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#### **EDITORIAL**

#### The Professional Organization and Communication

Professional organizations have been called "organized anarchies" by some management analysts. By this, presumably, they mean that individuals exert their skill and knowledge and work relatively independently of their colleagues but work closely with clients or patients that they serve. Despite standardized knowledge and skills, we all use considerable discretion in the application of those skills. Up until recently, there was little need for direct supervision in management and little need for mutual adjustment among physicians. The "organized anarchy" worked well.

With the coming of the need to "manage" professionals, their numbers, their income and their standards, then the professional organization and its administrators assume increased importance. Hence, our medical societies, with medical and lay leaders, have more and more "indirect" power, as well as quite direct power in levying mandatory dues and in the control of our incomes.

As a result of this increasing power in our lives, it is quite right that The Medical Society is now reexamining its organization and changing its structure. The recent survey soliciting our views on all aspects of The Society is an effort at communication with members that becomes essential. This survey comes at a time when it is also appropriate to look at all aspects of our communication policy.

Our failure to communicate with society, the government and among ourselves is felt by many to add to our present morale problems.

Many members may now believe it is time to carefully scrutinize perceived communications problems. To do this properly, however, doctors will have to be prepared to pay more attention to the information they receive from The Society. Members will also have to be willing to personally play a role in improving and developing new strategies because, complaining "I don't know what is going on" won't stand up, if you don't read mail from The Society or if you have no interest in activities that would enhance both internal and external communications.

This Medical Journal, for over seventy-one years of its existence, has been an important part of communication strategy and useful for education of ourselves and others outside the profession. Its general mission has been to provide a vehicle for physicians to publish research, educational, historical, and sometimes creative work at a level that would meet the high standards of Nova Scotia physicians. As an educational and scientific publication it has been allowed favourable mailing rates and been able to attract advertising on the basis of its stated mission. (It has also been supported by a subscription from all members and an outside subscribers list).

Other vehicles for communication, such as newsletters and *Informed*, have also evolved with need which continues to change at an ever increasing rate. An example of this change is the Peer Review Program that is now beginning, with established guidelines being applied to all four Atlantic provinces. With many other issues being common to the region, a mutually supported and administered journal has been explored but with limited success: discussions will continue.

More efficient cooperation between *The Nova Scotia Medical Journal*, *Newsletter*, and *Informed* has also been considered with examination of all options of expansion, joining or simply maintaining what we have. One rapidly reaches the conclusion that what we need is better communication both within and outside The Society, not more or less. Nor should we make change for the sake of change. While we wish to be pragmatic especially relative to cost, there are many complexities that limit change, such as mailing costs and advertising revenue. What looks expensive may save money and what looks like a saving may be more expensive or less efficient.

It would be best if a policy concerning communication was developed prior to deciding a vehicle but once again professional organizations don't do this very well, especially in changing times.

Because we are democratic and despite being autonomous professionals, we must effectively coordinate our efforts. It is only by good communication that we will avoid being an "organized anarchy".

J.F.O'C.

#### Atlantic Provinces Medical Peer Review

#### UPDATE

The Program is still in its developmental stage but it is progressing well. An initial core of fifteen assessors has been selected, five in Nova Scotia, four in each of Newfoundland and New Brunswick and two in Prince Edward Island. A workshop has been held for these fifteen, conducted by Dr. Victor Waymouth who administers the Program in British Columbia. The office practices of each of these fifteen is to be assessed by two of the others as an educational roundrobin. The first have already been done and they will all be completed by the end of May.

Reports on the initial fifteen assessments will be reviewed by the Assessment Committee in June and then policy decisions will be made by the Steering Committee on a number of procedures.

We expect to carry out 35 to 40 assessments in the second half of the year on physicians who will be chosen by random selection.

We are experiencing a small glitch in getting uniform Legislation passed in each of the four provinces. We are having no problem in New Brunswick but the Legislatures in each of the other provinces are disrupting the usual scheduling by holding elections.

Victor D. McLaughlin, MD Executive Director

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#### Preparations are already underway for the annual billing of The Medical Society dues.

With the growth of The Society, the variety of billing requirements, changes in our mailing list and membership records, it is important to plan ahead and start preparations early.

We know that the status of some members has already changed and that others intend to change in the

coming year.

Unless notified, we will be billing according to last year's records.

## Constitutional Implications of Geographical Limits on Physician Deployment

Stephen G. Coughlan,\* LLB, PhD and Dale Darling,\*\* MA, LLB

Halifax, N.S.

The Medical Society of Nova Scotia, at its last annual meeting, approved a motion to "begin discussions on methods to limit physician deployment to only those areas where a need can be demonstrated". It is possible that this motion only intended that particular incentives should be offered to draw doctors to areas of the province where they are most needed, or similar measures. However, the language of "limits" sounds more like legislative restrictions on where doctors can practise: government action of a sort which, in other provinces, has been found to violate rights guaranteed under the Canadian Charter of Rights and Freedoms. Whether the Provincial Government can respond to the motion of the Medical Society, and if so how, is therefore a legal question of some weight.

This paper will set out the constitutional issues involved in any attempt to limit the issuing of billing numbers. It is not intended to provide advice to government, or formulate appropriate legislation: it should, however, acquaint the interested observer with the necessary considerations.

Two major constitutional questions arise in connection with any attempt to restrict the practice of medicine by restricting the issuance of billing numbers. The first is whether the contitution is relevant at all - whether the action of the government can even be challenged under the *Charter*. The second issue is whether, assuming that a *Charter* challenge can be mounted, it will be successful.

These issues have already been addressed in British Columbia, where a particular attempt to restrict billing numbers was found to be unconstitutional. It does not automatically follow, however, that courts in Nova Scotia would reach the same decision, even if faced with exactly the same scheme. Further, there might be room to differ from the scheme instituted in British Columbia, and enact policies which withstand *Charter* scrutiny.

#### WOULD COURTS IN NOVA SCOTIA FIND THAT THE CHARTER IS RELEVANT?

In British Columbia, a scheme was enacted whereby billing numbers were denied to doctors who wanted to practise in areas where the Medical Services Commission felt that sufficient medical services were already available. In addition, other doctors were granted numbers that were only usable within a limited geographic area, or which allowed them to practise only on a *locumtenens* basis. The intent behind the scheme was both to limit costs, and also to help see to it that medical services were made available across the province.

A number of doctors who were denied full billing privileges challenged the scheme in court. They argued that their rights under the *Canadian Charter of Rights and Freedoms* were infringed. In particular, they complained of a violation of s.7 of the *Charter*, which states that:

Everyone has the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice.

The doctors claimed that in being denied the opportunity to practise medicine (either at all, or in an unrestricted way), they were being denied their rights to liberty and security of the person.

The initial hurdle for this argument is the question of whether the *Charter* is applicable at all. It is generally accepted that the *Charter* does not create or protect economic rights. No reference to property rights is made in the *Charter*, and that omission was deliberate. Supreme Court of Canada and provincial Court of Appeal decisions have concluded that the *Charter* "does not concern itself with economic rights". In particular, the s. 7 guarantee "does not extend to an unconstrained right to transact business whenever one wishes". At first blush, therefore, one would expect that the right to bill for medical services wherever one wishes - the right to earn a living - would be considered an economic right, and therefore not protected by the *Charter*.

However, the British Columbia Court of Appeal makes a distinction between a "right to work" and a "right to pursue a livelihood or profession". The latter issue, says the Court, raises questions of "dignity and self-worth" which bring the issue into the sphere of "liberty" as meant in s. 7. Accordingly, they hold that the doctors' *Charter* rights were infringed, and so a challenge can be mounted to the legislation.

The first question in determining whether legislation restricting billing numbers in Nova Scotia could be successfully challenged must be whether the Nova Scotia Court of Appeal would accept the distinction made in British Columbia. Provincial Courts of Appeal are not bound to follow one another's decisions, and do often disagree on fundamental points. In Ontario, for example, the distinction made in British Columbia seems to

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have been rejected. The Ontario Court of Appeal has held in several decisions that s. 7 provides no guarantee with respect to employment, and further that "there is no constitutional right to practise medicine". An Ontario lower court case, considering these decisions and those from British Columbia, concluded that the law in Ontario was unchanged, and that s. 7 does not "encompass the liberty to carry on a business or to practise a particular profession...".5

This disagreement can only be resolved by the Supreme Court of Canada. To date, however, no definitive statement on the issue has come from that court. Chief Justice Lamer has discussed the British Columbia Court of Appeal decisions, holding that "the distinction sought to be drawn by the court between a right to work and a right to pursue a profession is, with respect, not one that aids in an understanding of the scope of 'liberty' under s.7 of the Charter". However, Justice Lamer was speaking only for himself: the majority of the Court expressed no opinion on the point.

In the meantime, the question is what decision the Nova Scotia Court of Appeal would reach on the issue. Our court has never been required to address the restriction of billing numbers directly. However, in a different context, the Court has quoted the British Columbia decisions and accepted that disciplinary proceedings against a doctor can potentially violate s. 7 of the *Charter*. Accordingly, it seems likely that they would accept the British Columbia approach in this context as well, and therefore that restrictions on billing numbers could in principle violate the *Charter*. In that event, it becomes necessary to consider how legislation can be framed so that it survives *Charter* scrutiny.

#### WHAT TYPE OF RESTRICTIONS WILL NOT VIOLATE THE CHARTER?

The rights guaranteed in the *Charter* are not absolute: rather, they are all subject to "such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society".8 Further, the guarantee to life, liberty and security of the person in s.7 is specifically not absolute: one is only guaranteed "the right not to be deprived thereof except in accordance with the principles of fundamental justice". In practice, these two sets of limitations are not perfectly distinct, but the interplay between them is not crucial to this discussion. The important point is that even if restrictions on billing numbers violate the liberty of physicians in some way, that limitation might still be upheld under the *Charter*.

The Supreme Court of Canada has decided that the "principles of fundamental justice" include not just procedural rights, but substantive rights as well. Thus, for example, some deprivations of liberty – imprisonment for crime – can be justified, so long as the procedures leading to that result are fair. Other interferences with liberty or security of the person, however, can be so extreme that no amount of procedural fairness along the way will be satisfactory: a process that would result in a person being tortured, for example, will not be

substantively fair, no matter what procedural safeguards are built in.

In British Columbia, the Court held that the scheme for restricting billing numbers failed on both procedural and substantive grounds. It is instructive to see what features caused that scheme to fail, in order to assess how a "Charter-proof" scheme might be crafted.

The procedural complaints about the British Columbia system are most readily dealt with. In general, the Court said that the scheme is "based on the application of vague and uncertain criteria, which combined with areas of uncontrolled discretion, leaves scope for arbitrary conduct".9 Specific shortcomings were also noted. Decisions were to be made by one person, who was not required to give the applicant a hearing, or to provide reasons for the decision made. There was no method by which an applicant could determine in which part of the province billing numbers might be available, and no way to challenge the evidence as to the need for physicians in a given area. Indeed, the Court noted that information about need might have been provided by the physicians already working in the area, who could be considered the competitors of physicians hoping to move there. Finally, the fact that doctors with existing, unrestricted numbers could move freely within the province would mean that an applicant was not assured of remaining in the same place in the queue for numbers.

A procedure which avoided most or all of these short-comings would be more likely to pass *Charter* scrutiny. A plan could, for example, entitle any doctor refused a number (or granted a more restricted number than he or she applied for) the right to appeal the decision. The newly-constituted Health Services and Insurance Commission, already intended to deal with denials of the right to bill under MSI in a different context, might be a natural candidate to take on this task. Information about the number of doctors in each part of the province, and the criteria to be used in determining whether more are needed, could be made freely available, allowing applicants to know both in general and in their particular case the factors affecting the decision.<sup>10</sup>

More difficult to deal with are the substantive complaints. Some of the more extreme statements from the British Columbia Court suggest that *no* scheme that interfered with a physician's unrestricted right to practise, and to bill the compensation scheme for practising, anywhere in the province could be successful. In that event, of course, no proposed changes would help. However, some more specific objections are made, and it seems they can be answered.

One criticism, for example, is that the scheme imposes the entire burden on new or out-of-province doctors, since they are the only ones who will suffer from new restrictions on billing numbers. As these doctors are not especially responsible for the excess cost of the health care system, it is unfair to ask them to shoulder the entire burden.

Two answers could be made to this objection. First, it would be possible to introduce a scheme that attached

geographic restrictions to existing billing numbers. This solution seems unlikely to be adopted, and indeed would probably be subject to *Charter* challenge itself. Secondly, though, such an extreme step is not necessary. In Nova Scotia, it would not be true that new and out-of-province doctors were being asked to shoulder the entire burden. Restrictions on billing numbers would be part of a package of steps to contain costs, including caps on billings which apply to all physicians. Although restrictions on billing numbers would not affect all doctors equally, no one group would be responsible alone. Further, other measures, such as giving doctors with restricted billing numbers priority in obtaining unrestricted numbers when they become available, could reduce the impact on those most affected.

Similarly, the British Columbia Court observes that the measure is intended to achieve cost control and control over allocation of physician services around the province: however, the government did not show that "the distribution of medical services is a societal concern of such magnitude that it merits interference with such basic liberties". 11 In Nova Scotia, this evidentiary problem does not arise. The Royal Commission on Health Care noted that "the distribution of services in certain areas and among certain types of medical practice was identified as a concern during the Royal Commission's Public Hearings". 12 The Royal Commission concluded that "there is a need to control the factors of supply, utilization, remuneration, and distribution of physicians and their services". 13 Indeed, the resolution of the Medical Society itself, calling for methods "to limit physician deployment to only those areas where a need can be demonstrated", is evidence of the seriousness with which the problem is regarded.

The British Columbia court should not be taken to have excluded *any* possibility of restricting billing numbers: it merely calls for "less intrusive means". It is true that the financial problems of the health care system cannot be addressed solely through restrictions on billing numbers. But at the same time, it is unrealistic to think that total costs can be reduced – or that greater regional control over funding could be instituted, as the Royal Commission recommended – in the face of a complete inability to control the 21% of expenditures that are accounted for by payments to physicians. <sup>14</sup>

Measures to restrict the deployment of physicians, if they are to include restrictions on billing numbers, must be carefully crafted. It seems likely that such limits can withstand a *Charter* challenge: however, they must be designed with that eventuality in mind, and must respond in advance to the concerns about openness, fairness, and a reasonable division of the burden that will inevitably arise.

#### ACKNOWLEDGEMENT

The authors thank Rita Ellis for her contribution to this article.

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- See Reference re Compulsory Arbitration, [1987] 1 S.C.R. 313 at 412, or Attorney General (Quebec) v. Irving Toy Ltd., [1989] 1 S.C.R. 927.
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   See Khaliq-Kareemiv. Health Services and Insurance Commission (N.S.) (1989), 89 N.S.R. (2d) 388 (N.S.S.C.A.D.).
- 8. See s. 1 of the Charter.
- 9. Wilson, footnote 1, p. 196.
- Though it is worth noting that criteria like these, dealing with the ratio of doctors to the population, were set out in the British Columbia plan, but did not save it.
- 11. Wilson, footnote 1, pp. 197-198.
- 12. The Report of the Nova Scotia Royal Commission on Health Care Towards a New Strategy, (Halifax: Nova Scotia Royal Commission on Health Care, December 1989), p. 20.
- 13. Ibid.
- 14. Ibid., p. 16, figure 2.4.

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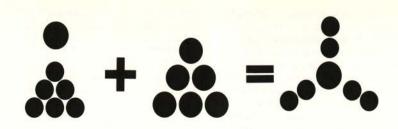
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## Complications of Parenteral Neuroleptics and Their Management

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Halifax, N.S.

Neuroleptics (also known as antipsychotic drugs or major tranquilizers, e.g., haloperidol and chlorpromazine) have been consistently effective and safe in clinical practice for managing agitated, excited, belligerent and other expressions of psychomotor "over-arousal" since their introduction in the 1950s. Because this type of problem behaviour is distressing and potentially dangerous for the patient or others (as in a delirium or in an acute schizophrenic episode), it is necessary to bring it under control as quickly as possible. In these acute situations, oral administration is often not very satisfactory for several reasons - it takes too long to achieve a steady state, the correct dose is difficult to predetermine since there can be a twelve fold difference in plasma levels of patients taking similar oral doses, and there is a very significant hepatic first-pass destruction (some studies have shown that up to 70% of oral haloperidol is destroyed by first-pass

For these reasons and because of trial and error experience over the years, the giving of neuroleptics by intramuscular and occasionally by intravenous injection has become the standard approach for managing the early phases of such clinical syndromes as deliria, acute schizophrenic decompensations, other acute paranoid syndromes, the manic phase of bipolar illness (usually with lithium) and, in general, whenever there is excited, overactive, belligerent or agitated behaviour requiring a tranquilosedating drug.

Theoretically, any neuroleptic available in a water vehicle for intramuscular use can be used but, in recent years, it is evident that haloperidol (Haldol®) and to a lesser extent loxapine (Loxapac®) have emerged as the agents of choice. There are good reasons for this. The bulk of the injection is small (e.g., an effective dose of haloperidol is 5 mg i.m. which is contained in 1 ml; similarly, an effective dose of loxapine for a delirious patient might be 25 mg i.m. which is contained in 0.5 ml) and therefore there is less discomfort and tissue damage. There is also less hypotension and other autonomic effects with these drugs in comparison with aliphatic phenothiazines such as chlorpromazine (Largactil®) or methotrimeprazine (Nozinan®). However, there is an

increased risk of extrapyramidal side effects but these are only occasionally troublesome.

One of the positive features of potent drugs like haloperidol that is sometimes mentioned is the 'low sedation' effect. This can sometimes be advantageous in schizophrenic illnesses but may be disadvantageous, for example, in an agitated delirium. Hence, when sedation is particularly required, there is a current fashion to add a benzodiazepine like lorazepam 2 mg i.m. to the haloperidol or other high potency neuroleptic. Intramuscular haloperidol and lorazepam can be mixed in the same syringe and are stable for up to 24 hours if protected from light.1 Loxapine is a dibenzoxazepine neuroleptic and therefore is chemically different from haloperidol or the phenothiazines. It has been reported to be as effective and has fewer extrapyramidal side effects than other neuroleptics for psychotic symptoms and possibly may be more effective for the agitated, excited and aggressive behaviour of some older demented patients.2

The frequency of intramuscular injections can vary from a standard approach with the injection given every four hours for about one or two days (and if there is a good response reduce the dosage or increase the interval), to a more 'rapid technique' where the neuroleptic is given every half or one hour until symptomatic and behavioral improvement is evident. With the 'rapid technique', amelioration of the psychomotor agitation is often achieved within a couple of hours.3 Intravenous neuroleptics, especially intravenous haloperidol, are sometimes used in coronary care units for deliria and other confusional states when intramuscular injections are usually avoided because they interfere with the correct reading of cardiac muscle enzyme estimations. The intravenous technique may occasionally be used for severe psychotic excitement although for practical reasons this route may be unworkable in these patients.4

Whether the neuroleptic is given i.m. or i.v., it is important to individualize the dosage and to start with a standard 5 mg injection of haloperidol or 25 mg of loxapine with lower doses for elderly patients. Depending on the response this dosage is continued or is increased or decreased as necessary. Dosages beyond 100 mg of haloperidol in 24 hours (or an equivalent dose of other neuroleptics) are not recommended since there is an unacceptable increase in adverse effects. As a matter of interest, the current practice of adding a benzodiazepine like lorazepam to haloperidol has meant using much smaller doses of the neuroleptic than for-

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merly with a ceiling dose of haloperidol, probably under

40 mg per day.

However safe and effective parenteral neuroleptics are in general, there is always the risk of complications and serious adverse effects in certain patients. This is especially so in 'medically ill' as distinct from 'psychiatrically ill' patients since one has to contend with the medical or surgical illness as well as with the pharmacokinetic impact of concurrent drugs. The complications may vary from simple soreness and redness at the injection site (this can be minimized by allowing the alcohol from the wipe to completely evaporate) to a very serious and frightening laryngeal spasm.<sup>5</sup>

The purpose of this paper is to alert the clinician to the more important and life threatening adverse effects that can follow parenteral neuroleptics and to outline some

treatment strategies.

#### EXTRAPYRAMIDAL COMPLICATIONS

These are the most obvious and best known adverse effects of neuroleptics. Dopamine receptor blockade in the corpus striatum (with acetylcholine dominance and increased GABA outflow) has been suggested as the mechanism involved. An interesting paradox is that fewer extrapyramidal effects are noted with parental and high dose neuroleptics than with smaller doses taken orally. Further, giving anticholinergic drugs prophylactically will not always prevent basal gangliar reactions and they may be undesirable with parenteral neuroleptics because of their potential to cause additional atropine-like C.N.S. effects.

The following adverse effects are noteworthy:

#### **Acute Dystonic Reaction**

This is an abrupt onset of muscle stiffening and twisting which can involve many different muscle groups. The muscles of the face, neck, spine and extremities can be involved and sometimes it includes the muscles that control eye movements (oculogyric crisis). The clinical picture is so unusual and the posture so distorted that it is sometimes labelled "bizarre" or "hysterical". It is a highly distressing and frightening experience for the patient and requires emergency treatment. Fortunately, it can be relieved within several minutes by an injection of any anticholinergic drug including benztropine mesylate (Cogentin®) 2 mg i.m. or i.v. or diphenhydramine (Benadryl®) 50 mg i.m. or i.v. Diazepam 10 mg i.v. or 4 mg of sublingual lorazepam may also be used if the anticholinergic drugs are not available. Sometimes a repeat injection is required within the hour. The patient should remain in a quiet darkened room to facilitate recovery. The tablet form of the anticholinergic drug should be given for 2 to 3 days after the injection to make sure the neurotransmitter balance is reestablished. If neuroleptics are still indicated for the patient they may be reintroduced cautiously, with a concomitant anticholinergic regime and careful monitoring.

#### Laryngeal and Pharyngeal Dystonia

This is an uncommon acute extrapyramidal reaction that involves spasm of the muscles of the larynx. The patient is acutely distressed, gasping for air, gagging and pleading that they "cannot breathe". There is usually cyanosis. If the pharyngeal muscles are involved, the patient appears to have a bulbar-palsy like syndrome and gags, cannot swallow and complains of tightness in the neck muscles. This complication is considered striopallidal and responds promptly to benztropine or diphenhydramine as described under Acute Dystonic Reaction.

#### Acute Parkinsonism

Parenteral neuroleptics can induce in some patients an abrupt, rapidly worsening parkinsonism with varying degrees of tremor and rigidity. A variant of this is a depressive-like akinesia which causes the patient to complain of fatigue, weakness and sleepiness. These can be promptly reversed by using the usual anticholinergic drugs as described under Acute Dystonic Reaction. With akinesia there is no need to use the drugs parenterally and, if the neuroleptic continues to be required, anticholinergics should be coadministered with the neuroleptic.

#### Akathisia

This literally means 'unable to sit still' and refers to a neuroleptic complication with both subjective and objective features. The etiology is complex and there appears to be more involved than simply neurotransmitter disturbance in the basal ganglia.8 The patient complains of a distressing restlessness and a compelling need to be in constant motion. There may be complaints of a 'crawling' sensation in the legs or an 'inner anxiety' in the abdomen which is relieved by walking. Objectively, the patient looks agitated and distressed and it is often difficult to distinguish this side effect from the original agitated psychomotor state or psychotic excitement for which the neuroleptic was first prescribed. Mild states of akathisia, which include muscle cramps and restlessness, may occur shortly after the neuroleptic injection but they are transient and are not usually bothersome.

The treatment of this condition can be a problem although, if the neuroleptic is stopped, the side effect improves fairly rapidly. If the neuroleptic must be continued, reducing the dosage or increasing the interval between injections can help. Antiparkinson drugs may help some patients with akathisia but for others seem to give only partial relief. For other patients, they often do not work at all. Propranolol, 20 to 80 mg a day is often the most useful corrective drug but it is contraindicated if the patient has bronchial asthma, left ventricular failure, bradycardia or Raynaud's disease. Other drugs reported as occasionally useful include amantadine, benzodiazepines and clonidine.<sup>9</sup>

#### Hypotension (Hypotensive Crisis)

Severe hypotension can occur occasionally following parenterally neuroleptics. The mechanism is via centrally mediated pressor reflexes and alpha adrenergic receptor blockade. Neuroleptics like haloperidol, loxapine and perphenazine (Trilafon®) are much less likely to cause this than aliphatic compounds like chlorpromazine (Largactil®) and methotrimeprazine (Nozinan®). Profound orthostatic hypotension can also occur. The sudden drop in blood pressure may precipitate syncope which may be difficult to differentiate from a seizure. Although patient idiosyncrasy is likely the main risk factor for this complication, large initial doses parenterally can also be responsible. Management includes giving noradrenaline (Levophed) with elevation of the feet and lowering of the head. Adrenalin (epinephrine) should not be used since it will cause a further lowering of the blood pressure. When neuroleptics are given i.m or i.v., it is prudent to start with modest doses and to have the patient reclining.

#### Cardiac Arrhythmias

There is a large published literature on this topic and useful comprehensive reviews are available. <sup>10,11</sup> In general, very few serious adverse cardiovascular effects have been reported with parenteral neuroleptics even using the rapid technique. <sup>12</sup> Neuroleptics have direct effects on the heart and blood vessels and indirect effects through the central nervous system and autonomic reflexes. Hypotension is the most common cardiovascular effect that clinicians are likely to see. The drugs also have a direct depressant action on the myocardium and can display antiarrhythmic properties like quinidine (repolarization abnormalities) and prolongation of the PR and QT intervals with depression of the ST segment and flattening and other deformation of the T wave.

Most of the serious cardiac complications including arrhythmias have been reported with oral thioridazine (Mellaril®) and chlorpromazine (Largactil®) or following very large oral doses of these and other neuroleptics and especially following overdoses. The literature on the direct cardiac effects of parenteral neuroleptics is scanty. Most of the papers discuss cardiac arrhythmias and sudden cardiac death following toxic overdoses of oral drugs or when patients have had underlying heart disease.

Among the neuroleptics, haloperidol appears to have the least adverse cardiovascular effects which explains its popularity in coronary care and medical intensive care units. This feature may be explained by it having relatively little autonomic blocking activity. There is an interesting report of the safety of i.v. Haldol® in very large doses (from 45 to 530 mg per day) in four patients who became confused and delirious after coronary artery bypass surgery and required neuroleptics: each patient recovered completely without cardiovascular or extrapyramidal side effects.13 It should be noted that stopping the neuroleptic and getting a cardiology consultation is the best approach if cardiac arrhythmias develop during parenteral neuroleptic therapy. Cardiac arrest is noted in the literature but it must be very rare.14 It may be part of a neuroleptic malignant syndrome. In these cases, there are other signs of neuroleptic toxicity

(CNS signs and especially those of the basal ganglia) for several hours or even days before the cardiac complications become known.

#### Neuroleptic Malignant Syndrome

This is one of a number of serious toxicoses (others include acute lethal catatonia, comatose state with hypertension and heat stroke) associated with neuroleptics that is not widely recognized by physicians. If it is not diagnosed and treated early and appropriately, it can be fatal. Good comprehensive reviews of its features and management are available in the literature. 15,16 It is characterized by fever, diaphoresis, hypertension, tachycardia, muscle rigidity or dyskinesias and various levels of coma. There are no apparent signs of infection. Laboratory findings include increase in the CPK, leukocytosis and elevation of liver enzymes. As the syndrome develops over a few days, cardiac arrhythmias can occur. It is usually seen in psychiatric patients after long periods of oral or long-acting depot injections of neuroleptics but has been observed on rare occasions following a few intramuscular injections.17 There appears to be an increased risk if high doses are used initially.

The management is to stop the neuroleptic and to apply life support measures including cooling blankets, restoring fluid and electrolyte balance, monitoring blood pressure and cardiac rhythm etc. If the patient becomes hypoxic, oxygen is given but it may be necessary to consider intubation and assisted ventilation. The drugs often used in the management include: a) several doses of an anticholinergic to assess its usefulness, e.g., benztropine 2 mg i.m.; b) dantroline sodium to relieve the muscle stiffness (with raised CPK, etc.) 100 to 300 mg daily in divided doses and; c) a dopamine agonist such as bromocriptine 5 mg tid or amantadine 100 mg bid. It may take from several days to as long as a few weeks for a significant improvement to occur with this syndrome, in spite of the best intensive medical care. It is important, therefore, for the clinician to monitor carefully all patients who are receiving i.m. or i.v. neuroleptics so that this type of rare complication can be recognized early and the offending drug stopped.

#### Hyperthermia/Hypothermia

Neuroleptics can disturb normal body temperature by acting centrally on the thermoregulatory centre in the hypothalamus and peripherally by blocking the alpha-adrenergic receptors. The patient may show hyper or hypothermia. There appears to be an individual sensitivity to this adverse effect, although vigorous exercise or being exposed to sources of high external heat (e.g., sauna) can also induce hyperthermia in patients receiving neuroleptics. Reducing the dosage will normally correct it. 18

#### **Acute Urinary Retention**

On some occasions, neuroleptics parenterally can cause an abrupt urinary retention with a grossly distended bladder. This is probably explained by competitive inihibition of acetylcholine at the neuromuscular junction of the nerves to the detrusor muscle. It is dose related and more common if an antiparkinson agent is co-administered. It may also occur in men over sixty with prostatic hypertrophy. It sometimes responds well to a cholinergic drug, bethanechol (Urecholine®) subcutaneously 2.5 or 5 mg or orally 10 mg to be repeated up to four times daily. <sup>19</sup> The neuroleptic dose will need reducing or may even require stopping if the adverse effect persists. Paradoxically, diphenhydramine (Benydryl®), a H1 receptor blocker, has also been used successfully.

#### Seizures

It is impossible to know accurately the incidence of seizures following parenteral neuroleptics. The risk is relatively low, probably less than 1% in non-epeleptic patients but higher in patients with preexisting epilepsy. The dopamine blocking effect of neuroleptics is the usual explanation for lowering the seizure threshhold. Low potency sedative phenothiazines like chlorpromazine are more likely to produce convulsions than haloperidol. Least risk (as given in tables) is said to occur with fluphenazine (Moditen®) and perphenazine (Trilafon®).20 The risk also appears to increase with very high doses i.m. or with a sudden large increase in dosage. It is necessary to make sure the patient is not hypoglycemic or hyperthermic. If, after the usual neurological workup, it is decided that the neuroleptic is the cause of a seizure, then a dose reduction or the use of a less epileptogenic neuroleptic should be instigated. If seizures continue and if the neuroleptic cannot be stopped or changed to another type of sedative, then it is necessary to add an anticonvulsant (eg phenytoin) as a temporary measure during the neuroleptic therapy.

#### Severe Neurotoxicity

Inability to walk and talk, and muscle rigidity, have occurred in patients who develop neurotoxicosis when given haloperidol parenterally. A similar complication has been described as occurring occasionally in manic patients who are treated with high doses of lithium combined with a parenteral neuroleptic. An acute 'encephalopathic syndrome' has also been described. The neuroleptic drug should be discontinued promptly in these cases.

#### **Exacerbation of Psychosis**

In general one has a right to expect a sedative effect from a neuroleptic but occasionally a parodoxical excitement occurs. It cannot be predicted beforehand and it can be accompanied by confusion and sometimes profound insomnia. Occasionally, hallucinations have been described. It is often impossible to know whether or not the original psychosis is failing to respond to the neuroleptic chosen or if there is an additional 'toxic effect' from the neuroleptic itself. Only stopping the neuroleptic can help to sort this out. It is said to be more

likely in elderly debilitated patients. The etiology is unclear and different explanations have been proposed including individual sensitivity. Some cases may represent an anticholinergic side effect known as the 'central anticholinergic syndrome'. <sup>21</sup> Another unexpected effect has been described when a manic patient is treated with a parenteral neuroleptic (to reduce psychomotor agitation) and develops a profound depression over a few days. In all these cases it is probably best to stop the neuroleptic and to consider using a medication from another class of psychoactive drugs such as an azapirone (eg buspirone) or a benzodiazepine (eg clonazepam).

#### CONCLUSION

The adverse effects of neuroleptics are numerous but most are simply annoying or embarrassing (e.g., dry mouth, parkinsonian tremor) and not dangerous. However, with parenteral neuroleptics, life threatening complications can and do occur. Early recognition and effective management is essential. Neuroleptics given parenterally should be used with caution in geriatric or debilitated patients, in patients with hepatic or renal disease, in patients with chronic respiratory diseases, when thyrotoxicosis is present and in patients with hypocalcemia (increases the risk of dystonic reactions). Neuroleptics are contraindicated in patients with toxic CNS depression and in those comatose from any cause. The following general guidelines regarding parenteral neuroleptics may be helpful to clinicians:

- a) use minimum doses to start and observe closely, titrating the dose and frequency of injection to the individual patient.
- b) have available a parenteral antiparkinson drug such as benztropine (Cogentin®) or diphenhydramine (Benadryl®). Giving an antiparkinson agent concomitantly from the beginning may not prevent extrapyramidal complications.
- c) Since untoward cardiovascular effects are usually dose related, these can be minimized by using low doses to start. The patient should be either lying down or reclining and instructed to rise slowly to the upright. Blood pressure is recorded at regular intervals.
- d) Transition from parenteral to oral neuroleptics should take place when psychotic features and psychomotor agitation are effectively controlled. The oral dose in the next 24 hours should be double the parenteral dose required in the previous 24 hours.
- e) If a complication occurs with a phenothiazine neuroleptic, sometimes changing the class of drug, to a butyrophenone (Haloperidol®) or a dibenzoxazepine (loxapine) can be helpful on some occasions.

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#### A Special Care Dementia Unit

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The Special Care Unit on V3 West in the Veterans' Memorial Building at the Camp Hill Medical Centre, provides a program designed to meet the needs of independently mobile veterans with moderately advanced irreversible dementia. The program is characterized by a commitment to the interdisciplinary approach, the use of assessment instruments, an adapted environment, attention to behaviour problems, the provision of specific activities, the utilization of family/team conferences, the incorporation of admission and discharge criteria and the provision of family support meetings.

The program concentrates on helping the veteran function at his/her maximum ability level in a comfort-

able and supportive environment.

"Residents (of an institution) are the reason for the existence of a program. It is their needs which must be met and they are the prime beneficiaries."

#### DEMENTIA

The elderly population of Canada continues to grow and with it, the number of cases of dementia. Dementia is defined as a clinical syndrome of usually progressive cognitive deterioration that eventually causes functional impairment. Deficits occur in intelligence, memory, affect, judgement, orientation and visuospatial skills and eventually involve all facets of cognition.<sup>2</sup>

Alzheimer's Disease is the most common form of dementia, affecting about 60% of cases. Vascular dementia is the next most common form and many people have more than one reason for their dementia.<sup>3</sup>

The data for dementia pose a challenge to long term care institutions. About 10% of those over 65 and up to 40% of those over 85 suffer from a type of dementia.<sup>2</sup>

Family caregivers of people with dementia have been called "the hidden victims of the disease" as they shoulder increasing responsibility, disruption of their lives and stress. The lack of a family caregiver frequently leads to institutionalization and even with attention from a conscientious family and community support, the behaviourial problems of the demented patient may become too much to handle at home. Incontinence is often a

major factor in the decision to institutionalize the elderly person with dementia. Most families find this a very difficult decision and in fact the family may need more support during the transition from home to institution than the patient.<sup>4,5</sup>

#### SPECIAL CARE UNITS

Many residents of long term care facilities suffer from dementia, with all degrees of associated cognitive impairment and behaviourial problems. The needs of the less seriously affected resident can often be met with the regular resources of the facility and the patient can be integrated with those who are cognitively intact. However, when the dementia has progressed to a moderate level and the person is still ambulatory, a specialized program response in an adapted environment may be most useful in meeting these residents' unique needs. 4.6

Although the need for special units to care for the institutionalized elderly with irreversible dementia continues to be debated, the recent trend has been toward providing segregated areas. Experience in several Canadian centres suggests that creating separate spaces and programs for cognitively impaired residents with problem behaviours and special needs can reduce major reactions, altercations and other incidents, while improving quality of life, safety and security for all residents. Such improvement depends on clear goals and selection criteria for the separate program, appropriate attitudes, training and numbers of staff and a physical and program environment adapted to the needs and abilities of the resident.

When demented patients are mixed with other elderly patients in facilities not designed to manage wandering and agitation, their disruptive behaviour frequently makes it necessary to sedate or physically restrain them, resulting in a deleterious effect on the course of the illness, let alone the patient.<sup>8</sup>

#### CAMP HILL'S SPECIAL CARE UNIT

V3 West, one of four long term care units in the Veterans' Memorial Building at the Camp Hill Medical Centre, has been developed as a special care unit for veterans with irreversible dementia. The goal of this unit is to help the veteran function in comfort at his/her maximum cognitive, physical, emotional and social levels.

The program of the unit is a component of the long term care program of Camp Hill Medical Centre, approved by the Long Term Care Management Committee and supported by Veterans Affairs Canada.

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The program is characterised by the following:

#### 1. Commitment to the Interdisciplinary Approach to Care

The interdisciplinary team members come from medicine, nursing, social work, physiotherapy, occupational therapy, psychology, pharmacy, pastoral care, recreation, arts and crafts, dietary and palliative care. The veteran's interests, needs and abilities are assessed by the interdisciplinary team and a personalized plan of care is developed by the team in conjunction with the family. The plan encourages the veteran's self esteem and the maintenance of abilities.

#### 2. Use of Assessment Instruments

The Folstein Mini-Mental State Examination is used as a measurement of cognitive function and may be supplemented by neuropsychological assessment through the Department of Psychology. The neuropsychological assessment can be very useful in helping to understand a veteran's behaviour and how to best deal with it.

Nursing utilizes a functional assessment inventory as described by Wilden & Froese.<sup>7</sup> This is a numerically scored assessment of orientation, continence, ability to follow directions, personal needs (hygiene and cleanliness), socialization, behaviour, attention, memory, feeding and verbal skills.

The physician completes the Comprehensive Geriatric Assessment form developed by the Centre for Health Care of the Elderly at Camp Hill. This form correlates any medications with the active problems.

The other disciplines also use their specific assessment instruments.

#### 3. Adapting the Environment

The unit provides a safe, protected, quiet environment to support and enhance the veteran's functioning level. There is no through traffic. Corridors are wide with grip rails on the walls. The floors are not carpeted and are of low gloss to reduce glare.

The unit offers freedom of movement to the veterans and wanderers are kept safe by security doors. Although the unit is not designed as a circular walking track for the veterans to pace without meeting a door, use of the nursing station space completes a circular path. An outside patio with protective fencing also provides a walking circuit in all seasons.

Colouring on the unit is subdued. The sitting and dining area is set up with small tables to encourage eating to be pleasurable and a sociable occurrence. Sensory overload that can contribute to confusion and disorientation is minimized. To reduce extraneous stimuli, there are no television sets or radios in the hallways or sitting and dining area and the hospital intercom system is used only for emergencies. The private and semi-private bedrooms are comfortable and veterans' families are encour-

aged to bring in particular personal objects meaningful to the veteran. There is a second lounge area that provides activity and leisure space. Pet therapy has been introduced to the unit through a "Resident Cat". Veteran and family response to this cat is positive.

#### 4. Addressing Behaviourial Problems

Behaviours which can be a problem for the veteran and/or other residents and staff are a relatively common occurrence. The program makes a special effort to assess problematic behaviours and uses a behaviour problem sheet for accurate documentation of the behaviour and associated factors.

The cause of the behaviour is always sought and when it cannot be detected and the behaviour corrected, attempts are made to modify it through the modalities of calming, reassuring and redirecting the veteran's interests. Special interdisciplinary staff training is being developed in behaviour management and validation therapy is employed.

Guidelines for the use of neuroleptic medication have been developed. These include identifying the specific behaviour, using non-medication treatment strategies first where possible, tailoring the medication profile to the veteran, using the smallest effective dosage of medication, monitoring the veteran closely for side effects, conferencing regularly and attempting to reduce/discontinue the drug.

#### 5. Attention to Activities

In keeping with the goal to help residents function at their maximum level, the veterans are encouraged to perform activities of daily living as independently as possible. Clear identification of tasks to be done and encouragement to perform those tasks which the veterans can master, reinforces the veterans' sense of control and helps them adapt successfully to the environment. The veteran may need assistance in washing and dressing every morning, but is never forced. This means that some days he may not shave or agree to a change of clothes. This situation is corrected on the days the veteran is agreeable. The same principle applies to sleeping and within reason the staff accept individual preferences in the time of going to bed and getting up in the morning.

Regular daily activities are predictable and structured. The program recognizes that a veteran's participation in planned activities is a reflection of his/her present ability, past and present interests and comfort level. Residents of V3 West participate, when appropriate, in many of the activities of the Veterans' Memorial Building, including outings. Activity calendars are available in each veteran's room so that they and their family members can be aware of all activities available during the month.

Offering the veterans choices in these activities allows them some measure of control and responsibility and can result in more independence in self-care and improved social functioning.<sup>10</sup>

Specific activities have been developed as part of the V3 West program and take place on the unit. A reminiscence group functions weekly under the direction of the social worker. The occupational therapist conducts a cooking group and regular exercise groups are held by the physiotherapist. Staff from recreation spend one-on-one time with veterans on V3 West and Red Cross Arts and Crafts have a regular program on and off the floor. Special social functions are held with the veteran, their families and the V3 West team. A family support group meets quarterly at the family's request. Developed from these meetings has been a Welcoming Committee for new veterans, a Special Social Events Committee to develop and furnish the Family Room and other activities to support the veterans and families. The veterans and families use the Family Room as a special private place to socialize.

#### 6. Use of Family/Team Conferences

It is often extremely difficult for families to accept and adjust to institutionalization of their family member with dementia. Care giving at home had frequently become an all consuming role in what has been referred to as "the 36 hour day". 11

Admission to the unit may be accompanied by severe guilt feelings for the family, especially the wife, who has to maintain a relationship and role in a very different setting than her home. The team members consider the veteran and his/her family as a unit and work to provide on-going understanding and support to the family during this difficult period.

Interdisciplinary conferences with active family participation, are held every six months or more frequently if necessary. Together, the team and the family review the veteran's status for the better understanding of all. Strengths and problem areas are identified and discussed. The goals from the last meeting are reviewed and new goals developed for the care plan. The veteran's continued appropriateness for the unit is confirmed.

#### 7. Use of Admission and Discharge Criteria

Selection criteria are important for the success of a special care unit for cognitively impaired persons. With limited resources, it is essential that the veterans admitted to the unit are those who would benefit most from the program. The admission criteria identify an appropriate resident and the discharge criteria identify residents who are no longer able to respond to the program.

#### V3 West Program Admission Criteria:

- The veteran is eligible for admission to the Veterans' Memorial Building.
- 2. Dementia is the primary medical diagnosis.
- 3. The dementia is irreversible. Reversible dementias have been ruled out pre-admission.

- The veteran does not exhibit psychotic behaviour. It is important that behaviour is not so disruptive as to compromise the therapeutic milieu of the unit.
- An interdisciplinary assessment has been completed within the past three months. The assessment includes the V3 West Functional Assessment (with a result in the vicinity of 20-40) and a Folstein Mini-Mental State Examination (with a result in the vicinity of 10-20).
- 6. The veteran is independently mobile.
- Veterans not admitted to the unit program on V3 West are admitted to other units within the Veterans' Memorial Building.

#### Program Discharge Criteria:

- The veteran's cognitive function has significantly altered so that he/she no longer benefits from the program.
- An acute or chronic health condition has developed rendering the veteran unable to participate in the program.
- Veterans discharged from the unit program are transferred to other units within the Veterans' Memorial Building.

#### CONCLUSION

It makes good sense for long term care facilities to group residents who have common needs and the potential to be a problem to others. Efficient and effective care can result, with an improved quality of life for the resident. However, segregation should not mean isolation and special care units for persons with dementia must not become "back wards" in the facility. Merely grouping residents does not result in a special care unit. A definite program is required. The development of a program to meet the needs of demented persons requires considerable interest, attention and organization. The team members on V3 West find rewards in observing the beneficial effect of the program on the veterans, a significant professional accomplishment.

Camp Hill Medical Centre is fortunate in having excellent facilities in the Veterans' Memorial Building and an interdisciplinary team on site. However, most important for the success of the unit is the positive attitude of the professionals involved. Absolute requirements for a special care unit to be effective are an appreciation of the needs of people with advancing dementia, and interest and enthusiasm in developing ways of meeting them. V3 West is a particular example of such a unit. Other long term care facilities with different resources may develop in other ways, with the bottom line for all being the development of a program that works.

References on page 110.

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#### Psychopharmacologic Factors in Exercise

#### A PRELIMINARY INVESTIGATION

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This investigation describes heart rate responses during a submaximal cardiovascular test of four psychiatric patients, each taking a different psychotropic drug. Subjects #1 and #2 with diagnoses of schizophrenia (paranoid) and receiving phenothiazines, demonstrated tachycardia at rest and at each level of exertion during the submaximal cardiovascular test. A similar tachycardia was observed with subject #4, with a diagnosis of bipolaraffective disorder and receiving an antidepressant tricyclic. Subject #3 with a diagnosis of schizophrenia (undifferentiated), was on an anticonvulsant (mood stabilizer) and showed bradycardia. The interaction between the prescribed drug and exercise is discussed, as well as the cost-benefits of various treatment designs.

Psychotropic drugs have been the treatment of choice for many psychiatric disorders. These drugs have been effective in decreasing the number of relapses and rehospitalizations among individuals with major affective disorders and schizophrenia. In addition to drug therapy, adjunct therapies have been shown to be helpful in reducing the rate of rehospitalization. One such therapy currently creating an interest in programs for individuals with major affective disorders and schizophrenia is exercise. Overall, results have been encouraging although several investigators have expressed concerns after the interactive effects of drugs and exercise.

Few studies have investigated the effects of psychotropic medication on cardiovascular responses to exercise. In the studies that have, large doses of chlorpromazine (1.5-3.6g/day) were prescribed to inpatients with schizophrenia during exercise<sup>8,9,10</sup> and showed that stroke volume was reduced, leading to a reduction of cardiac output and arterial blood pressure. These maladaptations of circulation were identified as potential sudden death factors among patients receiving phenothiazines.<sup>8,9,10</sup>

However, no conclusive data exist concerning the effects of psychotropic drugs during exercise. Discrepancies found may be due to differences in drugs, differences in dosages, differences in acute and long term effects of the drugs, individual metabolic or cardiovascular effects, as well as the differences in the intensity, duration and mode of exercise. In addition, along with

the social stigma of mental illness, taking medication reinforces a person's belief that he/she is ill, producing a low self-esteem.<sup>11</sup> In an attempt to deny that they have a problem, some patients may stop taking medication only to suffer a relapse.

Considering the limited data available and the concerns expressed in the literature, the following case studies examined the heart rate responses (HR) during a standardized cardiovascular test of individuals carrying a diagnosis of schizophrenia or a major affective disorder and receiving psychotropic drugs.

#### TESTING

The cardiovascular test consisted of cycling on a stationary cycle using the Pollock *et al.* (1978) protocol. <sup>12</sup> The subjects cycled at three different work loads, for four minutes per work load. The initial work load was 25 watts. HR was recorded at 30 second intervals using a heart rate monitor (PE 3000 Sport Tester<sup>TM</sup>). Work loads for the second and third stages were dependent on HR responses from the previous stage.

#### MEDICAL STATUS OF SUBJECTS

These case studies were conducted as part of a psychiatric rehabilitation program. All subjects met diagnostic criteria for schizophrenia or major affective disorder according to DSM III-R. <sup>13</sup>

Before testing, subjects were required to undergo a physical examination by a physician to ensure that there were no contraindications to the cardiovascular test. Subjects were informed of the risks and stresses involved with the testing and were required to provide signed consent before testing. The entire research program was ethically approved by the medical center and the university research ethics committees.

#### Case No. 1: The Antipsychotic Phenothiazine, Flupenthixol

She was an eighteen year old female with a diagnosis of schizophrenia (paranoid) with symptoms onset prior to the study, and with one previous hospitalization. She had a history of drug abuse and attempted suicide from overdose of medication, as well as a history of seizures (petit mal epilepsy); electroencephalogram-abnormal). Psychological reports suggested that the subject had negative and self-destructive impulses (Rorschach charts), lacked self-worth with constricted social behavior. She experienced auditory hallucinations, and during inpatient status, had abdominal pain caused by episodes of

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vomiting. The medication prescribed was flupenthixol (Fluanxol®) (3mg QHS).

Upon transfer to outpatient status, she entered the testing period. For the first four tests, she did not regularly perform aerobic activity. As can be seen in figure 1, she showed a disproportional increase in HR with increased exertion. In addition, when the telemetric HR monitor was worn during normal activities, the tachycardia was also observed although not as severe (eg., sitting quietly, HR  $\geq$  105 beats/min; in conversation, HR  $\geq$ 110 beats/min; and walking up and down stairs HR  $\geq$  120 beats/min). The tachycardia was confirmed when she maintained a HR  $\geq$  225 beats/min (predicted maximum HR: 220-18=202) during minimum exertion for a five minute period.

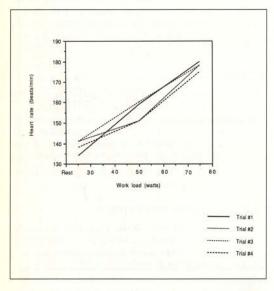


Fig. 1

The heart rate responses of case no. 1 for various levels of work load during four test sessions (3mg flupentixol).

After the fourth test session, she began a six week aerobic training program. After three weeks of training four sessions per week, 20 minutes per session, her HR did not differ from past tests. In addition, during a sixth test at the end of week 6, HR again did not differ from the previous five tests, although appropriate training stimuli was administered.

#### Case No. 2: The Antipsychotic Phenothiazine, Trifluoperazine

In the second case, a twenty-one year old female with a diagnosis of schizophrenia (paranoid) with symptoms onset prior to the study and multi-hospitalizations, performed the cardiovascular test on two different occasions. Before and between the testing sessions, activity

levels were very low and the subject demonstrated withdrawn behavior, although self-report scores (Beck Depression Inventory) <sup>14</sup> did not differ significantly (1st test; 25; 2<sup>nd</sup> test: 23). She was prescribed trifluoperazine (Stelazine®) (3mg p.o. @ 18:00) during the first test. Before the second test, trifluoperazine was discontinued and the subject was not on medication. Figure 2 shows a tachycardia condition during the initial test, but not during the second test.

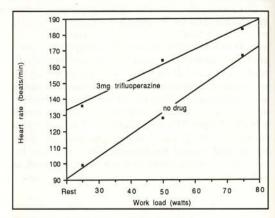


Fig. 2

The heart rate responses of case no. 2 for various levels of work load with 3mg trifluoperazine and with no drug.

#### Case No. 3: The Anticonvulsant (mood stabilizer), Carbamazepine

He was a twenty-one year old male with a diagnosis of schizophrenia (undifferentiated). A highly motivated individual, he had attention deficiencies which impaired his ability to plan and problem solve, but he was able to function in a social situation. His medication was carbamazepine (Tegretol®) at a therapeutic dose.

He entered an aerobic exercise program after he was identified by fitness appraisers as below average for his sex and age group in cardiovascular fitness, although the subject had a very low resting HR. It was speculated that the medication induced the bradycardia condition. He was tested at three week intervals during the twelve week program. The volume of work performed was progressively increased during the exercise program. However, in five cardiovascular tests conducted at three week intervals no consistent change in HR was observed (Figure 3).

#### Case No. 4: The Antidepressant Tricyclic, Clomipramine

He was a 22 year old male with a diagnosis of bipolaraffective disorder. He was a university student prior to symptoms onset with one hospitalization. Throughout the testing period, he displayed a high level of welldeveloped social behavior, and he was undergoing a progressive withdrawal from clomipramine (Anafranil®). Figure 4 highlights that he appeared to have a tachycardia condition during the first two tests but not during the third test. During the testing period, he was not exercising regularly. In addition, observations from these tests showed that with each decrease of 25mg of clomipramine, corresponding heart rate decreased approximately 11 beats/min.

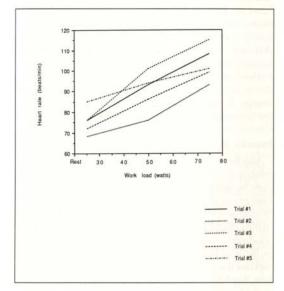


Fig. 3

The heart rate responses of case no. 3 for various levels of work load during five test sessions over a 12 week aerobic training program (at therapeutic dosages of carbamazepine).

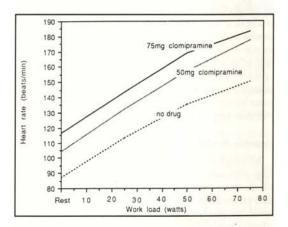


Fig. 4

The heart rate responses of case no. 4 for various levels of work load and dosages of clomipramine (revised figure from Campagna & Pelham, unpublished data).

#### DISCUSSION

Not until the 1950s was there real progress in finding somatic therapies for psychopathologies. Neuroleptics/antipsychotics (including phenothiazines) and antidepressants (tricyclics) have direct but different effects (manipulations) on the neurochemistry of the brain. Phenothiazines have a beneficial effect for many victims of schizophrenia by making the receptors in the brain less sensitive to the neurotransmitter dopamine. On the other hand, tricyclics increase the amount of the neurotransmitters norepinephrine and serotonin, and relieve the symptoms of depression. However, undesirable effects may also be produced from pharmacological interventions. <sup>11</sup> In addition, it is not yet clear how to identify, what side effects may occur, and to whom.

Considering the attention given by the cardiologist to the potential interactions between drug and exercise in the rehabilitation of cardiac patients, it is somewhat surprizing to note that very little effort has been made by the psychiatrist, or the sportsmedicine specialist into examining the potential interactions between exercise and psychotropic drugs. As well, little information (research) exist on the widely prescribed sedatives and anxiolytics (eg., benzodiazepines; diazapam).

#### Cardiac contraindications

In past research, cardiac function has been shown to be impaired with megadoses of chlorpromazine during exercise. 89,10 A summary of the data from the present study suggests that this phenomenon may be widespread among psychotropic drugs given in therapeutic doses. In the tachycardia exhibited by cases nos. 1, 2 and 4, with increasing levels of low-intensity exercise, a greater increase in HR was exhibited, resulting in greater metabolic demands placed on the myocardium. Under these conditions, there is little doubt that the cardiovascular system can provide the metabolically active myocardial tissues with enough oxygen to keep the cell redox state normal. Cases nos. 1, 2 and 4 appear to be in artificial (drug-induced) cardiac inefficiency.

Supporting evidence from other researchers has suggested that psychopharmacological agents lower the level of physical work capacity of patients. 7 In fact, the interaction between psychotropic drugs and norepinephrine and epinephrine, released by the autonomic nervous system during exercise, potentially may cause an overexcitable condition of the heart, leading to ventricular fibrillation. 8,9,10 In addition, although tachycardia may appear as an isolated phenomenon, psychopharmacological research has suggested that it is often accompanied with hypotension, as well, phenothiazines have been suggested to induce quinidine-like effects on electrocardiograms. During sedentary periods, these changes have little clinical importance. However, for an individual in an active state, (in the above case studies, low-intensity exercise, which is equivalent to many activities of daily living) these changes may be the precipitant for cardiovascular inefficiencies which may compromise the health of the individual.15

#### **Neural and Hormonal Contraindications**

Although no direct neural or hormonal measurements were recorded in this study, the abnormal HR responses to exercise in all four case studies would indirectly lead to the suggestion that the sympathoadrenal activity to exercise in these subjects was altered. Normally, as work load increases, sympathetic activity increases in an attempt to maintain homeostatic functions. In addition, appropriate B-adrenergic stimulation has been suggested as one of the key mechanisms responsible for central cardiological conditioning. As mentioned earlier, no training effects were observed in case no. 1 (tachycardia) or case No. 3 (bradycardia) suggesting central autonomic adaptations did not occur with the progressive training stimuli. Along these suggested lines are the studies by Carlsson et al. 8,9,10, where they reported substantially large plasma and urine norepinephrine differences, at rest and during exercise in patients receiving large doses of chlorpromazine when compared with patients not receiving drug therapy. They suggested that the suppressive effect of the drug on training is of clinical importance, referring to the risk of circulatory disturbances.

Other pharmacological interventions have shown similar results. Training studies have shown that the β-adrenergic blocking agent, propranolol reduced the compensatory sympathetic tone to the myocardium during exercise, reducing myocardial contractility, HR, myocardial oxygen consumption by 30%, and maximum exercise capacity. <sup>16,17</sup> However, in this study, phenothiazines (potential α-adrenergic blockers) <sup>15</sup> demonstrated a suppressive effect on training.

In addition, unlike the studies of Carlsson *et al.* <sup>8,9,10</sup> in this study, several psychotropic drugs in therapeutic doses have been suggested to control the mechanisms of extrinsic neural and hormonal cardioregulation. Little is known how these drugs effect other functions and regions of the medulla.

#### Training Effect

It is well known that regular aerobic exercise has a positive training effect. <sup>18</sup> A typical central cardiovascular change associated with the training effect is a decrease in HR at given submaximal work load rates. <sup>12</sup> However, after undergoing a progressive exercise program of at least 6 weeks, neither the HR in case no. 1 or case no. 3 showed changes from baseline scores during testing. Although peripheral adaptations may have occurred, there was no HR adaptation.

Although prescribed exercise HR were based on the Karvonen equation<sup>15</sup>, they were inappropriate for central adaptations, both in the tachycardia condition of case no. 1 and the bradycardia condition of case no. 3. This has also been observed in cardiac patients on β-blockers. Designing an appropriate prescribed exercise HR, should be of considerable interest to mental health professionals, after future research has clarified some of the unanswered questions.

#### Unknown risks

Again, the question must be raised as to the potential risks for individuals who exercise and use benzodiazepines. Over the past twenty years, there has been a boom in fitness activities and for many individuals, the reasons to exercise are to relieve stress and to relax. In a recent survey, it was shown that 85% of primary care physicians in the United States prescribe exercise in the treatment of depression. 19 In addition, the benzodiazepine, diazapam is the most widely prescribed drug in North America. Indeed, a drug that has the potential to produce cardiovascular side effects15, at risk for drug abuse and drug dependence. In addition, research has shown that exercise may be superior (tranquilizing effect) to an associated benzodiazepine anxiolytic (meprobamate).20 Consequently, considering that drug therapy and exercise must interact, it would seem important that more energy should be directed towards the investigation of the interaction of these two therapies.

#### **Exercise Bioenergetics and Psychopharmacokinetics**

Another important question deals with the potential relationship between the bioenergetics of submaximal exercise and the pharmacokinetics of psychotropic drugs. Energy cost is a linear function of the work performed. 12 During activity, there are increased demands for energy in the cellular processes of muscular contraction. Under conditions of submaximal activity, energy is derived from an increase in metabolism. However, cellular physiology dictates the metabolism of psychotropic drugs.11 Therefore, hypothetically, a mechanism may be involved that individuals receiving these drugs and undergoing progressive exercise are, in fact overstimulated. Although, this cascade of exercise-induced metabolic events is somewhat speculative, there may be a positive potentiality here. It is true that metabolism is increased during exercise and the activity level of some drugs is influenced by metabolism.11 Therefore, it is possible, as is the case for diabetics and insulin, to reduce the dosage of psychotropic-treated patients who exercise. In fact, the important pharmacological principle of drug potency to side effects would suggest a lower dosage would be the optimum for the individual who exercises. Reducing the dosage for an active individual would achieve maximum benefits with minimal side effects. For the cases above, this may help in normalizing heart rate.

#### **Possible Benefits**

Although the above case studies suggest that exercise may attenuate the cardiovascular side effects of some medications, other researchers have suggested that exercise potentiates tricyclic medication<sup>21</sup> and reduces the need for psychopharmacological agents.<sup>7</sup> In a schizophrenic population, patients who sustain long term exercise programs (6 months or longer), a complete withdrawal from medication (phenothiazines) was achieved and was time correlated with these programs.<sup>22</sup> These

studies suggest exercise and drug therapy are not antagonists, or contraindicated, but synergistic.

On the other hand, a cardiovascular test may be a useful diagnostic procedure to identify side effects (ie., arrhythmias) before they reveal themselves in less than ideal conditions.

Central to the concept of drug and exercise interaction is the notion that the side effects of drug therapy interferes with normal social and occupational functioning. In addition, 20% of patients with schizophrenia do not respond to antipsychotics.<sup>11</sup>

Before the discovery of neuroleptics, activity was an effective treatment for individuals with schizophrenia.<sup>23</sup> However, it is somewhat presumptuous to believe that exercise is a requisite treatment in all or even in a majority of patients in psychological difficulty. To date, empirical studies have not substantiated the effectiveness of exercise therapy. The drug therapy-holistic programs of Lukoff *et al.*<sup>24</sup> would seem to be the next exploratory step in optimizing treatments for individuals with a psychiatric disorder.

Today, psychopharmacological therapy is the prime therapy in relieving the symptoms of psychopathlogy. However, since nonpsychiatric physicians treat 60% of patients with psychiatric disorders<sup>25</sup> the above discussion is addressed to all physicians. It raises several questions that should be explored by the psychiatrist, sportsmedicine specialist and the general practitioner in future research before exercise coupled with medication is advocated as the treatment of choice for mild or major psychopathologies.

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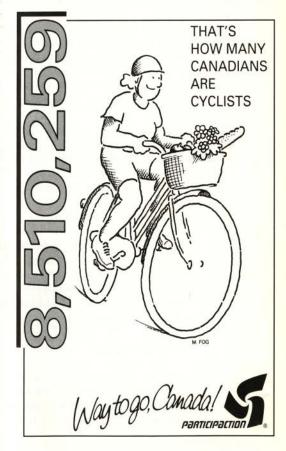
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## **MSNS POLICY SUMMARY**

(Approved by MSNS Executive Committee, February 20, 1993)

#### ALTERNATIVE MEDICINE

Within society there appears to be a small but growing degree of dissatisfaction with "traditional medicine" and its perceived inability to meet certain needs. An apparent dichotomy exists between patients' desire for the best in terms of "high tech" sophistication and their desire for "demedicalized" medicine with a human face. The needs of some who seek help are not met by traditional medicine. Part of the difficulty lies in the inclination of traditional medicine towards the classic disease oriented approach which seeks a defined pathological process with a specific therapy. This approach has been very successful in managing acute illnesses but has proved less helpful when managing many chronic illnesses. It has also been less than completely satisfactory in dealing with problems related to life stresses which may manifest themselves as physical symptoms.

These and other factors lead many individuals to seek "alternative" forms of treatment from medical and nonmedical practitioners. There has been a tendency in the past for physicians to condemn these forms of therapy out of hand. However, it must be acknowledged that through the years, some elements of accepted conventional practice have not stood the test of careful scientific appraisal. It would therefore seem hypocritical to reject nontraditional therapy simply because it is unconventional.

This does not imply that standards should not apply to alternative forms of medical therapy. The Medical Society of Nova Scotia is dedicated to the provision of high quality medical services to the people of Nova Scotia and believes that the same standards should apply to the provision of all medical services. The following two principles form the basis of The Society's policy regarding this issue:

#### · Objective scientific testing

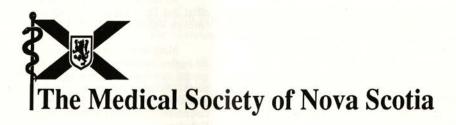
At the core of scientific medicine is the requirement to prove that the benefits of a proposed therapy far outweigh the risks. The randomized clinical trial has been demonstrated to be the best tool for this purpose. To be considered ethical, all new therapies must be subjected to objective scrutiny within a randomized clinical trial to prove a beneficial outcome. It is recognized that this is not always feasible but should be considered the "gold standard."

#### Informed consent

Patients must be informed regarding their diagnoses, the nature of proposed therapies, and the risks and potential benefits of their treatments. In the case of an experimental treatment, patients must be fully informed that the benefits of the therapy have not been proven.

# PROCEEDINGS OF SPECIAL MEETING OF COUNCIL AND SPECIAL GENERAL MEETING

Of



Dartmouth April 3, 1993

#### THE MEDICAL SOCIETY OF NOVA SCOTIA

## PROCEEDINGS OF SPECIAL MEETING OF COUNCIL AND SPECIAL GENERAL MEETING

Saturday, April 3, 1993

#### Ramada Renaissance Hotel 240 Brownlow Avenue Dartmouth, Nova Scotia

Dr. Kim Crawford, Chairman of the Executive Committee and General Council, called the meeting to order at 9:00 a.m. In his opening remarks, the Chairman noted that the purpose of this meeting was twofold:

- (1) to adopt By-Law amendments to coincide with changes to The Society's Executive Committee resulting from November 1992 Council's decision to endorse a new Society Executive Committee structure (total 34 with membership as follows: 15 from branches (2 from each of the following: South West, Valley, Cobequid, Northumberland, Cape Breton, and 5 from Halifax which includes Dartmouth and Bedford-Sackville); 7 Officers; 10 from sections (5 from general practice, 2 from surgery, and 3 from medicine); and 1 each from students and PARI-MP.), and
- (2) to consider the Section of Surgery's recommendation to Council 1992 calling for the sectionalizing of the global budget which had subsequently been tabled until the next meeting of the whole Society.

By-Law Amendments: Dr. Peter Littlejohn, By-Laws Committee Chairman, spoke to the proposed By-Laws Amendments as approved by the Executive Committee and circulated to the membership via Society letter of March 3, 1993. These were approved by Council on April 3, 1993 and follow these Proceedings, together with the new structure for the Board of Directors. Hopefully, the restructured Board of Directors reflecting the approved By-Law changes will be in place by the June meeting.

Section of Surgery Recommendation: In introducing the following motion Dr. Finlayson cited the reasons for it being put forth, these being most specifically government generated costs, and the controls (especially manpower controls) upon physicians as a result of the global budget. He expressed the view that if this motion were passed it would allow surgeons and anaesthetists some direct responsibility for their manpower situation.

"THAT for the duration of the current agreement between The Medical Society of Nova Scotia and the Department of Health; the global budget for Insured Medical Services be compartmentalized to create a separate "envelope" within the global budget for the Division of Surgeons and Anaesthetists which includes certified specialists in anaesthesia, general, plastic, CV, thoracic, neuro, and orthopaedic surgery, obstetrics & gynecology, ENT, ophthalmology, and urology. The envelope shall be calculated on the basis of MSI payments for fiscal 1990-91, plus any relevant adjustments. Changes to the Master Unit Value for surgery and anaesthesia shall be calculated within that envelope."

Thoughtful, lengthy discussion ensued regarding the impact of this motion on the medical profession as a whole.

An amendment to this motion was introduced to the effect that The Society explore the creation of a separate envelope with a time limit of six months.

Many members expressed grave concerns regarding the original motion's potentially divisive nature. It was the general consensus of the meeting that The Medical Society needs to remain unified in order to: negotiate effectively with government; to provide moral leadership in the area of health care reform and the determination of health care priorities for Canadians. It is essential that The Society make it clear to governments, the public, and its members that the medical profession is a serving profession not a self-serving one.

The motion and amendment were subsequently voted on and defeated by a wide margin. However, it was generally agreed this matter deserves the concerted efforts of the entire profession and that The Society should give attention to the concerns of the surgical specialists and other issues in this same area.

The meeting adjourned and was immediately followed by a special general meeting which ratified the actions of the special meeting of Council. The general meeting adjourned at 10:55 a.m.

The President commented on several other areas of Society initiatives including: CMPA and CME rebates, the extended health care plan, and physician resource controls.

Approved By-Law Amendments and Restructured Board of Directors Follow

#### THE MEDICAL SOCIETY OF NOVA SCOTIA

## By-Laws Amendments Approved by Special Meeting of Council

April 3, 1993

#### **EXISTING**

#### **PROPOSED**

For the purpose of clarification the term "Executive Committee" in all references shall be changed to "Board of Directors".

12.6 Staffing Committee

12.6.1 The Staffing Committee shall consist of the President as Chairman, the Past President, the President-Elect, and the Treasurer. It shall meet at least twice yearly.

Council in 1992 approved proposals for the re-structuring of the Executive Committee. In order to accommodate this, several By-Law amendments are necessary:

Section 4.1.3 requires amending since each Branch will not be specifically entitled to nominate a member to the Board of Directors. The following is proposed:

4.1.3 Each Branch shall be entitled to nominate for the Executive Committee of The Society the number of members to which it may be entitled under Section 12 of these By-Laws.

4.1.3 Each Branch shall be entitled to nominate members of the Board of Directors for the region to which that Branch belongs, as set out in section 12.3.2.1 (ii) of these By-Laws.

Section 6.1.3 needs to be amended:

6.1.3 In order to determine representation of Branch Societies to the Executive Committee and Council, each member will indicate with which Branch Society he should be counted.

6.1.3 Whereas a member of The Society may belong to more than one Branch or to more than one Section, he should indicate to which Branch and Section he is primarily affiliated.

It would seem appropriate to revise Section 12.3.2.1 to determine the nominating process for Branch and Section representatives to the Board of Directors, and to put the composition of the Regions and Divisions into the Rules and Regulations.

Although not discussed to date, it would be reasonable for each representative to the Board of Directors from Branches, Regions, and Section Divisions to be able to appoint alternates.

Committee and the procedure it shall follow shall be agreed upon by the Sections involved. In nominating representatives and their alternates, the Divisional Nominating Committee shall consider the number of members in each Section within the Division, and the distribution of representatives over as many Sections as possible.

The nominations of each Divisional Nominating Committee shall be forwarded to the Nominating Committee of The Society, and shall be signed by the Chairman of each Section within the Division. Should the Sections fail to agree on this matter, it shall be referred to the Nominating Committee of The Society for resolution.

12.3.2.1 (iv) One representative each shall be nominated by the Professional Association of Interns and Residents of the Maritime Provinces, and the Dalhousie Medical Students Society.

#### Section 12.3.3.2 requires some editorial revision:

12.3.3.2 Branch Representatives to the Executive Committee, and their alternates, shall be nominated annually. No member shall be nominated to the Executive Committee in either capacity for more than three years consecutively. After an absence of one year such a member will again be eligible for nomination.

12.3.3.2 Representatives to the Board of Directors (of both Branch Regions and Section Divisions) shall be nominated annually. No member shall be nominated to the Board of Directors for more than three years consecutively. After an absence of one year such a member shall again be eligible for nomination.

The Rules and Regulations need amending to accommodate the above:

1.2 For the purpose of nominating representatives to the Board of Directors the branches shall be organized into regions, with the number of representatives as follows:

Cape Breton (Two representatives)
Cape Breton Medical Society
Inverness-Victoria Medical Society
Sydney Medical Society

Cobequid (Two representatives)
Colchester-East Hants Medical Society
Cumberland Medical Society

12.3.2.1 (ii) Branch Societies, the Interns & Residents Association of Nova Scotia, and Dalhousie University Medical Students who are duly paid-up members of The Medical Society according to Section 6.6.1 of these By-Laws, may each appoint one member to the Executive Committee. If there are 100 or more members a second appointment may be made.

12.3.2.1 (ii) For the purpose of nominating representatives to the Board of Directors, Branches of The Medical Society shall be organized into Regions, as delineated in section 1.2 of the Rules and Regulations accompanying these By-Laws.

Branches within each Region shall form a Regional Nominating Committee which shall, prior to the Annual Meeting of The Society, nominate representatives, and their alternates, to the Board of Directors, according to the number of representatives allocated to that Region.

The composition of each Regional Nominating Committees and the procedure it shall follow shall be agreed upon by the Branches involved. In nominating representatives and their alternates, the Regional Nominating Committee shall consider the number of members in each Branch within the Region, and the distribution of representatives over as many Branches as possible.

The nominations of each Regional Nominating Committee shall be forwarded to the Nominating Committee of The Society, and shall be signed by the President of each Branch within the Regions. Should the Branches fail to agree on this matter, it shall be referred to the Nominating Committee of The Society for resolution.

12.3.2.1 (iii) For the purpose of nominating representatives to the Board of Directors, Sections of The Medical Society shall be organized into Divisions, as delineated in Section 2.3 of the Rules and Regulations accompanying these By-Laws.

Sections within each Division shall form a Divisional Nominating Committee which shall, prior to the Annual Meeting of The Society nominate representatives, and their alternates, to the Board of Directors, according to the number of representatives allocated to that Division.

The composition of each Divisional Nominating

Halifax-Dartmouth-Bedford (Five representatives) Bedford/Sackvile Medical Society Dartmouth Medical Society Halifax Medical Society

Northumberland (Two representatives)
Antigonish-Guysborough Medical Society
Eastern Shore Medical Society
Pictou County Medical Society

South West (Two representatives) Lunenburg-Queens Medical Society Shelburne Medical Society Western Medical Society

Valley (Two representatives) Valley Medical Society

2.3 For the purpose of nominating representatives to the Board of Directors the Sections shall be organized into Divisions, with the numbers of representatives as follows:

General Practice (Five representatives) Emergency Medicine General Practice

Medicine (Three representatives)
Internal Medicine
Paediatrics
Pathology (Laboratory Medicine)
Psychiatry
Radiology

Surgery (Two representatives)

Anaesthesia
Obstetrics & Gynaecology
Ophthalmology
Orthopaedics
Otolaryngology
Surgery
Vascular Surgery
Urology

#### Attachment to Proceedings of Special Meeting of Council April 3, 1993

#### The Medical Society of Nova Scotia

#### Composition of Board of Directors As Approved by Special Meeting of Council April 3, 1993

#### Society Officers

President	- Dr.
Past President	- Dr.
President-Elect	- Dr.
Chairman, Executive	- Dr.
Vice-Chairman, Executive	- Dr.
Treasurer	- Dr.
Honorary Secretary	- Dr.
Member-At-Large	- Dr

For the purpose of nominating representatives to the Board of Directors the Branches shall be organized into regions, with the number of representatives as follows:

#### **Branch Representation:**

G B . C	Б.	41. D
Cape Breton (including	Dr.	- Alt Dr.
Cape Breton, Inv-Vic. &	Dr.	- Alt Dr.
Sydney Medical Societies)		
Cobequid (including	Dr.	- Alt Dr.
Col.E. Hants & Cumber-	Dr.	- Alt Dr.
land Medical Societies)		
** ··· / · · · · · · /		
Halifax/Dartmouth/	Dr.	- Alt Dr.
Bedford (including	Dr.	- Alt Dr.
above Medical	Dr.	- Alt Dr.
Societies)	Dr.	- Alt Dr.
	Dr.	- Alt Dr.
Northumberland (includ-	Dr.	- Alt Dr.
ing AntGuys, Eastern Shore,	Dr.	- Alt Dr.
& Pictou Medical Societies)		
Southwest (including	Dr.	- Alt Dr.
Lun-Queens, Shelburne	Dr.	- Alt Dr.
& Western Med. Societies)		
Valley (including present	Dr.	- Alt Dr.
Valley Medical Society)	Dr.	- Alt Dr.
valies interieur seciety)	DI.	- Alt DI.

For the purpose of nominating representatives to the Board of Directors the Sections shall be organized into Divisions, with the numbers of representatives as follows:

General Practice (Five) (including Emergency Medicine & GP Sections)	Dr. Dr. Dr. Dr. Dr.	- Alt Dr. - Alt Dr. - Alt Dr. - Alt Dr. - Alt Dr.
Medicine (Three) (including Internal Medicine, Paediatrics, Pathology, Psychiatry & Radiology)	Dr. Dr. Dr.	- Alt Dr. - Alt Dr. - Alt Dr.
Surgery (Two) (including Anaesthesia, Obs./Gyn., Ophthalmology, Orthopaedics, Otolaryngology, Surgery, Vascular Surgery. & Urology)	Dr. Dr.	- Alt Dr. - Alt Dr.

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#### The Problems with Pap Smears

Stewart Cameron,\* MD, CCFP

Halifax, N.S.

The Pap smear has been in use as a screening test for cervical cancer since the 1940s. Since that time, improved diagnostic and treatment facilities for patients with abnormal smears have become available, resulting in substantial reductions in the rates of mortality from invasive cervical cancer. In British Columbia, death rates have declined approximately 72%. Mortality has been reduced even though the stage-specific survival rates have not improved. This indicates the beneficial effect of early detection and treatment of premalignant disease.

Cancer of the cervix is theoretically a preventable disease. Yet, women still die from this malignancy. Why have cervical cytology screening programs not lived up to their promise? A recent review noted that the cervical smear is "perhaps the only effective cancer screening test known today". However, the review continues, "screening for carcinoma of the uterine cervix has not eradicated the disease in any of the populations studied to date". The Canadian death rate from cervical malignancy has been estimated to be twice as high as it could be with more effective programs.

We have the paradoxical situation where many women are not having Pap smears at all, while some women are receiving too many Pap smears. It has been stated that many cytologically normal women are screened too frequently, which is an inappropriate use of resources.<sup>3</sup>

Some of these problems can be overcome by a formalised program approach to cervical cytology screening. The new manual from the N.S. Gynaecological Cancer Screening Program provides clear guidelines appropriate to the Nova Scotia population.

Effective use of the Pap smear also requires rigorous standards of collection and interpretation. Even so, the technique has a number of intrinsic shortcomings. It must be remembered that the Pap smear is not a diagnostic test but a screening tool, and that no objective analysis has ever been carried out on the best way to perform it.

#### WHAT NEEDS TO BE ADDRESSED?

The Pap test is a method of sampling the cells of the cervix to detect pre-malignant changes. Such dysplastic cells can then be treated, to prevent invasive cancer. A period of 4.5 years has been quoted as a representative time period for the conversion. One study has suggested that only 16% of patients with mild dysplasia progress to more severe disease, with over 60% of mild dysplasias regressing spontaneously.

If invasive cancer of the cervix is a preventable disease, then any woman found to have late stage cervical cancer represents failure of the screening program. There are several reasons for such failures.

• Data from British Columbia show a disturbing pattern. The Cancer Control Agency of B.C. recently published data on 437 women who presented with invasive cervical cancer from 1985 to 1988. 39% of these women had never been screened at all. An additional 10% had not had Pap smears for over 5 years. Thus, failure to have a recent Pap smear accounted for about half of the program deficiency. Some women may not know of the importance of cervical cancer screening and may not visit physicians to have them performed. Others may decline the screening fearing embarrassment or discomfort. There are also physicians who do not offer or promote the Pap smear to their patients.

In particular, several authors claim that Pap screening programs are not targeting older women in the high risk age groups. <sup>68</sup> The B.C. data revealed that 55% of the women with invasive disease were age 50 or over.

- Patient failure to follow a recommended treatment has also been noted as a cause for the development of invasive cancer of the cervix.
- Various studies report false negative rates of from 6 to 56%. This type of error can be due to inadequate sampling of the cervical transformation zone. In the B.C. data, 71 of 437 women with cancer had recently had a Pap smear that was reported as normal. In 32 of the 71, it appears that the smears did not adequately sample the cervix.
- Laboratory interpretation errors occur. In younger women with cervical cancer, failure to have a Pap is relatively less common than having a pap reported incorrectly. One study of women under 35 with cervical cancer showed that most had recently had "normal" cytology, and that half of these were missed malignancies. The B.C. data revealed that 39 Pap smears had been read incorrectly among the 71 women with cancer and a recent normal Pap. The expertise of the laboratory performing the interpretations is therefore highly important.
- Some women are not properly identified in the cytology registries. If the registry is not made aware of changes of patient name, medical number or address, it can lead to failure to appropriately monitor and follow a woman's cytology status.
- Physicians are also cause for error, if they fail to act correctly on positive cytology or do not respond appropriately to abnormal signs and symptoms.

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#### CURRENT STATE OF THE ART

British Columbia has one of the best models for cervical cancer screening. The province was the first with a Canadian screening program in 1949. All Pap smears in that province are read in one site, the records are computerized, and the program monitors the treatment of each patient. Computerized letters are sent to all physicians with recommendations for action and follow-up on Pap smears. Failure to act as directed results in further letters which call for results.

In B.C. the system has sufficient reliability that ,when mild dysplasia is first reported on a smear, the usual recommendation is to repeat the smear in six months. The 1991 Report of the National Workshop on Screening for Cancer of the Cervix also recommends that usually, only women with moderate to severe abnormalities (CINII and CINIII) be referred for colposcopy. They advise that women with mild dysplasia be retested every six months, with referral only if the abnormality progresses or persists for two years. However, these practices require the existence of standardized, quality controlled laboratories and a computerized registration system for monitoring follow-up, such as those in place in B.C.

In Nova Scotia, the above conditions are not all currently in place. Until they are, referral for colposcopy is recommended for women with any degree of dysplasia.

While the Pap smear is not a perfect test, there is irrefutable evidence that screening for cervical cancer is effective in reducing mortality. Despite the limitations,

the most common reason for failing to prevent cervical cancer is not performing the smear in the first place. Physicians must offer them to all women at risk, and ensure that they are performed with attention to a woman's comfort and dignity.

There are several other ways of improving the efficiency of cervical cytology screening. Laboratory reporting should be of high quality, and the results should be registered, monitored and followed up appropriately.

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## More Effective Cervical Cancer Prevention A REVIEW OF THE NEW PROVINCIAL CYTOLOGY MANUAL

Stewart Cameron,\* MD, CCFP

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A new cervical cytology manual is being distributed to Nova Scotian physicians this year, and it is one of several initiatives to address deficiencies in the provincial cervical screening program. The manual makes several recommendations which are at odds with current practice in other provinces, but may have to stand until other improvements are enacted which bring Nova Scotia up to national standards.

Nova Scotia has not realised the reductions in cervical cancer deaths reported in other Canadian provinces, and several reasons have been proposed for this. A substantial percentage of women at risk in this Province are not being screened. There are also many different approaches to the collection of smears, the treatment of abnormal smears, and to patient follow up. Physicians in this Province who sought guidance would often encounter conflicting advice from the literature, from consultant colleagues and their peers.

A new cytology manual was produced in 1992, for distribution this year. It will provide guidance to physicians to help them manage cervical cancer screening in a systematic fashion. As noted in the introduction by Dr. Rob Stokes, the manual is to "assist physicians... and promote a standardized approach to obtaining cervical cytology." Nova Scotia's cervical cancer prevention efforts are currently not up to national standards. The manual is one aspect of a reorganised program in this province, designed to address the deficiencies.

The collection and interpretation of Pap smears started in Nova Scotia in 1961. A Cytology Registry was commenced in the 1970s, but there was no permanent, formal program to oversee gynaecologic screening. Numerous deficiencies were noted in the province's program when it was reviewed by the Pap Smear Committee of the Medical Society in 1985. The registry's data were not easily accessible and the results were of questionable reliability. Colposcopic and cytologic databases were not integrated. There was no standardized province-wide quality control of laboratories reading smears. Large numbers of women were not being screened.

In 1989, The Medical Society of Nova Scotia endorsed a standing committee under Dr. Robert Fraser to reorganise the provincial program. The Gynaecological Cancer Screening Programme became formally operational in November of 1992, with recognition by the Department of Health.

In this province, there are nine regional laboratories interpreting Pap smears and, in general, reliability is good. Cytology laboratories do send copies of results to a central registry, which has been kept since 1978. Follow-up however, is left to the discretion of individual physicians or clinics. A system of sending letters to doctors with recommendations was tried in Nova Scotia in the 1970s, but it was stopped when it appeared physicians were not acting on the suggestions, or providing updates to the registry.

A consensus report on Pap smear screening standards was released in 1991 by a national workshop. This report makes the proviso that "the screening frequencies should be established... only when the following are in place: high quality lab services with adequate internal and external quality control systems, and information systems to monitor screening frequencies and to issue reminders to attend at the recommended intervals".

Clearly, several of these conditions have not been met in this province. The standards and the recommendations of the 1991 Report of the National Workshop are therefore not always applicable in Nova Scotia.

The deficiencies in the provincial program are now being addressed. Under the auspices of the N.S. Gynae-cological Cancer Screening Program, an improved computerised registry was launched in January 1993. It allows for computerized collection of cytology results, and colposcopic data should be integrated into the database within two years. The registry has the capability to print out follow-up letters for physicians. There are also efforts to develop a single set of external quality control standards for cytology laboratories.

In addition, the cytology manual was developed to assist physicians in the proper collection, identification and follow up of Pap smears. It makes clear recommendations on the frequency for screening and the follow up of abnormalities.

The current shortcomings in the program in this Province are why several of the recommendations are different from national standards and other published guidelines. Nova Scotian physicians should appreciate that, until provincial cytology services and the registry are brought up to national standards, this province will be required to follow different guidelines.

The new manual is generally concise and easy to read. The diagrams are helpful. The 26 page guide can be easily skimmed in a few minutes.

One of the first topics covered is avoiding patient discomfort and embarrassment. The new manual pro-

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vides suggestions for making the patient's experience a positive one.

Some conditions are recommended for the ideal smear, such as the avoidance of douching or recent intercourse. Wisely, the manual avoids suggesting that these conditions are essential. It seems better to take a smear even if conditions are not perfect, rather than lose the opportunity to perform one at all.

The manual provides information on the microanatomy of the sampling areas, proper collection of the sample and its fixation. A description of the cytology terminology is included, although there is little detail given, which

may be quite appropriate.

The regular use of the endocervical brush is advised. It is clear that it's use does result in improved sampling of the transitional zone. <sup>24</sup> The Nova Scotia cytology manual advises the use of a brush in all non-pregnant patients with a uterus.

Most of the material presented is fairly conventional practice across the country. The publication differs substantially from national standards when it makes recommendations for management of dysplasia, condyloma and the frequency of screening.

#### DYSPLASIA

The National Task Force Report recommended that cases of mild dysplasia be retested in six months. The new provincial cytology manual recommends referral for colposcopy of *all* patients with *any* degree of dysplasia. This, unfortunately, subjects a large number of women to colposcopy who, in other provinces, would only be followed with repeat Pap smears. Presumably, liberal use of colposcopy ensures that a greater percentage of women developing neoplastic changes are correctly diagnosed. Once the appropriate systems are in place in this Province, the recommendation should be reassessed, which will likely require three to five years.

#### CONDYLOMA

There is a body of opinion that any woman with vaginal or vulvar warts should be colposcoped, as six per cent of them will have cervical dysplasia of moderate or greater degree. Some gynecologists therefore recommend colposcopy for all women with evidence of HPV infection, including those with vulvar condylomatous disease, and those showing koilocytosis or dyskeratosis.<sup>5,6</sup>

The Nova Scotia Gynaecological Cancer Screening Program advises that smears showing evidence of HPV (which will be reported as "Abnormal") should be repeated in six months and referred for colposcopy if persistently abnormal. The program also recommends colposcopy for any patient with genital tract condylomata. Since HPV infections are among the commonest of sexually transmitted diseases, the recommendation will mean that large numbers of women will potentially be referred for colposcopy, placing a large burden of work on the colposcopic centres. It has the potential to create longer waiting lists, which can extend to many months in

some areas. This approach subjects many women who will never develop malignancy to colposcopy. It is also expensive to the health care system.

When improved quality control and better information systems are in place, this recommendation should be revised to meet national standards.

#### FREQUENCY OF SCREENING

The new provincial manual suggests annual Pap smears. However, the American Cancer Society has recommended that after three normal annual Pap smears, the patient can be followed by a Pap smear every three years. This approach is also supported by the Canadian Workshop Report. One member of the panel, Dr Aileen Clarke has stated in an interview that persistent annual screening is not cost effective.<sup>7</sup>

As previously stated, these recommendations presuppose a level of service which is not currently available in Nova Scotia. Until such a system is in place, annual screening may be indicated.

The Nova Scotia cytology manual did not make any recommendation about when physicians can safely stop performing Pap smears. The National Workshop report suggested that women over age 69, with two satisfactory smears without significant epithelial abnormality in the last nine years, can be dropped from the screening program, provided they have never had severe dysplasia or carcinoma-in-situ.

There is no evidence to suggest that women who have never been sexually active require Pap smears. However, it has become common practice to perform them on all women over the age of 18, and when oral contraceptives are prescribed. The provincial manual recommends screening for all women over age 18 regardless of sexual activity.

There is also no evidence to support performing smears on women who have had a hysterectomy for benign conditions. This is provided that they have always had normal smears before the hysterectomy, and the pathology report on the operative specimen confirmed a normal cervix. Smears post-hysterectomy might help detect vault dysplasia resulting from HPV infection. This condition is much less common than cervical dysplasia. The value of screening for vault dysplasia in previously normal women does not appear to have been studied.

The manual also includes copies of cytology forms from the various centres. A single standard requisition is to be produced in the future.

#### CONCLUSIONS

The new cytology manual is an important step towards improving the cervical cytology program in this province. The manual, and other initiatives of the reorganized screening program, should result in reductions of death rates from cervical cancer in this province.

The Gynaecological Cancer Screening Program in this province continues to advise liberal referral for colposcopic examinations. Such a practice results in colposcopy for a number of women who, in other provinces, would only require a repeat Pap smear. While this policy may have to stand for now, it comes at a cost, both economic and in patient well-being.

Referral for the examination subjects some women to considerable anxiety. Even with careful explanation and patient education, some patients equate any abnormal smear with cancer. Most family physicians have had patients who experienced considerable distress awaiting colposcopy and then biopsy results.

Colposcopic examinations add to the cost of our health care system. With the current pressures on health care, we must ensure that we do not overuse more expensive technologies where less expensive ones would do.

It will be necessary to move towards national standards in Nova Scotia. This will mean greater coverage with the lower cost Pap smear screen, and relatively less reliance on colposcopy. After the appropriate infrastructure is in place to handle Pap smears, the failure to screen all women at risk must be addressed. The enhancements that are planned for this province's program should allow for the adoption of nationally recommended standards in the future.

#### ACKNOWLEDGEMENT

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#### COMPLICATION OF PARENTERAL NEUROLEPTICS AND THEIR MANAGEMENT

Continued from page 86.

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"It is one of the most beautiful compensations of this life that no man can sincerely try to help another without helping himself."

Ralph Waldo Emerson (1803-1882)



(Triamcinolone Acetonide Nasal Inhaler)

#### THERAPEUTIC CLASSIFICATION

Corticosteroid for nasal use

ACTIONS AND CLINICAL PHARMACOLOGY: Triamcinolone acetonide is a potent anti-inflammatory steroid with strong topical and weak systemic activity. When administered intranasally in therapeutic doses, it has a direct anti-inflammatory action on the nasal mucosa, the mechanism of which is not yet completely defined. The minute amount absorbed in therapeutic doses has not been shown to exert any apparent clinical systemic effects.

INDICATIONS AND CLINICAL USE: Nasacort" (triamcinolone acetonide) nasal inhaler is indicated for the topical treatment of the symptoms of perennial and seasonal allergic rhinitis unresponsive to conventional treatment.

CONTRAINDICATIONS: Active or quiescent tuberculosis or untreated fungal, bacterial and viral infection. Hypersensitivity to any of the ingredients of Nasacort\* (triamcinolone acetonide).

WARNINGS: In patients previously on prolonged periods or high doses of systemic steroids, the replacement with a topical corticosteroid can be accompanied by symptoms of withdrawal, e.g. joint and/or muscular pain, lassitude, and depression; in severe cases, adrenal insufficiency may occur, necessitating the temporary resumption of systemic steroid therapy. Careful attention must be given to patients with asthma or other clinical conditions in whom a rapid decrease in systemic steroids may cause a severe exacerbation of their symptoms.

Pregnancy: See Precautions.

PRECAUTIONS:

- The replacement of a systemic steroid with Nasacort" (triamcinolone acetonide) has to be gradual and carefully supervised by the physician. The guidelines under "Administration" should be followed in all such cases.
- During long-term therapy pituitary-adrenal function and hematological status should be assessed.
- Patients should be informed that the full effect of Nasacort" therapy is not achieved until 2 to 3 days of treatment have been completed. Treatment of seasonal rhinitis should, if possible, start before the exposure to allergens.

 Treatment with Nasacort" should not be stopped abruptly but tapered off gradually.

- 5) Corticosteroids may mask some signs of infection and new infections may appear. A decreased resistance to localized infections has been observed during corticosteroid therapy; this may require treatment with appropriate therapy or stopping the administration of Nasacort\*.
- 6) The long term effects of Nasacort are still unknown, in particular, its local effects; the possibility of atrophic rhinitis and/or pharyngeal candidiasis should be kept in mind.
- 7) There is an enhanced effect of corticosteroids on patients with hypothyroidism and in those with cirrhosis. Acetylsalicylic acid should be used cautiously in conjunction with corticosteroids in hypothrombinemia.
- 8) Because of the inhibitory effect of corticosteroids on wound healing, in patients who have had recent nasal surgery or trauma, a nasal corticosteroid should be used with caution until healing has occurred.
- Patients should be advised to inform subsequent physicians of prior use of corticosteroids.
- Until greater clinical experience has been gained, the continuous, long-term treatment of children under age 12 is not recommended.
- 11) Pregnancy: The safety of Nasacort" in pregnancy has not been established. If used, the expected benefits should be weighed against the potential hazard to the fetus, particularly during the first trimester of pregnancy.

Like other glucocorticosteroids, triamcinolone acetonide is teratogenic to rodents and non-human primates (see under TOXICOLOGY). The relevance of these findings to humans has not yet been established. Infants born of mothers who have received substantial doses of glucocorticosteroids during pregnancy should be carefully observed for hypoadrenalism.

12) Lactation: Glucocorticosteroids are secreted in

 Lactation: Glucocorticosteroids are secreted in human milk. It is not known whether triamcinolone acetonide would be secreted in human milk, but it is suspected to be likely. The use of Nasacort<sup>-</sup> in nursing mothers, requires that the

- possible benefits of the drug be weighed against the potential hazards to the infant. 13) Children: Nasacort is not presently recom-
- 13) Children: Nasacort" is not presently recommended for children younger than 12 years of age due to limited clinical data in this age group.
- 14) Fluorocarbon propellants may be hazardous if they are deliberately abused. Inhalation of high concentrations of aerosol sprays has brought about cardiovascular toxic effects and even death, especially under conditions of hypoxia. Aerosols are sate when used properly and with adequate ventilation, but excessive use should be avoided.
- 15) To ensure the proper dosage and administration of the drug, the patient should be instructed by a physician or other health professional in the use of Nasacort" (see Patient Instructions).

ADVERSE REACTIONS: Adverse reactions reported in both controlled and uncontrolled studies involving 1148 patients who received Nasacort" (triamcinolone acetonide) are provided in the following table:

Adverse Experience	Nasacort % (n = 1077)	Placebo % (n = 545)
Headache	20.4	19.4
Upper Respiratory		
Infection	5.3	8.1
Nasal Irritation	5.1	4.2
Throat Discomfort	4.6	3.3
Dry Mucous		
Membranes	3.5	2.2
Epistaxis	4.6	6.6
Sneezing	3.1	5.5
Sinusitis	2.1	3.7

When patients are transferred to Nasacort\* from a systemic steroid, allergic conditions such as asthma or exzema may be unmasked (see Warnings).

of exzema may be unmasked (see Warnings).

SYMPTOMS AND TREATMENT OF OVERDOSAGE: Like any other nasally administered corticosteroid, acute overdosing is unlikely in view of the 
total amount of active ingredient present. However 
when used chronically in excessive doses or in 
conjunction with other corticosteroid formulations, 
systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such 
changes recur, the dosage of Nasacort" (triamcinolone acetonide) should be discontinued slowly 
consistent with accepted procedures for discontinuation of chronic steroid therapy. (see Administration). 
The restoration of hypothalamic-pituitary axis may 
be slow; during periods of pronounced physical 
stress (ie. severe infections, trauma, surgery) 
a supplement with systemic steroids may be

DOSAGE AND ADMINISTRATION: See Warnings. Nasacort" (triamcinolone acetonide) is not recommended for children under 12 years of age.

Careful attention must be given to patients previously treated for prolonged periods with systemic corticosteroids when transferred to Nasacort". Initially, Nasacort" and the systemic corticosteroid must be given concomitantly, while the dose of the latter is gradually decreased. The usual rate of withdrawal of the systemic steroid is the equivalent of 2.5 mg of prednisone every four days if the patient is under close supervisions. If continuous supervision is not feasible, the withdrawal of the systemic steroid should be slower, approximately 2.5 mg of prednisone (or equivalent) every ten days. If withdrawal symptoms appear, the previous dose of the systemic steroid should be resumed for a week before further decrease is attempted.

The therapeutic effects of corticosteroids, unlike those of decongestants, are not immediate. Since the effect of Nasacort depends on its regular use, patients must be instructed to take the nasal inhalations at regular intervals and not as with other nasal sprays, as they feel necessary.

In the presence of excessive nasal mucus secretion or edema of the nasal mucosa, the drug may fail to reach the site of action. In such cases it is advisable to use a nasal vasoconstrictor for two to three days prior to Nasacort" therapy. Patients should be instructed on the correct method of use, which is to blow the nose, then insert the nozzle firmly into the nostril, compress the opposite nostril and actuate the spray while inspiring through the nose, with the mouth closed.

An improvement of symptoms usually becomes apparent within a few days after the start of therapy. However, symptomatic relief may not occur in some patients for as long as two weeks. Nasacort" should not be continued beyond three weeks in the absence of significant symptomatic improvement.

Adults and Children 12 years of age and older: The recommended starting dose of Nasacort\* is 400 µg per day given as two sprays (100 µg/spray) in each nostril once a day. If needed, the dose may be increased to 800 µg per day (100 µg/spray) either as

once a day dosage or divided up to four times a day, i.e., twice a day (two sprays/nostril), or four times a day (one spray/nostril).

After the desired effect is obtained, patients may be maintained on a dose of one spray (100 µg) in each postril once a day (total daily dose; 200 µg per day)

nostril once a day (total daily dose: 200 µg per day). AVAILABILITY. Nasacort" ((iriamcinolone acetonide) is a metered-dose aerosol unit containing a microcrystalline suspension of triamcinolone acetonide in the propellant dichlorodifluoromethane and dehydrated alcohol USP 0.7% w/w. Each canister contains 15 mg triamcinolone acetonide. Each actuation releases approximately 100 µg triamcinolone acetonide of which approximately 55 µg are delivered from the nasal actuator to the patient (estimated from in-vitro testing). There are at least 100 actuations in one Nasacort" canister. The device should not be used after 100 inhalations, since the amount delivered thereafter per actuation may not be consistent. It is supplied with a nasal adapter and patient instructions: Box of one.

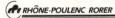
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#### Melanoma

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Halifax, N.S.

The purpose of this article is to document current information relating to the epidemiology, etiology and prevention of cutaneous melanoma. Cutaneous melanoma has become a common form of cancer.<sup>1</sup> Recent research has advanced our understanding of this condition and the article will outline our approach to the treatment and control.

#### TRENDS

The incidence of melanoma has almost tripled in the past four decades.<sup>2</sup> Projection studies suggest that melanoma will develop in 1:90 North Americans by the year 2000.<sup>3</sup> This dramatic increase is most likely related to a change in sun exposure habits which have occurred over the last 40 years. Society has determined that a good tan is a pre-requisite for a healthy and successful life. The effect of a thinning of the ozone layer will undoubtedly have detrimental effects on our skin in the years to come unless proper protective measures are taken. The five year survival rate in melanoma now rests at about 81% which is considerably better than the 49% rate given in

#### TABLE I

#### RISK FACTORS OF SIGNIFICANCE

- 1. Changing mole.
- 2. Adulthood versus childhood.
- Family history of melanoma.
   Personal history of melanoma.
- Large numbers of nevi.
- 6. Dysplastic nevi.
- 7. Large congenital nevi (?)
- 8. Small congenital nevi.
- 9. Race.
- 10. Ethnicity: Celtic high, Hispanic low, Asian Indian very low.
- 11. Freckling trait.
- 12. Light complexion.
- 13. Blue or grey eyes.
- 14. Blond or red hair.
- 15. Poor tanning ability.
- Easy sunburning (blistering or severe sunburns, especially in childhood or adolescence).
- 17. Migration from less sunny climate to more sunny climate before age 10.
- 18. Chronic cumulative sun exposure.
- 19. Exposure to suntanning lamps.
- 20. White collar indoor workers versus outdoor workers.
- 21. Socioeconomic status.
- 22. Postgraduate education.
- 23. Immunosuppressive states (?)

1950.3 This improvement in survival is due to earlier diagnosis and treatment.

#### THE GENETICS OF INDIVIDUALS AT RISK

In the literature there have been recent reviews identifying risk factors for those that may develop melanoma. Several phenotypic factors of significance in predicting melanoma include eye color, hair color, complexion, freckling, trait and ability to burn/tan. People with blond or red hair, who often have blue or grey eyes and fair complexion, respond to intense solar damage. All these factors increase the risk of melanoma developing with a relative risk usually in the range of two to three-fold. Table I shows risk factors of significance. Non-phenotypic factors also exist. Melanoma is very rare in childhood with rates approximately 1 per million per year from birth to age ten. Family history of melanoma is a major risk factor. About 1:10 melanoma patients has a family member with melanoma.

The field of precursor lesions for melanoma is subject to an ongoing debate. There is controversy in the literature about how one should manage large congenital nevi and whether or not prophylactic excision is indicated. The familial atypical multiple mole melanoma (FAMMM) syndrome appears to be inherited as a dominant gene. Thus it is important to take a family history in patients with melanoma and to examine relatives if there is any suggestion of a familial occurrence.

The term *dysplastic* has been criticized because pathologists and clinicians have various concepts and definitions of the work. It seems reasonable to refer to unusual nevi as *atypical nevi* or *atypical moles*.

Nevertheless, dysplastic nevi as a term appears in the literature and it is important to have a concept of what people are talking about. The histological features diagnostic of dysplastic nevi include architectural atypia, and atypical cellular stromal reaction. Atypical nevi may be recognized in children and young adults. We now recognize that there is both a familial type and a sporadic form of dysplastic nevus syndrome. These nevi are usually larger than regular nevi, may have indistinct margins and may change with time. Close follow-up of these patients is necessary.

#### RISK FACTORS FOR MELANOMA

#### Ultraviolet Radiation

Most people feel that external ultraviolet radiation is the major causative factor for human cutaneous melanoma. Most evidence supports the hypothesis that the risk of melanoma depends more on intermittent exposure to the sun, especially early in life rather than

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cumulative exposure. 7,8,9 The fact that our earth's ozone layer has been depleted has made us all much more concerned about the possibility of receiving ultraviolet light damage. There is reason to be concerned that this may result in an increase in melanoma in the coming decades. 10,11 Since most feel that melanomas in light skinned people are due to UVR, then it should be preventable by a reduction in sun exposure and by efforts to avoid intermittent and intense exposure to sunlight. Avoidance techniques are important and public education must be intensified. Such activities to promote public education are underway in Australia. 12 Although no increase in melanoma has been shown in patients receiving ultraviolet A treatment for the treatment of psoriasis, 13,14 the safety of artificial sources of ultraviolet radiation can be brought into question. Dermatologists are opposed to the use of sunbeds or sun lamps by individuals who wish to obtain a "tanned look" during the winter months.

#### **Non-Solar Factors**

Although sun exposure plays a leading role in the development of melanoma, there are other factors that must be considered. It has been suggested that chemicals in the environment may play a role. There is a higher incidence of melanoma in the southwest of England and some have suggested that arsenic in the environment may be a risk factor. <sup>15</sup> Occupational exposure to polychlorinated biphenols (PCBs) has been associated with melanoma risk by Bahn *et al.* <sup>16</sup>

In addition to an increased occurrence in family members with melanoma, some genetic disorders such as xeroderma pigmentosa and albinism show a higher incidence of melanoma.

#### **Immunological Factors**

From an immunological standpoint, cutaneous melanoma is becoming one of the most intensively investigated types of cancer. Serological analysis has demonstrated that there are three classes of cell surface antigens on melanoma cells.<sup>17</sup> Several melanoma specific glycoproteins are being used in diagnostic tests in the hope that antibodies may be generated and vaccines may be found for immunotherapy.

It appears that melanoma is a very complex disease process involving genetic and environmental factors. It seems that ultraviolet radiation plays a variety of roles in the disease as a tumour initiator, tumour promoter and inhibiter of local immune responsiveness. It appears that exposure to ultraviolet light hastens the progress of disease by adversely affecting the local immunological state of the host's skin. Three of the ten recognized risk factors for melanoma are immunosuppression, sun sensitivity and excessive sun exposure. The fact that immunosuppression is a significant risk factor for melanomas suggests that at least some melanomas may be amenable to immunological therapy. It also suggests that those physicians who look after immunosuppressed pa-

tients should be very vigilant for signs of cutaneous melanoma.

#### Hormonal and Reproductive Factors

The use of oral contraceptives and the risk of malignant melanoma has been intensively studied. No significant trend has been reported and the data therefore indicate that oral contraceptive use does not substantially increase the risk of developing malignant melanoma of the skin. Data on exogenous female hormones other than oral contraceptives are very limited. From the point of view of determining counselling it seems reasonable to indicate to our patients that recent investigations do not prove an increased risk to melanoma related to the use of oral contraceptives, post-menopausal estrogen therapy or reproductive therapies.

#### **Dietary Factors**

There have been experimental studies suggesting that dietary anti-oxidants may reduce, and that poly-unsaturated fat may increase the carcinogenic effect of ultraviolet radiation. It has also been suggested that retinoids, vitamin C and vitamin E may inhibit the growth of melanoma. Alcohol intake has been postulated as a promoter of the growth of melanoma, but it is important to realize that very few epidemiological studies specifically tested these hypotheses and that currently there is insufficient data to conclude in favour of any of these associations and melanoma. Thus although reports exist in the literature about diet and its importance in melanoma, the data are incomplete and unsubstantiated.

#### **HUMAN MODELS AND MELANOMA**

As stated earlier there are a variety of special exposures or genetic defects where humans may serve as models for melanoma. Xeroderma pigmentosa and albinism are two of them. Further study in these situations may yield more definitive conclusions to allow us to understand melanoma in the population at large. There have also been numerous case reports of melanoma in human immunodeficiency virus infected patients. 18.19

#### PUBLIC AND PROFESSIONAL EDUCATIONAL PROGRAMS IN MELANOMA<sup>20</sup>

We know that people who have intermittent exposure to ultraviolet light are more prone to develop melanoma, especially when they have other risk factors. Thus if we can identify these people, we should be able to educate them so as to avoid this excessive sun exposure. This difficult but important task must be done by the individual physician with a patient, by those of us involved with patients who have been identified with melanoma, and with the community at large. This is especially important as we know that the longer the delay in diagnosis the worse the prognosis. Public education is expensive and we are all aware of the medical costs and/or impact on our budgets.

# SCREENING FOR MELANOMA AND OTHER SKIN CANCERS

The rationale for screening relates to the fact that early detection is the key in this condition. We know that the longer a melanoma has been present on the skin the worse the outcome. In many centres pigmented lesion clinics have sprouted up and this has occurred in Halifax. A multidisciplinary approach to the management of melanoma is done in a clinic which now exists at the Camp Hill Medical Centre. Here, a dermatologist, a pathologist, a plastic surgeon, a medical photographer, a dedicated nurse and a medical oncologist work together in patient evaluation, treatment and education. Any unusual looking changes are photographed and any changes which may appear over a period of time can be determined at the following visit when previous photographs are used in comparison. It is important that self screening be performed by all. Skin examination as part of a complete physical examination is also very important for primary physicians. If unusual pigmented lesions exist then these should either be excised or another opinion sought.

# MELANOMA MANAGEMENT

Essential to the proper management of melanoma are accurate diagnosis, staging, and prognostic evaluation. At this time there is really only one effective form of management – surgery.

Early recognition and diagnosis is the most critical aspect of management. When the lesion is suspected to be a melanoma, a biopsy should be performed promptly. Recent studies have dispelled previous concern that the biopsy of a melanoma

promotes its dissemination. 21,22,23 Once the diagnosis of malignant melanoma has been confirmed histopathologically, the tumour must be staged to determine prognosis and treatment. In the past the accepted treatment of a stage I melanoma was surgical excision with surgical margins of up to 5 cm.24 New data however suggest that narrower margins may suffice. 25,26 Current treatment recommendations are for a conservative margin (1 cm) for thin primary tumours (less than 1 mm in depth), and more extensive margins (up to 3 cm) for thicker primary tumours. In general, lymph node dissection of clinical stage I disease does not appear to benefit patients with lesions that have a low risk of metastasis (thickness of less than 1.5 mm) or patients with thick lesions (greater than 4 mm). There is controversy in the literature as to what one should do with a melanoma which is between 1.5 and 4 mm in thickness. Non-randomized studies suggest a benefit for patients with these lesions from elective radical lymph node dissection. There is no question that most would suggest lymph node dissection for those with clinically enlarged nodes. Thus when clinically suspected nodes are identified, regional lymph node dissection is always recommended except in patients with uncontrolled distant metastases.

Once the disease has advanced beyond surgical management the prognosis is quite grave. Of the chemotherapeutic agents the most commonly used is Dacarbazine (DTIC) which has an aggregate rate of response of approximately 15 to 25%. 27,28 There are a number of other experimental therapies, of which the most exciting is immunotherapy. In the past, Bacillus Calmette-Guerin (BCG) has been known to cause non-specific immune stimulation. Multiple anecdotal reports have shown BCG to be beneficial but most of the randomized control studies have failed to show any benefit.<sup>29,30,31,32</sup> The use of immunotherapy, however, is being developed to a greater extent and attempts are underway to develop a tumour vaccine. Adoptive immunotherapy represents a recent advance in immunotherapy. In this therapy, either circulating lymphocytes interact with interleukin II to form lymphokine activated killer (LAK) cells, or lymphocytes derived from the tumor, termed tumor infiltrating lymphocytes (TILs), are used. The response rate of LAK therapy in advanced melanomas is approximately 27%.33 TIL adoptive therapy is reportedly more effective and less toxic.34,35

# FOLLOW-UP SCHEDULE FOR MELANOMA

A melanoma follow-up schedule that is currently used at the Pigmented Lesion Clinic at Camp Hill Medical Centre is the same one used at the Massachusetts General Hospital (Table II). <sup>36</sup> Obviously this must be tailored to the risk of recurrence or the risk of development of a secondary primary melanoma.

TABLE II

	FOLL	OW-UP*
Thickness group (mm)	Frequency (mo)	Duration (Yr)
< 0.76	6	1 - 2
0.76 - 1.49	6	5
≥ 1.50	3	2
	6	Next 3 yr

<sup>\*</sup>Ten-year annual follow-up for all melanoma patients. Those with dysplastic nevi may require more frequent follow-up and follow-up for life.

#### PATIENT COUNSELLING

Obviously patients must be counselled about prognosis and other issues that concern them. Sun protection, dysplastic and congenital nevi and family screening must be a part of this.

#### CONCLUSIONS

While we wait for a better understanding of the cause of melanoma, it is important that all physicians be aware of the factors that are important to communicate to our patients. As a society we must do better to preserve the ozone layer. The regulation of tanning parlours, and the fostering of habits to use regular sunscreens and thus

achieve better sun protection especially in children and adolescents, are important considerations. Public education must be undertaken so people will be aware of what to look for and thus identify suspicious pigmented lesions earlier. Patients with dysplastic nevi require skin examination at least once or twice a year. Serial photography may help physicians evaluate pigmented lesions during these follow-ups. Treatment must be individualized and a successful strategy for preventing death from melanoma must include an increased public and professional education.

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# Head Injury and Bicycle Helmet Use in Child Cyclists in Nova Scotia

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Objective: To document the circumstances of head injury and the pattern of bicycle helmet use in child cyclists in Halifax County, Nova Scotia.

Design: Retrospective chart review and prospective telephone interview.

Setting: The Emergency Department of a tertiary-care children's hospital in Halifax, Nova Scotia.

Patients: Between January 1988 and March 1990, 722 child cyclists were assessed in the Emergency Department of the Izaak Walton Killam Children's Hospital (IWK) for bicycle related injuries. 58(8%) had head injuries. To document the pattern of head injury and bicycle helmet use in this subset, we conducted structured telephone interviews with the parents of 44 of these children between 7 and 31 months following injury.

Results: 36 of the subjects were boys, ranging in age from 4.0-15.6 years ( $\bar{x}$ =9.2 yrs). Eight subjects were girls, with an age range of 4.6-13.3 years ( $\bar{x}$ =7.2 yrs). 90% of injuries occurred in the street, driveway or sidewalk, and all occurred within 5 blocks of home. Only 1 injury involved a moving motor vehicle. Six children required hospitalization as a result of the head injury. The average length of hospitalization was 6 days, with a range between 3 to 13 days. There was no significant age difference between those admitted to hospital and those sent home (p=0.20). The most common injury sustained was a mild concussion. Stunt riding, excessive speed, and loss of control were the most frequent mechanisms of injury. There was no relationship between mechanism of injury and sex (p < 0.50). Older children tended to sustain more injuries as a result of unsafe riding practices, whereas younger riders had injuries most often attributable to inexperience. 70% of parents felt their child's injury was preventable. No child was wearing a helmet at the time of injury, although 4/44 (9%) claimed to own one. After injury, 14/40 (35%) of the children obtained a helmet. At follow-up, 4/18 (22%) of helmet owners were wearing the helmet regularly. In most cases, no helmet was purchased despite the head injury. There was no relationship between injury severity and obtaining or utilizing a helmet.

Conclusion: We conclude the prevalence of bicycle helmet use is low in children brought to the IWK for bicycle related head injuries. Bicycle helmet use increases slightly following a bicycle related head injury, but its use is not sustained.

In Canada in 1989 there were an estimated 5.5 million child cyclists. In children, bicycle accidents are second only to indoor falls as the leading cause of head injuries, <sup>24</sup> and head injuries are the most common cause of bicycle related fatalities. <sup>59</sup> Recent data indicate the frequency of bicycle related head injuries can be reduced through the use of bicycle helmets <sup>10-12</sup> and the use of helmets can reduce the risk of head and brain injury by 85% and 88% respectively. <sup>7</sup> Despite these facts, it is estimated that only 2 to 5% of child cyclists wear helmets. <sup>2,6,7,10,13-15</sup> This study was undertaken to document circumstances of injury and bicycle helmet use patterns among head injured child cyclists presenting to the Izaak Walton Killam Children's Hospital (IWK).

#### **METHODS**

The IWK in Halifax is a 200 bed tertiary-care referral centre for the Maritime provinces. All patients seen there for the management of an acute bicycle-related head injury between January 1988 and March 1990 were potential participants in the study. Subjects were identified retrospectively through the hospital medical records department, using specific ICD-9 head-injury codes in conjunction with the Canadian Accidental Injury Reporting (CAIR) data base. The latter is a system which has been in place at the IWK for the past several years, and is used by Emergency room physicians to document details of any accident involving a consumer product. Open and closed head injuries were included, as were patients with skull or facial bone fractures, and head or facial lacerations. All cases in which the bicycle rider was fatally injured were excluded; there were only two such cases in Nova Scotia over the study period (Personal communication: Ms D. McCready, Nova Scotia Department of Transportation).

Information including the patient's age at the time of injury, the circumstances of injury, and an estimate of injury severity was obtained through chart review. The chart review was followed by a structured telephone interview, with the child's usual caregiver, 7 to 31 months post injury. All interviews were conducted by the same author using a standardized, previously piloted, questionnaire. Open and closed ended questions were used to document the characteristics of the injury, the pattern

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of bicycle helmet use pre and post injury, the parents' socioeconomic status, and the patients' present functional status. The interviewee was also asked to provide a retrospective opinion as to the extent to which the child's injury was potentially preventable.

# DATA ANALYSIS

Data obtained from the questionnaire was analyzed descriptively. Non-parametric chi-squared analyses were performed on factors including injury preventability, mechanism of injury and level of education of helmet purchasers. Student's t-tests comparing age and preventability of injury, as well as age and mechanism of injury were also performed. A p-value of less than 0.05 was considered significant.

# RESULTS

During the 27 month period studied, 722 patients presented to our hospital with bicycle injuries, of which fifty-eight (8%) involved head injuries. Thirteen subjects were lost to follow-up, and one was excluded because of the parent's complete inability to recall any details of the injury. Thus 44 of the 58 potential subjects (76%) were included in the study. Thirty-six were boys, who ranged in age from 4.0 to 15.6 years old (mean age 9.2 years); eight were girls, who ranged in age from 4.6 to 13.3 years old (mean age 7.2 years).

Eighty-seven percent of the subjects were seen in the Emergency Department, assessed, and sent home with the standard head injury sheet. Five patients (11%) required hospital admission because of the severity of their injuries. There was no significant age or sex difference between those admitted to hospital and those sent home (p=0.20).

Twenty-five (57%) of the riders had over 2 years of bicycle riding experience. All the riders requiring hospital admission had been riding for at least 2 years. Seventeen bicyclists received bicycle safety instruction prior to their accidents, and seventeen did not. Fourteen of the 44 riders (32%) had had either previous or subsequent bicycle injuries which required medical assessment.

At the time of injury, most subjects (61%) were riding standard coaster bicycles with foot brakes. The rest of the riders were evenly distributed amongst various geared, mountain and BMX bicycles. Eighty percent of bicycles were less than 2 years old. Only one parent said major repairs were necessary on their child's bicycle at the time of injury.

# CIRCUMSTANCES OF INJURY

Over 90% of all injuries occurred on the street (59%), driveway (20%) or sidewalk (11%). On all occasions the surface was dry and, in 63% of injuries, the surface was paved. All injuries occurred within 5 blocks of home, usually while the cyclist was out for a recreational ride. Most often, the incident occurred during the daylight hours, with only 16% occurring at dusk or later. Five out of 44 injuries involved motor vehicles, but only one of

these 5 involved a moving vehicle. The other 4 injuries occurred when inexperienced riders were temporarily distracted and rode into parked cars. None of the injuries involving a motor vehicle required hospital admission.

# MECHANISM OF INJURY

The mechanism of injury is outlined in Tables I and II. The totals in Tables I and II are greater than the total number of subjects in the study because more than one mechanism of injury was operational in some cases. Stunt riding, excessive speed and/or loss of control were the most common causes of injury, especially in older males who had at least 2 years of bicycle riding experience. Unavoidable obstacles and inexperience were the next most common reasons for injury, typically occurring in the younger, novice bicyclists. A chi-square analysis of mechanism of injury versus sex failed to reveal any significant difference. A Student's t-test of mechanism of injury versus age was not significant (t=0.3219,p > 0.5).

TABLE I
MECHANISM OF INJURY: "UNSAFE RIDING"

	Male (n = 23)	Female (n = 4)	Total* (n = 27)
Too fast/out of control	9 (39%)	2 (50%)	11 (41%)
Stunts	6 (26%)	1 (25%)	7 (26%)
Inattention	5 (22%)	0	5 (18%)
Traffic safety infractions	2 (9%)	0	2 (7%)
Night riding	1 (4%)	1 (25%)	2 (7%)

<sup>\*</sup>Total greater than 44 in Tables I and II due to multiple mechanisms of injury in some subjects.

TABLE II
MECHANISM OF INJURY: "SAFE RIDING"

	Male (n = 18)	Female (n = 5)	Total* (n = 23)
Unavoidable object	7 (39%)	1 (20%)	8 (35%)
Inexperience	3 (17%)	2 (40%)	5 (22%)
Equipment failure	2 (11%)	1 (20%)	3 (13%)
Unfamiliar equipment	2 (11%)	1 (20%)	3 (13%)
Road conditions	2 (11%)	0	2 (9%)
Driver error	1 (6%)	0	1 (4%)
Medical condition	1 (6%)	0	1 (4%)

<sup>\*</sup>Total greater than 44 in some subjects due to multiple mechanisms of injury in some subjects.

# TYPE OF INJURY

The most common injury sustained was a mild concussion, with or without a documented period of loss of consciousness (Table III). Other common injuries included extracranial skull hematomas and superficial facial abrasions. Four patients had brief, documented loss of consciousness, 3 patients had linear skull fractures, 2 patients had transient cranial nerve paresis (III,

VI), and one patient had an intracerebral hematoma. All these latter patients required hospital admission. The average length of hospitalization was 6 days, with a range between 3 and 13 days.

TABLE III

TYPE OF INJURY		
No loss of consciousness	40	
Loss of consciousness < 15 min	4	
Extracranial hematoma	23	
Facial abrasion	10	
Extremity abrasion	6	
Facial hematoma	5	
Skull fracture	3	
Dental injury	3	
Facial fracture	2	
Cranial nerve injury	2	
Intracerebral hematoma	1	
TOTAL*	99	

<sup>\*</sup>Total greater than 44 due to multiple injuries in several patients.

# HELMET USE

Four out of 44 subjects (9%) claimed to own bicycle helmets at the time of their injury; however, none of the owners were wearing them when they were hurt (Table IV). The reasons for not wearing the helmet varied, but included peer pressure (20%) and discomfort (20%).

TABLE IV
HELMET USE PATTERNS

THEME! COLINITER TO	
Total	n = 44
Owned helmet at time of injury	4 (9%)
Obtained helmet post-injury	14 (32%)
Helmet owner post-injury	18 (41%)
Pre-injury helmet use:	n = 4
0-25% riding time	3 (75%)
75 – 100% riding time	1 (25%)
Helmet use immediately post-injury:	n = 18
Never	5 (28%)
< 25% riding time	1 (6%)
25 – 74% riding time	4 (22%)
75 – 100% riding time	8 (44%)
Helmet use at time of survey:	n = 18
Never	9 (50%)
< 25% riding time	1 (6%)
25 – 74% riding time	4 (22%)
75 – 100% riding time	4 (22%)

Following injury, 14 out of 40 riders (35%) obtained helmets, for a total of 18 helmet owners post-injury. Initially, 8 out of 18 (44%) of the new helmet owners wore their helmets at least 75% of the time but, by 6 to 12 months later, only 4 out of 18, or 22% of new helmet owners were still wearing them at least three quarters of the time. The remainder were using them on an intermittent basis or not at all. There was no relationship between injury severity and obtaining or utilizing a helmet.

The reason cited by the majority of parents for not purchasing a helmet after the injury is "never thought of it" (45%). Twenty-nine percent of parents were deterred by the belief that their child would not wear a helmet. No parent reported cost as a major factor in not obtaining a bicycle helmet. A chi-squared analysis between helmet purchasers and parental level of education failed to show any significant difference.

#### PREVENTABILITY

Seventy percent of interviewed parents felt their child's injury was "likely preventable". For the most part, the injuries of the older children were felt to be the most amenable to prevention; this corresponds with the tendency of the older children to sustain more injuries as a result of unsafe riding practices. Younger riders had injuries most often attributable to inexperience, the circumstances of which were felt to be less likely preventable. A chi-squared analysis of preventability and sex showed no significant difference; similarly, a Students t-test between preventability and age failed to disclose any significance (t=1.19, p < 0.30).

# DISCUSSION

The description of riders and the epidemiology of injury in our study is consistent with that previously reported. <sup>15-19</sup> In our study, most of the injured cyclists were non-helmeted preadolescent boys, 8 to 9 years of age, with at least 2 years riding experience. Only 5 out of the 44 incidents involved a motor vehicle, and only one of these 5 incidents involved a moving motor vehicle. It is important to emphasize that the vast majority of bicycle related injuries do not involve motor vehicles.

Of the types of injury sustained, the most common were mild concussion, facial abrasions and extracranial skull hematomas, and probably all could have been prevented with a bicycle helmet. Less common, but more serious injuries such as skull fracture and cranial nerve palsies may also have been prevented. Dental injuries and abrasions on areas other than the head and face generally are not prevented by wearing helmets.<sup>20</sup>

Four out of 44 (9%) riders in the study owned helmets at the time of injury, although none were wearing them. Following a head injury, which was considered significant enough to require medical attention, we expected that both the rider and the parents would be acutely sensitized to the necessity of wearing bicycle helmets. Surprisingly, this did not prove to be the case. Fourteen (35%) of cyclists obtained a helmet after injury but, at the time of interview, only 39% of these were still wearing them at least 50% of the time. In most cases, no helmet was purchased despite the head injury; the most common reason given was that it was never considered. There was no relationship between injury severity as judged by hospital admission and obtaining or using a helmet. We conclude that the prevalence of bicycle helmet use is low in children brought to the IWK for medical attention following a bicycle related head injury, and although use

increases slightly following a bicycle related head injury, this is not sustained.

These facts may appear discouraging, but lack of awareness of the importance of bicycle helmets is probably the factor in the bicycle helmet campaign most amenable to change. Increasing public awareness through the media, the use of prominent spokespersons, as well as school and community promotions have been shown to be effective. <sup>16,21-25</sup> Our data suggest that it may be possible to target a subpopulation of riders, namely preadolescent boys involved in unsafe riding practices, whose injuries are for the most part preventable. Although other studies have shown that educated parents believe in bicycle helmet safety more than less well educated parents, <sup>14,24</sup> we did not find the level of education to correlate with a parents' decision to purchase a helmet before or after injury.

Important as it may be to convince the adults of the necessity of bicycle helmets, it is just as important to convince the children to wear the helmets. It seems that factors such as peer pressure and cosmesis weigh more heavily on a young person's mind than the possibility of brain damage; to change this, more energy must be spent in raising the image of the bicycle helmet in the eyes of children.

Bicycle injuries can happen anywhere, anytime, and both experienced and inexperienced riders are susceptible. Bicycle helmets reduce the risk of serious head injury by 85%. Children should protect their heads each and every time they get on a bicycle; adult riders can help by setting an example. We present this information to increase awareness among Nova Scotian physicians of the local trends in child cycling habits. We hope all physicians involved in the care of children will find this information of use in promoting bicycle helmet safety concepts to their young patients and their parents.

# **ACKNOWLEDGEMENTS**

The authors wish to thank Ms Valerie Schaffner, Health Records Department of the Izaak Walton Killam Children's Hospital and Mr. Peter King, Editorial Services, Dalhousie University for their assistance in the completion of this project.

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# **Medical Humanities**

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Osler taught humanistically because he could do nothing else. He was not a humanist by choice – he was a humanist. He saw the danger of science unchained and tried to offset the influence of science without humanism. His method of doing this was to remind his students constantly of the human interplay that they were studying – that every patient was a complex human being with a family and a home and problems and sensitivities. He once said, 'care more particularly for the individual patient than for the special features of the disease'.

Charles G. Roland, MD

# STEPHEN HAWKING AND THE BLACK HOLES

How many have bought the book A Brief History of Time, by Stephen Hawking? (A sea of hands go up).

"How many actually finished reading the book?" (A few hesitant hands go up).

"How many of you understood the book? (Stares).

Those of us who bought the book and who have followed the stories about Hawking, who suffers with amyotrophic lateral sclerosis, were impressed by the vision of a seriously disabled person advancing the knowledge of the universe while imprisoned in a slowly disintegrating body.

Hawking has no use of his limbs, cannot speak except through an electronic synthesized voice, and has a tracheostomy. Given that many ALS patients live 3 to 4 years, his longevity over more than twenty years is amazing, and his productivity during this time is a remarkable tribute to his strengh of character and fortitude. The "world class" level (to borrow a Toronto term) of his work has led people to announce him as the successor to Einstein, and to await his award of the Nobel Prize.

Not all agree. Physicists seem to see him as an important contributor to the field, but among many others. They don't see him in the top list for the Nobel, except as a sentimental favorite, which may sound unkind and meanspirited.

Most of us do not know how to evaluate these complex questions but, as physicians, we see him as an outstanding example of the power of coping and of motivation over severe adversity. Most would accept someone tossing in the towel when weakness of grip and stumbling gait interfere with normal activities, but how do we then explain the Stephen Hawkings, Paul Gauettes, Terry Foxs, and the many unknown brave people who struggle

on despite the slings and arrows and seemingly insurmountable hurdles? It reminds me of a poem Janet learned in school:

Courage does not lie alone in dying for a cause, To die is only giving. Courage is to have the hurt, to feel The daily daggers of relentless steel And keep on living.

Understanding coping behavior will be an important area of research in the next decade, with interesting studies already underway. It is noteworthy that it is designated as a new thrust of the Canadian Institute of Advanced Research.

## BROWSING AMONG THE BOOKSELLERS

Although I enjoy wandering the aisles of our local second hand booksellers, I also await the Boxing Day sale at Schooner Books. Even John Doull, the Bookseller, was there perusing the books on books and the Canadiana. He knows my interests, and passed a few down to me from

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the ladder where he stood. I got an excellent set of *The Life and Letters of the Right Hon. Sir Charles Tupper, Bart, KCMG* (Edited by E. M. Saunders D.D., Cassell and Co., Toronto. 1916. 2 Vols.) and a few other items.

One interesting tiny privately printed brochure was, As a Layman Sees It, 1963, by Dr. Hugh W. Schwartz, who was Professor and Head of the Department of Ophthamology and Otolaryngology at Dalhousie University in the 1940s, retiring as Professor Emeritus in 1952. The notes, previously published in The United Churchman, are the thoughtful struggles of a physician with his religious beliefs and his comments and understanding on miracles, the concept of chosen people, revelation, faith and various scriptural issues. There is a long tradition of physicians publishing their struggles with religious thought and, although this slim volume won't open very wide the windows of theology, it is reassuring when physicians continue to think deeply about the human condition and grapple with a philosophical understanding of our life on this planet and in this universe.

# THE GRENFELL ADVENTURE

Since this past year was the anniversary of the Grenfell Mission, it is a good time to read a book on this impressive Victorian venture. I liked the volume by Dr. Gordon Thomas, From Dogsled to Sattelite. Thomas, who now lives in Baddeck, was one of the successors of Grenfell, as medical director of the services to outport Newfoundland and Labrador.

Another of Grenfell's successors, Dr. Tony Paddon, later the Lieutenant Governor of Newfoundland, recorded his reminiscences in *Labrador Doctor*, James Lorimer Press, 1992. His father had come to Newfoundland with Grenfell, and these physicians and their staff, down to the current director, Dalhousie medical graduate Dr. Peter Roberts, provided a concept of health care that always recognized the life and culture of the people they served.

# THE HISTORY OF A GREAT JOURNAL

The idea of a history of a medical journal might sound soporific, but the Mirror of Medicine: a History of the British Medical Journal Oxford University Press, 1990, by P.W.J. Bartrip is a great read. The leading world journals are the New England Medical Journal, Lancet, British Medical Journal, Journal of the American Medical Association and the Annals of Internal Medicine by all the measures of circulation and citations, and they have dominated medical publication in this century. The first issue of the BMJ was on October 3, 1840, when it was called the Provincial Medical and Surgical Journal, and it cost 7d. It is interesting to see how frank and hardhitting the journals were in the old days, undeterred by modern concerns over law suits and professional courtesy.

#### PHYSICIANS AND POETRY

Poetry is a form I wish I found easy, but I don't. Some I enjoy but I watch with admiration the ease my wife and

daughter have with this form. I'm sure I should spend more time and effort but, like my periodic efforts to clean up my workshop or straighten up my files, I occasionally read a book of poetry because I feel I should improve my lowly existence. It gives me a sense of pleasure when I enjoy a poet, but I also recognize that those who know would recognize I have probably selected someone easy and, well, not of the first order.

Keats was a physician, of course, but some years ago I was asked to review a book that suggested his medical training influenced his poetry, and I was not convinced. Dannie Abse, another physician-poet, speaks to me in ways I understand. Many physicians have written poetry, including some Nova Scotians, and it is a way to express intense feelings, and encapsulate them with, as Coleridge said, the best words in their best order.

As the late Dr. Don Hatcher left the Deanship at Dalhousie, he passed me a small volume of Japanese Haiku poems, with an inscription that said these beautiful 17 syllable poems would bring me the "instant psychotherapeutic relief and tranquility all Deans require from time to time." And it's true. They really do create a sense of calm as the images float through your brain. Sit quietly, take a big breath, and think about this one, as an example:

In the open shop Paperweights on Picture books Young springtime breeze

Kito

Unfortunately, only when I stepped aside as Dean and passed the mantle to Dr. John Ruedy did I have the time to read these small gems. Better late than never.

A friend in England gave me permission to reprint this poem, which was first published in the journal *Circulation* in 1966.

# On Watching a Heart Operation

This is the heart, but not as poets dreamed it, Rich fountain of a thousand different flows, This is the heart as Harvey's genius schemed it, Four-chambered pump with petals like a rose. This is the heart, but not as poets see it, Insurgent centre of tumultuous joy, This is the heart as surgeons' scalpels free it And scientific stratagems employ. This is the heart torn from its tender sac, Denied its pulses, cheated of its blood, It manages its own triumphant flood. And looking in the theatre I view A love as keen as any Venus knew.

Helen Forsyth, October 28, 1965 (*Circulation*, 1966; **33**:516).

# **Current Topics in Community Health**

By: Judith Read Guernsey, M.Sc., Ph.D. Department of Community Health & Epidemiology Dalhousie University, Halifax, N.S.

# A CASE FOR OCCUPATIONAL HEALTH IN NOVA SCOTIA

The unfortunate and highly publicized recent occurrences at Westray, one year ago, triggered tremendous concern for the lives of men who had been subjected to the less than adequate working conditions, and for the families who have had to cope with the consequences. More recently, the saga of Camp Hill Hospital continues to unfold with recent public demonstrations. The tragic loss of lives, this past winter, resulting from ice accumulation on a scallop dragger jolted Nova Scotians into realizing the hazards which fishermen face every day in the course of making a living. There is less visible evidence of similar situations occurring in other occupations, but, by no means less devastating for loved ones: construction injuries and fatalities; asphyxiation from inhalation of welding fumes; and chainsaw accidents. The challenge before us, more than ever before, is to assure improved working environments for our citizens without creating greater financial stress for our governments and private industries.

The often heard response to this challenge is that Nova Scotians simply cannot afford the costs associated with improving working conditions. The hidden costs which we must bear as a society: a bankrupt Worker's Compensation Board, ever increasing diagnostic and treatment costs which are paid through MSI, losses in workforce productivity, go unrecognized as counter arguments. Dr. Bradford Brooks, during his recent visit to Nova Scotia, pointed out that personnel costs may be in the range of 300 dollars per square foot per year, while engineering and maintenance costs average around 5 dollars per square foot per year. Some formal initiatives to improve work environments could go far to protect our important investment in our human resources - the people of this province - and, is so doing, reduce our overall economic burden.

Dr. Mastromatteo, in his presentation to Dalhousie University Faculty of Medicine's Global Environment conference in April of last year, lamented the current "piece meal approach" to occupational and environmental health by governments in this country. This absence of proactivity has spurred the rapid proliferation of specialty groups, including ergonomists, employee assistance counsellors, stress management consultants, kinesiologists, physical fitness consultants, building auditors, occupational psychologists, ecological allergists,

indoor air quality experts, environmental physicians, occupational toxicologists, and loss control specialists.1 Mastromatteo reminded us of the rich scientific tradition which we have in occupational and environmental medicine and argued persuasively for coordinated action. He called for a number of initiatives to strengthen support for occupational medicine and the other traditional occupational health specialties. A key recommendation was the establishment of an independent federal agency which would have, as its mandate: identify and evaluate priority occupational and environmental risks; establish independent panels to make recommendations on health risks of worker or public concern; consolidate and administer research funding; and evaluate educational and training needs for occupational and environmental health.

Dr. Mastromatteo also identified large deficiencies in our current abilities to meet our educational needs in occupational and environmental health. He advocated the establishment of regional training centres, similar to the National Institute of Occupational Safety and Health Educational Resource Centers in the US, which provide educational opportunities in safety, toxicology, epidemiology, ergonomics, and other relevant information for occupational health professionals. Most Canadian occupational physicians, occupational nurses, occupational hygienists and certified safety professionals currently receive their advance training at these centres in the US or in Great Britain. Unfortunately, there are only four universities which provide graduate degrees in occupational health in Canada. There is not a single programme in the Atlantic region. This paucity of organized training centres not only requires students to go further afield for their education but may represent missed job opportunities for our youth. Data from the Canadian Registration Board of Occupational Hygiene indicate that, of those occupational hygienists registered to practice in Canada, over 30% are US citizens who have been hired by multinational corporations to work in their Canadian operations.2

What are our special needs in the Atlantic Region? Many companies, such as Michelin, already have in place a complete team of occupational health personnel. Small industry, including small business and individual-operator-owned activities such as fishing and farming, deserves attention. The Nova Scotia Department of Labour reports that there are between 16,000 and 20,000 workplaces in the province for which it must monitor working conditions. Given that there are only 30 provincial inspectors and consultants, small businesses (those with fewer than 50 employees) would likely welcome the greater availability of occupational health and safety

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information and resources at low cost. With regard to fishing, occupational stress among fishermen is likely to be high at present. Other problems, such as low back pain from lifting fishing crates, cutting hazards and crab workers' asthma, are aspects for which training programs could be formally developed and locally implemented. Hazards in farming range from pesticides, liquid nitrogen, silo gas, and moulds, to accidents from tractor overturns, and asphyxiation from manure pit drownings. For most fishermen and farmers, family physicians represent their sole sources of health information. Yet, physicians receive little training in occupational health and safety issues and are ill-equipped to provide this information to their patients. Fishing and farming, therefore, represent special cases for which carefully designed approaches should be implemented.

How might development of solutions to these problems of small industries be achieved? An approach, worthy of consideration, is one which is oriented within a health promotion framework. This process, which evolves through increased awareness and understanding, enables people to take greater responsibility for and improve their health.4 This positive approach calls for involvement of many different individuals and institutions in addition to those directly engaged in the health sector, and, interestingly, reflects the intent of existing hazard communication legislation (WHMIS). For example, in some provinces, occupational health and safety is overseen by an independent tripartite council comprised of labour, industry and governmental representatives. New Brunswick adopted this model in 1979 with the establishment of the New Brunswick Occupational Health and Safety Commission at a time when their accepted work time loss rate was 60 per 1000 employed per annum.5 This figure has steadily declined since then and in 1992 reached an all-time low of 33.9 per 1000 employed. Key features in this approach are the prominent roles that education, communication, and involvement play in achieving outcomes.

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# Notice

The MD Advisory Board has been requested to undertake an advisory role for "Strategy" - the Association's financially orientated newsletter. The Advisory Board members will act as a conduit for comments received from physicians concerning the publication. The next meeting of the Board will be during the Annual Meeting of CMA in August. Any members that have concerns or comments they would like addressed at the meeting are asked to contact Dr. E.V. Rafuse, 6035 Coburg Road, Halifax, NS B3H 1Y8 or Tel. # (902) 422-8353 or FAX (902) 423-5069.

New Brunswick Occupational Health and Safety Commission, 1993.

# rovent (ipratropium bromide)

INHALATION SOLUTION 250 µg/mL

# THERAPEUTIC CLASSIFICATION

Bronchodilator

# INDICATIONS AND CLINICAL USES

Atrovent (ipratropium bromide) solution is indicated for the therapy of acute exacerbations of chronic bronchitis. Atrovent solution, when used in conjunction with a B2-adrenergic stimulant solution such as fenoterol or salbutamol, is indicated for acute asthmatic attacks. It is to be administered by compressed air or oxygen driven nebulizers.

#### CONTRAINDICATIONS

Known hypersensitivity to Atrovent (ipratropium bromide), to any of the product ingredients, or to atropinics.

Atrovent (ipratropium bromide) solution in the 20 mL multidose bottle contains preservatives (benzalkonium chloride and disodium ethylene diamine tetraacetic acid -EDTA-disodium). It has been reported that these preservatives may cause bronchoconstriction in some patients with hyperreactive airways.

The 2 mL unit dose vial does not contain preservatives.

Atrovent should not be used alone for the abatement of an acute asthmatic attack since the drug has a slower onset of effect than that of an adrenergic B2 agonist.

Care should be taken to ensure that the nebulizer mask fits the patient's face properly and that nebulized solution does not escape into the eyes. There have been isolated reports of ocular complications (i.e., mydriasis, increased intraocular pressure, angle closure glaucoma) when nebulized ipratropium bromide either alone or in combination with an adrenergic B2 agonist solution has escaped into the eyes. In the event that glaucoma is precipitated or worsened, treatment should include standard measures for this condition.

# **PRECAUTIONS**

# General:

-Patients should be instructed in the proper use of the nebulizer.

-Caution is advised against accidental release of the solution into the eyes.

In patients with glaucoma, prostatic hypertrophy or urinary retention, Atrovent (ipratropium bromide) should be used with caution. If a reduced response to Atrovent becomes apparent, the

patient should seek medical advice.

Atrovent solution, when administered to patients with acute severe asthma, should be used with concomitant B<sub>2</sub>-adrenergic stimulant therapy.

# Use in Pregnancy:

The safety of Atrovent in pregnancy has not been established. The benefits of using Atrovent when pregnancy is confirmed or suspected must be weighed against possible hazards to the fetus. Studies in rats, mice and rabbits showed no embryotoxic nor teratogenic

#### **Use During Lactation:**

No specific studies have been conducted on excretion of this drug in breast milk. Benefits of Atrovent use during lactation should therefore be weighed against the possible effects on the infant

# Use in Children:

The efficacy and safety of Atrovent in children younger than 5 years has not been established.

#### Use with Other Drugs:

In patients receiving other anticholinergic drugs, Atrovent should be used with caution because of possible additive effects

In patients with glaucoma or narrow anterior chambers, the administration by nebulizer of combined Atrovent-Bo agonist solution should be avoided unless measures (e.g., use of swimming goggles) are taken to ensure that nebulized solution does not reach the eye. Exposure of the eyes of such patients to a nebulized combination of Atrovent and a B2 agonist solution has been reported to result in increased intraocular pressure and/or acute angle closure.

Atrovent solution with preservatives (i.e. from the 20 mL multidose bottle) should not be mixed with sodium cromoglycate, as this produces a cloudy solution caused by complexation between the preservatives and sodium cromoglycate. If the patient's condition requires the administration of sodium cromoglycate, it should be given in combination with Atrovent solution without preservatives (i.e., from the unit dose vial).

#### **ADVERSE REACTIONS**

The frequency of adverse reactions recorded in 214 patients receiving Atrovent (ipratropium bromide) solution was as follows, given by percentage of patients reporting: Dry mouth or throat, 9.3; Bad taste, 5.1; Tremor, 4.2; Exacerbation of symptoms, 4.2; Burning eyes, 0.9; Nausea, 0.9; Sweating, 0.9; Cough, 0.9; Headache, 0.5; Palpatations, 0.5.

The adverse effect judged to be most severe was exacerbation of symptoms. This occurred in 8 patients treated with Atrovent solution alone, 6 of whom withdrew from the clinical studies

Bronchospasm occurred in 3 patients with acute severe asthma who received Atrovent solution alone. In two patients, this was reversed after therapy with 82 sympathomimetic solution. The third patient received no

other therapy.

The following table compares the incidence of adverse effects of the combination of Atrovent and a B2 agonist (either fenoterol or salbutamol) solution with that of the Ba agonist alone.

ADVERSE EFFECT	ATROVENT + β <sub>2</sub> AGONIST (% of 94 patients)	B <sub>2</sub> AGONIST (% of 96 patients)	
Tremor	31.9	26.0	
Dry mouth	16.0	28.1	
Bad taste	16.0	13.5	
Vomiting	2.1	2.1	
Palpitations	2.1	1.0	
Headache	1.1	2.1	
Cough	1.1	0.0	
Flushing	1.1	0.0	
Dizziness	0.0	1.0	
Numbness in I	eg 0.0	1.0	

There have been isolated reports of ocular effects such as mydriasis, increased intraocular pressure, and acute glaucoma associated with the escape of nebulized ipratropium bromide-alone or in combination with a B2 agonist solution into the eyes.

#### DOSAGE AND ADMINISTRATION

In adults, the average single dose is 1-2 mL of Atrovent (ipratropium bromide) solution, containing 250-500 μg of ipratropium. In children, aged 5-12 years, the recommended dose is 0.5-1 mL (125-250 µg of ipratropium). This should be diluted to 3-5 mL with preservative free sterile Normal Saline [Sodium Chloride Inhalation Solution, USP 0.9%] or with a bacteriostatic sodium chloride solution, 0.9% preserved with benzalkonium chloride (see PHARMACEUTICAL INFORMATION).

Nebulization should take place using a gas flow (oxygen or compressed air) of 6-10 L/minutes and the solution nebulized over a 10-15 minute period. The Hudson Updraft™, Bennett Twin Jet® and Inspiron Mini-Neb® nebulizers, with facemask or mouthpiece have been used. The manufacturers' instructions concerning cleaning and maintenance of the nebulizer should be strictly followed.

Treatment with Atrovent solution may be repeated every 4-6 hours as necessary.

#### PHARMACEUTICAL INFORMATION Stability and Storage Recommendation:

20 mL Bottle: Unopened bottles of Atrovent (ipratropium bromide) solution should be stored at controlled room temperature (below 30°C). Solutions diluted with preservative free sterile Sodium Chloride Inhalation Solution, USP 0.9% should be used within 24 hours from time of dilution when stored at room temperature and within 48 hours when stored in the refrigerator.

Dilutions may also be made with a bacteriostatic sodium chloride solution 0.9% which contains benzalkonium chloride as the bacteriostatic agent (see WARNINGS). This diluted solution may be stored at room temperature and used within 7 days.

Controlled laboratory experiments using mixtures of Atrovent solution with Alupent® (orciprenaline sulfate), Berotec® (fenoterol hydrobromide) or salbutamol sulfate (6mg/mL preserved with benzalkonium chloride) solutions and diluted with a sterile bacteriostatic sodium chloride solution 0.9% (i.e. normal saline), preserved with benzalkonium chloride, indicated that such mixtures were stable for 7 days at room temperature. For the preparation of such mixtures, it is recommended that only sterile solutions of bacteriostatic sodium chloride 0.9% preserved with 0.01% benzalkonium chloride be used to maintain the level of preservative in the mixture.

The safety of preservatives other than benzalkonium chloride has not been established.

Incompatibilities: Atrovent solution with preservatives (i.e. from the 20 mL multidose bottle) should not be mixed with sodium cromoglygate solution, as this produces a cloudy solution caused by complexation between the preservatives and sodium cromoglycate. If the patient's condition requires the administration of sodium cromoglycate, it should be given in combination with Atrovent solution without preservatives (i.e., from the unit

2 mL Unit Dose Vial: Unopened unit dose vials of Atrovent solution should be stored at controlled room temperature (below 30°C) and protected from light. If required, the solution should be diluted with a preservative free sterile sodium chloride solution 0.9% and used immediately. Any solution remaining in the vial must be discarded.

The solution is physically compatible with Alupent® (orciprenaline sulfate), Berotec® (fenoterol hydrobromide) or salbutamol sulfate (6 mg/mL) solutions. If such mixtures are prepared, they should be diluted with preservative free sterile sodium chloride solution 0.9% and used immediately. Any unused portion of such combined solutions must be discarded.

# **AVAILABILITY**

20 mL Bottle: Atrovent (ipratropium bromide) solution is provided as 20 mL clear, colourless or almost colourless solution containing 250 µg/mL (0.025%) Atrovent in isotonic solution. This solution is preserved with benzalkonium chloride 250 µg/mL and EDTA-disodium 500 μg/mL at pH 3.4 in an amber glass bottle with

2 mL Unit Dose Vial: Atrovent solution is also provided as 2mL of clear, colourless solution containing 250 µg/mL (0.025%) ipratropium bromide in isotonic solution, presented in a plastic single use vial. One vial contains a total of 500 µg of ipratropium bromide.

The complete Product Monograph for Atrovent (ipratropium bromide) Inhalation Solution is available to health professionals on request. Patient Information/ Instructions are provided with the solution.

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3. Beck R, Robertson C, Galdes-Sebaldt M, Levison H.
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