PROVINCE OF BRITISH COLUMBIA

FINAL REPORT OF THE HYPERBARIC OXYGEN THERAPY ADVISORY PANEL

August 6, 2010

EXECUTIVE SUMMARY

PURPOSE OF THE REPORT:

This report was prepared by the Hyperbaric Oxygen Therapy Advisory Panel and provides their findings and recommendations to the Minister of Health Services. The panel was asked to provide its recommendations on what the standards and requirements should be for practitioners for the provision of hyperbaric oxygen therapy in British Columbia. The Panel was to operate under the assumption that the practice of HBOT will become a restricted activity under the *Health Professions Act*. The work of the Panel was conducted over the period of January to July 2010.

Hyperbaric oxygen therapy involves providing concentrated oxygen to patients in a pressurized chamber. It has been provided in BC for many years. Providing HBOT to clients can be a very effective therapy for many conditions, however, providing HBOT is not without risks. Explosions and fires can occur if there are problems with the equipment or if proper protocols and procedures are not followed by those providing the HBOT. Serious injuries and deaths have occurred in the past in other jurisdictions. In addition, like any complex health care procedure, there are risks to the patient.

PANEL PROCESS:

The panel reviewed background documents, including those prepared by a Working Group struck by the Ministry of Health Services in 2006, visited three HBOT facilities (one public, two private) and received a total of three written and four oral presentations. Limitations of the Panel process are noted in the body of the report. In coming to its recommendations, the Panel was guided by three important principles:

- The health and safety of both patients and workers should be of primary importance.
- Insofar as possible, all British Columbians should have reasonable access to HBOT services.
- The patient's right to make choices based on appropriate and accurate information should be preserved.

OBSERVATIONS, FINDINGS AND KEY ISSUES:

The panel addressed its observations related to both patients receiving treatment and the facilities and chambers used in the delivery of HBOT. Patient issues include the appropriate assessment, referral and planning of treatment, informed consent, record keeping and documentation, patient monitoring, response to emergencies, and assessing the effectiveness of treatment. Issues related to the facilities or chambers include the physical plant, fire suppression, accreditation and inspections, manuals and protocols, training of technical staff, servicing and maintenance of equipment.

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MAIN REPORT

PURPOSE OF REPORT:

This report was prepared by the Hyperbaric Oxygen Therapy Advisory Panel to provide their findings and recommendations to the Minister of Health Services on what the standards and requirements should be for practitioners for the provision of hyperbaric oxygen therapy in British Columbia.

BACKGROUND AND CONTEXT FOR THE REPORT:

Hyperbaric oxygen therapy involves providing concentrated oxygen to patients in a pressurized chamber. It has been provided in BC for many years, both in one public facility (Vancouver General Hospital) and in eight known private facilities across BC. In addition, HBOT is available at a number of diving operations in BC.

Providing HBOT to clients can be a very effective therapy for many conditions, much of which has been documented in the literature. In addition, new information and research is constantly evolving and other conditions may be identified in the future as also benefiting from HBOT.

However, providing HBOT is not without risks. Explosions and fires can occur if there are problems with the equipment or if proper protocols and procedures are not followed by those providing the HBOT. Serious injuries and deaths have occurred in the past in other jurisdictions.

In addition, like any complex health care procedure, there are risks to the patient—if they have not been screened properly; if there are certain pre-existing conditions; if incorrect dosages are provided; if there is not appropriate patient monitoring, etc.

A number of well respected health care practitioners across BC have asked the Ministry of Health Services to take steps to ensure the health and safety of clients and staff is protected.

In response to these requests, the Ministry of Health Services established a Working Group in 2006 to look into this issue. This Working Group included representatives of key organizations who all have some role or interest in the safe provision of HBOT in BC. The Working Group included the Ministry of Health Services; the College of Physicians and Surgeons of BC; the College of Naturopathic Physicians of BC; WorkSafe BC; Health Canada; the BC Safety Authority, the Provincial Health Services Authority, and a patient safety representative. This group met three times between December 2006 and March 2007.

The Working Group reached a number of conclusions, including:

1. The issue of safety in private hyperbaric clinics (PHC's) is not the responsibility of any one agency or body but a shared and collective responsibility of a number of agencies and bodies, both at the federal, provincial and local levels.

2. There is no one solution to ensuring health and safety, but rather there are a number of possible solutions that need to be implemented concurrently, and in a coordinated fashion.

3. There need to be both short and long term solutions to address the issue of health and safety in a comprehensive manner.

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A meeting was also held in September of 2008 with representatives of private HBOT's and, at this meeting, the private operators agreed that it was important to have mechanisms in place to ensure the health and safety of patients, families and staff. This group appreciated the need for some regulation but also wanted to ensure that access to private clinics was not limited by such policies or legislation. They also agreed with the working group that better information and communications were needed in relation to provision of hyperbaric oxygen therapy in BC.

As a result of the findings of this Working Group and the meeting with representatives of private operators, the Ministry of Health Services came to the conclusion that there would be a benefit to establishing an independent Panel to provide recommendations

relating to the standards and requirements for practitioners for the provision of hyperbaric oxygen in BC.

The Minister of Health Services, the Hon. Kevin Falcon, then appointed a three person Panel to conduct a review and make recommendations.

In late 2009, the panel was appointed, consisting of the Paul Pallan (Chair), Denise Heap and Pat Coward. The panel consisted of members who were seen as independent and non- partisan, but who had significant legal, health care and management experience.

Terms of reference were provided to the Panel (see Appendix 1). The Panel's appointment term is until September 30, 2010.

The panel conducted its work between January and July 2010. This report presents its findings and recommendations.

It is important to note that the Panel was to operate under the assumption that the practice of HBOT will become a restricted activity under the *Health Professions Act* and was the first Panel to be established under this framework. As such this was a learning experience for both the Panel and the Ministry of Health Services.

THE CURRENT SITUATION IN BC:

At the present time, there are two professions which have enacted rules/regulations to ensure their members who are providing HBOT do so in a safe manner. They are the College of Physicians and Surgeons of BC and the College of Naturopathic Physicians of BC. Persons who are providing HBOT who are not licensed members of one of these professions are currently not under any regulatory structure which may specify standards or requirements for providing HBOT.

In addition, as identified by the Working Group, specific agencies and bodies, at the national, provincial and local levels, have responsibilities for overseeing certain aspects of HBOT. However, there are gaps that exist in the current regulatory structure and potential risks to health and safety of clients and staff that result from these gaps.

LIMITATIONS:

The Panel is an advisory panel, not a decision-making body. All and any decisions made as a result of the Panel's recommendations will be the responsibility of the Ministry of Health Services.

The Panel will not address requirements for practitioners who operate diving operations -- unless such operations also provide HBOT for other conditions. In the discussions with the Working Group, it was agreed that the use of chambers in the diving industry for prophylactic decompression appears to be adequately regulated by WorkSafe BC.

The Panel's mandate does not include a review of the evidence for or against various indications for the use of hyperbaric oxygen therapy. At the present time, Health Canada has a list of 13 approved conditions for which it is satisfied that there is sufficient evidence to warrant the provision of HBOT (see Appendix 2). While many practitioners argue that there are many other conditions (off-label) for which HBOT can be an effective therapy, this issue is outside the mandate of the Panel.

The Panel was also provided with many opinions and comments related to public funding of HBOT (currently funding is only provided for patients who receive HBOT in publicly funded facilities). While this was clearly an important issue for clients and those providing HBOT, this is outside the terms of reference of the Panel.

Another limitation included the fact that the Panel did not interview individual clients who were receiving HBOT.

The Panel, by design, were independent members who were selected for their management, health care and legal backgrounds but they are not "experts" in the field of HBOT.

Finally, like any complex process, there is always the limitation of time and resources—the Panel was asked to conduct their work over a period of 8 months and with a limited budget and resources. We are confident that this was sufficient to do our work, however, we could have done more in- depth work and more research if additional time and resources were available.

DESCRIPTION OF THE PROCESS UNDERTAKEN:

After the Panel was appointed we met with representatives of the Ministry of Health Services. We were given a summary of the background on the issue to provide context; discussed the terms of reference; and reviewed our roles and responsibilities.

We were provided with background documents, including the proceedings of the Working Group; and current legislation (i.e. the *Health Professions Act*); etc. The initial work of the Panel involved reviewing these documents, developing an action plan to conduct our review, and clarifying the process we would use to carry out the review.

Early in the process, the Panel decided it was important to be as inclusive as possible and provide an opportunity for people to provide their input to the Panel. The Panel also wanted to act fairly and equitably so there would be no perception of bias or treating one party differently from others. The Panel, while appreciating the support from the Ministry of Health Services, was also mindful of ensuring that it acted independently and was not influenced by the Ministry.

After reviewing materials and establishing some ground rules for operation, the Panel decided it would be informative and important for the Panel members to carry out a

small number of site visits where HBOT is currently being provided. Members agreed it would be useful to visit the one publicly funded facility at VGH; one privately operated facility which was not being operated by a medical doctor or naturopath; and one privately owned facility under the supervisions and direction of a naturopath. Meetings were arranged for all of these sites and the Panel spent several hours at each site — reviewing the physical plant; and interviewing operators of the facility. These visits were extremely helpful to the Panel and illustrated the diversity of the various operations in BC.

In addition, the Chair was specifically asked by one private practitioner to visit his HBOT operation in Vancouver. The Chair complied with this request and visited the site.

Concurrently with the site visits, the Panel also began to organize a process for inviting and receiving submissions from interested parties. It identified potential organizations which may have an interest in presenting their views to the Panel (e.g. Colleges, private HBOT facilities). These organizations were sent letters, signed by the Chair, inviting them to provide submissions to the Panel. Written submissions were requested by April 2, and May 5 was established as the date when those wanting to could make an oral presentation to the Panel.

The Panel received three written submissions. In addition, four oral presentations were made on May 5 with each presenter also providing the Panel with copies of their presentations, therefore, a total of 7 submissions were made to the Panel. The Panel then reviewed and considered all of the information presented, along with site visit notes, readings and other documents, and developed its plan for writing the final report.

OBSERVATIONS, FINDINGS AND KEY ISSUES:

The Panel determined that one of the clearest ways of presenting its findings was to separate those relating to the individual or patient from those dealing with the facility or chambers used in the delivery of HBOT. What follows is a brief discussion of these primary observations, findings and key issues as they relate to both these components, followed by a set of recommendations prepared by the Panel.

The Patient:

In order to safely provide HBOT to a patient, the Panel identified a number of key issues that must be addressed by the practitioner/provider of this treatment. These include:

1. *Assessment* - As with any medical treatment, it is vital that all patients who undergo HBOT first be given a proper medical assessment including a full medical history, examination (if necessary), and review of current symptoms and treatments previously undertaken. The assessment should be done by a practitioner who is trained (qualified) to do so.

It is only through doing an assessment that the practitioner can confirm the patient's diagnosis and identify any risk factors or contraindications (e.g. having undergone

doxyrubicin chemotherapy within the last week or having optic neuritis) before undergoing HBOT. In addition, the practitioner can confirm the reason for the patient's visit to the clinic and satisfy him/herself that the patient is an appropriate candidate for undergoing HBOT at their facility.

The results of the Assessment must be recorded in writing or kept electronically in a file dedicated to that patient and accessible to other treating personnel at that facility.

The Panel is aware that some facilities adopt a far more casual approach to assessing patients before providing them with treatment. In the Panel's view, it is not appropriate (for either on or off label treatment) to simply ask the patient two or three questions on the fly and immediately book them for treatment.

2. *Referral* - The practitioner must have sufficient skills and training to identify when it is appropriate to refer the patient to another practitioner who may be able to provide more appropriate care and treatment to the patient.

3. *Planning* - After a proper assessment of the patient, the practitioner must develop an appropriate treatment plan to address the needs of the patient, including frequency and duration of treatments and levels of pressure to be used.

A planning document must be added to the patient's file and be accessible to other treating personnel at the facility.

4. *Informed Consent* - Good communication between provider and patient is critical. The practitioner must ensure that Informed Consent is secured from each patient. The Informed Consent must be in writing and include a full discussion in plain language of all the risks, potential complications and side effects that could be experienced when undergoing HBOT. It should also be supplemented by an unbiased discussion of the strength of evidence supporting HBOT therapy for the patient's particular condition.

The Panel was concerned that some practitioners did not provide sufficient information to ensure Informed Consent, especially around the real risks and potential benefits of HBOT. A related issue concerns providing information about the financial costs for treatments and the difference between the charges in a private facility versus a public facility.

The signed Informed Consent document must also be included in the patient's file.

5. *Record Keeping and Documentation* - The practitioner must open a file on each patient seen in an HBOT clinic whether or not the patient decides to proceed with the treatment. It is a part of any professional's role to properly document and record all relevant information related to the patient, to ensure both safety and accountability. This patient file should be kept for as long as the appropriate regulatory bodies under the HPA require.

The Panel was concerned that not all HBOT facilities were scrupulous about record keeping. The Panel found this practice dangerous and unprofessional for both the patient and the providers.

6. *Patient monitoring* - There must be a fully trained and qualified staff person monitoring each patient while they are in the chamber. The staff can then make any adjustments needed as treatment progresses and can respond to any medical complications experienced by the patient.

Complications range from very serious and life threatening though rare (e.g. respiratory failure, tension pneumothorax, seizures and congestive heart failure) to more common side effects, which can be very frightening to the patient (e.g. refractive changes, middle and inner ear damage, confinement anxiety and low blood sugar)

7. *Response to Emergencies* - Although rare, serious and adverse events do occur. The Panel felt strongly that each practitioner must ensure that at least one person on their staff is properly trained and qualified to respond in an appropriate and timely manner to all potential medical emergencies.

It is difficult to understate this requirement since it is critically important for the safety of every patient who enters an HBOT chamber. Practitioners must be vigilant that all medically trained staff receive on-going training and certification.

8. Assessing Effectiveness of Treatment - It is important that each practitioner be able to determine, while the patient is undergoing treatment, whether the HBOT is effective and meeting the desired treatment goals for the patient.

Facilities/Chambers:

With respect to the operation of these chambers, certain basic issues became clear in the course of our study. They are as follows:

1. *Physical Plant* - A critical factor in providing HBOT in a safe manner is having a chamber and physical plant that meets or exceeds all safety standards. This includes having the HBOT chamber inspected by Health Canada and using the chamber only for approved purposes.

2. *Fire Suppression* - Given the great risk and devastating consequences of fire related incidents, it is essential that all necessary fire suppression equipment be available and in good working order to ensure the continued safety of staff and patients. Regular servicing and independent inspections by Work Safe BC and local fire departments should be carried out and noted in writing.

3. *Accreditations and Inspections* - All providers should ensure that their facilities are accredited by the Undersea and Hyperbaric Medical Society (UHMS) or their governing

Colleges and all required inspections (BC Safety Authority, WorkSafe BC, local fire departments, etc) are performed regularly.

4. ***Manuals and Protocols*** - The provider should create and maintain manuals and protocols for medical and systems emergencies (including fire); maintenance and servicing of all equipment (including a set timeline for accomplishing each task); and operating procedures for using the chamber.

5. ***Training*** - It is essential that all technical staff be appropriately trained in order to ensure they are familiar with the operation of all the boilers, pressure vessels and other equipment that they will be operating. Such training should also be updated regularly.

6. ***Servicing*** - Regular servicing is essential for the continued safe operation of the chambers. It should either be done by properly trained technical staff or contracted out to the required professionals on a regular basis (e.g. at least annually).

7. ***Maintenance*** - In order to ensure overall safety for staff and patients, it is essential that all HBOT providers have a regular, comprehensive and enforced maintenance program for each chamber in their facility and all other equipment which supports their operation.

It is the Panel's view that all of the issues set out above concerning both patients and facilities, must be addressed when developing standards and requirements for practitioners to provide HBOT in BC.

RECOMMENDATIONS OF THE PANEL:

In coming to its recommendations, the Panel felt guided by three important principles:

(a) The health and safety of both patients and workers should be of primary importance.
(b) Insofar as possible, all British Columbians should have reasonable access to HBOT services.
(c) The patient's right to make choices based on appropriate and accurate information should be preserved.

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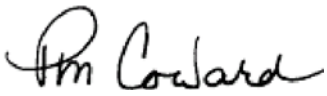
CONCLUSION:

We strongly urge the Ministry of Health to consider the recommendations made in this report and take actions to implement those that it considers appropriate. Having said this, we also appreciate that other bodies at the local, provincial and federal levels play a significant and important role with respect to HBOT and it will be important for all agencies and bodies involved with HBOT to meet their responsibilities if HBOT is to be provided safely in BC.

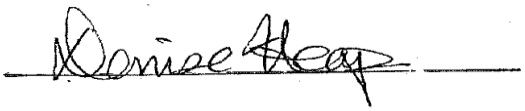
Implementation of the recommendations in this report will be an important step in protecting the health and safety of clients receiving HBOT, as well as the staff involved in the provision of HBOT.

Respectfully submitted,

Paul Pallan, Chair



Pat Coward



Denise Heap

August, 2010

APPENDIX 1

HYPERBARIC OXYGEN THERAPY ADVISORY PANEL

TERMS OF REFERENCE
January, 2010

MANDATE

The purpose of the Hyperbaric Oxygen Therapy (HBOT) Advisory Panel is to recommend what the standards and requirements should be for practitioners for the provision of hyperbaric oxygen therapy in British Columbia.

SCOPE

The panel is to operate under the assumption that the practice of HBOT will become a restricted activity under the *Health Professions Act.* Only Medical practitioners and Naturopathic practitioners are currently authorized to perform this activity in

British Columbia.

The panel's mandate does not include a review of the evidence for or against various indications for the use of hyperbaric oxygen therapy.

ROLES & RESPONSIBILITIES

1. Propose specific criteria for evaluating what the standards and requirements should be for practitioners to provide hyperbaric oxygen therapy in British Columbia (This could include recommended Ministerial regulations respecting limits or conditions on service, or the delegation to unregulated persons that would override standards of practice set by the colleges).
2. Review pertinent reports, studies, and other documents that may assist in making recommendations.
3. Review practices and experiences in other jurisdictions.
4. Gather and review information and submissions from professional colleges and other interested parties. (Note: Panel is responsible for organizing presentations from interested parties. Meetings will be open to the public in accordance with Part 1.1 – Advisory Panels, Section 6.4 of the *Health Professions Act*.)
5. Recommend what the standards and requirements should be for the provision of hyperbaric oxygen therapy in British Columbia.

6. Advise the Minister of Health Services within 6 months of the panel being established, of the panel's findings, conclusions and recommendations.
7. Retain all records of proceedings, including submissions (for *Freedom of Information Act* purposes. Records will be filed with the Ministry of Health Services at the end of the advisory process.

CHAIR

Paul Pallan

MEMBERSHIP

Paul Pallan, Pat Coward and Denise Heap

Members:

- Academia: University of Victoria, Occupational Health, Safety and Environment/University of British Columbia, School of Environmental Health
- Lawyer: Experience in health law/medical legal litigation
- Other Jurisdiction Expert
- Former distinguished public servant

ACCOUNTABILITIES

Reports to the Assistant Deputy Minister of Health Human Resources. Timing of reporting to be determined.

COMMITTEE OPERATIONS

Meetings will be held once a month, or at the call of the Chair.

ADMINISTRATION

Remuneration to panel appointees will be made according to Treasury Board Directive 1/08, *Remuneration Guidelines for Appointees to Crown Agency Boards*:

Section 4.3
The Minister responsible
(b) May approve remuneration of up to $350 per diem for the Chair of an Advisory Board in his/her portfolio of Crown Agencies.

Section 7.1
In accordance with Treasury Board Directive 1/08 the Chair is entitled to remuneration in respect of travel time undertaken in the course of his or her duties if he or she resides more than 32 kilometres from the destination location.

Section 7.2
All appointees incurring transportation, accommodation, meal and out of pocket expenses in the course of their duties as members of the panel will be reimbursed in accordance with Group II rates, policies and procedures.

APPENDIX 2

Approved Uses of Hyperbaric Oxygen Therapy
Health Canada

1. Air or Gas Embolism
2. Carbon Monoxide Poisoning
3. Clostridal Myositis and Myonecrosis (Gas Gangrene)
4. Crush Injury, Compartment Syndrome, and Other Acute Traumatic Ischemias
5. Decompression Sickness
6. Enhancement of Healing in Selected Problem Wounds
7. Exceptional Blood Loss (Anemia)
8. Intracranial Abscess
9. Necrotizing Soft Tissue Infections
10. Osteomyelitis (Refractory)
11. Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
12. Skin Grafts and Flaps (Compromised)
13. Thermal Burns