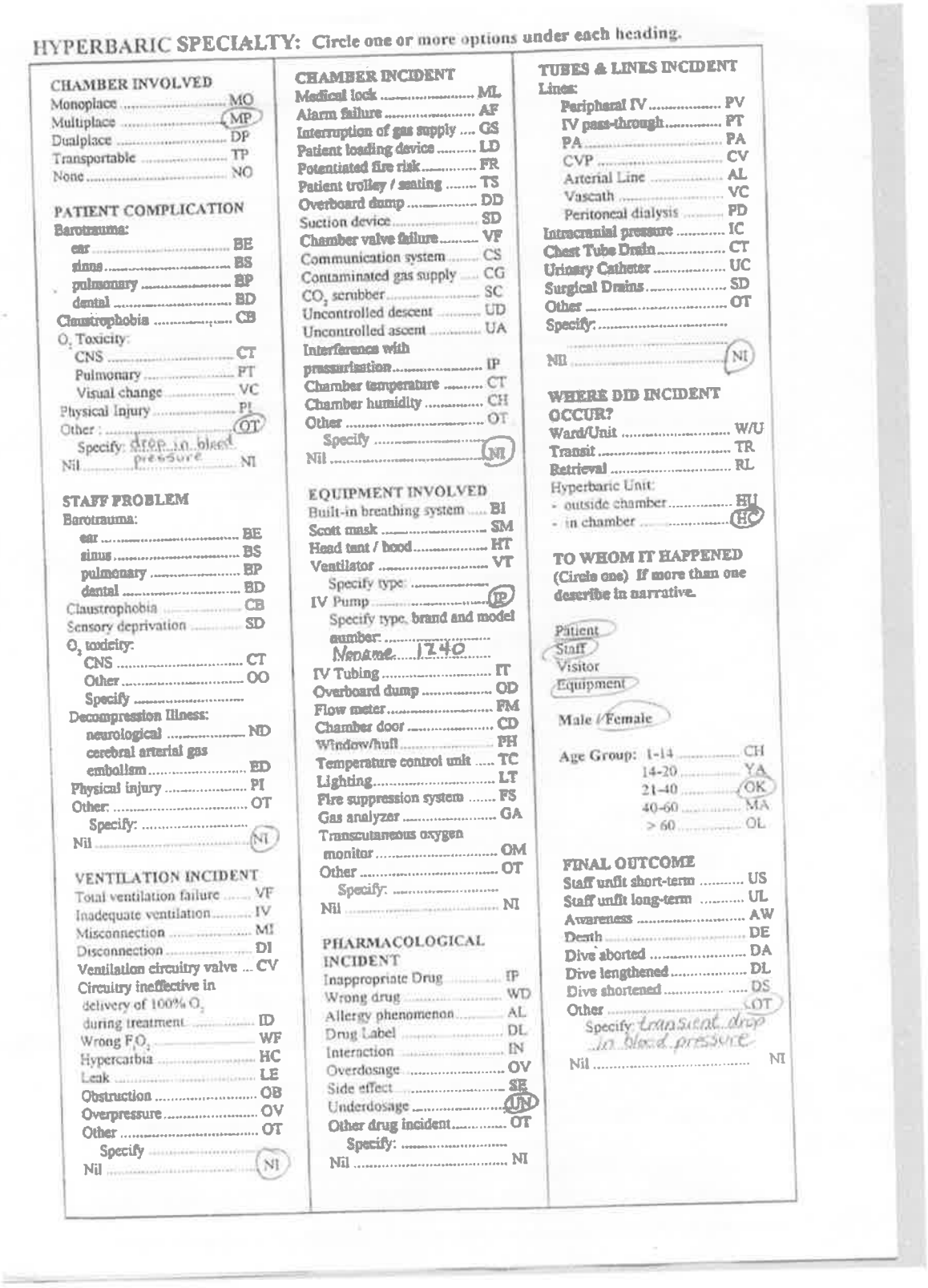
The reporter is asked to select if patients, staff, visitors, or equipment are involved in the incident. If more than one of the above are involved, they are to circle all that are involved in the incident. For instance, suppose an intravenous pump infusing a life-sustaining medication to a patient malfunctioned in the chamber causing the patient's blood pressure to drop. The nurse promptly corrected the problem and the patient recovered quickly without sequelae. The reporter would then circle "Patient complication-other" and specify drop in blood pressure, circle "Equipment Involved - IV pump" and specify type and model, circle "Pharmacological Incident-Underdosage and circle "Patient", "Equipment", and 'Staff" for the "To Whom It Happened" category (see Figure 4.1).

When incidents are analysed, one incident may be classed into multiple categories. In the Results Chapter, they are discussed in the category they most represent. Discussion of the incident is not repeated under all the categories in which it has been classed. However, some incidents that have been classed in multiple categories may have attributes that are relevant to discussion in both categories. When this is the case, the incident may be discussed in both categories. All incidents are accounted for in the Results Chapter.

On the third page of the form the reporter is required to give a narrative account of the incident including the factors that either contributed to or minimised the event or that may prevent a similar event in future. After giving the description of the event the reporter is asked to judge whether the incident was preventable by selecting the choices of: "YES", "NO", or "UNDECIDED". A space at the bottom of the page was left empty for the coder to ascribe key words to the incident.

The fourth page of the form has items that are either multiple choice or narrative to identify factors that contributed to or minimised the incident. It culminates with a comment section.

There are forty-one contributing factors that are offered to the reporter to tick. These forty-one are categorised into three types, system-based, team-cognitive, and personal-cognitive. System-based and personal-cognitive contributing factors are then divided into subgroups as shown in Table 4.1.



HYPERBARIC SPECIALTY: Circle one or more options under each heading.

CHAMBER INVOLVED
Monoplace ..... MO
Multiplace ..... MP
Duoplace ..... DP
Transportable ..... TP
None ..... NO

PATIENT COMPLICATION
Barotrauma:
ear ..... BE
sinus ..... BS
pulmonary ..... BP
dental ..... BD
Claustrophobia ..... CB
O_2 Toxicity:
CNS ..... CT
Pulmonary ..... PT
Visual change VC
Physical Injury ..... PI
Other : ..... OT
Specify: drop in blood pressure
Nil ..... NI

STAFF PROBLEM
Barotrauma:
ear ..... BE
sinus ..... BS
pulmonary ..... BP
dental ..... BD
Claustrophobia ..... CB
Sensory deprivation ..... SD
O_2 toxicity:
CNS ..... CT
Other ..... OO
Specify .....
Decompression Illness:
neurological ..... ND
cerebral arterial gas embolism ..... ED
Physical injury ..... PI
Other: ..... OT
Specify: .....
Nil ..... NI

VENTILATION INCIDENT
Total ventilation failure ..... VF
Inadequate ventilation IV
Misconnection ..... MI
Disconnection ..... DI
Ventilation circuitry valve ... CV
Circuitry ineffective in delivery of 100% O_2 during treatment ..... ID
Wrong F_iO_2 ..... WF
Hypercarbia ..... HC
Leak ..... LE
Obstruction ..... OB
Overpressure ..... OV
Other ..... OT
Specify .....
Nil ..... NI

CHAMBER INCIDENT
Medical lock ..... ML
Alarm failure ..... AF
Interruption of gas supply .... GS
Patient loading device ..... LD
Potentiated fire risk ..... FR
Patient trolley / seating ..... TS
Overboard dump ..... DD
Suction device ..... SD
Chamber valve failure ..... VF
Communication system ..... CS
Contaminated gas supply ..... CG
CO_2 scrubber ..... SC
Uncontrolled descent ..... UD
Uncontrolled ascent ..... UA
Interference with pressurisation ..... IP
Chamber temperature ..... CT
Chamber humidity ..... CH
Other ..... OT
Specify .....
Nil ..... NI

EQUIPMENT INVOLVED
Built-in breathing system ..... BI
Scott mask ..... SM
Head tent / hood ..... HT
Ventilator ..... VT
Specify type: .....
IV Pump ..... IP
Specify type, brand and model number: .....
Nename 1240
IV Tubing ..... IT
Overboard dump ..... OD
Flow meter ..... FM
Chamber door ..... CD
Window/hull ..... PH
Temperature control unit ..... TC
Lighting ..... LT
Fire suppression system ..... FS
Gas analyzer ..... GA
Transcutaneous oxygen monitor ..... OM
Other ..... OT
Specify: .....
Nil ..... NI

PHARMACOLOGICAL INCIDENT
Inappropriate Drug ..... IP
Wrong drug ..... WD
Allergy phenomenon ..... AL
Drug Label ..... DL
Interaction ..... IN
Overdosage ..... OV
Side effect ..... SE
Underdosage ..... UN
Other drug incident ..... OT
Specify: .....
Nil ..... NI

TUBES & LINES INCIDENT
Lines:
Peripheral IV ..... PV
IV pass-through ..... PT
PA ..... PA
CVP CV
Arterial Line ..... AL
Vascath VC
Peritoneal dialysis ..... PD
Intracranial pressure IC
Chest Tube Drain ..... CT
Urinary Catheter ..... UC
Surgical Drains ..... SD
Other ..... OT
Specify: .....
Nil ..... NI

WHERE DID INCIDENT OCCUR?
Ward/Unit ..... W/U
Transit ..... TR
Retrieval ..... RL
Hyperbaric Unit:
- outside chamber ..... HU
- in chamber ..... HC

TO WHOM IT HAPPENED (Circle one) If more than one describe in narrative.
Patient
Staff
Visitor
Equipment
Male / Female
Age Group: 1-14 ..... CH
14-20 ..... YA
21-40 ..... OK
40-60 ..... MA
> 60 ..... OL

FINAL OUTCOME
Staff unfit short-term ..... US
Staff unfit long-term ..... UL
Awareness ..... AW
Death ..... DE
Dive aborted ..... DA
Dive lengthened ..... DL
Dive shortened ..... DS
Other ..... OT
Specify: transient drop in blood pressure
Nil ..... NI

Figure 4.1: Sample Form

System-Based	Personal-Cognitive	Team-Cognitive
Management Pressure to proceed Poor decision by management	***Knowledge-based*** Inadequate / wrong knowledge Inexperience / inadequate training Unfamiliar environment Unfamiliar equipment Unfamiliar policies / protocols	Communication problem Poor team work Lack of supervision Inappropriate behaviour / action
Infrastructure / Equipment / Monitors Lack of suitable bed / facility Lack of suitable equipment / monitor Malfunction of equipment / monitor Poor design of equipment / monitor Poor instructions for use	***Rule-based*** Failure to check equipment Failure to follow policy / protocol[1] Failure to attend (when asked)	
Staff/ Protocols / Policies Insufficient number of staff for the job Insufficient training for the job No or poor policy / protocol Failure to use / enforce policy-protocol	***Skill-based*** Haste Distraction Inattention Absent- mindedness Fatigue Stress Unwell	
Supplies / Labelling Lack of supplies Inaccessible supplies Poor labelling	***Technical*** Inexperience with procedure Technical problem with procedure	
	Violation Took a "short cut" Knowingly broke the rules Took a risk	
	Chance Chance event Unexpected allergy / anaphylaxis	

Table 4.1: Contributing Factors

[1] Failure to use/enforce policy/protocol is the non-use or the inability to enforce the use of an existing policy or protocol. This differs from the rule-based failure to follow policy/protocol in that the person did not follow the policy or protocol in the prescribed manner.

The fourth page of the form also includes the address of the Australian Patient Safety Foundation for those who wish to send the report directly rather than through their own Unit system.

4.4 Research protocols and procedures

Once registered, the participating Unit is issued with a "Starter Kit" that includes ten HIMS Incident Forms, instructions for the hyperbaric medicine unit coordinator or "person on the spot" (POS), an information sheet explaining the concept of the HIMS reporting system, a POS Registration Form, and a promotional poster.

Upon enlisting in the study, the participating unit nominates a "person-on-the-spot" (POS). This person acts as their Hyperbaric Unit's educator and facilitator for HIMS. The POS ensures that the staff are familiar with the concept of HIMS and the POS makes the incident forms visible and readily available to staff. A locked box for depositing the forms is recommended. The POS empties the forms from the box at regular intervals and deletes any identifying features from the form. The forms may then be used within the unit at staff meetings as a quality improvement tool if all staff members agree to this. The forms are posted by the POS to a post office box in Adelaide for collection.

When the reports arrive in Adelaide, they are stamped with the date of their receipt and the envelope destroyed. The form is assigned a number and the data from the form is checked for any identifying features, which, if detected, are removed. The information on the form is then entered into the computer database. No data is entered that identifies the Unit or indicates when the incident occurred. This ensures anonymity and prevents legal disclosure, as the information can not be linked to any country or hyperbaric facility. The database software used for the study is Foxpro™ (Fox Software, Inc. Perrysburg, Ohio, USA). After data entry, the data are converted into an Access (Microsoft Access for Windows 95, Version 7.0, Microsoft Corporation©) database to facilitate the completion of simple queries and to allow for ease of international HIMS participants to keep their own unit's HIMS database on internationally common software.

4.5 *Analysis*

The author reads the narrative of the incident and codes it by assigning key words. The key words are generic categories that classify key components of the incident. New keywords can be added to the keyword list when required to enable the narrative to be classed as it appears, rather than making it fit into less descriptive classifications. The key word list is, therefore, a continually evolving, data derived list. Examples of key words for an oxygen toxicity seizure are: CNS (central nervous system), seizure, 2.8 ATA (pressure in atmospheres absolute), critical, and ventilated for an oxygen toxicity seizure in a critically ill, ventilated patient. Furthermore, if the narrative also states that the patient has a high fever and is on steroids (both decrease oxygen seizure threshold), the high fever and steroids would also be assigned as keywords.

Any words that may lead to identification of the reporter are deleted. The form is corrected for any obvious omissions of tick box entries derived from the narrative. For example, if the narrative describes an incident involving patient ear barotrauma and the tick box for "patient complication- barotrauma" is not ticked, the researcher will tick that box. Caution was exercised not to make any alterations to the form unless it was explicitly clear that an omission was made. If there is any doubt in deciphering the written text, the suspected word is put into brackets in the narrative text. Once the data is entered, the computerised entries are each checked for any errors or omissions from the original written form.

The initial analysis is completed by running queries to count the number of positive responses for each question. Total numbers of incident types, location, preventability, contributing factors, and who was involved in the incident are examined. Total numbers of each subtype of incident are also counted. The narratives of the most commonly occurring incidents are studied for any similarities or specific differences.

The incidents within the sub-group "other" are also reviewed. If there are several of the same type of "other" incidents they are grouped together. Incidents classed as equipment and chamber type incidents, are often the same incident. Again, the incident is only fully described once unless it has significant relevance to one of its other groupings.

As is typical of narrative analysis, the descriptions of the incident type categories are reviewed again. Noted are any contributing or minimising factors and any other information that is useful in identifying similar patterns to particular groupings of incidents. For example, in the ear barotrauma sub-group, information was sought regarding:

1. any pre-existing condition
2. the level of patient teaching
3. the pre-treatment ear examination
4. the number of treatments the patient had previously
5. if the barotrauma occurred on pressurisation or decompression
6. if the patient complained of pain or discomfort
7. the degree of barotrauma
8. if the treatment was aborted
9. if the patient required myringotomies or grommets

The same analysis is used for each type of incident sub-group, based on known factors of hyperbaric incidents as found in the literature and the author's experience.

Once all common features of the incident groupings are identified, those that are grouped under multiple incident type groupings are examined for their common features.

Contributing factors are then counted and examined by general groupings of system-based, team-cognitive, and personal-cognitive. Each of the "tick-box" listed contributing factors is then analysed to see if there is a relationship between the specific contributing factor and the main incident type groupings. This was performed by using SPSS® 6.1 for Power MacIntosh. Cross-tabulation with two-way tables was used to analyse the relationship between the type of incident and contributing factors. The Pearson Chi-square test was chosen because it is the most appropriate test to examine the relationship between categorical variables. The assumption in using the Pearson Chi-square test is that there are sufficient numbers of expected frequencies between variables on the two-way table. When the numbers are low, this test cannot calculate the probability of frequencies precisely. Therefore, the Fisher's Exact test was also used in the analysis since some of the numbers in the categories of contributing

factors or incidents were low. Also using two-way tables, the Fisher's Exact test lends itself to low numbers since it computes the exact probability by counting all possible tables that can be constructed based upon marginal frequencies.

These tests are beneficial to determine the significance of particular contributing factors to particular groupings of incidents. With larger data, the relationship between each individual incident type (rather than groupings of incident types) and their contributing factors can be made to obtain more specific information on the contributing factors to incidents.

A summary of the analysis process is provided in Table 4.2

Analysis Process
Data entry/coding/checking
↓
Access Queries/Counts (Descriptive)
↓
Narratives (Interpretive)
↓
Review of and assignment of types and sub-groups
↓
Contributing factor relationships (significance testing of category comparisons)
↓
Minimising factors review

Table 4.2: Analysis Process

4.6 *Ethical Issues / Confidentiality*

This study has ethical approval from the Royal Adelaide Hospital and the University of Adelaide Ethics Committee (Appendix G). The central ethical issue is anonymity of the participants. The study has addressed the issue of anonymity in a number of ways. Table 4.3 lists the initiatives taken to provide anonymity for the reporter.

1. the form has no place for name or any identifying features.
2. the envelope is shredded upon receiving the forms.
3. all the data is entered into one central database.
4. once the data is entered and checked, the form is shredded
5. legal protection for the participant to report incidents was obtained at both the state and federal levels of government in Australia
6. the database programmer, a hyperbaric doctor, and the researcher have signed confidentiality statements and security clearance with the APSF
7. the list of HIMS participating units is confidential

Table 4.3: Anonymity

The participants are advised not to report any incident that they fear may result in medico-legal risk on the instruction page of each Incident Report Form. Consent is assumed by the anonymous and voluntary submission of the incident form.

4.7 *Strengths and Limitations of the Design*

Collection of qualitative data for incident monitoring is reported and critiqued by Runciman (1993). Qualitative data, as used in this study, can lead to the formation of hypotheses that can be

tested with quantitative research methodologies. The research methodologies complement each other. This study, while not providing incidence rates of specific types of incidents, gives richly informative data on the factors surrounding the incidents. Research of complex subjects like those that examine human error and systems are best suited to qualitative research methods. This allows a broader perspective of analysis that is not restricted to the confined testing of a set hypothesis. It also facilitates the discovery of new information that may have otherwise been missed in quantitative research where data collection is restricted to finite measures. Additionally, it is relatively inexpensive to administer compared to quantitative studies. The use of quantitative studies is valuable, but they could be more cost efficient and yield more benefit once a strong hypothesis has been developed from the qualitative research. The analysis of the qualitative data should give justifiable answers that align with evidence from the literature and provide recommendations that can influence clinical practice.

Some limitations of this study include reluctance of staff to complete the incident report form because of their previous experiences with incident reporting being a mandatory and disciplinary procedure. This limitation should be lessened by the training of the "Person On the Spot (POS)". The POS educates staff members about the concept of anonymous incident reporting and helps them to see the value that will result from cumulative incidents being reported, analysed and quality improvements being made. The HIMS video also assists the POS in educating staff. Posters were also given to the POS to help promote the study in their Unit.

Risk of medico-legal disclosure is also present. The limitations of legal disclosure are reduced by the inclusion of the HIMS study as a project of the APSF and protected from legal disclosure by the Health Insurance (Quality Assurance Confidentiality) Amendment Act 1992 of The Commonwealth of Australia and the South Australian Health Commission Act 1976:64D: "Disclosure of confidential information for certain purposes".

Underreporting is a limitation of the study. Anonymity and emphasis on no culpability were used to encourage reporting. Promotion and education regarding the inevitability of human error and the importance of systems and factors out of the control of the practitioner in contributing to the incident were all tactics implemented to reduce the causes for underreporting. Even so, underreporting will remain a limitation.

Maintaining anonymity in this study is paramount to ensure a "blame-free" method of reporting incidents. Blaming the practitioner does not improve the system and it allows the same incidents to continue to occur.

Voluntary incident reporting is a useful tool for safety and quality improvement (Tyler & Nickman 1992, Chen et al. 1998, Frey & Kehrer 1999). Even in mandatory reporting systems, an element of voluntary reporting is present. The responsibility of completing the report rests with the reporter. There are also limitations with voluntary reporting. Knowledge and misconceptions of voluntary reporting systems can lead to underreporting. Attitudes such as the incident being trivial or too well known, and that there is not enough time to report or that reporting is too bureaucratic have been shown to reduce voluntary reporting (Eland et al. 1999). It allows the reporter to decide when to report incidents, therefore not representing all the types of incidents. It has been demonstrated to show only a small proportion of the total adverse events that occur (Cullen et al. 1995).

Automated incident reporting has been used to help overcome the deficiencies of voluntary incident reporting in anaesthesia (Cooper 1996), but this method cannot easily be applied in hyperbaric. Most events in hyperbaric are not easily detected by monitors, and are subsequently not automatically recorded. In fact, much of what occurs to patients in chambers is only viewed and known to the inside attendant and/or the chamber technician. Therefore, the use of voluntary incident reporting is valuable in the hyperbaric setting. Nevertheless, the role of automated markers for monitoring critical events may be an additional tool to detect some types of hyperbaric incidents.

Chart review as a method of tracking incidents also has its disadvantages. It is time consuming, costly, lacks the discovery of many of the causes of the incidents, and does not tend to include the "near miss" incidents. Other methods such as direct observation, record review, and interview may reduce the incidence of underreporting and provide incidence rates, but with the loss of collecting the personal cognitive, and systems factors which may be contributing to the incidents. Although these other methods may be able to capture some of these elements, they are costly to sustain compared with a self-reporting system.

The ability to report incidence rates of particular types of incidents is a limitation of the current study. The total number of hyperbaric treatments (denominator) from which the incidents (numerator) occurred is unknown. To preserve anonymity, no record of the number

of units actively reporting was kept. Comparisons cannot be made between units. Individual units may compare their own data to the international data or to other consenting units, but the researcher does not identify incidents by their originating unit. While this may be a limitation it is also a strength of the study. It prohibits the natural human tendency to point blame at any one unit. The study directs energy to be focused on looking at the international pool of data for causative and preventative factors, a much more productive and positive approach. In summary, the qualitative methodologies used in this study are most suited to this type of research.

CHAPTER 5

Results

The period of data collection lasted for twenty months, from January 1996 to September 1997 inclusive. The total number of incidents reported in this period was two hundred. There were forty-five participants from seventeen countries enlisted in the study. To ensure anonymity, the reports have no identifying information, therefore data on participation rates and comparisons between different Units cannot be made from the central database.

There was no mortality resulting from incidents in this study. The outcomes of the 200 reports are summarised in Table 5.1. Fourteen of the two hundred reports resulted in staff members being unfit to work in a pressurised hyperbaric chamber, thirteen temporarily and one permanently. The category of "Other" outcomes included repair of equipment, altered dive profiles, no further problem, prolonged stay, offending component removed, delays in treatment starting, delays in oxygen breathing, potential lung aspiration, and chamber flush.

Outcome	Number
Nil	56
Aborted Treatment	48
Awareness	39
Staff Unfit	14
Lengthened Treatments	10
Patient Cancellations	7
Shortened Treatments	6
Myringotomy	4
Other	25

Table 5.1: Outcomes From Reports (N=200)

Of the forty-eight aborted treatments, nineteen were related to barotrauma and sixteen were associated with anxiety. Various other causes for abortion of treatment included: chest pain, vertigo, and inability to equalise pressure in ears (two each) dental barotrauma, endotracheal

self extubation, dyspnoea, nausea, arrhythmia and hallucinations, vomiting post-operatively, and a patient's wife delivering twins, forcing him to urgently exit the treatment.

"Other" outcomes included: delays in treatment starting, problem identification and resolution, repair of equipment, changing treatment profiles, prolonged hospital stay, potential pulmonary aspiration, and patients unfit for treatment for a short time.

The reporter was asked if the incident was preventable. The reporters judged forty-four percent of all the incidents as preventable (Figure 5.1).

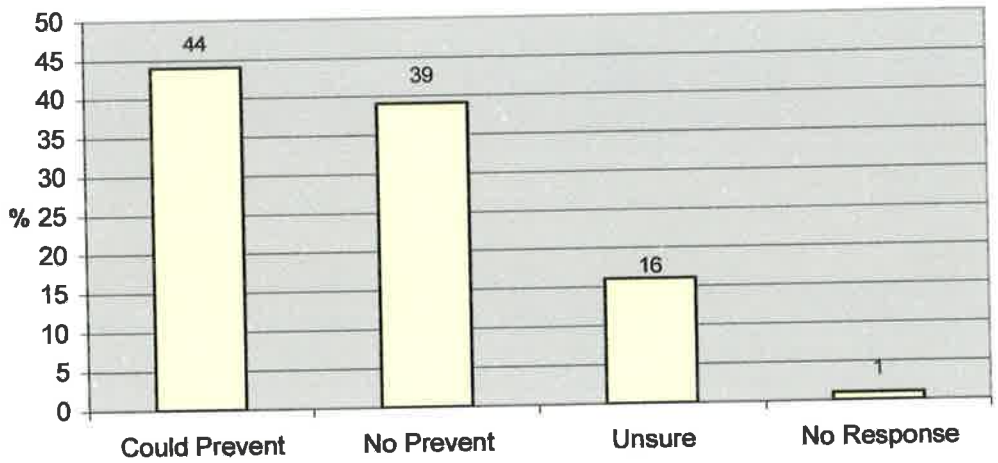


Figure 5.1: Were They Preventable?

5.1 Demographics

5.1.a Where the Incident Occurred

Most of the incidents that occurred in multiplace hyperbaric chambers (eighty-nine percent). Eleven occurred in monoplace chambers, three in dualplace chambers, and nine did not involve a chamber (Table 5.2).

Chamber Type	Number
Multiplace	177
Monoplace	11
None	9
Dualplace	3

Table 5.2: Type of Chamber Involved (N=200)

The location of the incident is shown in Table 5.3. Most of the events took place inside the chamber (164). One incident began in theatre, continued in and outside the chamber, and then onto the ward. On four reports, the location was not indicated.

Location	Number
In Chamber	164
Outside Chamber	18
In and Outside Chamber	8
Ward/Unit	3
Transit	2
Ward/ In and Out of Chamber	1
Not indicated	4

Table 5.3: Where Incidents Occurred (N=200)

5.1.b Who/What Involved

Patients were most frequently involved (135), staff were involved in fifty-three of the incidents, equipment in twenty-nine, and a visitor in one. In 118 incidents, patients exclusively were involved in the incident. Staff were exclusively involved in thirty-nine incidents, equipment only were eighteen and a visitor in one. The remainder of the responses (twenty) involved varying combinations of patient, staff, visitor, and equipment. Four reports had no response.

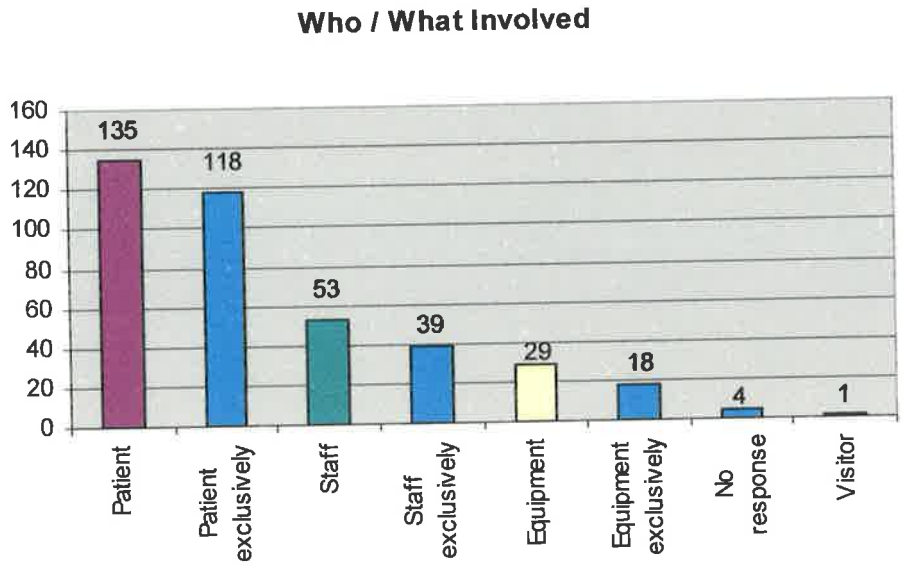


Figure 5.2: Who / What Involved (N = 200 reports)

5.1.c Age of Involved

Ages of those involved were documented on all but thirty-three reports. The HIMS Incident Report Form allowed for the reporter to make more than one selection in the "To Whom It Happened" category (patient, staff, equipment, visitor). When this occurred, the age designated to that selection could not be differentiated between the selected person/equipment. Since age could not be determined when both patient and staff were selected, age is not reported on for this group. When either patient or staff were selected in addition to equipment (eleven incidents), it could logically be suggested, by reading these reports, that the staff and the patient in this population were older than the type of medical equipment in use (Figure 5.3). It is an anomaly of the form design that has created the

difficulty in age analysis. This problem has been further described in the Discussion Chapter Six.

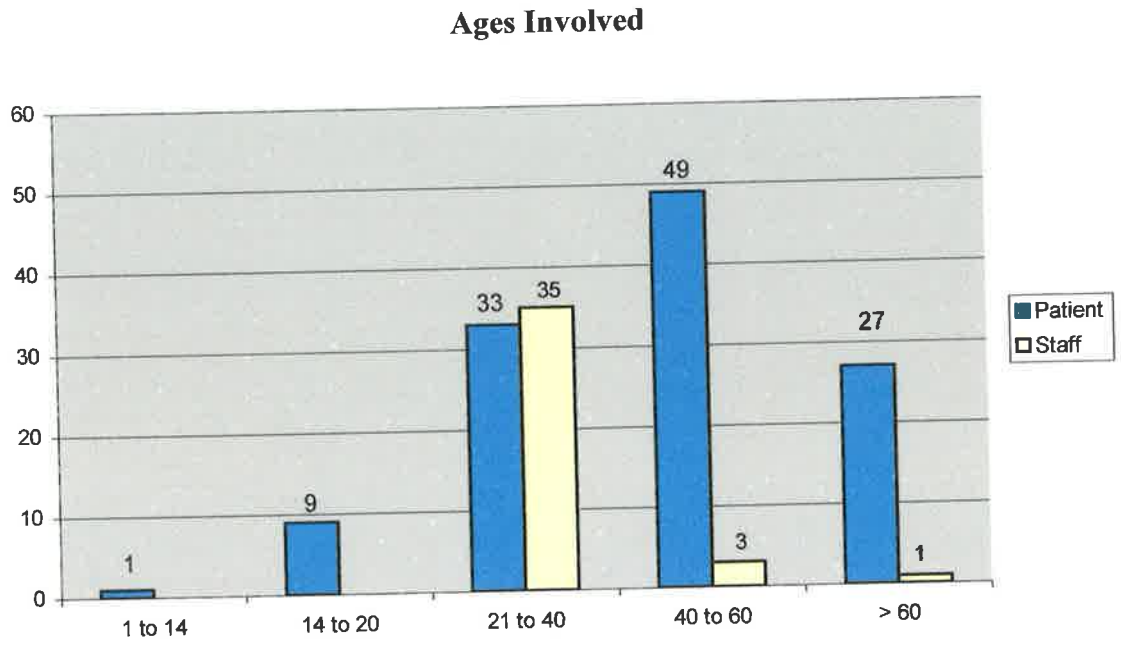


Figure 5.3: Ages Involved (N=167 reports)

5.2 *Types of Incidents*

Categories of the types of incidents included problems relating to: patients, equipment, chamber system, staff, ventilation, intravenous (IV)/invasive pressure lines/patient drainage tubes, and drug administration. The results are reported under these headings.

Patient problems (110) were the most frequently reported of all the incidents. Equipment problems also featured (seventy-four), with chamber system (forty-two), staff (thirty-one), and ventilation (eighteen) problems also reported. Intravenous lines/drainage tube problems (nine) and drug administration problems (six) were reported less frequently.

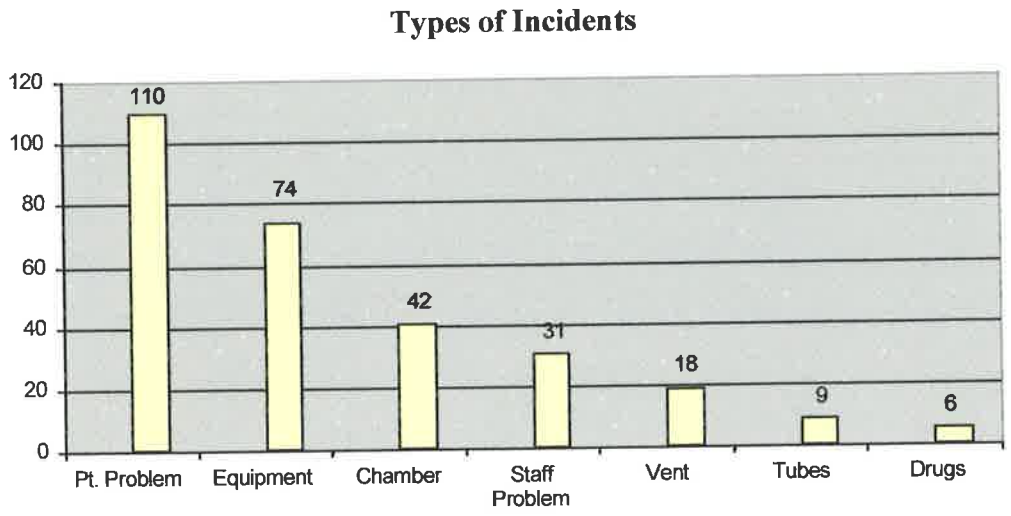


Figure 5.4: Types of Incidents (N = 290)

5.2.a Patient Problems

The most commonly reported incidents were patient problems. They are grouped into the four categories of barotrauma, oxygen toxicity, psychological reactions and other, as shown in Figure 5.5 and are reported under these headings.

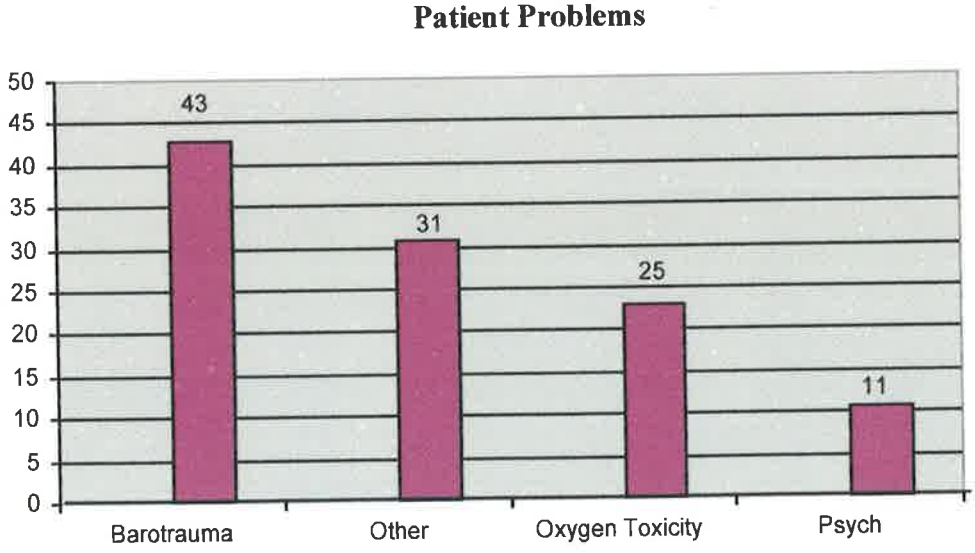


Figure 5.5 :Patient Problems (N=110)

Barotrauma

Forty-three patients suffered some form of barotrauma. Barotrauma (twenty-two percent of all incidents) is the most frequently reported patient problem. Thirty-four of the forty-three (seventy-nine percent) reported cases of barotrauma affected the ear. There were seven reports of sinus barotrauma, and one each of dental and pulmonary barotrauma.

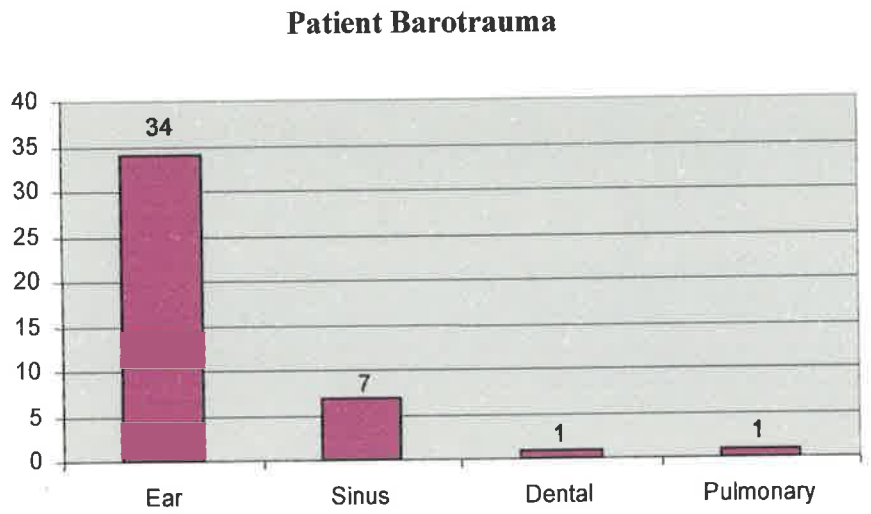


Figure 5.6 : Patient Barotrauma (N=43)

All patient ear barotrauma affected the middle ear. In one report of vertigo with middle ear barotrauma, the narrative did not include any description of other inner ear barotrauma symptoms. Thirty-five percent of all incidents involving ear barotrauma resulted in aborted treatments, and forty percent of all aborted treatments in the study (forty-eight), were a result of either ear, sinus, or dental barotrauma.

Ear barotrauma necessitated myringotomies in seventeen (fifty percent) of the thirty-four cases of ear barotrauma. One patient who had myringotomies with pressure equalisation tube placement for hyperbaric treatment developed bilateral middle ear infections.

All of the ear barotraumas except for two occurred on compression. These two resulted from a reverse middle ear squeeze on decompression, one of which caused a temporary stop in the course of the patients treatments.

One ventilated patient had bilateral Grade IV barotrauma. Nine of the ear barotrauma reports did not occur on the first treatment. Two of those nine described acute rhinitis to be the cause,

and one reported haste in getting to treatment on time to be a major contributing factor. Claustrophobia was a significant factor in one patient developing ear barotrauma that resulted in the patient not attempting any further hyperbaric treatment. An uncontrolled compression was the cause of another patient's barotrauma, which subsequently resolved with decongestant therapy.

All but one of the sinus barotrauma patients and the dental barotrauma resulted in aborted treatments. The sinus barotrauma was unexpected in all but one of the patients that experienced it. One patient had recurrent sinusitis and was cleared by an otolaryngologist for pressure exposure. The patient was unable to tolerate pressurisation and the treatment was aborted. There was a single case of dental and of pulmonary barotrauma. These are not commonly reported complications. In this study, the patient with pulmonary barotrauma reported chest pain one day after her first hyperbaric exposure, prior to entering the chamber for the second time. Clinical examination was consistent with pneumothorax and was confirmed by chest x-ray. The pneumothorax resolved without intervention and hyperbaric treatment was abandoned.

Oxygen toxicity

Oxygen toxicity was the next most frequently reported patient problem. Figure 5.7 gives a breakdown of how oxygen toxicity was manifested by the patient.

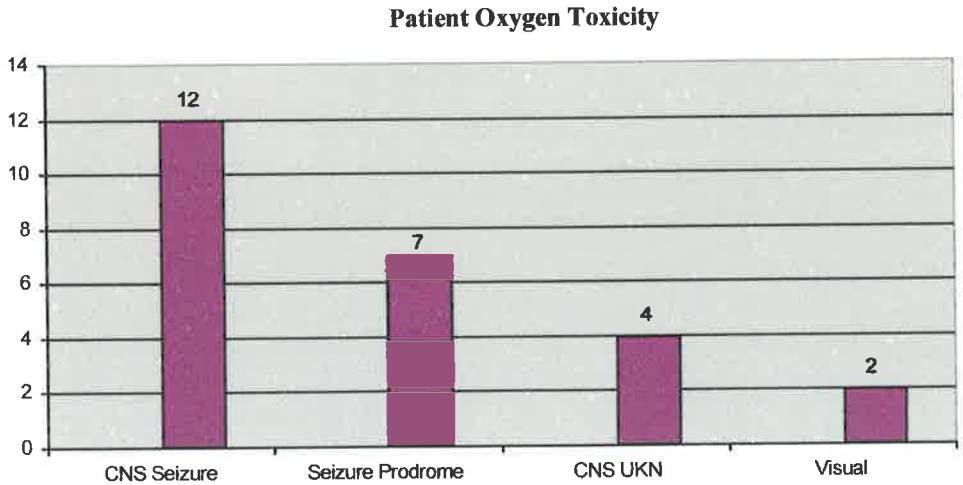


Figure 5.7: Patient Oxygen Toxicity (N=25)

Central nervous system (CNS) oxygen toxicity was reported twenty-three times. This represented twelve percent of the total reports and twenty-one percent of the patient problems. Not all CNS oxygen toxicity resulted in grand mal seizures. Twelve of the twenty-three reports specified that a grand mal seizure had occurred, seven had prodromal symptoms of oxygen toxicity, and four of the reports circled the category of patient oxygen toxicity on the report form but did not describe the symptoms of the toxicity. Of the thirteen reports of CNS oxygen toxicity that specified the treatment pressure, twelve were at pressures of 2.4 ATA or greater. One reported seizure prodrome at 2.0 ATA and the treatment was aborted. One of the patients that had a grand mal seizure had also been drinking alcohol and two were on mechanical ventilation.

There were no reports of pulmonary oxygen toxicity in patients. Visual changes as a result of breathing oxygen were reported twice. One patient developed myopia and one hyperopia.

Psychological reactions

Psychological reactions to the treatment were the third most commonly reported patient complication (eleven reports). Anxiety was described in all of the reports. Seven of the reports described confinement anxiety that resulted in four of the patients electing to discontinue further hyperbaric treatment. Four cases of patient anxiety resulted from witnessing a fellow patient having a grand mal seizure in the chamber. All of these patients required their treatment to be aborted. The reporter did not specify if these four patients planned to return for any further hyperbaric treatment.

Other

There were thirty-one other patient complications that occurred less frequently. They included; vomiting (four), three each of ear clearing difficulty, hypoglycaemia, vertigo, and physical injury due to poor design of chamber, and chest pain/angina (two). Thirteen singularly occurring incidents are listed in Table 5.4.

1. paraesthesia with bradycardia	8. heavy perspiring while wearing oxygen hood
2. self endotracheal extubation	9. endotracheal tube cuff leak
3. "hangover" in the chamber	10. difficulty in exhalation of breathing circuit
4. generally feeling unwell	11. central venous IV site, pain with dyspnoea
5. syncope	12. urge to urinate
6. cardiac arrhythmia	13. aggressive patient
7. ear infection	

Table 5.4: Other Patient Problems

Interestingly, the lack of toilet facilities led to a significant injury in one patient and abortion of treatment in another. At the completion of a treatment, a patient quickly arose from his seat in the chamber in an attempt to prevent another male patient from exiting the chamber. He was trying to assist a female patient to get to the bathroom first. In his haste, he hit his head on the low ceiling of the chamber and required nine stitches to close the head wound. In the other related incident, a patient had a sudden urge to urinate that resulted in hypertension, anxiety, and abortion of the treatment.

Two of the other patient complications were nausea and vomiting related to alcoholism. On his first treatment, the patient was described as pale, with tremor and intermittent periods of vomiting. Later the staff commented that he smelled of alcohol although the patient denied it, saying he gave up alcohol twenty-four hours previously for the hyperbaric treatment. Another patient was pale and diaphoretic with vomiting in the chamber. He had undergone over 50 treatments previously. The patient did not admit alcohol intoxication. When his wife came to pick him up near the end of the treatment, she was notified of his illness in the chamber. She had no hesitation in describing his previous night's drinking binge.

In another incident, a psychiatric patient with a recent history of aggression was put into a chamber with two other patients and a staff member. The patient became physically and verbally aggressive. The treatment was aborted with all other occupants fearful of attack.

5.2.b Equipment Problems

The categories of equipment and chamber system problems sometimes overlap since chamber systems may at times include equipment linked with the chamber and vice versa. There may also be more than one equipment problem in a report. There were seventy-four incidents associated with equipment. Predictably, the most common types of equipment involved in the incidents are those affiliated with the delivery and scavenge of chamber gas. This equipment included oxygen hoods (fourteen), built-in-breathing system (BIBS) circuits (twelve), overboard dump (OBD) system (eight), breathing masks (seven), monitors (six), ventilators (four), suction devices (three), and an array of equipment items implicated in twenty reports.

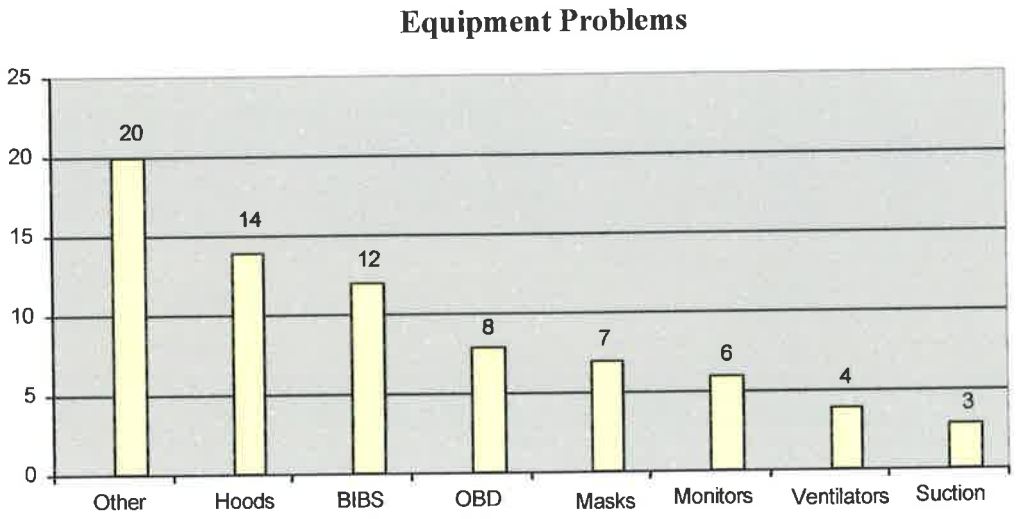


Figure 5.8: Equipment Problems (N=74)

Hoods

The problems involving oxygen hoods were varied. Three of the incidents resulted in deflation of patients hoods, one from supply regulator failure, one from a faulty overboard dump system, and another caused by an inexperienced nurse operating the hood system.

Sometimes, one problem leads to another. In one such case, the nurse noticed static electricity in a patient's hood. The nurse removed the hood and wetted the patient's hair. Upon replacing the hood on the patient's head, the nurse noticed the oxygen flow to the hood had not been turned off and was flowing freely into the chamber atmosphere. The technician advised the nurse that the oxygen tubing to the hood was disconnected. Upon inspection, the nurse found the exhaust tubing had become disconnected from the hood, not the supply tubing.

Interestingly, after this continual leak of oxygen into the chamber, the oxygen analyser remained at twenty-one percent.

In another hood incident, the exhaust manifold for the hood system became disconnected. Exhausted gas from three hoods was being dumped into the chamber atmosphere at one hundred litres per minute. There was a swift rise in chamber pressure, followed later by an increase in chamber oxygen concentration to thirty percent.

Other hood problems were oxygen leaks from the hoods, flow meter to hood stuck at fifty litres per minute, no oxygen flow to hood although the patient's hood was fully inflated, and detection that a patient had been using petroleum based ointments in his hair after twenty treatments of doing so. There were three reports in which a hood was being worn by the patient at the time of the incident, but the hood was not a factor in the incident occurring.

Built-in-breathing system (BIBS)

A review of the twelve reports implicating BIBS revealed an assortment of difficulties. No gas supply to the BIBS and inadvertently omitting to open the valve for the overboard dump of individual BIBS circuits occurred twice each. In a training dive to thirty metres (four ATA), the doctor inside the chamber asked the outside technician to turn on the oxygen supply to the BIBS so he could demonstrate the use of the BIBS at pressure. The technician fulfilled the request without question. Fortunately, a doctor outside the chamber, knowing the high risk of CNS oxygen toxicity at this pressure breathing oxygen[1], took charge of the situation and turned off the oxygen supply before any adverse event took place. The doctor had taken several breaths of oxygen at this pressure by the time the oxygen was turned off.

Other BIBS problems included a BIBS regulator failure which caused an oxygen leak and necessitated an attendant to enter the chamber to repair it, incorrectly set-up patient's BIBS circuit sent into the chamber, patient having difficulty getting mask off and attendant not observant of the problem, and omission of an attendant to don the BIBS circuit for a required decompression.

[1] Breathing one hundred percent oxygen at pressures greater than three atmospheres absolute is high risk for the development of central nervous system oxygen toxicity in the form seizures

In one event, an attendant had chest pain breathing oxygen via a BIBS circuit on decompression. The chest pain occurred for five minutes, was relieved when oxygen breathing was discontinued, and re-appeared when oxygen breathing on the BIBS was recommenced. There was no return of symptoms in subsequent treatments.

Two reports involving the use of BIBS were patients developing oxygen toxicity, but BIBS were not implicated as a causative factor.

Overboard dump system (OBD)

A miscellany of events comprised eight overboard dump system (OBD) incidents. Three were caused by not checking or unfamiliarity with equipment. Incorrect adjustment of valves for turning on and off the OBD caused slow loss of chamber pressure in one incident, hood deflation in one patient, and breathing difficulty for half an hour in another patient. OBD's that dump several hoods' gases simultaneously were faulty in three instances. Disconnection of exhaust tubing to the OBD was reported in this section previously as hood problem. An o'ring failed in an OBD causing it to malfunction. Poor maintenance was attributed to the incident.

Breathing masks

Five of the seven incidents that had an association with breathing masks were also reported as BIBS events, and have been previously described in that section. The other two included an exhale valve diaphragm inserted backward in a BIBS system connected to a mask, causing a patient difficulty in breathing and a claustrophobia attributed to the application of a Scott™ mask on a patient's first treatment.

Monitors

Monitors were involved in six incidents. Half of these reported failure of electrocardiograph (ECG)/ invasive pressure monitor function, one of which occurred an hour into the treatment of a ventilated patient. Haste played a role in one monitoring incident. When preparing a patient for treatment in the chamber following surgery, a patient's pulmonary artery (PA) pressure tracing did not show on the monitor. The doctor chose not to monitor this parameter and nursing protocol of continuously monitoring PA waveform was not followed. After the treatment, it was found that the cable was plugged into the monitoring panel incorrectly. In

one instance, an Ohmeda ™ volume monitor detected an endotracheal cuff leak on a ventilated patient in the chamber. Replacement of sterile saline in the endotracheal cuff had been neglected prior to pressurisation.

Ventilators

Ventilators had reported faults in the hyperbaric chamber. The Bird® Mark 7 was specified in two of the reports. One failed to deliver an adequate tidal volume. After a replacement ventilator was put into use, it was found the pressure monitoring cable was not securely connected to the in-built nebuliser attachment. The other Bird® Mark 7 fault was a reduction in tidal volume with increasing chamber pressure, and simultaneously an unalterable lengthened inspiratory time. A large reduction in tidal volume with pressurisation also occurred with a Drager Oxylog ventilator. The patient was not adequately ventilated, so hand-ventilation was commenced until a new ventilator was sent into the chamber. At 1.0 ATA, the ventilator worked fine. A Drager Hyperlog was in use when a patient developed an endotracheal cuff leak but was not contributory in this occurrence.

Suction devices

Suction devices were implicated in three incidents. All were suction devices left on in multiplace chambers, causing a slow leak in chamber gas, resulting in gradual loss of pressure. Two of these occurred after hyperbaric nurse training courses where the students had left the suction valve turned on in a training exercise. When the subsequent treatment commenced, the fault was detected.

Other equipment

The remaining twenty equipment related incidents are listed in Table 5.5.

1. Temperature control unit (2)	9. Gauge line penetration
2. Infusion pumps (2)	10. Portable monitor
3. Chamber computer (2)	11. Absence of naso-gastric tube syringe
4. Chamber door (2)	12. HP air supply
5. Flow meter	13. Air conditioner
6. Lighting	14. Electrical switch on chamber panel
7. Window hull	15. Oxygen sensor
8. Toaster oven	16. Valve

Table 5.5: Other Equipment Associated in Incidents (N=20)

There were some reports from the group of equipment associated incidents from Table 5.5 that were of particular interest.

On one occasion, a nurse had been left in the Unit during lunch break while all other staff members went out for lunch. The nurse put her sandwich in a toaster oven in the lunchroom near the chamber. After leaving the lunchroom to answer a multitude of telephone calls and attend to visitors to the Unit, a group of firemen entered the Unit asking the location of the fire. The sandwich was burning in the lunchroom and the inaudible smoke detector had alerted the fire brigade. The automatic shut-off feature of the toaster was not set correctly.

On another occasion, adaptors had been screwed inside a chamber penetration used for gauging chamber pressure. A small pipe was inserted for the purpose of monitoring chamber oxygen levels. Immediately after completing the next treatment pressurisation, the pressure gauges climbed from 2.4 ATA to 3.4 ATA. Pressure was then reduced to 2.4 ATA and the treatment continued without incident. It was believed that a piece of dried paint (moved when thread of adaptor was screwed in) restricted the gauge outlet during compression, and was then released following the pressure change, allowing for a true gauge pressure reading.

Three staff members developed headaches after exposure to fumes from an electrical fire in the Unit. Persistent attempts to locate the source of the offending odour was made by the fire officer and staff in the Unit. Finally, it was found that an electrical wiring assembly for chamber lighting on the chamber control panel had produced amperage overload, causing an electrical fire.

In a separate incident, a volatile liquid leaked into chamber entry lock from unidentified ruptured cylinder. It was believed to be a component of a redundant thermostatic control. The leak was not easily located as the cylinder was installed inside the cooling/heating system ducting. The manufacturer installed the cylinder and its presence was unknown by chamber staff.

After a routine treatment, staff in the chamber area detected an acrid burning smell. The fan for a fibre optic chamber light had overheated and burned out. Chamber lights are routinely turned off when the chambers are unattended.

A portable monitor was mistakenly left underneath the patient trolley during a patient's hyperbaric treatment. The monitor was sent to biomedical engineering following the treatment.

5.2.c Chamber Problems

The total number of incidents categorised as "Chamber Incidents" was forty-two (twenty-one percent all reports). Some element of fire risk was described in eleven of the reports, over board dump problems in five, pressurisation problems in seven, wrong pressure in four, gas supply problems in four, and ten other assorted chamber problems.

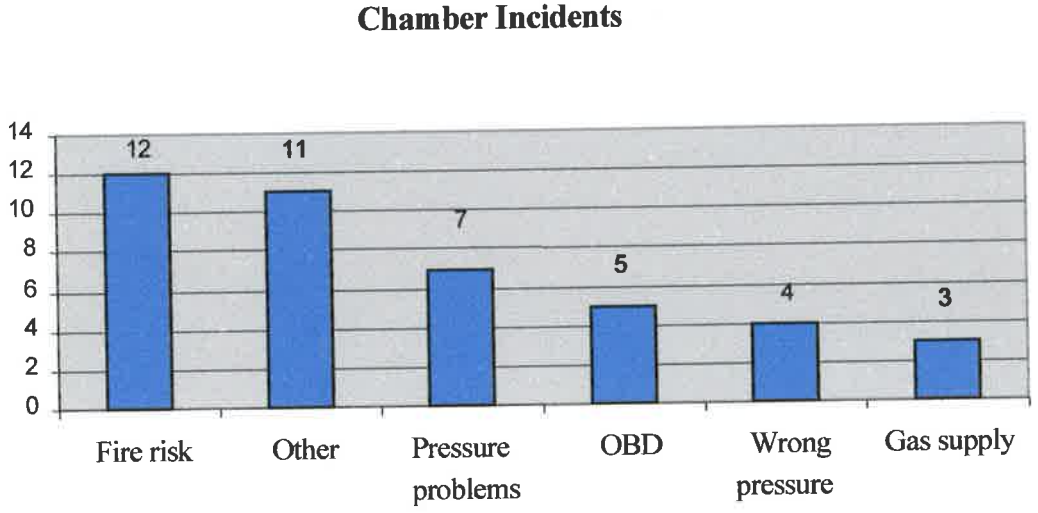


Figure 5.9: Chamber Incidents (N=42)

Fire risk

Of the eleven incidents related to fire risk, seven were related to an elevated oxygen concentration in the chamber atmosphere. Hoods were involved in five of the elevated oxygen concentration reports. These hood problems were attributed to oxygen leaks from splits in the plastic of the hood, disconnection of exhaust equipment, hood over-inflation, and malfunction of an oxygen sensor.

Five described a prohibited substance, item, or static electricity as a fire risk. Items listed were; watches, non-hyperbaric approved monitor, packet of alcohol solution for eyeglass cleaning, and hair ointment.

Other chamber incidents

There were ten other chamber type incidents.

Chamber communication systems were not effective on two occasions, contributing to the creation of the incident. The communication systems were additionally impeded by noise from pressurisation, decompression, and an air-conditioning unit.

A potentially serious error occurred involving a monoplace chamber. A plug used for blocking the intravenous penetration in the chamber door was inadvertently placed into the chamber door from the outer side of the door. A patient was being pressurised when the plug blew out of the door at a high velocity, narrowly missing the head of another patient sitting in a wheelchair at the end of the chamber. Fortunately, a curtain for patient privacy had been drawn around the chamber being pressurised and caught the plug before reaching the sitting patient.

Quite unexpectedly, a hospital maintenance worker approached the chamber panel. The chamber technician thought he was checking a fire extinguisher. The worker then proceeded to drill on the panel of the chamber. The technician immediately stopped the drilling. A treatment was in session at the time.

A nurse was an attendant in a chamber and called for technician assistance via the chamber communication system. There was no answer from the technician. Shortly thereafter, another nurse heard the attendant's calls. The technician was nearby in the doctor's office, but out of audible range of the chamber communication system.

Other chamber problems included the inadvertent pressurisation of a patient's watch, a faulty regulator, a carbon dioxide scrubber problem, and a leaking air-conditioner making it non-operational.

The pot-pourri of chamber incidents ends with a description of a toilet incident. When a chamber toilet was being flushed, the technician forgot to close the outer valve before

emptying the holding tank. The result was a forceful ejection of toilet contents all over the toilet room.

Overboard dump

There were five chamber incidents that involved the overboard dump system. These were described previously in this chapter under the equipment incidents-overboard dump (OBD) heading.

Pressure problems

There were problems with pressurising chambers. Compression to the incorrect pressure occurred on four occasions and uncontrolled compression and interference in pressurisation occurred four times each. Several examples of these incidents are described.

A computer operated chamber was in use, when a nurse tripped over its power supply cable trying to find a monitor switch. The computer restarted resulting in a pressure increase inside the chamber from 2.4 ATA to 2.7 ATA. The compression was stopped and corrected by switching to manual controls. This resulted in one case of mild bilateral ear barotrauma. A chamber computer was again implicated in the interruption of compression of another treatment. The computer failed, after which compression continued with pneumatic controls. Restart of the computer corrected the problem and computer operation of the chamber resumed unremarkably.

During a long treatment, the humidity was ninety-eight percent and the temperature was twenty-eight degrees Celsius. The attendant asked for a flush through of chamber air. There was a sudden increase in pressure and temperature and ear discomfort in the attendant who immediately shut the main chamber air supply valve. The technician was notified and the chamber returned to original pressure.

One uncontrolled compression was caused when bottled air supply was changed over during a chamber flush. The chamber pressure changed from 1.9 ATA to 2.4 ATA, then back to 1.9 ATA. There were no ill effects reported from this error.

An incident described under the heading "chamber incident-other" in this chapter reported the "blow out" of a plug in a monoplace chamber door. The pressure being released from the chamber was kept in check by a staff member placing a finger over the remaining orifice until

the chamber pressure was reduced, the plug replaced properly, and the chamber re-pressurised.

Gas supply

Problems with gas supply were reported four times. One was a technical problem owing to a complex procedure of valve adjustments to change gas supply, one an omission of turning on gas supply to the chamber, and one lack of gas supply to a hood due to a faulty regulator. Chamber gas contamination was also reported. The inside attendant detected an oil or paint-like odour. At the completion of the treatment, outside staff confirmed the odour. Filter elements in air bank had traces of oil. The filter elements were overdue for replacement and there had been problems with the compressor previously.

5.2.d Staff Problems

Hyperbaric staff were involved in fifty-three incidents and had health concerns on thirty-one occasions. Cuts and bumps were the most common injury (seven), back strain and needle stick occurred once each.

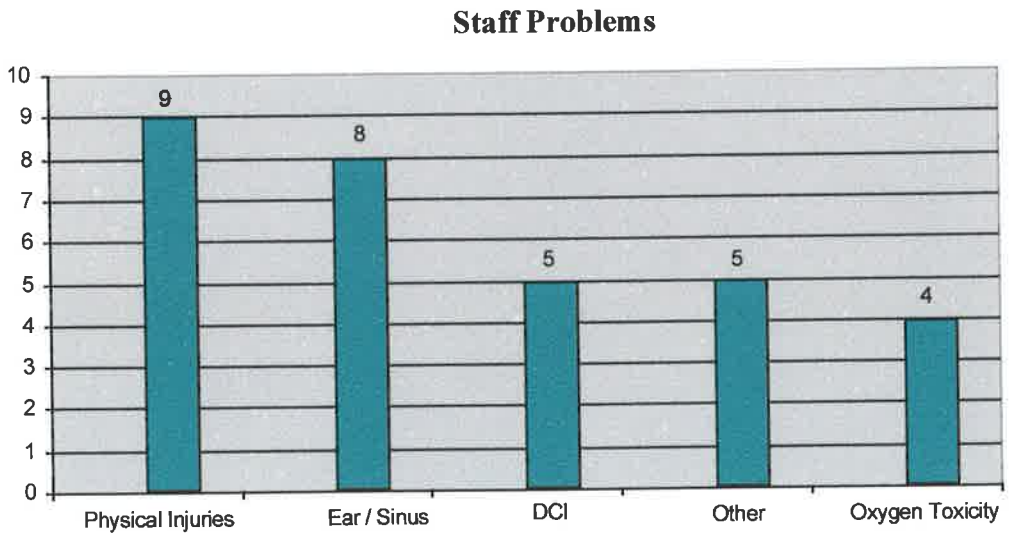


Figure 5.10: Staff Problems (N=31)

There were seven reports of ear clearing difficulties that resulted in six cases of ear barotrauma. After reviewing these cases of ear barotrauma in more detail, it was found that

five caused short-term unfitness to dive and one caused long-term unfitness. Two of the barotrauma cases were associated with training dives and two occurred on ascent, indicative of a reverse ear squeeze. The staff person acquiring long term unfitness from barotrauma reported vertigo, but no pain on ascent. There was evidence of middle ear barotrauma upon examination post-treatment. One case of sinus squeeze was also reported.

Decompression illness (DCI) was also reported. Of the five cases of DCI reported in this study, three occurred after 2.8 ATA exposures, one after six ATA, and one did not indicate the pressure exposure characteristics. All of the reporters described what they believed to be contributing factors to developing DCI. Notably, on three occasions, staff attributed DCI of the involved limb to be related to the stationary position of that joint during decompression. Other factors they identified were previous injury to the affected limb, fatigue, strenuous work, use of contraceptive pills, and an extended decompression profile. All were treated with recompression and had resolution of their symptoms. One nurse acquired pulmonary oxygen toxicity during the recompression therapy.

This case of pulmonary oxygen toxicity was one of two that were reported in the study. The other staff member developed symptoms of oxygen toxicity while oxygen breathing on decompression. While the diagnosis of pulmonary oxygen toxicity was not confirmed, the reporter was uncertain of any other diagnosis to attribute the symptoms. The symptoms of retrosternal burning sensation occurred while breathing oxygen and were relieved with withdrawal of oxygen. No further symptoms recurred in subsequent dives.

CNS oxygen toxicity occurred twice in attendants. On both occasions, the attendants were breathing oxygen for decompression. One nurse became lightheaded, pale, diaphoretic and needed to lie down at 2.0 ATA on an oxygen decompression from 2.8 ATA. Another nurse entered the chamber to care for the affected nurse. In the other report, the nurse developed symptoms of oxygen toxicity at 1.6 ATA, took off the oxygen mask, and had resolution of all symptoms.

Other staff problems included headaches in three staff exposed to fumes from burning electrical wires, and the omission of oxygen decompression due to poor communication between a fatigued technician and nurse.

5.2.e Ventilation Problems

Eighteen reports were categorised as ventilation problems. Most of these were connected to equipment incidents and three were also linked to chamber type incidents so are described in detail under those headings. Ventilation problems featured as faults in breathing circuitry (twelve), two gas supply problems, two endotracheal cuff deflations, one endotracheal self extubation and the absence of a spirometer for use of a ventilated patient in the chamber.

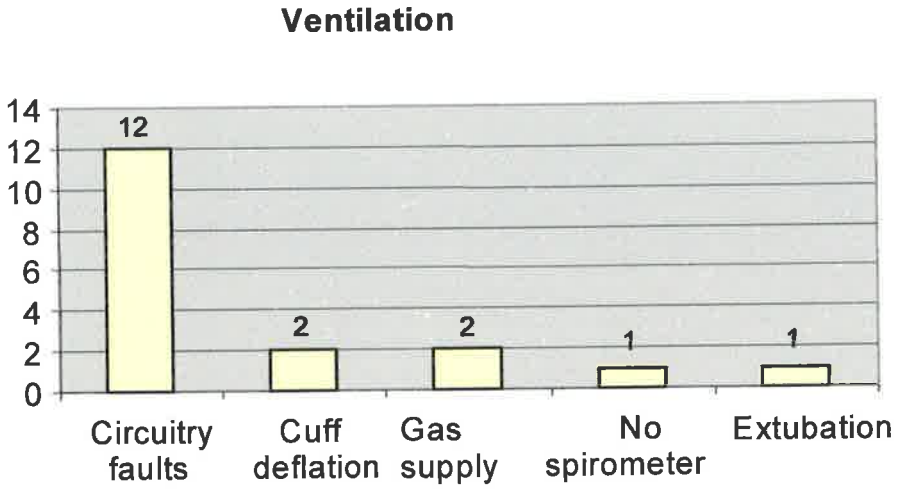


Figure 5.11: Ventilation Problems (N=18)

5.2.f Tubes and Line Problems

Intravenous (IV) and pressure line problems accounted for all but two of the nine problems in this category. IV site/ lines included problems with infusion rate and cannula dislodgment, pain at cannulation site, and intravenous pump fall and malfunction. The lack of obtaining a pulmonary artery wave form tracing was discussed as a monitor problem in the equipment section and the problem with a IV plug " blow-out" has also been discussed previously in the chamber problems review. The two other tube problems were endotracheal self extubation and cuff leak.

There were some noteworthy incidents in this group.

One nurse reported a grand mal seizure secondary to oxygen toxicity in a ventilated patient being treated in a multiplace chamber. The patient was receiving a blood transfusion in a peripheral intravenous (IV) line with a pressure bag on the blood bag to assist the flow rate of the transfusion. After the treatment was completed, the nurse became aware that the IV cannula had become dislodged during the seizure, causing the blood to flow into the bed linen instead of the patient.

In another incident, a critical patient was being transported to the hyperbaric chamber. A pole attached to the bed for the intravenous pumps fell off the bed and the infusion pumps fell to the ground. An infusion pump was broken and the dopamine infusion was stopped for a short time.

An in-line burette was in use on a patient in the chamber. The pump alarmed, so the in-line burette was removed from the system. The IMED[a] pump continued to alarm despite trouble-shooting actions. The IV pump and tubing was replaced with a gravity flow IV tubing set. The pump worked fine prior to and then after the treatment.

5.2.g Drug Problems

The total number of drug problems reported was six. One involved a patient that went from theatre, to hyperbaric, then to another Unit with an unlabelled infusion of propofol. Another patient was receiving intravenous antibiotics but the doctor had not written an order for them. The next dose was due while the patient was in the chamber. The hyperbaric nurse phoned the ward and a phone order was given. The ward staff then failed to bring the required antibiotic to the Unit for administration, so the drug was not given when required.

On one occasion, Haemaccel® caused an allergic reaction in a patient just prior to entering the hyperbaric chamber.

In another incident, a patient arrived in hyperbaric from theatre. The doctor drew up a paralysing drug in a syringe and passed it to the nurse unlabelled. There was inadequate communication regarding the strength of the drug, so the patient received a double dose of the drug. Fortunately, this did not result in any harm to the patient.

On another occasion a patient arrived for hyperbaric with an intravenous infusion. The hyperbaric nurse checked the order for the infusion and found it infusing at an incorrect rate. The rate was then corrected.

5.3 Narratives

Descriptions of the incidents were written by the reporter on page three of the HIMS Incident Report Form. To maintain anonymity, excerpts or re-wording of the actual narratives from the forms were used for descriptive purposes in the previous sections entitled "Types of Incidents". Inclusion of all the narratives would erode anonymity and is accommodated by the description of the incidents.

5.4 Contributing Factors

Chi-square analysis was used to analyse the relationship between types of incidents and their contributing factors.

Of all the factors reporters assigned to contribute to an incident, *chance event* was most commonly chosen, occurring in twenty-six percent of all reports. Of the fifty-two incidents with *chance event* selected, thirty-six were categorised as patient type incidents and eleven were chamber and/or equipment type incidents. There was a significant association (χ^2 $p< 0.01$) between "chance event" and incidents involving patients. The remaining five reports with "chance event" selected were scattered among the remaining types of incidents with no significant associations.

Although *chance event* is grouped under the heading of "Personal-Cognitive Factors", for ease in interpretation, it is evaluated independently and will be reviewed in the Discussion Chapter (Chapter Six).

Excluding *chance event,* the most common factors attributed to incidents occurring were from the subgroups of "skill-based", "infrastructure/equipment/monitors", "rule-based", "team-

cognitive", "staff/protocols/policies", "knowledge-based" and "management". Of those categories, the most frequently selected subgroups are depicted in Figure 5.12.

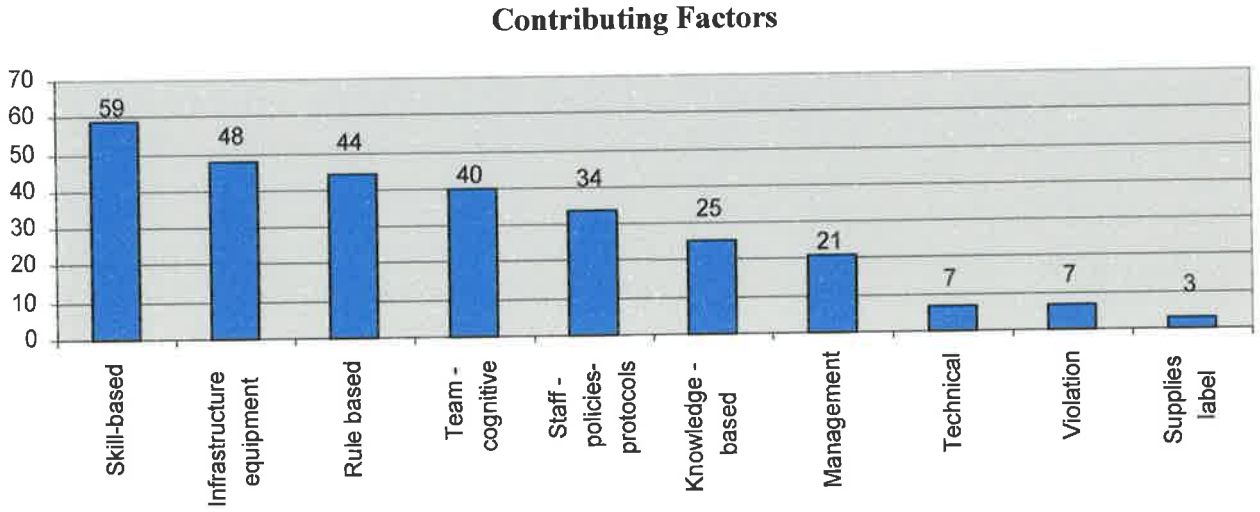


Figure 5.12: Contributing Factors Subgroup Frequencies (N = 229)

When patient type incidents were evaluated, a negative association of at least (χ^2 $p < 0.001$) was found with contributing factors in the categories or subgroups, infrastructure/equipment/monitors, staff/protocols/policies, team-cognitive, and rule-based. Knowledge based and technical contributing factors were also negatively associated with patient type incidents but less significantly (χ^2 $p < 0.01$).

Ventilation type incidents were significantly associated with infrastructure/equipment/ monitors, skill-based, knowledge and rule based (Fisher's Exact test $p< 0.05$ and χ^2 $p< 0.05$). Of these, malfunction of equipment or monitor and poor design of equipment were the most common equipment/monitor factors. Failure to check equipment and failure to follow policy or protocol were the most common rule-based factors.

Infrastructure/equipment/monitor and rule based contributing factors were significant (χ^2 $p< 0.05$) factors contributing to chamber type incidents. Specifically, failure to follow policy or protocol, failure to check equipment, and malfunction of equipment or monitor was most frequently occurring in this group.

Contributing factors significantly (χ^2 $p< 0.05$) related to equipment type incidents were infrastructure/equipment/monitor, rule based, technical, supplies/labelling and knowledge-based. Specifically, malfunction of equipment or monitor, poor design of equipment, failure to follow policy or protocol and failure to check equipment were most frequently ascribed to equipment type incidents.

Pharmacological incidents were significantly (Fisher's Exact test $p< 0.05$) associated with supplies/labelling, skill-based and rule-based contributing factors. Upon reviewing these incidents, moving the patient from one area to another highlighted drug labelling deficiencies that could have harmed the patient, had no intervention occurred.

Tubes and line type incidents were associated with team-cognitive, knowledge-based, and technical contributing factors (Fisher's Exact test $p< 0.05$).

A summary of the contributing factor categories and their association with particular grouping of incidents is shown in Table 5.6 and individual contributing factors listed in decreasing order of their frequency are listed in Table 5.7.

	Patient	Ventilation	Chamber	Equipment	Pharmacological	Tubes/lines
IEM*	0.005	FET** 0.05	<0.0000	< 0.0000		
Knowledge	0.005	0.05		0.05		0.005
Rule	<0.0000	0.005	0.0005	0.00005	0.005	
Skill	<0.0000	0.05			0.05	
Technical	0.05			0.05		0.005
Supplies/label				0	FET** 0.001	
Team-cognitive	0.0005					0.05

Table 5.6: Chi-Square Values for Contributing Factors

- *IEM = Infrastructure / Equipment / Monitor
- **FET = Fisher's Exact Test

Malfunction of equipment / monitor	24	Insufficient training for the job	4
Failure to follow policy / protocol	23	Inadequate / wrong knowledge	4
Failure to use / enforce policy-protocol	21	Unfamiliar environment	4
Failure to check equipment	18	Unfamiliar policies / protocols	4
Communication problem	17	Inexperience with procedure	4
Poor design of equipment / monitor	16	Insufficient number of staff for the job	3
Haste	15	Failure to attend	3
Distraction	15	Stress	3
Pressure to proceed	12	Technical problem with procedure	3
Inexperience / inadequate training	11	Knowingly broke the rules	3
Fatigue	9	Unexpected allergy / anaphylaxis	3
Poor decision by management	9	Lack of suitable bed / facility	2
Inappropriate behaviour / action	9	Poor instructions for use	2
Inattention	9	Poor labelling	2
Lack of supervision	8	Unfamiliar equipment	2
No or poor policy / protocol	6	Unwell	2
Poor team work	6	Took a "short cut"	2
Absent - mindedness	6	Took a risk	2
Lack of suitable equipment / monitor	4	Lack of supplies	1

Table 5.7 Frequency of Individual Contributing Factors

5.5 Minimising Factors

The free text describing minimising factors to the incident are listed in Table 5.8.

Close / good observation	23	Experience	5
Early detection	18	Good luck	4
Good training	7	Patient assistance	3
Good protocol	7	High awareness due to quality assurance activity	3
Good assistance	5	Quick staff response	3
Double checking	5	Patient recognised problem due to good patient teaching	2

Table 5.8: Minimising Factors

5.6 Incident Prevention

Forty-four percent of the incidents were judged by the reporter as preventable and thirty-nine percent unpreventable. Sixteen percent of the reporters were uncertain if the incident could have been prevented. Interestingly, of the reports that involved patient complications the response to the question of whether the incident was preventable (104) included, fifty-four (fifty-two percent) did not believe the incident could be prevented, twenty-eight (thirty-seven percent) believed it could have been and twenty-two were undecided. Staff complications were judged slightly more preventable than not. The reporters judged thirteen (forty-five percent) to be preventable, ten (thirty-four) not preventable, and six were undecided (twenty-nine total responses). With incidents related to any of the other type of incidents (equipment, chamber, pharmacological, or tubes/lines), sixty-seven percent of the time the reporter judged these types of incidents to be preventable and twenty-two percent not preventable.

CHAPTER 6

Discussion

"To error is common to all men, but the man who, having erred, hugs not his errors, but repents and seeks the cure, is not a wastrel" Sophocles

'Antigone', 1.1023

Chapter Five described the raw results of the study in the terms of incident frequency, associations with contributing factors, minimising factors, and some narrative description. This chapter will analyse and interpret the incidents with the view of gaining greater insight leading to safer hyperbaric practice. The individual topics in the chapter are based directly on the incident categories from the study. The discussion reviews the incidents by their type, contributing factors, their relationship to the literature, and the sixteen years of the author's clinical experience in hyperbaric nursing practice. The data are used to establish measures that if implemented, may reduce similar incidents from occurring. When the data are insufficient to draw conclusions, the contributing factors may show trends or give new consideration to the causation of some of incidents that deserve further study.

6.1 Demographics

In total there are two hundred reports from forty-five participants in seventeen countries on three continents. The reports represent an international sample of hospital/clinic based hyperbaric units. The reports are from multiplace hyperbaric chamber units predominantly with eleven (six percent) involving monoplace chambers.

There are a number of possible reasons for this small response from monoplace hyperbaric units. The mainstay of monoplace hyperbaric is concentrated in North America, Japan, Russia, and China. One North American monoplace facility did not join the study due to fear of litigation. Although advice was given not to report incidents incurring harm, the unit declined to participate. Although measures were taken to overcome language barriers, countries with a high number of monoplace hyperbaric units such as Japan, China, and Russia may not have joined the study due to the language barrier.

With more time, a promotion targeted at enlisting monoplace chamber units could be launched to increase the sample size for this type of chamber. The inclusion of more monoplace units may have uncovered types of incidents specific to monoplace chambers and made the study more applicable to this portion of the hyperbaric community. However, much of the data in this study is applicable to all classes of chambers.

Most incidents occurred inside the hyperbaric chamber (168), eighteen outside the chamber, eight occurred simultaneously in and outside the chamber and two occurred during transport for hyperbaric treatment. One of the incidents occurring during transport involved a critically ill patient. Critically ill patients requiring hyperbaric treatment must be transported to the chamber. Critical Care literature has well described the hazards of transporting critically ill patients outside of the intensive care unit (Waydhas, Schneck & Duswald 1995), yet only one incident of this type was reported in this collection of reports.

A "Person on the Spot" from one of the participating hyperbaric units reported that HIMS was not capturing the transport incidents in critical patients. It is likely that transport incidents in hyperbaric patients are underreported. This may be due to the mindset of staff accustomed to reporting only harmful incidents. Also, if incidents occur frequently, one may begin to accept that commonly occurring incidents are the norm and accommodate for them. For example, intravenous pumps and monitors failing when the bed jiggles passing over the entry to the lift, equipment slipping or falling, intravenous line being pulled or tangled, batteries going flat, and alarms activated erroneously may occur so commonly that the experienced clinician prepares for these disturbances without a thought of reporting them. Reporting these common occurrences with a view to re-design equipment or review systems, may reduce or prevent these distracting and potentially harmful incidents from occurring.

Secondly, the HIMS Report Form has options for selecting areas other than the chamber for where the incident occurred, but the instruction page of the form does not define the location of incidents that may be reported. Therefore, the reporter may fail to associate incidents occurring outside the hyperbaric unit to be a hyperbaric incident. Education and reinforcement of the value in reporting these types of incidents is required by the HIMS "Person On The Spot" and in HIMS teaching materials to assist in changing these attitudes. Instructions on the HIMS Report Form could specify that incidents occurring during transport are also to be reported. This would be advantageous to pursue in a future study.

Thirdly, it is more logistically difficult to report incidents that occur in areas other than in the chamber or hyperbaric unit. In transit, the clinician is occupied with tasks and upon completion of transit, continues to have immediate clinical obligations. When finished with these tasks, they may have forgotten to report or are no longer in an area where the forms are available, thus making it logistically inconvenient to report. The people transporting the patient may not be hyperbaric staff and therefore may not know that a reporting system exists. They may not have the information or the commitment to the unit to report the incident.

The majority of incidents involves patients (135) or include a patient problem (110). As the study intended, however, reporters also reported staff, visitor, and equipment incidents. The reporter was permitted to select as many of the "Who/What Involved" options on the HIMS Incident Report Form as applicable. Thirty-eight reports involved more than one selection of patient, staff, visitor, or equipment.

This led to an unexpected problem in the analysis of age distribution when more than one selection from "To Whom It Happened" (patient, staff, visitor or equipment) was circled (fifteen reports). In these reports it was not possible to determine to whom the source age could be attributed. This was due to an error in form design that will be corrected in the next distribution of HIMS Forms. This error did not deter from the findings in the study, as age information did not offer significant relevance to the incidents reviewed in this set of data.

Of the reports involving only the patient (119 reports) where age was recorded, patients are mostly in the forty to sixty year age group (forty-nine patients) followed by the twenty to forty year age group (thirty-three patients), and finally over sixty age group (twenty-seven patients). The remainder of the patients (ten), were aged twenty and under. This may be reflective of the population of patients being treated in hyperbaric but no international census

has been recorded on the average age of a hyperbaric patient. In this study sample, the incidents primarily involve adults. As a result, incident prevention strategies derived from these reports will reflect incidents occurring in the adult population. In no way does this imply that one should be complacent regarding safety of children and young adults in hyperbaric; this sample simply does not have the data on which to base advice. Over time, trends in age distribution may alter as treatment indications change.

The age of staff involved is typical of the international hyperbaric staff population, and therefore lends credibility to the validity of the sample population. Where age of staff does not contribute to the study thus far, a larger pool of data may begin to give information relevant to staff health problems such as age and attendant decompression illness. With more data, trends will determine the value of collecting staff age data.

6.2 Incident Prevention

While forty-four percent of the reporters judged the incidents to be preventable, they assessed patient complications to be less preventable than incidents relating to equipment, the hyperbaric chamber or staff. The contributing factors of those incidents that are judged as preventable are used to develop recommendations for changes in practice.

Analysis of the judgement on prevention of the incidents is not the author's declaration of the ability to prevent the incident. Each incident must be judged in its own context and is judged by staff of varying education and experience levels. Hence, it is the perception of the reporter that is useful. For example, when an experienced hyperbaric nurse studied the data, it appeared that some "unpreventable" incidents may have been preventable, but the reporter did not have the knowledge, experience, or the insight to categorise them as such. One of the useful tools in this study is for the HIMS "Person On The Spot" to take the incident forms from their Unit and discuss them at staff meetings so that other staff members may recognise contributing factors to the incident and preventative strategies that the original reporter may not have considered. This process may help a team to identify system and management problems that a single reporter may feel are out of his/her control. On a broader scale, it may be possible to identify those areas that may benefit from education or research.

There are incidents that are unpreventable. People are never totally predictable or controllable so some incidents will occur no matter how much attention is paid to their prevention. Hence, the classification of "unpreventable" remains on the HIMS Form.

6.3 Types of Incidents

6.3.a Patient complications

Ear barotrauma

Ear barotrauma is the most frequently (forty-three percent) reported patient complication. This is consistent with published literature (Bassett and Bennett 1977, Kindwall 1994c, Capes and Tomaszewski 1996, Kluger 1997). Twelve of the thirty-four ear barotrauma incidents (thirty-five percent) resulted in abortion of the treatment. This is a significant issue for the multiplace chamber units treating six to ten patients, as all the patients may need to decompress and then recompress to allow one patient to exit with ear barotrauma. A patient having difficulty clearing his/her ears and/or requiring exiting the chamber due to ear problems may result in the hyperbaric attendant having a prolonged pressure exposure in the chamber. This can increase the attendant's decompression requirements and his/her risk of developing decompression illness.

Ear barotrauma can be painful for the patient, and may result in treatment with myringotomies and pressure equalisation tube insertion. The literature cites a rate of two to thirty percent of patients having hyperbaric treatment require myringotomies (Fernau et al. 1992, Presswood et al. 1994, Blanshard et al. 1996, Beuerlein et al. 1997, Trytko 1997). In the current study, half of all the reported middle ear barotrauma resulted in the patient having myringotomies.

The procedure of myringotomy and the use of pressure equalisation tubes carry with it the risk of complications (McLelland 1980, Vrabec et al. 1998, Clements et al. 1998). Additionally, this procedure sometimes requires the administration of a general anaesthetic, thereby imposing additional risk. One of the patients in this study, having had pressure equalisation tubes placed for hyperbaric treatment, developed the complication of bilateral middle ear infection. While only one complication from myringotomy tube placement was reported in this study, the incidence and significance of these complications may not be recognised by hyperbaric

practitioners. Clements et al. (1998 p. 279) found that complications from pressure equalisation tube placement occurred in thirty-eight percent of patients and the complications became apparent at an average of nine months following hyperbaric treatment. To prevent complications, they recommended laser tympanostomy or the removal of the pressure equalisation tubes post hyperbaric treatment.

Even if the compression is managed well, and minimal barotrauma results, it is an inconvenience for the patient to miss treatments while the barotrauma resolves and complicates the logistics of maintaining timely treatment schedules.

Interventions to prevent ear barotrauma are essential. Patients should be taught ear auto-inflation techniques (Blanshard et al. 1996). Effective teaching with the patient correctly performing the procedure while the tympanic membrane is visualised is recommended. The patient must also be instructed to verbalise to the attendant or technician any discomfort or unrelieved sensation of fullness in the ear at any time during or after the treatment, but particularly during pressure changes. They also need to be aware that over forceful autoinflation techniques during pressure changes and Valsalva manoeuvre on decompression can result in injury. Farmer (1990) advises that any manoeuvre that increases cerebral spinal fluid pressure may increase the inner ear fluid compartment pressures and can result in round window or other inner ear membrane rupture. Although inner ear barotrauma of round or oval window rupture has not been documented in hyperbaric patients to date, it is reported to have occurred in hyperbaric nurse attendants twice (Pirone 1998).

Even with adequate patient teaching, the stoic patient may fail to report pain in their ear when it occurs. This is the case in two of the reports. In both instances, the reporter documents that patient teaching of auto-inflation had occurred and the patient had been encouraged to report problems. It was not until after the treatment that the patient reported having the experience of ear discomfort during the pressurisation. The prevention of patient ear barotrauma in this patient group hinges on the astuteness of the attendant/chamber operator in recognising the nonverbal signs of ear discomfort.

Different institutions use different evaluations for predicting ear barotrauma risk. Blanshard et al. 1996 and Capes & Tomaszewski (1996) examined the literature on tools that predict which patients may experience ear barotrauma from hyperbaric treatment. They found limitations and

discrepancies in the commonly used methods of otoscopy and impedance audiometry, and therefore did not conclusively favour any one tool. Although decongestants are commonly used, their effectiveness in reducing hyperbaric induced ear barotrauma has not been established. The practice of prophylactic myringotomies in unconscious or ventilated patients for the prevention of ear barotrauma is controversial. The literature clearly demonstrates a higher incidence of middle ear complications in patients with artificial airways (Presswood et al. 1994, Beuerlein et al. 1997) and an experienced hyperbaric and ear specialist recommended myringotomies for all intubated patients prophylactically for hyperbaric treatment (Farmer 1998). In practice, this is not the standard (Capes and Tomaszewski 1996, Weaver 1998). There is no evidence to show that even with the higher incidence of middle ear barotrauma, there is any long term effect on the ear or hearing of those that have sustained middle ear barotrauma and no reports of inner ear injury in patients receiving hyperbaric treatment (Farmer 1998, Weaver 1998). The work of Clements et al. (1998) has established the importance of follow-up care post pressure equalisation tube placement. Of particular importance, they found that short-term tympanostomy is effective in prevention of complications in patients requiring tympanic membrane aeration for hyperbaric treatment.

The complication of ear barotrauma in hyperbaric has been known for years and remains the most common complaint in hyperbaric patients. This is reflected in the HIMS reports by the prevalence and descriptions of the ear barotrauma. Research has focused on developing useful tools for identifying patients with eustachian tube dysfunction, but there are no researched strategies that outline a standardised approach to the prevention and management of ear barotrauma in hyperbaric. Perhaps uncertainty and lack of a standardised approach to the prevention of ear barotrauma explains why half of the reporters of ear barotrauma in this study judged ear barotrauma to be preventable and half judged it not to be preventable.

An example of HIMS used as a tool to improve safety was demonstrated by Mueller et al. in 1997. HIMS was used as a continuous quality improvement tool in their Hyperbaric Medicine Unit. A retrospective analysis was done to compare two consecutive, three month periods of HIMS reports (Mueller 1997). In the second period, a reduction in the incidence of barotrauma from fourteen to six occurred as a result of introducing a system-based change. Reducing chamber compression rate has continued to reduce this Unit's incidence of ear barotrauma (personal communication).

The Mueller et al. (1997) study is significant as it demonstrates that HIMS identifies safety concerns, and shows how HIMS data-derived preventative strategies are effective in reducing the problem. It is particularly significant in the study of prevention of hyperbaric induced ear barotrauma and suggests that further research of methods of compressing the hyperbaric chamber should be evaluated for prevention of ear barotrauma. The impact of reducing compression rate and/or momentarily stopping compression at graduated stages to assess for difficulty in patient ear clearing (particularly at pressures of greatest gas volume change) could be examined for ear barotrauma incidence rates. Furthermore, analysis of the effects of prolonged compressions for patient ear clearing on attendant decompression obligations may be useful in determining if hyperbaric attendants are being put at any greater risk of decompression illness. Additionally, the impact of ear barotrauma on the patient could also be explored.

There were three reports of ear clearing difficulty that did not result in middle ear barotrauma (listed in Results Chapter Five, under patient complication-other). While no injury occurred in these incidents, the reports described prolonged compression times that may have implications for attendant decompression obligations. Narratives from these types of reports may describe interventions that are useful in the prevention of ear barotrauma or as in the case of these reports, prolonged compression times. The clinician, not realising the benefit of reporting the positive aspects of their work (such as reporting techniques that were successful in the prevention of ear barotrauma), may not report the type of incidents that result in no harm. The clinician may not see the value of reporting frequently occurring events such as minor ear barotrauma that may have little or no apparent consequence to the overall management of the patient. They may not recognise the value of the narrative descriptions that lead us to understanding the factors that contribute to these incidents occurring or other aspects of the incident that provide information regarding other issues (such as prolonged compression time and attendant DCI risk). They may face time constraints that discourage the practice of reporting such "inconsequential" events. This became evident to the researcher in a discussion prompted by a presentation of HIMS data at an international meeting. In the discussion, several clinicians voiced their reservations about enrolling in the study. The clinicians expressed the difficulty of reporting every time a patient had "a little barotrauma". They had concerns regarding the time required to complete a report for such seemingly "petty" incidents when they were working in a busy clinical environment.

Certainly, documentation is time consuming and logistically can be difficult to complete in a busy clinical environment. It takes about three to four minutes to complete a HIMS form to

report ear barotrauma. While barotrauma may be considered insignificant or inconsequential to the clinician, the patient, having experienced the difficulty, may have a different opinion as to the significance of the event. Again, without reporting such incidents, we have little to guide us in the collective documentation of the factors that contribute to this most frequent complication of hyperbaric treatment or the impact it has on our patients. Research and evidence based standards for this hyperbaric induced malady are overdue.

Other barotrauma

The report of pulmonary barotrauma in this study is similar to one reported by Mueller, Tetzlaff, Neubauer, and Mutzbauer (1998). In the HIMS study, a pneumothorax was detected the day following a patient's first hyperbaric treatment. The patient reported chest pain prior to the commencement of the treatment. This was fortunate, if the pneumothorax had not been detected prior to hyperbaric treatment, the patient would have most likely required emergency chest drain insertion prior to decompression. In a monoplace chamber, where intervention can not be introduced until the patient is fully decompressed, the patient could have suffered more serious consequences. It was significant that in this report, a factor identified in minimising this incident was the presence of a trained hyperbaric doctor in the unit prior to the commencement of hyperbaric treatment. This doctor promptly made the diagnosis of pneumothorax.

The use of a chest x-ray as a routine screening procedure in all patients is not indicated. According to the literature, chest x-rays do not always detect the presence of pneumothorax (Murphy et al. 1991). In those in which a chest x-ray is clinically indicated, poor radiographic technique or interpretation may miss the diagnosis. High risk patients, such as the critically ill with a recent history of cardiopulmonary arrest with chest compression, may require prophylactic treatment for pneumothorax prior to treatment in a monoplace chamber (Murphy et al. 1991).

Oxygen toxicity

Central nervous system

The incidence of oxygen toxicity has been described in the literature as 1.3 per 10,000 patient treatments (Davis et al. 1988, p. 233), but the true incidence rate is not known. Reported incidence

rates may include only those patients exhibiting CNS oxygen toxicity in the form of a seizure and patients that are having hypoglycaemic seizures.

The data in this study showed that central nervous system (CNS) oxygen toxicity accounted for twelve percent (twenty-three) of all the reports. Seizures were documented in nearly half of the reports. Although oxygen toxicity seizures may occur with no warning, this study shows that in seven of the twenty-three reports of CNS oxygen toxicity, the observation and treatment of premonitory symptoms avoided seizure. The reports describing seizure prodrome cited close observation, early detection, and high awareness to be minimising factors of these events. This highlights the importance of having attentive staff that are trained to recognise the symptoms of oxygen toxicity and intervene to correct it. It also marks the need for the patient to be taught to report any unusual or untoward sensations to staff promptly, as some of the symptoms are only recognisable by the patient (nausea, aura, feeling vague).

In the oxygen toxicity reports that documented the treatment pressure (thirteen), oxygen toxicity reactions occurred at pressures of 2.4 ATA or greater with the exception of one at 2.0 ATA. Of the two ventilated patients that had seizures, one was difficult to discern due to the patient being paralysed and sedated. It was the nurse's initial observation of the patient's eyelids moving, and a short time later, the arms exhibiting subtle clonic activity that confirmed the diagnosis of oxygen toxicity. It requires an attentive hyperbaric attendant to see the less obvious signs of oxygen toxicity in the patient that may have symptoms masked by sedating or paralysing agents.

One of the oxygen toxicity reports described a patient having two grand mal seizures during a hyperbaric treatment that resolved after a period of air breathing on each occasion. After the treatment, the patient was in a confused state and had a blood sugar level of 1.2 millimoles per litre (mmols/l), (Robertson, Pirone & Bullock 1999). Symptoms of nausea, unresponsiveness, pallor, and seizure are common to both hypoglycaemia and oxygen toxicity. This report, although not confirming the diagnosis of seizure as a result of either oxygen toxicity or hypoglycaemia, highlights the need for the clinician to be cautious in making a differential diagnosis in patients presenting these symptoms during hyperbaric treatment. Blood glucose levels may need to be taken during the treatment to confirm the diagnosis and determine proper management. Repeated oxygen toxicity seizures may induce hypoglycaemia. Blood glucose testing, anti-convulsant therapy and cessation of treatment should be considered in the management of all patients that have seizures in the hyperbaric environment.

In another report of a patient having an oxygen seizure, it was found that alcohol had been consumed in excess by the patient prior to the treatment. While there is no evidence to link increased susceptibility to oxygen seizures with alcohol ingestion, the effects of alcohol ingestion can be confused with symptoms of central nervous system oxygen toxicity. When the nurse assesses patients prior to hyperbaric treatment, if alcohol ingestion is suspected, the effects on the patient require assessment and the safety risks of putting the patient into the chamber should be evaluated with the hyperbaric doctor. Considerations to be made when a patient presents for hyperbaric treatment with excessive alcohol consumption include: (a) the behavioural aspects of the patient, (b) nausea and potential for vomiting, (c) the level of alcohol content in the expired breath of the patient in a pressurised oxygen environment, (d) if diabetic, the impact on blood glucose control, and (e) the difficulty of differential diagnosis between side effects of alcohol and oxygen toxicity.

One attendant reported the dislodgment of an intravenous catheter in a patient having a grand mal seizure. The dislodgment of the catheter was not discovered until the whole blood transfusion was found soaked in the bed linen. The management of a patient having an oxygen toxicity seizure is particularly difficult for a lone practitioner in a physically small and isolated environment.

These incidents exemplify the need for attendants and doctors to screen for other compounding or precipitating factors in oxygen toxicity in order to prevent central nervous system oxygen toxicity seizures in the chamber.

Pulmonary

Pulmonary oxygen toxicity was not reported in any patients in this study. This is not surprising, as it has not been reported in the literature in patients treated with commonly used protocols. However, if the patient is receiving oxygen of greater than forty percent between treatments, or if the patient is having consecutive lengthy treatments, the risk is compounded. This complication to hyperbaric might be rare.

Visual

Visual changes from oxygen exposure in hyperbaric were only reported twice in this study. This is a low reporting rate compared to the frequency cited in the literature (Anderson et al. 1978, Lyne 1978, Palmquist et al. 1984, Dedi et al. 1998). One difficulty in the reporting of visual changes is their insidious nature. Unless patients are regularly asked or objective measurements are taken to investigate for this complication, it may remain unknown to the clinician and can even be a hazard to the patient driving themselves to the hyperbaric unit for treatment each day. Conversely, those patients that have pre-existing presbyopia may remark that they have improved vision. The effect of hyperbaric oxygen may temporarily reverse the degree of presbyopia.

Hyperbaric induced myopia normally resolves slowly over weeks to months. While there are studies demonstrating the incidence of hyperbaric induced myopia and their resolution rate (Lyne 1978, Palmquist et al. 1984, Anderson & Shelton 1987, Dedi et al. 1998) there are no studies that conclusively determine the risk factors for developing hyperbaric induced myopia or prospective trials comparing the incidence of myopia at the standard treatment pressures of 2.0 ATA and 2.4 ATA.

One report of visual change in this study describes hyperopia causing moderate morbidity in the patient. The patient had a total of sixty-two hyperbaric treatments at a pressure of 2.4 ATA. The patient complained of increased difficulty in needlework, with successive treatments. This is the first case of hyperopia ever recorded in the literature as far as can be ascertained. The report described a four week delay in the investigation of the patient's complaint of visual changes.

Even if the hyperopia was not directly linked to hyperbaric, care must be taken to ensure that patient complaints are given timely evaluation. There are anecdotal reports in the literature of blindness in patients treated in hyperbaric with a history of optic neuritis. (Nichols & Lambertson 1969, Davis et al. 1988, Kindwall 1994c). There is only one report of blindness in a patient having hyperbaric that did not have pre-existing optic neuritis. In this case it was accepted that other factors had contributed to the blindness, but the judge found that it was the duty of the hyperbaric staff to stop hyperbaric treatments in a patient who was intermittently confused, and complaining of visual problems. In that case, the blindness was said to have occurred on the

patient's final hyperbaric treatment for which there was no clinical justification for treatment (Walker 1980).

Psychological reactions

There were eleven reports of anxiety. Seven were confinement anxiety and four were stress reactions related to witnessing a fellow patient undergoing an oxygen toxicity seizure. These four patients were counselled prior to returning to the chamber for further treatment but subsequently had to abort treatment due to the anxiety from their previous experience. This is significant in that one event in a single hyperbaric treatment, resulted in four reports of patients experiencing problems that resulted in the cessation of their treatment.

Stress reactions in patients that witness other patient's complications in the hyperbaric chamber have not been previously described in the medical or nursing literature. While stress reactions from patients witnessing these type of events (for example, cardiac arrest in the ward) are not unique to hyperbaric, they are different in that people have no opportunity to avoid witnessing and being very close to the unfortunate event in the confined environment of the chamber. Furthermore, depending on staffing practices of some hyperbaric units, the patient witnessing the event may need to become the primary caregiver for the patient experiencing the problem until an attendant can be sent into the chamber. In the incident reported in this study, the reporter suggested that additional staff to assist in the chamber might have prevented such a reaction in the other patients. It was recommended that a mild sedative be given to patients returning for further treatment the following day.

The impact of patients having to assume such responsibility is unknown in these circumstances and requires review and thoughtful consideration when deciding if attendants are required in multiplace hyperbaric chambers. Current Australian guidelines require a registered nurse trained in hyperbaric nursing as an attendant in all multiplace chambers. This is not the case in all countries, where the patients look after each other and a doctor or nurse is on standby to go into the chamber in the event of problems. With the new designs of mono-lock (no facility for emergency entry into the chamber), multiplace chambers, one must question the absence of a hyperbaric attendant.

The other seven reported cases of patient anxiety described symptoms of confinement anxiety while being treated in a multiplace hyperbaric chamber. In three of the claustrophobia reports, it was indicated that the patient chose to forego any further hyperbaric treatment. In two of the reports, patients also displayed chest pain and difficulty breathing as symptoms of their anxiety.

The management of confinement anxiety and acute traumatic stress reactions is inherent in hyperbaric nursing practice. We should work with our colleagues in psychiatry and psychology in establishing best practice in the management of patients with anxiety.

Other patient complications

Two episodes of alcohol induced patient problems occurred during treatments. Patients with osteoradionecrosis are often treated in hyperbaric. These patients are often victims of squamous cell carcinoma of the oropharyngeal region. This disease is prevalent in patients who are smokers or have a history of alcohol abuse. When patients with a known history of alcoholism (commonly patients being treated for osteoradionecrosis of the mandible) exhibit symptoms of vomiting and pallor, alcohol ingestion or delirium tremons must be included as a differential diagnosis. It is sometimes difficult to distinguish between the symptoms of oxygen toxicity and alcoholic related symptoms. Again, it is important to assess patients prior to treatment to rule out excessive alcohol intake, hypoglycaemia, or risk factors for oxygen toxicity. Furthermore, it is the nurse's responsibility to teach the patients how they can help reduce the risks of side effects of the treatment.

Hypoglycaemia occurred in three incidents. Diabetic patients may experience a reduction in blood glucose levels as a result of hyperbaric treatments (Capelli-Schelpfeffer et al. 1996) and require blood glucose testing before and after each hyperbaric treatment (O'Malley et al. 1998). Two of the reports indicated that blood glucose testing had been performed prior to hyperbaric treatment. Of these two reports, one patient had a blood glucose of 4.2 mmols/l before treatment. The patient ate two sweets and commenced treatment. After the first thirty minutes of treatment, the nurse attendant offered the patient food, but the patient refused. Within minutes, the patient suffered a hypoglycaemic reaction. In the other report, the patient had a blood glucose level of 7.5 mmol/l and was given 240 millilitres of orange juice before treatment. The patient was asymptomatic during the ninety minute treatment, but immediately post treatment felt light-headed and had a blood glucose level of 1.85 mmol/l.

In the third report of hypoglycaemia in a patient during hyperbaric treatment, the reporter commented that the hypoglycaemic reaction could have been prevented if blood glucose testing had been performed prior to treatment.

One patient, whose incident is described previously in this chapter as a central nervous system oxygen toxicity seizure, also had hypoglycaemia. The patient was found to have a blood glucose level of 1.3 mmol/l after the treatment was aborted. Hypoglycaemia may be misdiagnosed as oxygen toxicity.

While the data are few, it supports the finding of O'Malley et al. (1998) and the use of protocol driven guidelines as a nursing standard for the management of diabetic patients.

One incident gave an account of an aggressive patient in the chamber. There is no room for aggressive patients inside a hyperbaric chamber. They are a physical threat to other patients and staff and may display diminished responsibility for caring for their own and other's safety. Other patients likely to fall into this group are the carbon monoxide poisoned and cerebral gas embolism patients that may have cerebral irritation as a manifestation of their illness. It is also known that the use of illicit drugs can lead to aggressive behaviour. Patients could have an aggression screen performed before treatment if there is suspicion or history of aggressive behaviour and the treatment discontinued until measures such as sedation and intravenous access are instituted. Policies for the management of aggressive patients should be established for hyperbaric unit staff to minimise the possibility of assault to staff or patients.

6.3.b Equipment Problems

There were seventy-four problems relating to equipment. Equipment and chamber incidents are inter-related and there were twenty-six equipment related incidents that were also categorised as chamber type incidents.

Hoods

Hood problems of inadequate inflation, leaks, and disconnections are all reported. Three hood deflation incidents were related to faults in the overboard dump system. One report described

all hoods connected to a common overboard dump system, with all hoods remaining adequately inflated despite no oxygen flow to one of the patients' hoods. This is a cause for concern, as many units rely on adequate hood deflation as an indicator of optimal oxygen supply to the patient. Unless the gas in the hood is analysed, there is no assurance the patient is not re-breathing carbon dioxide, which may cause carbon dioxide toxicity and predispose the patient to oxygen toxicity.

Another interesting report from this category was the incident in which the overboard dump manifold became disconnected. Three hoods were dumping oxygen into the chamber atmosphere. The intriguing point is that it was first noticed by a swift rise in chamber pressure. One would expect that large oxygen flow leaks would be first noticed on the chamber atmosphere oxygen analyser. Chamber designs vary, as does the placement of the chamber oxygen sampling port. Chamber design, location and number of oxygen sampling ports, and pooling effects of oxygen in the chamber are new issues to consider in multiplace fire prevention. This was highlighted in the Italian hyperbaric chamber fire disaster. There was an oxygen leak at the site of ignition but the oxygen analyser did not show elevated chamber atmosphere oxygen levels.

Three hood deflation incidents occurred. One, caused by a faulty oxygen supply regulator, resulted in another patient in the chamber having to remove the deflating hood from the affected patient. Another incident highlights the importance of training and supervision of our staff. A nurse, infrequently working in the chamber, turned the exhaust valves incorrectly, causing sudden deflation of the patient's hood. The patient suffered no physical harm, but it provoked anxiety in the patients and the nurse. The third incident involved a faulty overboard dump system. The overboard dump was cyclically scavenging the gas from the hoods causing periodic deflation of three patient's hoods.

Hood deflation is extremely dangerous. If undetected it can cause suffocation of the patient. Even when it is detected before the patient is in danger, it is quite a distressing experience for patients to have a plastic hood enveloping their face. These incidents are totally preventable and were caused by simple faults with a high degree of risk. System design can allow for venting to occur should a negative pressure be created in the hood. Hyperbaric staff must insist that hood systems be made to provide a margin for error, especially when the risks are great.

Built in breathing system (BIBS)

Built in breathing system problems were predominantly (on nine occasions) human error problems associated with failure to turn on supply or exhaust valves and incorrect use of the equipment. In one of the incidents the patient had been breathing from the tight-fitting demand valve mask for an hour and thirty minutes with the circuit exhaust valve closed. It would have been quite difficult for the patient to breathe in those circumstances and the patient would most likely have been re-breathing carbon dioxide. As with the hoods, many units do not have the facilities for measuring continuous oxygen or carbon dioxide levels within the breathing circuits.

In one potentially dangerous incident, a technician turned on the oxygen supply at the request of a doctor inside the chamber at 4.0 ATA to demonstrate the built-in-breathing system for students. A doctor outside the chamber averted the incident. Protocols for gas supply changes or safeguards against oxygen gas supply availability at pressures in which it is toxic should be introduced into the system to prevent such occurrences.

The report described above and the suction device incidents described in the Results Chapter Five (Equipment problems-suction) are examples of incidents occurring during training exercises. These reports illustrate the point that training exercises require as much care and attention to rules and safety as routine treatments.

Overboard dump system (OBDS)

Three OBDS incidents resulted in seven patient oxygen hoods over-inflating, with one of the incidents causing a rapid rise in chamber pressure and oxygen level (described previously under the "hood" incident in this chapter). Two incidents reported deflation of four patient's hoods. One of these incidents, in which the reporter described 'cling-wrapping the patient-but not too bad', was caused by the attendant turning on a quarter turn valve to the OBDS with the exhaust setting at its maximum.

Quarter-turn valves on the OBDS were also implicated in two other incidents. An attendant, failing to open the quarter turn valve to the OBDS, caused a patient wearing a tight-fitting face mask to have difficulty in exhalation (described in the BIBS section of this chapter). A quarter-turn valve to the OBDS was left on from a previous treatment, causing slow loss of chamber pressure.

There was one incident of an "o-ring" failure on an overboard dump system resulting from poor maintenance, but no adverse outcome occurred.

While there were just eight OBDS reports, twelve patients were affected leading to serious concerns for patient safety with hood deflation potentially causing suffocation, oxygen leaks, and ineffective gas scavenge. While operator error contributed to these incidents, design alterations of the OBDS, especially those involving quarter-turn valves, would eliminate the cause of some of these types of incidents.

Monitors

Four of the reports involved failure of electrocardiogram monitors during hyperbaric treatment. One incident involved a decision to break the protocol of monitoring the pulmonary artery pressure waveform, when the monitoring problem could not quickly be resolved in a critical patient prior to commencing hyperbaric treatment. It was later discovered that the cable for the monitor was plugged into the monitor panel incorrectly. Checking equipment prior to use and a procedure for failure of electrocardiogram/invasive pressure monitor failure may be considered to prevent and minimise these types of incidents.

The Ohmeda ™ volume monitor was instrumental in the identification of an endotracheal cuff leak in one report. Considering the risk of pressure related changes to an endotracheal cuff that has been incorrectly been filled with fluid, and in the absence of alarms on many ventilators used in hyperbaric, some form of monitoring should be standard practice. Disconnect alarms, or better still, end tidal carbon dioxide monitors should be used on all ventilated patients in the chamber. While end tidal carbon dioxide monitoring devices are not manufactured for use in hyperbaric chambers, engineers could be challenged with designing an effective system. Meanwhile, the use of the Ohmeda ™ has been shown to be effective in the hyperbaric environment (Youn & Myers 1989), and should be used until a better monitoring system is available.

Ventilators

Ventilator problems occur in three reports. A cable was not connected properly in one of the incidents. Pressure effects in two different ventilators, the Bird ® Mark 7 and the Drager

"Oxylog" resulted in reductions in tidal volume. All three of the incidents caused temporary ineffective ventilation of critically ill patients. In other environments, other staff are nearby to assist. This is not necessarily the case in hyperbaric chambers. Contingencies for ventilator failure inside the hyperbaric chamber must be considered. The inside attendant can hand-ventilate, but if a spare ventilator is not immediately ready for use in the chamber, a second attendant must enter the chamber and assist or the treatment must be aborted.

One reporter identified poor ventilator design to be a contributing factor. The problem is the ventilators in these reports are not designed for use in multiplace hyperbaric chambers. In fact, there are only two ventilators commercially available that are designed for this use. One is only available for the German market, and the other does not provide support service internationally. There appears to be limited corporate interest in producing multiplace hyperbaric designed ventilators for the international market. Often, hyperbaric units are placed in a position to use ventilators that restrict the capacity to ventilate the patient in modes best suited to the patient. These ventilators are not designed for hyperbaric use and therefore, perform inadequately with pressure changes if modifications can not be made to correct for these changes.

Although there are only three ventilator incidents in this study, two were directly related to the poor performance of ventilators that were not designed for use inside multiplace hyperbaric chambers. Although the frequency of this problem is unknown, the significance of unreliable ventilators in critically ill patients in the isolated environment of a hyperbaric chamber is obvious.

Fire risk

Five of the equipment incidents had an element of fire risk. The reports included electrical equipment left on a patient trolley, faulty electrical wiring of the chamber panel resulting in smouldering wires, food burning in a lunchroom adjacent to the chamber, a volatile liquid leak in a chamber air-conditioning system, and an overheated chamber light. The reporters suggested better checking for items of fire risk prior to starting treatments and inspecting devices installed or supplied by outside agencies for flammability properties. Electrical components of the chamber need regular safety checks. The reporter of the overheated light suggested that fibre optic fan-cooled chamber lights not be left on while the chamber is unattended. The incident involving the burning sandwich in the lunchroom highlights the

need for fire safety in all areas of the hyperbaric unit. The reporter of this incident suggested replacing lunchroom electrical appliances with an automatic timed power shut-off feature.

Fire risk was also identified in chamber incidents and will be described in the next section.

6.3.c Chamber Problems

Events leading to increased risk of fire are the most frequently reported in this category. Elevated oxygen levels in the chamber atmosphere were the most commonly identified fire risk events. Although chamber atmosphere oxygen analysers are an essential instrument for fire hazard identification, consideration to their location and number in the chamber need addressing (as described in equipment problem-hoods earlier in this chapter). These oxygen analysers are the only non-human monitors for measuring fire hazards in multiplace hyperbaric facilities currently in common use. Until additional technology is incorporated into hyperbaric practice, the remainder of fire hazard detection is left to the hyperbaric unit staff.

On five occasions prohibited substances, items, or static electricity were identified as fire risks in the chamber. According to a review of chamber fires by Sheffield et al (1998), the most common cause of recent hyperbaric chamber fires is prohibited sources of ignition carried inside the chamber by a chamber occupant. Strict protocols, perhaps checked by a second staff member, are necessary to avoid the inadvertent introduction of fire hazards. The policy of "no pockets" for patients or staff should also be initiated to lower the risk of inadvertently introducing hazardous items into the chamber.

Other chamber incidents

Although uncontrolled compressions were recorded on four reports, there were only two incidents, one of which was reported both by the inside attendant and the chamber technician. Having the two reports written by different persons for the same incident was insightful. It captured the inside attendant's perspective of how the incident affected occupants inside the chamber as well as the technician's description of the procedural difficulties which led up to the incident. In this incident, the effects of the problem were minimised by the inside attendant knowing how to stop the inflow of gas into the chamber. This demonstrates the usefulness having chamber gas supply valves easily accessible inside the chamber and of teaching all inside attendants the emergency procedure for in-chamber management of an

uncontrolled compression. The technician in this same incident was beginning to flush the chamber but did not have enough bottled air supply. When the supply was changed from the low pressure bank to the high pressure bank of bottled gas supply, gas flowed into the chamber at the same time that the technician was away from the panel changing over the gas supply. This incident highlights the need for reviewing procedures in changing chamber gas supply and chamber flushing.

The uncontrolled compression incident was also reported twice. In these reports, a nurse tripped over the power supply cable for the chamber computer, causing it to restart and commence pressurisation. Safe default settings for computerised chambers and emergency protocols must be employed and practised to minimise the potential harmful consequences of these incidents.

There were four gas supply problems. One was caused by omitting to follow procedures that resulted in the air supply to a monoplace oxygen driven chamber not being turned on. The error was first detected when the patients donned their breathing mask for the air break and found no gas supply to the mask. The event was quickly and easily rectified and caused no harm. Nevertheless, as the reporter identified, this incident could have had more ominous consequences in situations where a rapid change to air supply is critical, such as a patient having an oxygen toxicity seizure, or a fire in the chamber.

In another gas supply report, a patient had no gas supply to his/her breathing mask for twenty to thirty seconds. Again, there was no harmful outcome, but the technician described a complex combination of valve adjustments to change the gas supply. While it should not be easy to introduce new hazards during gas supply change procedures, they also should not be overly complex.

The other gas supply reports included a faulty regulator that the reporter stated could have been prevented with better equipment checking and a report of gas contamination. The air supply to the chamber was reported to have a paint-like odour and fortunately, no one suffered any ill effects. Traces of oil were found in the air compressor filter and the reporter of this incident attributed the problem to overdue maintenance.

The monoplace chamber incident that was caused by the incorrect placement of an chamber access port plug as discussed in the chamber problems section of the Results Chapter was addressed formally. The author sent a letter, to the monoplace chamber manufacturer

describing the incident with suggestions, as submitted by the reporter, for a design change preventing the same error. The company replied with a letter saying that action on only one such report in twenty-five years was not warranted. They went further to say that the event described was not a significant safety risk, and the likelihood of recurrence was extremely low. Furthermore they said, '...I shudder to think of what other dangerous mistakes that facility could be making'. This response was a disappointment. Further correspondence to the company describing how one report often represents other like events (incidents are often under reported) and that such a human error type event is not uncommon did not generate a reply. The issue was pursued further by re-enacting the incident and reporting the results of this testing to the company. There continues to be no formal response on this issue from the company. This same company has a good reputation for safety and this has been evidenced by their actions following another type of incident that occurred in one of their chambers.

This then presents a difficult situation. If manufacturers do not respond positively to such suggestions, alternative action may be required. Unless actual harm has occurred, the worthiness of the effort is questioned by those who may have the power to change these situations. When manufacturers do not see high enough risk in a problem to warrant costly design changes, they are not likely to use their budgets to address such complaints. The power of reporting these incidents in the literature must be utilised.

Finally, one chamber incident reported the contents of a chamber toilet being ejected into the toilet room, external to the chamber. Not withstanding infection control concerns, the incident would have caused an unpleasant cleaning exercise. Chamber toilet flushing protocols or system design changes would reduce the possibility of such occurrences.

6.3.d Staff Problems

Staff were involved in fifty-three incidents but were not the primary focus of the incident. Thirty-one reports, where staff health issues are described in the reports are discussed here. The injuries to staff included, ear barotrauma, decompression illness (DCI), pulmonary oxygen toxicity, central nervous system oxygen toxicity, fume inhalation and physical injuries.

Barotrauma

Middle ear barotrauma is recognised as a complication in hyperbaric attendants. Most often, it is mild and requires nothing more than minimal, self-administered treatment. The six reports of staff ear barotrauma included barotrauma from compression in three cases, two of which occurred in training dives. Two of the cases were barotrauma during the decompression phase. This is noteworthy, as it is more common for middle ear barotrauma to occur during compression. It is also of interest that two of the middle ear barotrauma incidents occurred on training dives. This may reflect the inexperience in ear clearing techniques in staff undergoing training. Meticulous attention to new staff in training exercises is required to prevent injury.

There was one report of inner ear barotrauma that resulted in long term morbidity for the nurse attendant. Hyperbaric medicine texts do not describe inner ear barotrauma as a risk for inside attendants. Only two cases of inner ear barotrauma in hyperbaric attendants have been described in the literature (Pirone 1998). Considering the long term morbidity associated with inner ear barotrauma, further study to examine the true incidence of this problem may be warranted.

Decompression illness (DCI) and CNS Oxygen Toxicity

The incidence of attendant DCI ranges from 0.01-1.3% and its frequency is rarely cited in the literature (Sheffield & Pirone, 1999, pp. 650-653). Primarily, the risk of DCI in an individual is related to the amount of nitrogen dissolved in body tissues resulting from the time and pressure of compressed air exposure and the amount of nitrogen off-gassed during the decompression. Bubbles in the tissue may form during the nitrogen off-gassing phase. There are a host of factors that influence an individual's predisposition to bubble formation from compressed air exposure, but the primary determinants of bubble formation are the amount of nitrogen load and the rate of decompression. Compared to in-water divers, hyperbaric attendants have well controlled, low pressure exposures. Although no comparative studies of the incidence of decompression illness between other occupational divers and hyperbaric attendants has been done, one would expect the incidence of decompression illness in hyperbaric attendants to be lower.

One method used to measure intravascular bubble formation from compressed air exposure is Doppler ultrasound. The monitoring of bubbles using Doppler ultrasound is useful for the development and testing of decompression tables. Using a specific technique for grading

bubbles with Doppler ultrasonic bubble detection, decompression stress of dive profiles can be evaluated and probabilistic models of decompression can be developed (Nishi 1993). In general, the incidence of DCI positively correlates with Doppler bubble grade; however, it is not a highly reliable method of predicting the development of DCI (Nishi 1993, pp. 444, 449). Subjects may have a significant load of circulating bubbles, yet not develop any symptoms of DCI and similarly, they may have minimal bubble load and have the classical presentation of DCI.

The risk factors and pathogenesis of decompression illness are not fully understood. Hence, with the infrequent nature of this hyperbaric attendant occupational injury, it is useful to collect information surrounding the incident, particularly the decompression profile and other contributing factors. Of the five reports of attendant DCI, the reporters identified factors they believed might have contributed to the development of the reported DCI. These factors included previous injury to the affected limb, fatigue, strenuous work, use of an oral contraceptive, an extended treatment profile, and in three reports, the stationary position of a limb. Stationary position of the affected limb during compressed air exposure or decompression is not said to be a risk factor for DCI in current hyperbaric and diving literature. It is of interest, however, that commercial divers have reported informally that the stationary position of a limb in the chamber, particularly on decompression, is commonly acknowledged as a risk factor for DCI.

In a study by Walker et al. (1995), nurse attendants were monitored for circulating intravascular bubbles by ultrasonic doppler post hyperbaric exposure. While twenty-one of thirty-seven exposures (fifty-seven percent) to hyperbaric caused various levels of bubble formation, there was no bubble formation in the single case of DCI that developed in an attendant during this study. Interestingly, one of the attendants that rested his head on his flexed arm during the treatment had a high grade of circulating bubbles, particularly at the subclavian vein site post stimulation via hand clenching. This attendant did not develop DCI.

This subject has been studied by researchers at NASA. The absence of DCI in astronauts during extravehicular activity in space prompted a study examining adynamia (no load - bearing activity by the lower limbs) as a factor that may reduce the risk of DCI. It was found that strict adynamia that allowed upper body exercise, was much safer than exercise at altitude (Conkin & Powell 1999). Theoretically, this may suggest that the stationary position of a joint during decompression in the hyperbaric chamber may be protective of DCI rather than induce

risk. However, applying these results to activity of individuals in the hyperbaric environment may not be valid.

These few anecdotal reports, together with the work conducted by NASA, suggest that more research to determine the effect of limb stasis during compressed air exposure as a risk factor for DCI should be conducted.

Oxygen is often used to assist the process of off-gassing nitrogen thereby reducing the risk of decompression illness in chamber attendants. A current review indicates that oxygen breathing and rotation of attendants are both useful in preventing DCI in attendants (Sheffield & Pirone 1999). When employing oxygen as a method of reducing attendant decompression illness risk, there is, however, a risk of oxygen toxicity. This HIMS data includes two reports of central nervous system oxygen toxicity prodrome in hyperbaric attendants. The reports indicated the toxicity was apparent at 2.0 ATA and at 1.6 ATA. This information illustrates that oxygen toxicity is a risk in hyperbaric attendants, even at the lesser pressures not commonly attributed to producing toxicity, and therefore caution should be exercised in its use. Early recognition of the symptoms of oxygen toxicity by the attendant is paramount in preventing oxygen toxicity seizure.

A useful example was given by a hyperbaric doctor who introduced oxygen breathing in attendants for decompression with a subsequent reduction in attendant DCI. He reported infrequent and random transient visual disturbances within an hour after decompression in hyperbaric attendants. The visual disturbances were described as a sparkling pattern of light that lasted for fifteen to twenty minutes (personal communication). If oxygen is used to reduce the risk of DCI, then adverse effects need to be reported and investigated. Additionally, oxygen must be used judiciously and in a manner such that it can be automatically withdrawn in the event of an oxygen toxicity seizure.

The outcome of the attendants with reported DCI in the HIMS data was full resolution of their symptoms with recompression. However, the report does not allow for longer term follow-up that may detect neurological sequelae or the impact of DCI on their hyperbaric career. A focused longitudinal study of attendant DCI would be more suitable for assessing outcome of attendants with DCI.

The incidence of attendant DCI is low, but with more HIMS data, information will be provided that can assist in identifying contributing factors and areas for research of this occupational disease.

From the analysis of the few (five) HIMS data, the related literature and anecdotal reports, more research on the subject of attendant DCI is recommended. Future studies should aim to establish levels of DCI risk in hyperbaric attendants using common treatment tables, identify methods of reducing DCI risk, and investigate the risk factors associated with attendant DCI.

Pulmonary oxygen toxicity

There were two reported cases of pulmonary oxygen toxicity in hyperbaric attendants. Pulmonary oxygen toxicity in attendants has not been described in the hyperbaric literature. One of the cases occurred after a hyperbaric attendant had breathed the required oxygen for decompression but developed DCI and was correctly treated in the recompression chamber immediately upon diagnosis of DCI. As the attendant was now a patient, oxygen breathing at pressure was required for the treatment of DCI. On this occasion, the attendant developed pulmonary oxygen toxicity. Pulmonary oxygen toxicity in an attendant after breathing oxygen on decompression from a patient treatment, followed by an oxygen recompression treatment for DCI, is understandable due to the oxygen dose delivered over time. Because it has not been described previously, it is interesting to consider the possibility that the risk of pulmonary oxygen toxicity may be higher in attendants being treated for DCI, as they have breathed oxygen for decompression immediately prior to their recompression. The other incident affected an experienced attendant on a routine treatment breathing oxygen for decompression. More data over a longer study period may reveal the significance of this finding.

Other problems

Other staff problems included nine physical injuries including cuts and bumps, back strain, needle stick, sinus squeeze, toxic fume inhalation from an electrical fire outside the chamber, and omitted oxygen breathing during decompression. While these incidents did not result in any significant harm to the staff, they demonstrate some of the types of injuries and potential health risks that occur in hyperbaric units.

6.3.e Ventilation Problems

Fourteen of the eighteen ventilation incidents were associated with equipment problems. A wide array of problems surfaced in this group. For example, disconnections, leaks, gas supply problems, incorrect assembly of equipment, endotracheal tube cuff deflations, accidental endotracheal extubation, and overboard dump problems were the types of problems encountered in this group. No common patterns that have not already been discussed under equipment problems in this chapter emerged in this group.

6.3.f Tube and Line Problems

There are various unique hazards related to intravenous infusions and invasive pressure monitoring in the hyperbaric environment, such as possible gas embolism from gas expansion in intravenous tubing, disconnection of tubing in patients in monoplace chambers, or inaccurate pressure readings due to invasive pressure bag deflation. The reports in this data are not unique to the hyperbaric environment.

6.3.g Pharmacological

These incidents included inaccurate and omitted labelling, drug order not written, missed administration, allergic reaction, and incorrect rate of administration. None of the pharmacological reports showed any features unique to the hyperbaric environment.

6.4 Contributing Factors

Chance event was the most commonly ascribed contributing factor to incidents in this study. Fifty-two of the 200 reports (twenty-six percent) selected the contributing factor to be chance event. This pattern was also seen in the Australian Incident Monitoring Study (personal communication with S. Helps from unpublished data).

Chance event as a contributing factor implies that it was out of the control of the staff to have prevented such an occurrence. It also implies that it would be difficult to predict its occurrence. Realistically, it may mean that we do not yet have the knowledge or resources to predict and or prevent its occurrence. As Voltaire so aptly described, 'There is no such thing as an accident. What we call by that name is the effect of some cause which we do not see.'('Lettres de Memmius III').

The option of choosing chance event as a contributing factor may reflect the reporter's inexperience or ignorance of the subject that related to the incident. For example, on a patient's first treatment, the nurse reported the patient was on high dose steroids and had a high fever. The patient had an oxygen toxicity seizure at 2.8ATA. The nurse then attributed the incident to chance event. In this case, it appears the reporter is not aware that these conditions decrease the threshold for oxygen toxicity seizures. Conversely, a more knowledgeable reporter, such as the experienced nurse may have recognised that the high dose steroids, high fever, and treatment pressure all increase the risk of a patient acquiring oxygen toxicity. The nurse could have then alerted the doctor so that prophylactic measures could have been taken to avert the toxicity. The nurse reporting the incident, not having the knowledge of oxygen toxicity risk factors, would have chosen chance event. If the nurse had been aware of the risk factors and decided to proceed with the treatment without action, then perhaps the nurse would have classed the contributing factor as inappropriate behaviour/action, took a 'short-cut", or pressure to proceed.

Some may select chance event because it is an easy, quick answer. No evaluation or further thought is required to determine contributing factors. Others may select chance event because it gives them an opportunity to excuse themselves from the incident. They may feel less likely to be blamed for the incident if they themselves declare it a chance event.

Thirty-six of the incidents assigning chance event as the contributing factor were those related to incidents that affected patients ($\chi^2 < 0.005$). The remaining eleven incidents with chance event chosen were in the equipment or chamber type incident groups.

A closer look at the type of incidents in the patient problem group attributed to chance event shows that twenty-nine were associated with recognised complications of hyperbaric treatment; ear equalisation problems (thirteen), oxygen toxicity seizures (eight), anxiety (five), sinus barotrauma (two), and visual change (one). With current knowledge, these

complications to the treatment are often difficult if not impossible to predict or prevent. Each complication is variable in the level of morbidity it produces. One may argue that some complications, such as mild ear or sinus barotrauma and small degrees of visual change, have an acceptable level of morbidity and do not warrant the resources of further investigation. For this reason, selecting chance event as a contributing factor is logical.

One example of an incident in this study attributed to chance event that is not unique to hyperbaric is the incident involving the self-induced endotracheal extubation. The patient had two previous treatments with "heavy' sedation in a monoplace chamber. On this occasion, it was reported that the restrained patient had respiratory difficulty and was able to break free of restraints and extubate him/herself. The patient was lightly sedated and was able to move all extremities to command and nod appropriately to questions. With hindsight, it is easy to say the patient should have had more sedation. The patient was in an environment in which the nurse could not physically come into contact with the patient to prevent extubation or correct respiratory problems related to the tube. However, it is important to consider the contributing factors identified by the reporter rather than introduce hindsight bias. To the nurse, the patient may have seemed coherent enough to be trusted not to pull out the tube. The reporter noted that the difference between this treatment and others was the patient had less sedation. The reporter chose "chance event" as the contributing factor and was uncertain of whether it could be prevented. This incident did have a level of predictability and could be prevented. The nurse made an incorrect judgement on the safety of not adequately sedating an intubated patient in the chamber. The nurse's judgement was influenced by a number of factors. Reporting incidents such as this provides information to assist others that are in the position of making similar judgements. This is useful, especially when pressures are placed on the individual to make judgements that may conflict with the interests of others. For example, if the intensive care doctors want to extubate the patient after hyperbaric, they would push to have minimal sedation for hyperbaric treatment. From a single report, little can be deduced. Over time, as more incidents are reported and analysed, the data will provide information that can be used to assist in the development of algorithms to guide clinical decision making in certain situations.

Contributing factors can be analysed by their relation to incidents. If the same contributing factors are consistently associated with a particular type of incident, then more insight into the cause of the incident may be gained.

Infrastructure/equipment/monitors and rule-based contributing factor categories were significantly related to ventilation, chamber, and equipment type incidents (for statistical significance of each, see Results Chapter-Five, Contributing factors). Furthermore, these types of incidents all shared a significant relationship with malfunction of monitor or equipment, failure to follow policies or procedures, and failure to check equipment. Strategies aimed at preventing these types of incidents should consider equipment checking and policy and procedure compliance interventions.

Poor design was associated as a factor that contributed to sixteen incidents. The equipment involved were oxygen hood circuits, overboard dump systems, physiological monitors, ventilators, IV pump and pole, chamber valve, air-conditioner, and a monoplace chamber IV port plug. Examination of potential equipment design modifications would improve safety in these types of incidents.

Pharmacology incidents were strongly associated with supplies or labelling of drugs (Fisher's exact test $p<0.001$). The data in this research shows that correct labelling of drugs is an important safety issue with the transport of patients to and from the hyperbaric chamber.

While having no statistical significance, some contributing factors were identified from the narratives and are worthy of mention. Conversation and telephone calls were identified as distracting chamber technicians and contributing to incidents on two occasions. While boredom from no interaction with the technician can be hazardous, distractions during critical stages of chamber operation are equally problematic.

Chamber noise, produced on pressurisation and decompression, and the use of temperature control units contributed to communication problems that exacerbated two incidents. Technology should aim to improve these engineering borne problems.

6.5 Minimising factors

Reporters, through prompted free text, most often described the factors that minimised the severity of the incident to be close or good observation. This highlights the need for having attentive staff observing patients in the chamber. It also reinforces the importance of an

attentive chamber technician. Attendants in the chamber are subject to nitrogen narcosis in mild degrees in addition to being isolated from normal external cues, so being attentive at all times may be hampered by their physical working environment. An investigation to examine the observations that the attendants make which minimise incidents could be conducted with a view to add other monitoring modalities to supplement and assist the attendant in observation. This investigation could be conducted using HIMS data once more data has been collected.

Also of note in the minimising factors is the recognition of symptoms and assistance from patients. This finding supports the notion that good patient teaching of the symptoms of the side effects of hyperbaric can help to reduce or prevent an incident. Patients having repeated treatments (twenty to forty daily treatments) become aware of the normal procedure and may notice a problem before the attendant. While the monitoring of patients inside of the chamber is the nurse's responsibility, the HIMS data shows that the patient's observations are also worthy of recognition. Nurses should encourage patients to communicate any observations that they suspect deviate from the norm and express any concerns regarding safety and hyperbaric treatment.

In summary, the data from HIMS have been analysed by reviewing the types of incidents and examining the narratives, contributing and minimising factors. The literature related to the incidents in the study has been reviewed and used to assist in the interpretation and formation of recommendations from the data. The data have provided an insight into the nature of incidents occurring in hyperbaric practice and provides information upon which to make safety improvement recommendations. The conclusion of this thesis identifies the major findings of the analysis.

CHAPTER 7

Summary and Conclusion

'Errors like straws, upon the surface flow; He who would search for pearls, must dive below.' Dryden

All for Love: Prologue

The prevalence of adverse events in health care has never before been so well recognised by both the providers and recipients of health care, (Kohn, Corrigan & Donaldson 1999, Barach & Small 2000, Brennan 2000). Anonymous incident reporting, utilising principles of the critical incident technique, can be useful in continuous quality improvement in the prevention of adverse events in health care (Holland 1993, Cousins 1998, Chen et al 1998, Frey & Kehrer 1999)

This study has presented the analysis of data collected by the anonymous, voluntary reporting of incidents that occurred in an international sample of clinical hyperbaric facilities. From the analysis, recommendations for safety improvement in hyperbaric practice are presented in this chapter.

As a part of this study, a review of incident reporting in health care, and both the history of safety and incidents that have been reported in clinical hyperbaric medicine practice were conducted. This review showed that operational safety in clinical hyperbaric medicine has been a priority, particularly in relation to fire, pressure and electrical safety. Advances in safety standards and design have resulted from volunteer efforts of numerous dedicated individuals and organisations. Clinical hyperbaric is indebted to those who made huge sacrifices, including the loss of life and high levels of morbidity, from the occupations of military and commercial diving, and in aerospace and deep sea exploration, resulting in the development of safety design standards. Before the HIMS study, hyperbaric incident reporting was limited to historical accounts, case studies, and systems that focused on incidents involving morbidity and mortality. Past attempts to establish systems for incident reporting were burdened with difficulties such as the fear of legal

risk and blame and no assurance of anonymity. Although better than no data collection, these retrospective reviews of anecdotal recollections were not considered to be reliable or valid enough to predict practice changes which would improve safety.

The literature review demonstrated the need for more studies of the adverse effects affecting patients having hyperbaric treatment. This gap in the literature also applies to staff that are chamber attendants, and equipment exposed to the hazards of a pressurised, confined environment. Research into occupational health and safety, decompression practices of hyperbaric attendants in clinical practice, and examination of the frequency of hyperbaric exposure in hyperbaric attendants is required.

The literature review of incidents in hyperbaric may be disturbing to readers. Such a concentrated account of adverse events occurring in hyperbaric clinical practice in the international literature, over a century, may overwhelm the reader with safety concerns. However, the reader is reminded that similar reviews of any other medical specialty could cause equal or greater concerns. Furthermore, such reviews are necessary to learn from past experiences and to improve safety in the future.

The primary intent of this study has been to identify incidents occurring in a sample of international hyperbaric medicine units, analyse factors that contributed or minimised the incidents and make recommendations for safety improvement. These aims have been achieved and will be discussed in this chapter.

Using self-selection sampling to enlist participant hyperbaric facilities into the study, multiplace facilities, representing English and non-English speaking nations and three continents were represented. Translation of the HIMS educational materials and presentations at international hyperbaric meetings was valuable in attracting international participation. While reports involving monoplace chambers were few, most of the information extrapolated from the data is of benefit to people working in all classes of hyperbaric chambers.

Two hundred reports of incidents were received and included in the study over a twenty month period. The data in these reports is richly descriptive and exhibit strikingly similar types of incidents to those reported in the literature, thereby supporting construct validity of the study. Studies of incidents in anaesthesia using the critical incident technique show similar trends in

types and causes of incidents (Staender et al. 1997) supporting the validity of extrapolation of the data to the whole of the clinical hyperbaric profession.

By its anonymous nature and by allowing the reporter to be descriptive in identifying contributing and minimising factors, the data also brought with it newly reported incidents and new information valuable to the development of recommendations for preventing both newly described incidents and those that are well known to the hyperbaric profession.

The methodology of this descriptive study reviewed the data by classifying the incidents, analysing the contributing factors statistically, and reviewing narratives and minimising factors. The data from this study were analysed and constantly related to like incidents reported in the literature and to the researcher's extensive clinical experience. While these literature reviews were time consuming, they were extremely valuable in the interpretation of the reports and in the formulation of safety recommendations. This interpretation of the data allowed the development of recommendations for safety improvement. This methodology proved to be a logical way of interpreting and validating the descriptive data, and using that information to establish relevant information for the hyperbaric clinician.

The recommendations from the study can assist in the development of safety improvement initiatives in hyperbaric practice. These initiatives include education, research, design changes, guideline and protocol development, and quality improvement activities.

7.1 Strengths / Limitations

The limitations of this study directly concur with the strengths. Voluntary reporting is both a strength and a limitation of the study and has been discussed at length in this thesis and the literature (Tyler & Nickman 1992, Cullen et al. 1995, Sanborn et al. 1996, Chen et al. 1998, Frey & Kehrer 1999). By allowing the reporter to choose what to report, bias is introduced into the study. However, one could argue that all reporting to some extent is voluntary. Furthermore, mandatory reporting requires identification of the reporter that is a deterrent to reporting. The combination of both mandatory and voluntary reporting may be required at the

local level, but for the purposes of this international study of incidents, voluntary reporting is the most appropriate method for enhancing the frequency of reporting.

It has been demonstrated that all forms of incident reporting have high rates of underreporting the actual incidence of adverse events (Sutton, Standon &Wallace 1994a, Cullen 1995, Sanborn et al. 1996) and HIMS is no different. One main feature of the HIMS, however, is its anonymous nature. The reporter is not threatened by possible punitive measures for disclosing all the details of the incident. This is a clear and welcome contrast to reporting methods that are used in the disciplinary process of nurses and minimises this deterrent to reporting. By having no identifying features on the form, anonymity of the reporter, the hyperbaric facility, and the geographical location of the reporter are assured. This avoids any blame directly or inadvertently being placed on any person or facility. Anonymity of the reporters in this study has been maintained.

Another strength particular to this study is the Australian Parliamentary protection acquired to protect the reporters and the researcher. This added protection eases the medico-legal threat that may deter reporting. The study also emphasises that any incident that may involve medico-legal threat need not be reported. It is not necessary to report incidents that are potentially a medico-legal concern to obtain the causative factors of incidents. The harmful incidents only represent the "tip of the iceberg" in incident analysis.

With anonymity, there are no identifying features so the study does not allow for follow-up of incidents. Information contained in the report is limited to the information available at the time of reporting. Later investigations or outcomes are not revealed. To have the capacity for follow-up would require some level of identification on the report and someone responsible for following-up the incident and adding details to the report. This could be a deterrent to the frequency of reporting.

As already established earlier in this thesis, anonymity prevents the total number of hyperbaric treatments (the denominator) from which the reported incidents originated (the numerator) to be known. This prohibits the much desired ability to calculate incidence rates. It must be remembered that there are few reliable methods of obtaining incidence rates due to the inherent limitation of underreporting that accompanies incident reporting. Although it is not the aim of this study, with sufficient data, benchmarks of incident rates can be determined.

The inability of the study to calculate incidence rates (quantitatively review the incidents) must be weighed against the strengths of this methodology. Incidents reported infrequently can be evaluated for their significance, where in quantitative studies, their value may remain undisclosed. For example, in the five reports of attendant DCI, three of the reports stated that a contributing factor to the to development of DCI was the stationary position of a limb during the pressure exposure. This data, being small in number, may not have any relevance in a quantitative study however, when analysed in a qualitative manner in association with anecdotal evidence and clinical experience, HIMS can use this information to look for common contributing factors to the incidents. The monitoring of these contributing factors may lead to a hypothesis that can be tested.

The data analysis allows for the trends in incidents to be established and monitored. If similar contributing factors begin to emerge, new key words can be used for coding the forms to allow monitoring the contributing factor for any significance. Furthermore, review of the literature and trends in clinical practice may elicit ideas for possible contributing factors that can be searched for on the HIMS database.

This method of reporting brings with it less apparent benefits of anonymously reporting incidents. Reporters have stated the process encourages them to self reflect on their practice and allows them to consider how systems are involved. Reporters have a chance to express emotional anger at the system, release anxiety, and for some it is an opportunity for confession and the release of guilt or sorrow. Health workers are often very dedicated to providing quality care and the ability for them to express themselves, albeit through an anonymous report, can have a therapeutic effect.

HIMS promotes the concept of reporting "near misses". Some may criticise the inclusion of reporting "trivial" incidents and "near misses", yet one of the most valuable lessons that has been learned from the investigation of the Chernobyl nuclear disaster is that the disaster was a result of many different failures over a wide space of time. The staff working on the day it occurred were merely bringing together the final steps to enable disaster to strike. We can learn from the valuable lessons of those that have a wealth of experience in the analysis of human and system error and apply it to improve safety in health care.

7.2 Logistical limitations

There were some logistical limitations in the study. Some features of the HIMS Report Form caused difficulties in analysis. First, the age of patients, staff, and equipment could not always be determined due to a flaw in the form design that was not picked up in the initial trial of the form.

Outcome categories were vague and need re-classification to be more useful. This is understandable given that the development of such general classifications is data derived and such an empirically driven framework requires the accumulation of data over time to refine it (Runciman 1996, p. 348).

Overlap of some items in the chamber and equipment categories created more work and made the analysis more difficult to conduct.

7.3 Other strengths

In the study, the reporters used narratives to describe the incident, allowing for free thought to describe what happened. Hyperbaric staff described ways they were preventing incidents. Whether it is the reporter who corrects his or her own errors, or the reporter that corrects for potentially harmful situations evoked by others, first hand knowledge of the "coal-face" worker is shared with others at the local and international level. This "positive" effect has benefits to the reporter (able to share their acquired knowledge), to the facility (as a quality improvement tool), and to the researcher (to analyse associations between minimising factors and types of incidents). The focus of the reporting becomes positive rather than negative.

The reports have been used at the local level as a quality improvement tool. When agreed by staff in a hyperbaric unit, the data has been reviewed periodically with all the staff. This provides regular feedback at the local level and allows for exchange of expertise of the multidisciplinary group of staff to review possible ways to prevent similar incidents. The administrators may recognise ways to improve hospital systems or supplies and the educator can provide useful information to train new staff and provide continuing education on issues that relate to specific

types of safety concerns. Nurses and doctors can identify ways to improve clinical practice, and the technician can contribute through procedure and equipment design improvements. The researcher can offer advice on how to examine the issue more thoroughly. Discussing the incidents in this fashion heightens awareness of the issues and brings together the team approach to resolving them.

The reporting system is designed for all staff members to use for any incidents that involve visitors, staff, patients, and equipment. It is generic and allows for a systems based approach to viewing corrective strategies.

7.4 Positive outcomes of the study

Besides the research outcomes of this study providing useful information, the process has been beneficial in the following ways.

The "POS" from each international region took responsibility for disseminating educational and promotional information regarding HIMS. They also are an important contact for providing and distributing feedback from the data at their regional meetings. One positive aspect is that this group has become very supportive not only of the study, but also of each other. HIMS has brought together an international group of talented, virtuous individuals, committed to improving the quality of care delivered in the hyperbaric environment. The strong commitment of this group to improve hyperbaric safety is demonstrated by their continuing efforts in supporting and promoting the study, despite the barriers of distance, language, and longevity of the study.

Some individuals who submitted reports to the study made contact to ensure their reports were on the database. This was a "risky" venture for them as it exposed their identity, yet the power of "confession" and the strong desire to let others learn from their experience surpassed any perceived threat of identity disclosure.

The study was greeted with enthusiasm from many clinicians, which has led to organisers of conferences to generously allow free prime booth space to promote HIMS at hyperbaric

professional meetings and has resulted in the invitation for HIMS to be on the agenda for several international safety symposiums.

Reviewing the incident with others locally can also develop an "esprit de corps". Instilling the mindset that as humans we all err and that error will naturally occur in the work that we do allows the clinician more freedom to reveal error. Establishing an environment that is non-judgmental and embraces the opportunity for refining and continually improving the manner in which work in order to safeguard against human error is required.

The whole process of reporting and reviewing the reports is educational. It provides opportunities for the multidisciplinary team to examine clinical situations from the perspective of others with different professional backgrounds and of varying levels of experience and knowledge. There is value in the regular, clinically relevant learning opportunities that come with multidisciplinary HIMS report reviews.

Mueller et al. (1997) demonstrated a decreased incidence of ear barotrauma in their hyperbaric facility as a result of participating in this study. This report demonstrates the ability of the study to be applied at the local level and to be used to measure the impact of corrective strategies derived from HIMS. This individual unit reporting the use of HIMS as a safety improvement tool serves to heighten awareness of the value in reporting and monitoring incidents.

These positive outcomes are encouraging. Although the data in this study was reported from 1996-1997, the study continues and there are now over six hundred reports collected over a three year period. Software programs are being designed to automate part of the analysis, provide a framework for internet reporting, and facilitate timely feedback of the data to the study participants.

7.5 Major Finding of the Research

Of the 200 reports collected during the twenty month period, no mortality was reported. Most of the reports (164) occurred inside the chamber and involved multiplace chambers (177).

Patients were most often involved in the incidents (135), but staff (fifty-three), equipment (twenty-nine), and a visitor were also involved.

Forty-four percent of the incidents were judged by the reporter as preventable, but there was a significant association (χ^2 $p< 0.01$) between patient incidents and incidents that the reporter classed as chance event and unpreventable. Thus, the reporter generally did not feel that patient type incidents were preventable.

The major finding of each type of incident are described next.

7.5.a Patient Problems

Barotrauma

Patient problems are the most frequently reported (110) and ear barotrauma is the most common of this type (thirty-four). Ear barotrauma resulted in twenty-five percent of all aborted treatments. Of the patients that sustained ear barotrauma, thirty-five percent required their treatment to be aborted and fifty percent required myringotomies. The overall significance of ear barotrauma from hyperbaric treatment including its impact on the alteration of treatment profiles, the long-term outcome of the health of the ear, and the patient's perception of the complication have yet to be researched.

Barotrauma of the sinus and teeth resulted in aborted treatments (six of seven reports). Pulmonary barotrauma occurred once and further injury was avoided by pre-treatment assessment by hyperbaric trained staff.

Oxygen toxicity

Oxygen toxicity is the second most commonly reported complication (twenty-five). Twenty-three of the reports described CNS oxygen toxicity. Seven of these reports cited that close observation with prompt intervention for premonitory symptoms of CNS oxygen toxicity may have prevented the patient from progressing to a grand mal seizure. The true incidence of CNS oxygen toxicity is unknown as the literature reports oxygen toxicity that progresses to seizure. This data shows that the prompt diagnosis of CNS oxygen toxicity may be difficult and the symptoms of oxygen toxicity can be confused with the symptoms of hypoglycaemia, alcohol intoxication, and anxiety.

Furthermore, the management of an oxygen toxicity seizure can be affected due to lack of assistance in a confined environment.

Effects of oxygen on the eye are only reported twice, but it is significant that one of the reports described a patient with vision loss in the form of hyperopia and that no investigations were made for four weeks from the initial complaint. No similar reports of this nature could be found in the literature.

Psychological reactions

Of the eleven reports of anxiety, seven were confinement anxiety and four were stress reactions to patients witnessing another patient having an oxygen toxicity seizure. Incidents of this type have not been described in the hyperbaric literature and there is little in the hyperbaric literature to guide the hyperbaric clinician in the assessment and management of a patient with confinement anxiety.

Other patient complications

Alcohol intoxication contributed to two patient problems in the study. Their symptoms made the differential diagnosis of hypoglycaemia and CNS oxygen toxicity difficult.

The hypoglycaemia reports, although few, demonstrated that blood glucose testing and better management of marginally low blood glucose levels prior to treatment might prevent hypoglycaemic reactions.

There was only one incident involving an aggressive patient in the chamber, but due to the inability for both the patients and the nurse to escape, this incident is seminal. The inside occupants must not be at risk of physical attack with no means of escape.

7.5.b Equipment and chamber problems

Equipment and chamber problems were inter-related, as were the contributing factors. Failure to follow policy or protocol, failure to check equipment, and malfunction of equipment or monitor

all significantly contribute to these types of incidents. Poor design or malfunction of equipment or monitor also were primary factors that contributed to these incidents.

Hoods

Oxygen hood incidents included disconnections resulting in oxygen leaks, inadequate oxygen supply to the patient, and hood deflation. Hood deflation, if undetected could be catastrophic. In this study, three accounts of hood deflation were caused by inexperienced staff, faulty gas supply equipment, and a faulty overboard dump system.

One hood incident was significant in that it highlighted that the first sign of an oxygen leak may be an increase in chamber pressure instead of an increase in chamber environment oxygen level. This introduces questions of oxygen pooling and location of oxygen sensors in chambers, and signifies that in chambers with high flow oxygen delivery devices, pressure rises are associated with oxygen leaks.

Built-in-breathing system (BIBS)

Human error in the use of equipment was a significant factor in the BIBS incidents. The reports did not result in harm but could have, if not corrected. A patient was exhaling into a mask with a quarter turn valve controlling the exhaust turned off. This could have led to carbon dioxide toxicity and also placed the patient at increased risk of oxygen toxicity.

In a "one-off" account of a training dive, oxygen was supplied to a doctor at 4.0 ATA upon his request. The error was quickly corrected. Important lessons from this are to question requests made of individuals at pressures greater than 3.0ATA, as they may have poor judgment from the effects of nitrogen narcosis, and to make it policy to change the gas supply to the chamber to a gas safe for breathing at that pressure.

Overboard dump systems (OBDS)

Overboard dump systems affected the safety of twelve patients. A delicate balance of gas supply and scavenge is required for proper hood inflation. There is not a high margin for error in these systems and when error occurs, the results can be serious. This study highlights the need for human factors engineering to establish mechanisms for safety improvement.

Ventilation/Monitors

The most significant causes of the ventilation and monitor incidents in this study are malfunction and poor design of equipment and failure to check and/or follow policy or protocol. Ventilator function may alter and endotracheal cuff deflation may occur under hyperbaric conditions. Detection of these complications of hyperbaric may be assisted by the use of expired tidal volume alarms. The need for ventilator design modifications is apparent.

Fire risk

Events that caused the elevation of oxygen levels in the chamber atmosphere were the most common cause of the fire risks in this study. This highlights the importance of efficiently operating equipment as a means on detecting oxygen related fire risks.

Prohibited items in the chamber, obscure items installed into chamber systems by non-hyperbaric trained staff, faulty electrical wiring, and fire hazards in the area surrounding the chamber are all identified in the increased risk of chamber fire.

Other Chamber Incidents

Associated with a high degree of risk, uncontrolled compressions are reported twice. Causes were due to the changing of gas supply during a flush of air in the chamber (corrected by a well trained nurse in the chamber) and the other a result of the accidental interruption of power to a computer driven chamber (corrected by a well trained technician utilising the manual override system). No similar causes for this type of incident were found in the literature so this may be new information that can assist in design, system, and protocol development.

Monoplace chambers have their unique hazards. Inexperience of a nurse caused the forceful ejection of a chamber access port plug, captured by a curtain separating the plug from a patient sitting nearby. No harm occurred but measures of this researcher to institute a human factors approach to design change with the manufacturer were fruitless. Alternate strategies to prevent this type of error are required.

A complex procedure for the changing of gas supply, omitting to check gas supply, and gas contamination from a poorly serviced compressor are reported causes of gas supply problems.

7.5.c Staff Problems

Minor middle ear barotrauma was reported in hyperbaric attendants, and in particular, two occurred during attendant training dives. Alarmingly, one nurse attendant developed inner ear barotrauma resulting in long term morbidity. This is a rare complication, making this type of reporting especially important for analysis of causative factors.

Decompression illness (DCI) is an uncommon, but well known risk for hyperbaric attendants (Sheffield & Pirone 1999). Notably, the stationary position of a limb during the pressure exposure was revealed as a contributing factor in three of five reports of attendant DCI in the current study.

Reports of pulmonary oxygen toxicity in staff of clinical hyperbaric oxygen units were not found in the literature. There were two cases reported in HIMS, although one of the reports was after a nurse had attended a patient in the chamber, breathing oxygen for the decompression, then required recompression for DCI that was acquired during that exposure.

Central nervous system oxygen toxicity occurred in two nurse attendants, at pressures of 2.0 ATA and 1.6 ATA. The toxicity did not progress to seizure. Again, other than from HIMS reporting, this finding has only been reported in the literature once.

7.5.d Minimising factors

The most common factors that reporters ascribed to minimising the incidents are close or good supervision and early detection. Mostly, these require well trained hyperbaric staff closely supervising the hyperbaric treatment. Monitoring, while mainly dependent on the inside attendant and the technician, could be enhanced with innovations in technology.

On a final note, credit must be given to the patients, as the patient's recognition of symptoms and their assistance to other patients were indicated as factors reducing the severity of the incident.

7.6 Recommendations of the Study

Recommendations for safety improvement in hyperbaric clinical practice as a result of this study are outlined in Table 7.1. They are listed under the general headings that have been used throughout the thesis and are also labelled with the type of initiative they represent. The initiatives include protocols/guidelines (PG), quality improvement (QI), education (E), research (R), and design modification (D). There is sometimes a fine line between research and quality improvement (Clarke 2000, Dunn 2000) and HIMS is a good example of research and quality improvement working simultaneously.

Recommendations for improving the study are listed in Table 7.2.

Table 7.1: Recommendations for Hyperbaric Practice

Patient Complications

Barotrauma

- Establish best practice for the prophylaxis and treatment of ear barotrauma QI, R)
- Evaluate efficacy of teaching program for patient ear equalisation techniques conducted by nurses to prevent patient ear barotrauma (QI,R)
- Conduct an international multidisciplinary workshop on the prevention and treatment of hyperbaric induced ear barotrauma (QI, E)
- Review the effect of compression rates on patient ear barotrauma (R,QI)
- Research the impact and significance of low grade barotrauma secondary to hyperbaric treatment on the patient, staff, and operation of a hyperbaric facility (R,QI)
- Research to improve the identification and management of the patient at risk of developing significant ear barotrauma from hyperbaric treatment (R,QI)
- Research the long-term outcome of ear health in patients receiving hyperbaric with an artificial airway with prophylactic myringotomies compared to those not receiving prophylactic myringotomies (R,QI)

Oxygen Toxicity

- Develop and promote the use of protocols to prevent the inadvertent administration of one hundred percent oxygen at pressures greater than three atmospheres absolute (especially in training dives) (PG)
- Improve the reporting of myopia in hyperbaric patients (PG)
- Research the efficacy of patient assessment, teaching and vigilant observation by nurses in the prevention of oxygen toxicity seizures in patients receiving hyperbaric oxygen treatment (R, QI)
- Research the efficacy of patient assessment, teaching and vigilant observation by nurses in the prevention of oxygen toxicity seizures in patients receiving hyperbaric oxygen treatment (R,QI)

- Conduct a prospective study of the incidence and the effect of treatment pressure on hyperbaric oxygen induced myopia (R,QI)

Psychological Reactions

- Develop and promote the use of guidelines for the nursing assessment, prevention, and management of the patient exhibiting confinement anxiety in the hyperbaric environment (PG, E)
- Educate nurses in the management of patient anxiety (E)
- Develop and promote the use of guidelines for the nursing assessment, prevention, and management of the potentially violent patient requiring hyperbaric oxygen treatment (PG, E)

General

- Encourage attentive observational behaviour of inside attendants for the identification of premonitory symptoms of oxygen toxicity, anxiety, and hypoglycaemia (PG, E)
- Ensure a hyperbaric trained registered nurse and/doctor has assessed the patient prior to receiving hyperbaric oxygen treatment (PG, E)
- Develop and promote the use of guidelines for the nursing assessment and management of the diabetic patient receiving hyperbaric treatment (PG, E)
- Develop and promote the use of guidelines for the nursing assessment and management of the patient suspected of alcohol intoxication prior to hyperbaric treatment (PG, E)
- Include in patient education the importance of reporting promptly to the nurse any alteration in the patient's well-being (either physical or psychological) so intervention can be instituted to prevent possible impending complications to treatment (PG, E)
- Establish the incidence of hypoglycaemia in patients convulsing during hyperbaric oxygen treatment (R)
- Research the type and incidence of adverse events (both potentially and actually harmful) in the transport of patients to and from the hyperbaric chamber (R,QI)

Equipment / Chamber Problems

Breathing and gas scavenge systems

- Design patient oxygen administration devices and overboard dump systems to prevent mask squeeze and hood deflation (D)
- Increase the use of monitoring aids for adequacy of oxygen delivery, oxygen leaks, carbon dioxide levels in breathing circuits and ventilator function (PG, D)
- Design specific ventilators for hyperbaric use (D)
- Develop safe protocols for changing gas supply (PG)
- Review the design of overboard dump systems, especially the use of quarter turn valves, to improve safety (D)
- Promote the use of disconnect alarms and expired airway volume metres on ventilated patients (PG)
- Develop a commercially available end tidal volume carbon dioxide monitor for ventilated patients undergoing hyperbaric oxygen treatment (D)
- A review of the limitations, complications, and management changes resulting from ventilator performance in the ventilated patient receiving hyperbaric treatment (R,QI)

Fire Hazards

- Develop checking protocols for items of fire risk prior to starting treatments (PG)
- Inspect all items or devices installed or supplied by outside agencies for fire hazards before use with the chamber (PG)
- Review fire hazards in areas within and adjacent to the hyperbaric chamber (lunch rooms, work shop) (QI, E)
- Promote the use of a "no-pockets" policy for patients and staff entering chamber (PG)
- Research the effect of location of environmental oxygen monitors in hyperbaric chambers on the efficacy of oxygen monitoring (R)

General

- Develop and promote the use of protocols for checking equipment before use (PG)
- Distribute information regarding possible dangers with the improper insertion of monoplace chamber pass-through plugs (E)
- Design and use hyperbaric chambers for patient use versus using chambers designed for commercial diving purposes for patients (D)
- Review chamber systems and work patterns to reduce noise (QI, D)
- Promote the introduction of protocols to minimise distractions during critical stages of hyperbaric work, such as setting-up of equipment, checking procedures, and compression phase of the treatment (PG, E)
- Train staff in the emergency management of an uncontrolled compression. Clearly mark and make accessible to staff controls for stopping in-flow of pressurising gas into the chamber (PG, E)
- Develop protocols for the flushing of chamber air (PG)
- Develop and promote the use of protocols for checking all gas supply to chambers (both monoplace air and oxygen supplies) are turned on and functional prior to starting treatment (PG)
- Develop regular preventative maintenance programs and monitor the adherence to the program (QI, PG)
- Review chamber toilet design and operational procedures to prevent hazards of both suction and explosive ejection of toilet contents (D)

Staff Problems

- Develop and promote the use of guidelines for aborting treatment or lengthening decompression times in situations where there is a prolonged compression (PG)
- Institute close supervision, monitoring, and training of new staff to prevent ear barotrauma (E)
- Establish the prevalence and significance of ear barotrauma in hyperbaric inside attendants (R)
- Conduct a longitudinal study of the long-term health of hyperbaric inside tenders (R)

- Study the incidence, risk factors, management and long-term outcome of hyperbaric attendants acquiring decompression illness from hyperbaric exposure (R)

- Develop a model for determining decompression risk of hyperbaric attendants (R)

Other

- Develop international guidelines for the education and training of staff working in hyperbaric facilities (PG, QI)
- Review the causes and impact of aborted hyperbaric treatments (R,QI)
- Increase reporting of incidents, including those that may not appear to have significance to patient or staff outcomes (QI)
- Utilise human factors engineering in the safety design of chamber and medical equipment design (particularly gas supply and scavenge systems and chamber control panel) (QI, D)

These recommendations are of no benefit unless they are utilised following the dissemination of this data. It is the responsibility of the hyperbaric medicine unit directors, safety directors, administrators, hyperbaric nurses, and technical directors to take on the tasks appropriate for use at the level of the hyperbaric medicine unit, and indeed they have already. Some of these recommendations such as quality improvement initiatives, protocols and guidelines and education can be instituted immediately at the local level by hyperbaric staff. Some staff training can be done as a multidisciplinary team or incorporated into local training programs by hyperbaric educators. Educational initiatives may require national and international training and standards organisations to evaluate and implement. Design changes may be made by the entrepreneurial technician or may require engineers and corporate support. Research initiatives will most likely require multidisciplinary cooperation, with multi-centred trials and the organisational support of professional bodies and funding agencies.

These recommendations can be promoted through the Undersea and Hyperbaric Medicine Society Web Site, through professional publications, safety training courses, at national and international hyperbaric meetings, and to all the participants in HIMS.

Despite the usefulness of data obtained from the present study, some improvements can be made. Table 7.2 outlines specific recommendations for the continuation of the study.

Table 7.2: Recommendations for Improving HIMS

- Improve and increase the frequency of communication with the Person on the Spot (POS) to:
    1. Reinforce the value of reporting incidents that seemingly do not appear to have long term significance
    2. Give regular feed back from reporting
    3. Encourage the use of the reports at the local level as a quality improvement tool
    4. Teach the process of using the reports as an multidisciplinary educational tool, with open-mindedness to view ways in which those incidents judged as "unpreventable" may be corrected
    5. Survey for difficulties with the process of the study
    6. Provide on-going support and encouragement in the continuation of the study
- Revise the HIMS Report Form to:
    1. Exclude the logistical limitations of age classifications and classing incidents that are coded in more than one category
    2. Improve the classification of outcomes
    3. Include examples of reportable incidents, encouraging the reporting of incidents occurring as a result of transport to and from the hyperbaric chamber
- Develop software to facilitate ease in analysis and to provide faster and more frequent feedback to the participants and professional organisations
- Once enough data of particular types of reports is collected, engage experts relating to that topic to assist in the analysis, interpretation and actioning the recommendations from the study
- Include regular involvement of a hyperbaric technician in the analysis of the reports
- Ease the ability of the "POS" to analyse and submit their HIMS Reports by supplying the HIMS Report Form on disk and providing a program for simple analysis of local data.

- Provide the infrastructure for the data to be sent securely over the internet to the international database.
- Give reports and recommendations from the HIMS data to the hyperbaric professional organisations for inclusion in their safety committees and to disseminate to hyperbaric clinicians via their web sites.
- Review the costs of continuing the study and secure funding for the running costs
- Continue to promote by presenting the data at hyperbaric scientific meetings and in the literature
- Continue to enlist participants by continuing the use of the "HIMS Booth" at hyperbaric scientific meetings and through hyperbaric newsletters

The research has generated new knowledge of safety in the practice of hyperbaric medicine. It is knowledge applicable to all members of the hyperbaric team, designers, manufacturers, researchers, and educators. It has reviewed the history of safety concerns in clinical hyperbaric practice and related new data to it. New perspectives to the factors contributing to the common problems in hyperbaric have been exposed. As professionals, it is our responsibility to take this information and advance safety practices in our specialty.

HIMS has demonstrated the ability to provide a powerful tool for continuous quality improvement and for the collation of data that can be used in the prevention of adverse effects of hyperbaric therapy.

'It is one thing to show a man that he is in error, and another to put him in possession of the truth'

John Locke, Essay
Concerning Human Understanding: BK. IV, Ch. 7, Sec. 11

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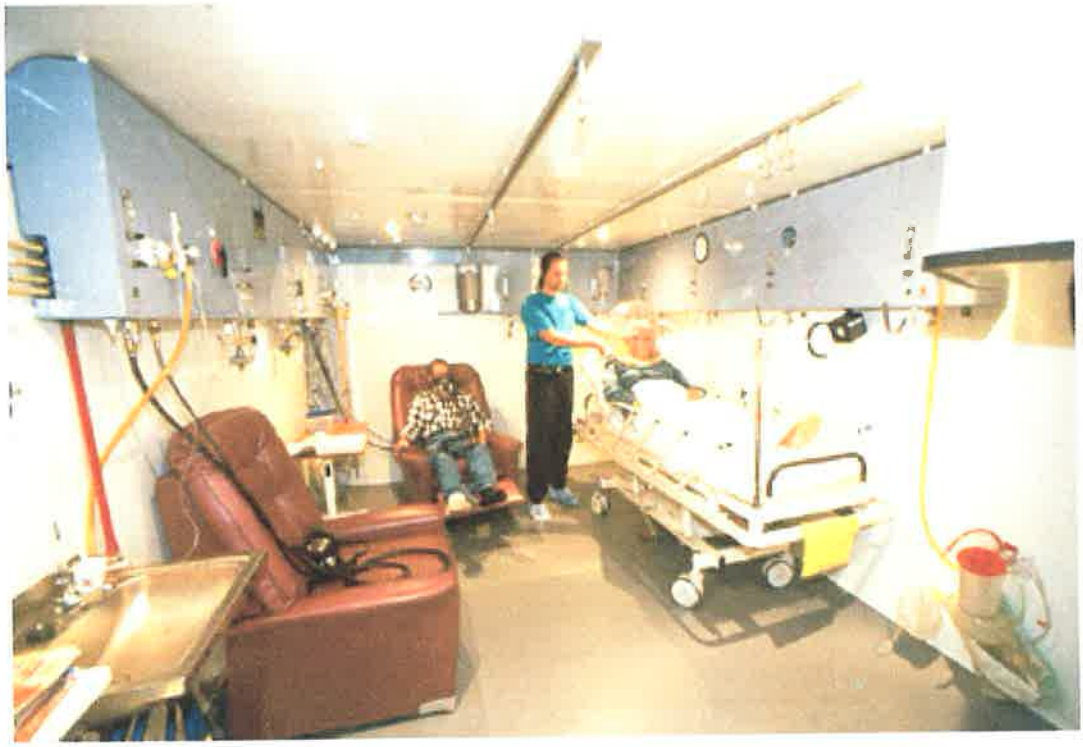
APPENDIX A: Types of Hyperbaric Chambers

Drager Multiplace Chamber ***Fink Walk-in Multiplace Chamber***



Interior of Fink Walk-in Multiplace Chamber

(Photographs courtesy of the Royal Adelaide Hospital)

Air Filled Monoplace Chamber

(Photograph courtesy of Hyperbaric Oxygen Therapy Systems)

APPENDIX B: German Hyperbaric Safety Publications

1. Accident Prevention Orders of the Workers Compensation

- VBG 1 General Orders
- VBG 4 – Electronic Plants and Operational Devices
- VBG 16 – Compressors
- VBG 39 – Dive Operations
- VBG 61 – Gases
- VBG 62 – Oxygen
- VBG 100 – Preventive Occupational Health
- VBG 103 – Medical Services

2. Information Sheets of the Workers Compensation

- ZH 1/112 – Safety at Work from Fire Prevention
- ZH 1/200 – Standards for the Prevention of Ignition Risks from Electro-static Loading
-ZH 1/201 – Directive for the Equipment of Workplaces with Fire Extinguishers
- ZH 1/307 – Leaflet: Handling of Oxygen
- ZH 1/383 – Leaflet: When does Oxygen become a Danger to Life?
- ZH 1/479 – Directive for Work in Compressed Air
- ZH 1/539 – Regulations for Divers Chambers
- ZH 1/587 – Leaflet for the Treatment of Illnesses caused by Work under Pressure

APPENDIX C: Hyperbaric Safety References

1. *Australian Occupational Diving Standard AS/NZS 2299.1: 1999*, publication of Standards Australia;
2. *Compressed Gas Association (CGA) Inc. Handbook of Compressed Gases*, Fourth Edition 1999, publication of the CGA;
3. *Hyperbaric Technicians and Nurses Association, Hyperbaric Nurses Course Standard*, 1995, publication of the Hyperbaric Technicians and Nurses Association, Townsville, Queensland.
4. *Undersea and Hyperbaric Medical Society (UHMS) Committee Report*; 1999; Undersea and Hyperbaric Medical Society, Kensington, Maryland;
5. Guidelines for Joint Commission on Accreditation of Healthcare Organizations (JCAHO);
6. *Guidelines For Clinical Multiplace Hyperbaric Facilities* - 1994, Undersea and Hyperbaric Medical Society, Kensington, Maryland;
7. *Monoplace Chamber Safety Guidelines*, Undersea and Hyperbaric Medical Society, Kensington. Maryland;
8. *US. Navy Diving Manual*, Department of the Navy, Washington, DC;
9. *NOAA Diving Manual*, Department of Commerce, Washington, DC;
10. Occupational Safety and Health Administration (OSHA), Washington, DC;
11. *U.S. Air Force Pamphlet 161 - 27 Operation of Hyperbaric (Compression) Chambers*, U.S. Government Printing Office, Washington, DC;
12. Canadian Hyperbaric Facility Standard Z2751-93; 13. Operations Committee Report, Kimbrell, P. (ed), Undersea and Hyperbaric Medical Society, Kensington, Maryland.

APPENDIX D: Types of Guidelines, Standards, and Codes

Hyperbaric System
Pressure vessel and piping
Medical devices

Operational
Facility construction
Fire safety, etc.

Personnel
Staffing
Training
Facility certification

Hyperbaric System
Pressure Vessel and Piping

Australia
AS 1210: Unfired Pressure Vessel Code (recognizes ASME Section VIII requirements)
AS 2299: Occupational Diving

Canada
CSA B51 - Boiler, Pressure Vessel, and Pressure Piping Code
Z305.1-92 - Non-Flammable Medical Gas Piping Systems

European Community
Pressure Equipment Directive (PED)
97/23/EEC
Effective 29 November 1999

France
CODAP: Code for the Design and Construction of Unfired Pressure Vessels (SNCT)

Germany
DIN 13256 Part 2: Pressure Vessels for Human Occupancy; Accessible Pressure Vessels for Hyperbaric Therapy; Safety Requirements and Testing. (German Institute of Standards)

Italy
VSR Rules: Collection (Raccolta VSR) Concerning Design Rules for Pressure Vessels. (Higher Institute for Accident Prevention and Safety at Work - ISPESL Rules)

Japan
JIS B8243: Construction of Pressure Vessels (Japanese Industrial Standards)

Sweden
Swedish Pressure Vessel Code (The Swedish Pressure Vessel Commission)

United Kingdom
BS 5500: Specification for Unfired Fusion Welded Pressure Vessels (British Standards Institute)

United States
ASME PVHO-1, Safety Standard for Pressure Vessels for Human Occupancy
ASME Section VIII, Division 1, Pressure vessels
ASME Section VIII, Division 2, Alternative Rules
B31.1 Power Piping

Classification Society Rules
American Bureau of Shipping (ABS)
Bureau Veritas (BV)
China Classification Society (CCS)
Det Norske Veritas (DNV)
Germanischer Lloyd (GL)
Lloyd's Registry of Shipping (LR)
Nippon Kaiji Yokai (Class NK)
Registro Italiano Navale (RINA)

Additional Guidelines and Standards
Australia, New Zealand, Singapore
HOTFIG
United Kingdom
British Hyperbaric Association Guidelines
  Electrical
  Fire Safety
United States
NFPA 99, Health Care Facilities, Chapter 19, Hyperbaric Facilities

Hyperbaric System: Medical Devices
Australia
"Therapeutic Goods Authority"

Canada
Medical Device Regulations, Schedule 1101
  7 May 1998

European Community
  CE Marking
  Medical Device Directive 93/42/EEC
  14 June 1998

Japan
JIS T 1001-1983: General Requirements for Safety of Medical Electrical Equipment
JIS T 7321-1989: Hyperbaric Oxygen Chambers

United States
Food and Drug Administration (FDA)
Medical Device Amendments to the Federal Food, Drug, and Cosmetic Act of 1976 (and subsequent amendments)
Class II Medical Device
PreMarket Notification required

Operational
European Community
European Committee on Hyperbaric Medicine (ECHM)
ECHM Recommendations for Safety in Multiplace Medical Hyperbaric Chambers (in draft)

Germany
DIN 13256 (German Industrial Norm), Part 2

Japan
JIS T 7321 - Hyperbaric Oxygen Chambers
Japanese Society for Hyperbaric Medicine's Guidelines for HBO Safety (1969)

Latin America
Latin American Chapter of UHMS Consensus Meeting (2000 in Mexico City) to develop guidelines

South Africa
Occupational Health and Safety Act of 1985
Department of Labour
South African Bureau of Standards
Technical Committee 48 (hyperbaric specific)

United Kingdom
BHA Guide to Fire Safety Standards for Hyperbaric Treatment Centers
BHA Guide to Electrical Safety Standards for Hyperbaric Treatment Centers
BHA Health and Safety for Therapeutic Hyperbaric Facilities: A Code of Practice (in draft)

United States
NFPA 99, Health Care Facilities, Chapter 19, Hyperbaric Facilities
UHMS Operations Committee Report
Standards of Practice

Personnel
Australia, New Zealand, Singapore
Hyperbaric Oxygen Therapy Facility Industry Guidelines (HOTFIG), HTNA
Australian and New Zealand College of Anesthetists (ANZCA) - in development

Canada
CSA Z275.1-93 - Hyperbaric Facilities

European Community
Joint effort to develop physician criteria
European Committee for Hyperbaric Medicine (ECHM) guidelines
European Diving Technology Committee (EDTC) guidelines

Germany
Germany Society of Diving and Hyperbaric Medicine (GTUM) guidelines
Association of German Hyperbaric Medicine Centers (VDD) guidelines

Japan
JSHM Guidelines

Latin America
Latin American Chapter of UHMS Consensus Meeting (2000 in Mexico City) to develop guidelines
Latin American Chapter of the UHMS Diving and Hyperbaric Medicine Training Course
Teaching Commission of the Latin American Chapter

South Africa
Southern African Undersea and Hyperbaric Medical Association (SAUHMA) guidelines

United Kingdom
BHA guidelines
Code of Good Working Practice for the Operation and Staffing of Hyperbaric Chambers for Therapeutic Purposes (Cox Report)
Health and Safety for Therapeutic Hyperbaric Facilities: A Code of Practice (in draft)

United States
NFPA 99, Health Care Facilities, Chapter 19, Hyperbaric Facilities
UHMS Operations Committee Report

Facility Certification
Germany
Facilities that are members of the Association of German Hyperbaric Centers (VDD)
Therapy Center for Hyperbaric Oxygen Treatment Certificate (since 1998)
Conducted by Germanischer Lloyd

Information used in Appendix C provided with permission by W.T. Workman from 'Standards Governing Hyperbaric Medicine Facilities-An International View', presented at the Hyperbaric Technicians and Nurses Association Safety Workshop held at the Stamford Plaza Adelaide, August 25, 1999.

Appendix E: Experience and Mishap Report Form

CHAMBER EXPERIENCE AND MISHAP DATABASE REPORT FORM

Date: _____ Time: _____ Day of Week: _____

Location: _____ Type of Hospital: _____

Address: _____ Type Clinic: _____

City: _____ State: _____ Country: _____

Type
[ ] HBO [ ] Diving [ ] Altitude

System
[ ] Monoplace [ ] Multiplace [ ] Bell
[ ] Hypobaric [ ] System

Cause

[ ] Fire [ ] Pressure [ ] Other

Injured _____ Years of Operation _____

of Fatalities ___ Compression Gas _____

Ignitions Source _____ Cause of Death _____

Type Equipment _____ Model _____ Manufacturer _____

Reporter _____ Telephone _____

Address _____ FAX _____

City _____ State ___ Zip _____ Country _____

Role _____

Victims

Name	**Age**	**Sex**	**Marital Status**	**Occupation**

Description of Incident:

APPENDIX F: Sample of HIMS Report Form

HYPERBARIC INCIDENT REPORT

You are invited to complete this report if an incident occurs during your clinical practice of hyperbaric medicine. **Please keep this form anonymous**

DEFINITION

Report any incident, no matter how seemingly trivial, which affected or could have affected the safety of the patient, hyperbaric chamber staff or visitor. The incident may be preventable or unpreventable.

ANONYMITY

The identity of the reporter, patient, chamber attendant, chamber operator, or hyperbaric unit should not appear on this report. The only person who knows this information is you. If you wish, report only those incidents which cause no harm. This is a declared quality assurance activity with no interest in personal blame.
No information on this form is available to the legal process in Australia. It is protected by the Australian Commonwealth Health Insurance (Quality Assurance Confidentiality) Amendment Act, 1992. Indemnity of this form in other countries varies by county and state laws.

If you are concerned, report only those incidents which pose no medico-legal risk.

INSTRUCTIONS

In addition to circling one or more options under each heading, write simply in your own words description of what happened. This narrative is the most important component of the report.
Place the completed report in the container provided.

QUALITY

This report will be sent to the Australian Patient Safety Foundation Inc. in Adelaide, Australia so that a broad range of anonymous hyperbaric incidents can be analysed. Your organisation will receive regular feedback from the international database.

COORDINATOR

A nominated hyperbaric staff member in your own unit is your local HIMS coordinator (POS). Feel free to discuss with them any incident or any difficulties which you may encounter with this report.

DETAIL

It is **not** necessary to be more specific about the date, place or procedure than is required by this form.
Please complete all sections so that your data will be more valuable. Avoid personal identifying details.
Please write legibly, or type your narrative if possible.

HYPERBARIC SPECIALTY: **Circle one or more options under <u>each</u> heading.**

CHAMBER INVOLVED

Monoplace	MO
Multiplace	MP
Dualplace	DP
Transportable	TP
None	NO

PATIENT COMPLICATION

Barotrauma:	
Ear	BE
Sinus	BS
Pulmonary	BP
Dental	BD
Claustrophobia	CB
O_2 Toxicity:	
CNS	CT
Pulmonary	PT
Visual change	VC
Physical Injury	
Other:	OT
Specify:	
Nil	NI

STAFF PROBLEM

Barotrauma:	
Ear	BE
Sinus	BS
Pulmonary	BP
Dental	BD
Claustrophobia	CB
Sensory deprivation	SD
O_2 toxicity	
CNS	CT
Other	OO
Specify:	
Decompression Illness:	
Neurological	ND
Cerebral arterial gas Embolism	ED
Physical injury	PI
Other	OT
Specify:	
Nil	NI

VENTILATION INCIDENT

Total ventilation failure	VF
Inadequate ventilation	IV
Misconnection	MI
Disconnection	DI
Ventilation circuitry valve	CV
Circuitry ineffective in	
Delivery of 100% O_2	
During treatment	ID
Wrong F_1O_2	WF
Hypercarbia	HC
Leak	LE
Obstruction	OB
Overpressure	OV
Other	OT
Specify:	
Nil	NI

CHAMBER INCIDENT

Medical lock	ML
Alarm failure	AF
Interruption of gas supply	GS
Patient loading device	LD
Potentiated fire risk	FR
Patient trolley/seating	TS
Overboard dump	DD
Suction device	SD
Chamber valve failure	VF
Communication system	CS
Contaminated gas supply	CG
CO_2 scrubber	SC
Uncontrolled ascent	UA
Interference with pressurisation	IP
Chamber temperature	CT
Chamber humidity	CH
Other	OT
Specify:	
Nil	NI

EQUIPMENT INVOLVED

Built-in breathing system	BI
Scott mask	SM
Head tent/hood	HT
Ventilator	VT
Specify type:	
IV pump	IP
Specify type, brand and model number:	
IV tubing	IT
Overboard dump	OD
Flow meter	FM
Chamber door	CD
Window/full	PH
Temperature control unit	TC
Lighting	LT
Fire suppression system	FS
Gas analyser	GA
Transcutaneous oxygen monitor	OM
Other	OT
Specify:	
Nil	NI

PHARMACOLOGICAL INCIDENT

Inappropriate Drug	IP
Wrong drug	WD
Allergy phenomenon	AL
Drug label	DL
Interaction	IN
Overdosage	OV
Side effect	SE
Underdosage	UN
Other drug incident	OT
Specify:	
Nil	NI

TUBES & LINES INCIDENT

Lines:	
Peripheral	PV
IV pass-through	PT
PA	PA
CVP	CV
Arterial line	AL
Vascath	VC
Peritoneal dialysis	PD
Intracranial pressure	IC
Chest Tube Drain	CT
Urinary Catheter	UC
Surgical drains	SD
Other	OT
Specify:	
Nil	NI

WHERE DID INCIDENT OCCUR?

Ward/Unit	W/U
Transit	TR
Retrieval	RL
Hyperbaric Unit:	
- outside chamber	HU
- in chamber	HC

TO WHOM IT HAPPENED

(circle one) If more than one describe in narrative.

Patient
Staff
Visitor
Equipment

Male / Female

Age Group:

1-14	CH
14-20	YA
21-40	OK
40-60	MA
>60	OL

FINAL OUTCOME

Staff unfit short-term	US
Staff unfit long-term	UL
Awareness	AW
Death	DE
Dive aborted	DA
Dive lengthened	DL
Dive shortened	DS
Other	OT
Specify:	
Nil	NI

DESCRIPTION OF INCIDENT

In your own words describe the incident:

- include details about any factors which you believe may have contributed to, or minimised the incident.
- note any measures which might be employed in the future to prevent any such incident.

If more than one incident ("multiple incident') please fill out a separate report for each.

Do you think this incident was preventable? YES NO UNDECIDED

KEYWORDS (For office use only)

CONTRIBUTING FACTORS: Tick as many boxes as you like

SYSTEM-BASED FACTORS

Management
Pressure to proceed
Poor decision by management

Infrastructure / equipment / monitors
Lack of suitable bed / facility
Lack of suitable equipment / monitor
Malfunction of equipment / monitor
Poor design of equipment / monitor
Poor instructions for use

Staff / Protocols / Policies
Insufficient number of staff for the job
Insufficient training of staff for the job
Nonexistent or poor policy / protocol
Failure to use or enforce policy / protocol

Supplies / Labelling
Lack of supplies
Inaccessible supplies
Poor labelling

TEAM-COGNITIVE FACTORS

- ❒ Communication problem
- ❒ Poor team work
- ❒ Lack of supervision
- ❒ Inappropriate behaviour / action

PERSONAL – COGNITIVE FACTORS

Knowledge-based

- ❒ Inadequate / wrong knowledge
- ❒ Inexperience / inadequate training
- ❒ Unfamiliar environment
- ❒ Unfamiliar equipment
- ❒ Unfamiliar policies / protocols

Rule-based

- ❒ Failure to check equipment
- ❒ Failure to follow policy / protocol
- ❒ Use of wrong protocol
- ❒ Failure to attend (when asked)

Skill-based

- ❒ Haste
- ❒ Distraction (specify .....)
- ❒ Inattention
- ❒ Absent-mindedness
- ❒ Fatigue
- ❒ Stress
- ❒ Unwell

Technical

- ❒ Inexperience with procedure
- ❒ Technical problem with procedure

Violation

- ❒ Took a "short cut"
- ❒ Knowingly broke the rules
- ❒ Took a risk

Chance

- ❒ Chance event
- ❒ Unexpected allergy / anaphylaxis

OTHER COMMENTS:

.....

Could this incident have been managed better?

.....

What factors minimised the outcome (e.g. early detection by monitor / alarm, good assistance, good plan / protocol, good supervision, good luck, consultation and conciliation)?

Please send to:APSF
GPO Box 400,
Adelaide SA 5001
Australia

Within Australia: Ph: (08) 8222 5544
Fax: (08) 8232 6938

Outside Australia: Ph: +61-8-8222 5544
Fax: +61-8-8232 6938

Appendix G: Ethics Approval

Royal Adelaide Hospital

Medical & Allied
Health Services
Level 2 Eleanor Harrald Building
South Australia 5000
Telephone:
Facsimile:

19th August, 1997

Ms C Pirone
CNC
HYPERBARIC MEDICINE UNIT

Dear Ms Pirone,

Re: - "The Hyperbaric Incident Monitoring Study: An international study of incidents occurring in Hyperbaric Medicine Units." RAH Protocol No: 970805

I am writing to advise that ethical approval has been given to the above project. Please note that the approval is ethical only, and does not imply an approval for funding of the project.

Human Ethics Committee deliberations are guided by the Declaration of Helsinki and N.H. and M.R.C. Guidelines on Human Experimentation. Copies of these can be forwarded at your request.

Adequate record-keeping is important and you should retain at least the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them if necessary, in the future. The Committee will seek a progress report on this project at regular intervals and would like a brief report upon its conclusion.

If the results of your project are to be published, an appropriate acknowledgment of the Hospital should be contained in the article.

Yours sincerely,

Dr M James
Chairman
RESEARCH ETHICS COMMITTEE

Royal Adelaide Hospital North Terrace Adelaide South Australia 5000 Telephone Facsimile

APPENDIX H: Types of Hyperbaric Oxygen Breathing Equipment

Patient Oxygen Hood

Automatic Overboard Dump

Patient Built in Breathing System (BIBS)