Canadian Cardiovascular Society
Consensus Conference 2003

Assessment of the Cardiac Patient for Fitness to Drive and Fly

<u>FINAL REPORT</u>

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Message from the Co-Chairs

Every year, the Canadian Cardiovascular Society sponsors a consensus conference. These conferences have traditionally produced documents that have served to provide guidance to the profession regarding topical or controversial issues.

This year's conference, *Assessment of the Cardiac Patient for Fitness to Drive and Fly,* first convened in October, 2002. Our primary panel was divided into two subgroups, the "Drive" subgroup, and the "Fly" subgroup, which met separately and developed two sets of recommendations. This final report is similarly organized into two major sections: *Assessment of the Cardiac Patient to Drive,* and *Assessment of the Cardiac Patient to Fly.*

This year's consensus conference has been a collaborative effort involving both physicians and non-physician stakeholders from across Canada. We are grateful to the volunteer members of the primary and secondary panels who have worked diligently toward the creation of this document. Our hope is that these guidelines will serve as a practical aid to those involved in the assessment of cardiac patients' fitness to drive and fly.

David Ross, MD
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TABLE OF CONTENTS

I. Driving document

D. Implementation

E. Summary Table of Recommendations

F. Table of Definitions

Appendix A: Risk of Harm formula derivation

Appendix B: Regulations governing reporting of medically unfit drivers and protection for physicians

II. Flying document

A. Introduction

B. Air travel and cardiovascular patients
      1. Effects of altitude
      2. Recommendations for specific cardiovascular conditions
            a. Angina
            b. Post myocardial infarction
            c. Congestive heart failure
            d. Valvular heart disease
            e. Congenital heart disease
            f. Cardiac surgery
            g. Therapeutic interventions
            h. Arrhythmias and post arrhythmia management procedure
      3. Indications for deep venous thrombosis prophylaxis
      4. Airport security screening for ICDs and pacemakers
      5. Medical resources on commercial aircraft
            a. Emergency medical kit
            b. Automatic external defibrillators (AEDs)
      6. Physician liability when advising patients on safety of flying

C. Summary Table of Recommendations

D. Recommendations for deep venous thrombosis prophylaxis with long duration air travel

Canadian Cardiovascular Society Consensus Conference 2003

Assessment of the Cardiac Patient to Drive and Fly

DRIVING SUBGROUP FINAL REPORT

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Consultants to the Primary Panel: Jim Brennan MD and Susan Nickle, LLB.

INTRODUCTION

In 1992, the Canadian Cardiovascular Society (CCS) Consensus Conference document, *Assessment of the Cardiac Patient for Fitness to Drive,* was published. Four years later, as a result of significant advances in the investigation and management of both arrhythmias and syncope, an update was deemed necessary by the CCS Task Force that penned the original document. This 1996 document has served as the standard of assessment since that time; it was incorporated into the Canadian Medical Association guidelines virtually unchanged, and is used by both physicians and regulatory authorities to aid in the determination of patients' fitness to drive a motor vehicle.

In 2002, after receiving suggestions from the CCS membership, the CCS Council selected *Fitness to Drive and Fly* as the consensus conference topic for 2003. The membership perceived that a further update was required, since significant developments had again occurred in the evaluation and treatment of cardiac disorders, rendering some of the recommendations obsolete.

Additionally, significant concern has been identified on the part of CCS members and their patients regarding legislation mandating compulsory physician reporting of patients who are potentially unfit to drive because of their disease or condition. Legislation in 7 of 10 provinces and all 3 territories requires that all physicians must report to the regulatory authorities all patients who may pose a risk on the road because of their medical condition (the remaining jurisdictions have discretionary reporting systems). As a result, the Primary Panel decided to

address these concerns, since reporting has become such an integral part of the risk assessment process for the majority of Canadian physicians who care for cardiac patients.

The Driving Subgroup Primary Panel first assembled in October, 2002 in Edmonton. Another face-to-face meeting was held in Montreal in June, 2003. (A previously scheduled meeting in Toronto had been cancelled due to the SARS crisis.) A number of conference calls and email communications also took place between members as the components of the report were assembled. Following the completion of the draft document and draft executive summary in August, 2003, further input was sought from a secondary panel comprised of a cross section of stakeholders and experts. This draft final report is now presented to the CCS membership for further review and approval.

Driving Subgroup Primary Panel

Members of the Driving Subgroup Primary Panel were assigned to work on specific tasks or specific sections of the report:

Disorders of rhythm; ICDs	Paul Dorian, MD and Magdi Sami MD
Heart Failure:	Heather Ross, MD
Syncope:	Andrew Krahn, MD and Robert Sheldon, MD
Coronary artery disease:	Paul Poirier, MD and Eric Cohen, MD
Mandatory physician reporting:	Brent Mitchell MD, George Klein MD, Peter Kryworuk LLB, Barry Hoffmaster PhD and Chris Simpson MD
Implementation:	Anil Gupta, MD and Stephen Hart, MD
Members at large:	Robert Hamilton MD, Jim Stone MD, and Jan Surkes MD

Original "Fitness to Drive" Task Force

The members of the original CCS Task Force that tackled this issue are acknowledged for having produced two outstanding documents in 1992 and 1996. The current Panel has been fortunate to

have had the opportunity to build on this solid foundation. The original Task Force members

included:

F James Brennan, MD (Chair)	Kingston
L Brent Mitchell, MD	Calgary
Robert S Sheldon, MD	Calgary
Ross A Davies, MD	Ottawa
Robert G Macdonald, MD	Saint John
B Ross Mackenzie, MD	Toronto
Henry F Mizgala, MD	Vancouver
S Neil Swirsky, MD	Winnipeg
James F Symes, MD	Boston
JL Guy Tremblay, MD	Quebec
Gary D Webb, MD	Toronto

Risk of Harm Formula

Under the leadership of Dr. Jim Brennan, the previous task force developed the ground-breaking

"*Risk of Harm*" formula (see *Appendix A*), which, for the first time, allowed the assignment of a

quantitative level of risk to drivers with cardiac disease. The development of this quantitative

approach included definition of the risk that society had previously considered to be acceptable.

This *standard of acceptable risk* served as the benchmark against which all other drivers with

cardiac disease could be measured.

The reader is encouraged to refer to *Appendix A* for the derivation of the *Risk of Harm* formula.

Based on the available literature, it was determined that a **commercial driver** (a tractor trailer

operator, for example) who faces a 1% risk of sudden cardiac incapacitation (SCI) in the next

year poses a 1 in 20,000 risk of death or serious injury to other road users or bystanders. Set as

the standard, this annual 1 in 20,000 risk can be applied in turn to a **private driver** to determine

the annual risk of SCI that would pose the same overall risk to society. Because private drivers

spend much less time on the road, and because they drive vehicles which are less likely to cause

harm in the event that an accident actually does occur, it can be calculated that a private driver

with a 22% annual risk of SCI also poses a risk to society of 1 in 20,000. Therefore, a private driver with a 22% chance of having a suddenly incapacitating event in the next year poses no greater risk to society than does a tractor trailer driver with a 1% chance of having a suddenly incapacitating cardiac event over the same time period.

The current panel has chosen to build on the solid foundation established by the previous task force. The updated recommendations reflect new information that has become available in the literature over the past 7 years, but the *Risk of Harm* formula remains the major assessment tool.

Table of Recommendations

Like the previous task force, the current panel has chosen to present the recommendations in a tabular format to facilitate easy reference. The sections in the Table of Recommendations that have undergone the most change and clarification are *Disturbances of Cardiac Rhythm*, *Syncope, Congestive Heart Failure*, and *Hypertrophic Cardiomyopathy*. Other sections have undergone less extensive change. The reader is directed to the appropriate section in this document for more in depth detail regarding these and other recommendations.

> **Specific recommendations for cardiac patients' fitness to drive are found in the Summary Table of Recommendations**

Cardiac Rehabilitation Programs

The issue of fitness to drive is frequently faced within cardiac rehabilitation programs in Canada. Special mention is made here of these programs, as programs with short waiting periods for admission or with facilitated entry initiatives often must adjudicate driving issues on behalf of both patients and referring physicians. Patients within cardiac rehabilitation programs include those with: 1) coronary artery disease including persons with angina and a history of mechanical revascularization (coronary artery bypass surgery or percutaneous coronary interventions); 2) cardiac rhythm disturbances; 3) pacemakers; 4) syncope; 5) valvular heart disease; 6) congenital heart disease; 7) hypertrophic cardiomyopathy; 8) left ventricular systolic dysfunction and/or congestive heart failure; and 9) patients who have undergone cardiac transplantation.

Within the cardiac rehabilitation population, fitness to drive is dependent on an individual's disease prognosis (functional capacity, ischemic burden, left ventricular systolic function, presence of arrhythmias) and their potential for disease progression, or risk factor burden (Can J Cardiol. 2001; Suppl B: 3B-30B). Functional capacity is arguably the most robust predictor of long term prognosis in this population and thus should be part of most fitness to drive assessments. (Circulation. 2002; 106: 666-671). Increasingly, cardiac rehabilitation programs are fully "risk stratifying" patients with respect to their disease prognosis and, in association with referring/attending physicians, this risk stratification process can be directly applied to any fitness to drive assessment. In addition, cardiac rehabilitation programs can be useful in returning professional drivers to active status (Arch Mal Coeur Vaiss 1992; 85; 987-992). Furthermore, the use of cognitive assessment tools can provide a means for continually evaluating an individual's mental fitness to drive (Scand J Psychol 2003; 44; 23-30).

Cardiac rehabilitation programs are uniquely positioned to evaluate patients with respect to symptom status. A significant change in symptom status, regardless of the underlying disease process, should prompt programs and their referring physicians to reassess a patient's fitness to drive. Within this context, cardiac rehabilitation programs need to be aware of and familiar with provincial regulations and reporting requirements with respect to motor vehicle driver's licensing and fitness to drive legislation.

Level of Evidence

There are no prospective, controlled studies where patients have been randomized to permit or to proscribe the driving privilege nor where patients have been randomized to receive or not to receive physician advice not to drive. Furthermore, the defined standard of risk used in this document, while sensibly derived, is arbitrary and was not based on any evidence other than what had been acceptable historically. Given that all recommendations for driving eligibility are based on a comparison to this arbitrary standard, they are based on expert opinion only. Wherever possible, best evidence was used to calculate the risks of driving, but it should be noted that the evidence itself does not support or deny driving license restrictions for cardiac patients nor the mandatory reporting of such patients by their physicians.

The Panel has made an effort to consider the inherently subjective nature of society's tolerance for risk, while also applying a scientifically-based risk assessment mechanism in an effort to make the recommendations not just acceptable to society, but also consistent and justifiable.

SPECIFIC RECOMMENDATIONS

The summary table of recommendations lists the disease-specific guidelines. The table is found later in this document, along with a list of specific definitions which have been adopted for use in this document. The summary table is reproduced in the Executive Summary for quick reference. Recommendations are given for both private and commercial drivers.

The table is divided into 6 sections:

I.   Coronary Artery Disease
     1. General Recommendations
     2. Specific Recommendations
II. Disturbances of Cardiac Rhythm
     1. Ventricular arrhythmias
     2. Paroxysmal supraventricular tachycardia, atrial fibrillation and flutter
     3. Persistent or chronic atrial fibrillation and flutter
     4. Sinus node dysfunction
     5. Atrioventricular and intraventricular block
     6. Permanent pacemakers
     7. Implantable cardioverter defibrillators (ICDs)
     8. Other
III. Syncope
IV. Valvular Heart Disease
     1. Medically treated, or untreated valvular heart disease
     2. Surgically treated valvular heart disease
V.   Congestive Heart Failure, LV Dysfunction, Cardiomyopathy, Transplantation
VI. Hypertrophic Cardiomyopathy

I.   Coronary Artery Disease

Myocardial infarction (MI) is characterized by well-known clinical, electrocardiographic (ECG), biochemical and pathologic characteristics. Cardiac troponin (I or T) biomarkers may now detect patients with small areas of myocardial necrosis weighing less than 1.0g ([1]). This is of importance since in general, more than 10g of myocardial tissue must be injured before a radionuclide perfusion defect can be resolved ([1]), emphasizing the sensitivity of these new markers. While the term myocardial infarction is now more and more defined by the presence of an elevated troponin, it is clear that the prognostic importance is dependent on infarct size, the clinical presentation, and the extent and severity of coronary artery disease (CAD). It should be emphasized that there is a continuum from minimal myocardial damage to the classic large MI often complicated by heart failure, shock or life-threatening arrhythmia. The term "MI" therefore, is a generic one which gives very little information about the underlying disease, the current status of the patient, the short or long term prognosis, or the fitness of the individual to drive.

In the CAD population, sudden cardiac death is a well-recognized phenomenon. While death is termed "sudden" in epidemiological literature, it may not be instantaneous; there may be preceding symptoms ([2,3,4]). Clearly, the patient who experiences chest pain during driving does not pose the same risk as the driver who has a sudden ventricular arrhythmia while behind the wheel. However, ventricular arrhythmias may be more likely to occur during the first 24 hours of an acute coronary syndrome. But, it is neither reasonable nor practical to impose a driving restriction on all people at risk for developing a coronary syndrome, given its high prevalence in

our society and given our inability to predict the timing of an occurrence with any degree of accuracy. Finally, most acute coronary syndromes will not be associated with sudden incapacitation (SCI).

Weiner et al. reported that symptomatic patients who could only exercise to stage 1 of the Bruce protocol and who had ST segment depression of at least 1 mm presented a 1-year mortality of $\geq$ 5% whereas a low risk group (annual mortality $\leq$ 1%) was constituted by individuals who could exercise into stage 3 of the Bruce protocol with less than a 1 mm ST segment depression [5].

Another issue is cognitive impairment. It has been shown that symptomatic coronary artery disease may be associated with lower performance in some cognitive domains [6,7]. This may be a more important issue for fitness to drive than coronary artery disease *per se*.

Percutaneous coronary interventions

Coronary atherosclerosis is a progressive disease, therefore even after a successful revascularization, recurrent cardiac events are to be expected. The ability of a symptom-limited exercise testing protocol to predict new cardiac events in stable patients who have undergone a revascularization procedure is limited since exercise testing will screen for coronary stenosis that will induce diminished coronary reserve with associated ischemic symptoms. It cannot predict those who are destined to have an unstable coronary syndrome due to a ruptured plaque.

In-stent thrombosis and restenosis remains the major limitations of percutaneous coronary interventions (PCI). In-stent thromboses usually occur early with symptoms whereas restenosis reflects a complex underlying pathophysiology that involves various combinations of residual coronary stenosis, recoil, and neointimal proliferation. Symptom status is an unreliable predictor of restenosis since many patients complain of non cardiac pain after angioplasty. The exercise ECG is also an insensitive predictor of restenosis, with a sensitivity of about 50% [8,9].

Coronary artery bypass graft (CABG) surgery

Exercise testing in an asymptomatic patient who has undergone uneventful CABG is not predictive of subsequent events when the test is performed within the first few years after the procedure [10]. The test provides more useful information in settings where likelihood of disease is enhanced (5-10 yrs post-CABG, typical ischemia symptoms, diabetes mellitus, hemodialysis or immunosuppressive therapy). Cognitive impairment after CABG is well recognized and a significant proportion of patients who undergo CABG develop some degree of decline in cognitive function [11,12]. In most patients, any cognitive changes after CABG are generally transient (1 month) and reversible. Early cognitive changes may be secondary to a combination of factors, including use of cardiopulmonary bypass and anesthesia [13]. Neuropsychological performance of patients with CABG does not seems to differ from comparable nonsurgical control after a 3-month follow-up [14].

Conclusions

Most patients with CAD pose a low risk to other road users while driving. Certain conditions, however, require a careful evaluation and judgment. It seems fair to conclude on both clinical

and physiological grounds that the cardiovascular workload imposed by driving a vehicle is very light, and the risk that driving will provoke a recurrent acute coronary syndrome incident causing incapacitation is extremely small. While a small percentage of acute coronary syndromes will present with sudden cardiac incapacitation, it is not possible with contemporary risk stratification to select these patients in a meaningful way.

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II. Disturbances of Cardiac Rhythm

The previous document on fitness to drive addressed disturbances of cardiac rhythm in a very comprehensive way. The current Panel felt that many sections required little, if any change, while other sections required extensive revision to accommodate new evidence and new practices.

The section on ventricular arrhythmias has seen the most change. The general trend away from electrophysiology study (EPS) guided risk stratification and towards risk stratification based on left ventricular (LV) function is reflected in the new guidelines, since the majority of implantable cardioverter defibrillator (ICD) trials have identified LV function as one of the most important determinants of risk. An additional section reviewing previously unaddressed diseases, such as Long QT syndrome, Brugada's syndrome, and Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC) has been added, as has a section on EPS procedures and catheter ablation. Finally, a new section on ICDs has been added specifically to deal with these patients, whether they be implanted for secondary or primary prophylaxis.

Implantable Cardioverter Defibrillators (ICDs)

The frequency of resumption of driving within 6 months of ICD implant was assessed in the Antiarrhythmics versus implantable defibrillator (AVID) study. These patients were largely from the United States. Fifty-eight percent of patients resumed driving an automobile, and the predictors of earlier resumption of driving were a younger age, male sex, and university education.

3.8% of patients reported having had an accident within the first 6 months, with only 1 out of 14 patients having an accident reporting arrhythmic symptoms before the accident, implying that the other events were unrelated to the device (1).

DiCarlo et al (2) reviewed driving restrictions in the midwest United States, and the compatibility with state laws. Fifty-three percent of responding cardiologists only advised those ICD patients who had arrhythmia induced presyncope or physical collapse to cease driving. The remainder advised all implanted patients to cease driving. Most cardiologists recommended a temporary driving abstinence for a period of 2-12 months (6±3 months). Minimal legal requirements in various midwest states were variable.

Conti et al (3) surveyed 82 patients who were followed 6±1.3 years, and drove 20.5±27 miles a day. All patients in this group had defibrillator shocks. Ninety percent of the 52 patients resumed driving, and none experienced device discharge while driving during the follow-up time period.

Curtis et al (4) surveyed 742 U.S. physicians who followed defibrillators patients. 452 physicians responded, and a total of 30 motor vehicle accidents related to shocks from implanted defibrillators were reported by 25 physicians over a 12 year period. The estimated fatality rate for patients with a defibrillator was 7.5 per 100,000 patient years, significantly lower than for the general population (18.4 per 100,000 patient years). The injury rate for ICD patients was also very substantially less than the general public, 17.6 versus 2224 per 100,000 patient years. Of 286 defibrillator discharges documented while driving, 10.5% resulted in any accident.

Trappe et al (5) examined the driving behaviour of 291 ICD patients. Fifty-nine percent of 241 patients continued driving post implant and were followed for 38±26 months. No patients died while driving; there were 11 accidents, but only 1 caused by the driver with an ICD and none were related to syncopal symptoms or ICD therapy. Five percent of all patients over this time received ICD therapy while driving; 74% of these occurred more than 2 years post implant. No patient had syncope or an accident with this event.

Freedberg et al (6) followed 125 ICD patients for 408±321 days. Sustained monomorphic VT, and low ejection fraction predicted a higher risk of future ICD therapy. Patients with minimally symptomatic tachycardia at first occurrence had a high likelihood of having asymptomatic subsequent symptoms, and were felt to be at very low risk for syncopal ICD therapy if the first event was asymptomatic or minimally symptomatic.

Larsen et al (7) followed 511 patients with an implanted defibrillator for a mean of 26 months. The monthly hazard rate for defibrillator discharge was 4.22% per month in the first month, declining to 1.81% per month at month 2 through 7, and subsequently 0.63% per month. This risk of defibrillator discharge per month was only slightly higher than the risk of any *traffic accident* involving death, injury, or major damage amongst all licensed Oregon drivers (0.4% per month) or drivers aged 16-19 (0.9% per month).

Bansch et al (8) retrospectively analyzed data on 421 patients with an ICD followed for 26±18 months. Thirty-six months after implantation, 19% of patients had any history of syncope. In patients with an ejection fraction of >40%, and without atrial fibrillation, only 8% of patients had syncope after 36 months. The risk factors for syncope or syncope with initial ventricular tachycardia and a rapid VT rate (cycle length <300 msec).

Akiyama et al (9) administered questionnaires regarding driving to 909 patients in the AVID study. Of the 758 patients who responded (83% of the total), 627 drove in the year prior to their index episode of ventricular arrhythmia. Fifty-seven percent of these drivers resumed driving within 3 months after randomization in the AVID trial and 78% within 6 months, and 88% within 12 months. Two percent of patients during follow-up had a syncopal episode while driving, and 11% had dizziness or palpitations that required stopping the vehicle. Eight percent of the patients with an ICD received a shock while driving. Of the 55 accidents during 1619 patient years of follow-up after resumption of driving, 11% were preceded by any symptom of possible arrhythmia (0.4% per patient per year). The annual incidence of accidents in the ICD population of 3.4% per patient year was substantially lower than the accident rates in the general driving population in the United States of 7.1% per patient year. In this study, there was no relationship between the duration of abstinence from driving after an episode of ventricular tachyarrhythmia and the subsequent risk of a motor vehicle accident. The authors felt that the data do not support a temporary restriction of driving in this setting.

The risk of symptoms that may lead to incapacity behind the wheel, with or without a defibrillator discharge, in patients with defibrillators implanted for secondary prophylaxis is very

low. Although there are extremely sparse data for patients receiving defibrillators for primary

prophylaxis, this risk is almost certainly even lower, and would clearly not be expected to be any

different than for patients with a similar a priori risk who do not receive primary prophylactic

ICD implantation.

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III.   <u>Syncope</u>

Introduction

Syncope is a common problem, affecting as many as 50% of people at some point during their life [1-3]. This therefore poses a substantial problem for regulatory agencies, which need to balance the risk to the public due to accidents with the economic and personal risk due to loss of the ability to drive by millions of Canadians. In the vast majority of cases, a single isolated episode of syncope will occur that may not be reported to a physician by the patient [4]. Most of these episodes represent vasovagal syncope, which can usually be diagnosed by history and do not warrant further investigation. When syncope is unexplained, further testing is necessary to arrive at a diagnosis and direct possible therapy. Because there is a small risk of recurrence and incapacitation during driving, consideration of restriction of privileges is intuitive to protect both the patient and the public [5-9]. Although emerging evidence assists recommendations with respect to estimating the risk of incapacitation, there is no evidence regarding the impact of restriction and little evidence regarding the comparative efficacy of interventions to allow systematic assignment of levels of evidence to recommendations. This is in keeping with the approach outlined in the introduction of this document.

Necessity to investigate the cause of syncope

The optimal investigation of patients with syncope is not the focus of these guidelines, but it must be remembered that some causes of syncope can be life threatening. Investigation is tailored by the initial clinical assessment. The major determinant of both prognosis and optimal testing algorithm is the presence of underlying structural heart disease. In the absence of

underlying heart disease, patients have a very low risk of life threatening ventricular arrhythmia, and a much higher probability of that their syncope is vasovagal. Bradyarrhythmias are a more frequent culprit with advancing age in patients presenting with syncope without significant structural heart disease. In those patients with significant underlying heart disease usually defined as left ventricular ejection fraction <35% or previous Q wave myocardial infarction, ventricular arrhythmia is a more frequent and life threatening etiology. Electrophysiological testing and consideration of implantable defibrillator use plays a major role in these patients if the diagnosis is not determined from preliminary non-invasive means.

Accidents and Neurally-Mediated Syncope

Typical vasovagal syncope occurs in the upright position, usually standing but occasionally sitting. A prodrome of one or more of nausea, warmth, diaphoresis, lightheadedness and darkening of vision precedes loss of consciousness in the majority of episodes. Patients often report ability to avert loss of consciousness by sitting or lying down quickly. The period of unresponsiveness is often brief (less than a minute), with fatigue but minimal confusion immediately after the episode. Sitting or lying down quickly and other physical maneuvers including raising the legs or isometric exercise that increases venous return can attenuate episodes. Often the diagnosis is established with tilt table testing, but this may not be necessary for the purposes of establishing the likelihood of having recurrences of syncope.

Unexplained and Neurally-Mediated Syncope

Three groups have reported that patients with otherwise undiagnosed syncope had identical outcomes regardless of whether they had positive or negative tilt tests [10-12]. Their perisyncopal

symptoms are similar, and their rhythms during clinical syncope when captured electrocardiographically are similar. In patients presenting for evaluation of unexplained syncope, the risk of recurrence within the ensuing year is 10 – 30% [4,10-18]. This risk is approximately 10% for a single episode, and 30% for recurrent episodes[10-12, 19-21]. Thus for purposes of driving restriction, patients with tilt-positive neurally-mediated syncope and patients with unexplained syncope without structural heart disease are combined. The estimation of their risk of injury or death unfortunately rests on a single report of 209 patients with recurrent neurally mediated (vasovagal) syncope who continued to drive after their initial episode [9]. Over the course of 1534 patient/years, only 5 of 6988 syncopal spells occurred while driving, and only 2 resulted in injury. It must be noted that this was a single centre study, with potential accrual biases both for underestimation and overestimation of risk, and the confidence intervals around the estimates are wide. Nonetheless, this sets Ac (the risk of syncope causing an injury due to a motor vehicle accident) at 2/6988, or 3×10^{-4}. These data suggest that the environment of driving is a very low risk environment for recurrence of vasovagal syncope.

This suggests that the likelihood of recurrence is sufficiently low based on the risk of harm formula that no restriction of driving is necessary. Because this calculation is based on a very small number of data points from a single study, the Panel felt that clinical prudence supported a one week self imposed suspension for private drivers and one month for light truck drivers. The exception to this is patients with syncope in the sitting position or that have sufficiently little prodrome that they may be unable to safely pilot a vehicle to the roadside in the event of a recurrence, who should consult with a qualified physician with experience in the investigation and treatment of syncope prior to considering resumption of driving.

In patients with recurrent neurally mediated syncope, symptoms may be sufficiently frequent that driving restriction is recommended. The calculations and recommendations are specified below. These recommendations are made regardless of therapy, since the data on treatment efficacy are not sufficiently compelling that reinstatement or continuing driving privileges can be contingent upon a specific treatment algorithm (see below). Finally, some syncope frequently occurs or recurs in specific situations or environments. Prolonged standing and blood phobia are typical triggers, aggravated by volume depletion and venous incompetence. Assuming these circumstances can be avoided while driving, no restriction is necessary.

Reversible Causes and Diagnosed Syncope

Some patients will have a suspected diagnosis on initial investigation that requires confirmation with additional testing, such as echocardiography to confirm the physical findings of aortic stenosis. These diagnosed patients often have a reversible or treatable cause of syncope. Once recognized and prevented or treated, driving restriction is unnecessary. A brief period of observation after treatment is advised before driving is resumed, such as a 1-week period after pacemaker implant for documented symptomatic bradycardia. A patient with a reversible or treatable cause of hypotension or arrhythmia that is resolved or treated can return to driving once treatment is in place or the inciting event has resolved. An example would be a one-week observation period after marked hemorrhage or dehydration resulting in symptomatic hypotension.

The presence of structural heart disease (reduced ejection fraction, previous myocardial infarction, significant congenital heart disease) constitutes a potentially high-risk patient that should undergo driving restriction pending clarification of underlying heart disease and etiology of syncope. Specific recommendations are made below and in Sections I, IV, V and VI.

Impact of treatment

There are few comparative trials suggesting a superiority of one treatment compared to another for a specific etiology of syncope. For this reason, treatment may be implemented to prevent recurrence, but is not necessarily required to enforce driving restrictions. A notable exception to this is documented culprit arrhythmias and their appropriate treatment. Patients with documented symptomatic bradycardia require pacemaker therapy. A one-week period of observation after pacemaker implantation is sufficient after verification of pacemaker function to permit resumption of driving. Implications of ventricular arrhythmias on driving privileges is a much more complex issue. This is comprehensively dealt with in Section II. Clearly treatment must be in place and a period of observation completed prior to resumption of driving privileges.

Syncope while driving

Finally, special consideration is given to patients who have syncope while driving a motor vehicle. In a recent paper by Blitzer et al, 71 patients with syncope while driving were referred to an Electrophysiologist for evaluation[22]. A presumptive diagnosis was made in 57 of the 71 patients (80%), with vasovagal syncope the most common etiology (30%). Tachyarrhythmias were present in 42% of patients, with supraventricular tachycardia in 25% and ventricular tachycardia and 17%. Ten percent of patients had AV-block. No patient had sinus node disease.

Although these figures represent referral bias in patients suspected of having a cardiac etiology of syncope diagnosed by an electrophysiologist, they clearly indicate that extensive testing including tilt and electrophysiological testing tailored to the baseline characteristics of the patient is likely to lead to a diagnosis in the majority of patients who experience syncope while driving.

Assumptions Underlying the Recommendations

Several assumptions that underlie the summary recommendations warrant emphasis. The first is that the annual risk of recurrent syncope after a single episode is 10%, and after recurrent syncope is 30%. In a private driver with a single episode of syncope, the risk of harm is less than 1 in 20,000, so that an intuitive 1 week waiting period is recommended, though the annual risk does not exceed acceptable risk. A similar process leads to a 1 month waiting period for a light truck driver (taxi cab, delivery vehicle), and a one year waiting period for a heavy truck driver (termed commercial driver in the table). In recurrent syncope, the syncope frequency is the reciprocal of the intersyncope interval. Therefore the time between syncopal spells is a predictor of eventual syncope frequency, and therefore risk. Based on this assumption, the threshold of number of syncopal events within a year that would increase the risk of harm to greater than 1 in 20,000 is five events. The Panel felt that in the interest of simplicity and safety, this could be reduced to a formal recommendation to suspend drivers with more than a single episode within a year of their most recent event for 3 months for a private driver, and one year for a light truck driver. The heavy truck driver receives a full year suspension because the risk of harm formula suggests that a safe threshold is not reached for at least a year. At all times, and for legal purposes, we expect that physicians will use these as approximate guidelines whose use should be modified according to idiosyncratic factors such as the length of a reliable prodrome,

reversible or avoidable precipitating factors, and position from which the patient faints. Patients should be reassessed after the recommended waiting period. If they have not had another episode, reinstitution of driving privileges can be considered.

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IV. **Valvular Heart Disease**

No major changes were felt to be required in this section, other than to add "mitral valve repair" to the list. A distinction is drawn between those in sinus rhythm versus those not in sinus rhythm, given the increased risk of thromboembolic phenomena in the latter group. This is similar to the risk stratification used in other valve surgery categories.

V.   Congestive Heart Failure, LV Dysfunction, Cardiomyopathy, Transplantation

Congestive Heart Failure (CHF) currently affects approximately 500,000 Canadians with an estimated 50,000 new cases per year. The prevalence of heart failure increases with increasing age (1) such that 1% of Canadians over age 65 and 4% of Canadians over 70 have CHF (2). The overall one-year mortality after diagnosis is between 25-40%. The age-adjusted mortality for CHF is 106/100,000, which is greater than the mortality for Acquired Immune Deficiency Syndrome (AIDS) and breast cancer combined. The median survival for heart failure patients is currently 1.7 years for males and 3.2 yrs for females with a 5-year age adjusted mortality rate of 45% based on the time period 1990-1999 (1).

CHF is a chronic condition. It remains the commonest syndrome that brings a patient to hospital for medical admission. The all cause re-admission rates are 46% within 3 months of discharge and 54% within 6 months. Results of randomized controlled trials in the CHF population have shown that 19% of all patients diagnosed with CHF require at least 1 hospital admission within 1 year of diagnosis and >40% have readmissions within 3-6 months of hospital discharge. In addition there is a marked increase in mortality with decreasing ejection fraction and increasing functional class (3-5). The mortality from CHF results from sudden cardiac death either with or without premonitory symptoms, progressive heart failure and death from non-cardiac causes. This increased risk of death clearly impacts fitness to drive.

Mortality – based on functional class

In order to assess the risk one must look at published CHF trials (Table 1). The assumption is

that all patients are on recommended therapy for CHF (CCS consensus guidelines). If not then

the risk can be estimated by looking at placebo mortality. Nonetheless it is well established that

patients who enter clinical trials have better outcomes than those who do not. As such these risks

likely underestimate the true representative risk to the average CHF patient. Patients with

asymptomatic left ventricular (LV) dysfunction have a better outcome with a 27% 5-year and

59% 12-year mortality in the placebo group and 23% 5-year and 53% 12-year mortality in the

enalapril treated group (6). However these data were published prior to the routine recommended

use of beta blockers for treatment of asymptomatic LV dysfunction and in fact the mortality may

be substantially lower. An estimate of the mortality with different functional classes (FC) and

therapies is illustrated in Table 1.

There are only two studies that have addressed the truly severely afflicted CHF patient,

specifically RALES and REMATCH. In the RALES study the one-year mortality ~~on~~ in the

placebo group was 25% and the two-year mortality 41%. However only a small percentage of

patients in this study were on beta blockers. The REMATCH trial reflected the critically ill CHF

patient. Based on the overall 92% mortality in the optimally medically treated arm, patients who

are truly in an advanced FC by the REMATCH definition should not drive. Specifically: NYHA

class IV for at least 60 days, ejection fraction (EF) < 25%, VO2 < 14 or New York Heart

Association (NYHA) class III-IV with at least a 14 day inotrope or intraaortic balloon pump

(IABP) support within the last 60 days. In addition, data from the United Network for Organ

Sharing (UNOS) suggests that patients who have a left ventricular assist device in place, or are

on inotropes (either intermittent outpatient or home inotropes) have at least a 0.5-2% mortality per week (www.unos.org) and are therefore medically unfit to drive.

Fitness to drive becomes less clear in the FC IV patient who improves to FC III with diuretic therapy. However if this patient becomes FC III and is on optimal therapy then the one-year mortality is approximately 11-18% (COPERNICUS, RALES) and would be within the recommended acceptable risk limits (i.e. < 22%) for private driving but would be unacceptable for commercial driving, since a sizable proportion of these deaths would be sudden.

Functional Class II patients are at proportionally higher risk of sudden death and less risk of progressive heart failure (10), but are overall at lower risk. Based on the beta blocker and angiotensin converting enzyme inhibitor (ACEI) trials the annual risk of death in the treatment arm was 7.2-10.4% and the annual risk of sudden death in a FC II-III patient is approximately 4-7.3% (10,11). These risks are within the risk of annual sudden cardiac incapacitation of 22% and as such patients who are FC II-III are fit for driving a private motor vehicle, but again this risk would be too high to allow commercial driving.

Functional Class I patients are at the lowest risk for an incapacitating cardiac event and are therefore acceptable for private driving. For those patients with an EF less than or equal to 30% there is a 10% annual risk of death and a 5% annual risk of sudden cardiac death. Commercial driving therefore is not recommended for patients with an EF less than 30%, since the acceptable annual risk for commercial drivers has been set at 1%.

Cardiac Transplantation

Given that the highest risk of rejection is early after transplant and decreases with increasing time from transplantation (12) patients who receive a cardiac transplant should not drive privately until at least 6 weeks post transplant. This should be evaluated on an individual basis as many patients may remain deconditioned at the 6 week mark post transplant and may still be unfit to drive. Commercial driving should be based on cardiac function and functional class. Patients who are > 6 months after transplant, on stable immunotherapy, with a grade I LV and FC I are acceptable for commercial driving. For those patients > 5 years after transplantation, because of the increased risk of underlying transplant coronary artery disease an annual exercise or dobutamine stress echo or mibi or coronary angiography should be performed. These patients are acceptable if there is no evidence of active ischemia.

Table 1 (incl references 13-17):

Study	Age	Etiology (% CAD)	Gender (% male)	FC	Mean EF (%)	Median Survival	MORTALITY Placebo (%)	MORTALITY Treatment arm (%)
ACEI								
SOLVD prevention							27% - 5 year	23% - 5 year
SOLVD treatment							51% - 5 year	47% - 5 year
Spironolactone								
RALES	65	54-55	73	III –69-72 IV – 27-31	25		One year - 25 Two year - 41	One year - 18 Two year - 32
BBL								
Copernicus - 2289	63	67	80	III-IV	19.8		18.5 – one year	11.4 – one year
CIBIS II	61	50	80	III-83 IV-17	27		13.2	8.8
MERIT-HF	63	65	77	II-41 III-56	28		11	7.2
BEST				III IV			16 – one year 28 – one year	12 – one year 20 – one year
RST								
MIRACLE	64	50-58	68	III-90% IV-10%	22			
LVAD								
REMATCH	66-68		80	IV	17	150d MM 408d VAD	One year - 75 Two year - 92	One year - 48 Two year - 77
ICD								
MADIT	65	100	84	I-II 70-73% III-23-25 IV-4-5	23		One year - 10 Two year - 22	One year - 9 Two year - 16

(Packer et al NEJM 2001;344:1652-1658; BEST NEJM 2001;344:1659-1667; Rose et al NEJM 2002;345:1435-1443;MADIT NEJM 2002;346:877; RALES NEJM 1999;341:709-717; MERIT HF Lancet 1999;353:2001-2007; CIBIS II Lancet 1999;353:9-13; Coletta AP et al, European Journal of Heart Failure 2002;4:661-666; Abraham et al MIRACLE NEJM 2002;346:1845-53)

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VI.   <u>**Hypertrophic Cardiomyopathy**</u>

Syncope and sudden death are well-recognized consequences of hypertrophic

cardiomyopathy. The quest to identify those at high risk for these potentially disabling events

has been hampered by the great heterogeneity of this disease (1-3), and a possible

overstatement of risk due to the bias created by referral patterns to centres with expertise (4-

6).

It is well known that syncope, a previous aborted cardiac arrest, one or more episodes of

sustained ventricular tachycardia (VT), and a history of sudden death in young family

members are strong indicators of a high risk for sudden death (1-3). Other indicators have

also been identified, but appear to have a lower positive predictive value. These

characteristics include asymptomatic non sustained VT on ambulatory monitoring, extreme

left ventricular hypertrophy and an abnormal blood pressure response during exercise (1,2, 7-

12).

While a high resting outflow tract gradient predicts a higher risk of progressive decline, it

appears to be an extremely poor predictor for sudden incapacitation (12), and therefore this

should have very little to do with the assessment of the patient to drive.

The presence of even one of these risk factors would put the annual risk of sudden

incapacitation at a value of greater than 1%, thereby disqualifying the commercial driver

from driving (from the *Risk of Harm* formula). However, to exceed the 22% threshold which

is required to disqualify the private driver, all or nearly all of the risk factors would need to

be present. It therefore becomes practical to simply consider symptoms associated with

cerebral ischemia. If a private driver has had symptoms compatible with cerebral ischemia,

he or she should probably be restricted from private driving.

Given the ongoing degree of uncertainty regarding risk assessment, individual-based decision

making will play a large role. It should be remembered that the vast majority of patients with

hypertrophic cardiomyopathy pose no increased risk to other road users. A simple

echocardiographic diagnosis of mild or moderate hypertrophy, or an ECG finding of

hypertrophy should not, in the absence of other risk factors, lead to a suspension of the

driving privilege.

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MANDATORY PHYSICIAN REPORTING

Ethical and Practical Considerations

Introduction

Motor vehicle accidents (MVAs) are the most common cause of death in young people in Western society. In Canada, MVAs are responsible for 11.1 deaths per 100,000 population, while in Europe, this rate ranges from 6.4 in the United Kingdom to 28.8 in Portugal (1). Governments and other authorities in many jurisdictions have addressed this problem with a variety of measures, including seat belt legislation, impaired driving legislation, speed limit reductions, and graduated drivers' licenses for new or inexperienced drivers.

One area of attention in many countries has been the driver with a medical illness. Restricting drivers who may endanger other road users or bystanders intuitively makes sense. Governments have responded to the issue in a variety of ways. Some, like those of the Netherlands, Germany and Belgium, have no legislation at all. They rely on health professionals and patients to follow guidelines and use common sense in the determination of fitness to drive. In the United Kingdom, physicians may, at their discretion, report patients to the licensing authorities, who may in turn suspend driving privileges. In Canada, legislation has been enacted in many jurisdictions (Manitoba, New Brunswick, Newfoundland and Labrador, Northwest Territories, Nunavut, Ontario, Prince Edward Island, Saskatchewan, and Yukon Territory) that requires physicians to report all patients who may be unfit to drive because of a medical condition. In

Alberta, Nova Scotia and Quebec, physician reporting is discretionary. In British Columbia,

physician reporting is mandatory if the patient has been warned by a physician not to drive but

continues to do so. In most provinces and territories, legislation is in place to protect physicians

from legal action from their patients for this apparent breach of doctor-patient confidentiality.

Responsibility for reporting, then, lies with the medical profession in most Canadian

jurisdictions. In the United States, six states (California, Delaware, Nevada, New Jersey, Oregon,

and Pennsylvania) have mandatory physician reporting legislation; the other states have either no

reporting system or have a discretionary reporting system in place.

Despite apparent public support for mandatory physician reporting, the issue has become a major

concern for many physicians, who are called upon to balance their patients' independence and in

many cases, their economic well-being with the duty to protect society. Few issues alienate

patients from their doctors as much as this one does. Patients often feel that their doctor no

longer represents their best interests, and a deterioration in the physician-patient relationship may

result which could lead patients to withhold important historical information that physicians need

to make therapeutic decisions. For example, a patient whose license has been suspended because

of undiagnosed syncope may elect not to be truthful about recurrences of syncope, because a

return to driving hinges on the absence of a recurrence.

The *process* of mandatory reporting is also widely viewed as problematic by physicians in

Canada. When reporting patients whose increased risk to drive is temporary (such as after an

"undifferentiated" syncopal spell, after coronary artery bypass surgery, or after a leg fracture),

physicians frequently discover that the process of suspension is so slow that the license

suspension often is issued to the patient after the high risk period has passed, making the whole process pointless. Indeed, a January 9, 1997 decision of the Ontario Court (General Division) in the case of Lax vs Denson (2) found that, because an average of 88 days elapses from the time of report filing to license suspension, an injury from an MVA sustained by the plaintiff could not have been avoided even if the physician had reported the patient, because the injury occurred only 10 days after hospital discharge.

From a patient's point of view, having a license suspension lifted following the passage of the high risk period is frequently an extremely cumbersome and time-consuming process. Many patients are prohibited from driving for much longer than had been intended. It is not unusual for the Ministry to request from the physician additional information and tests which are often unnecessary and non-contributory. For example, patients who have had an episode of loss of consciousness due to "cardiac" syncope are frequently asked to undergo neurologic investigations such as electroencephalograms (EEGs) and computed tomography (CT) of the head. These factors which contribute to delays in license reinstatement appear to be a major source of patient and physician frustration.

Cardiac patients are felt to be responsible for between one-quarter and two-thirds of accidents attributable to sudden incapacitation at the wheel (3-5), although the vast majority occur in patients with no previously recognized cardiac history (6). Given that cardiac patients comprise a large proportion of potentially unfit drivers, Canadian investigators (7) examined the mandatory reporting system as it pertains to cardiac patients in Ontario. This study found that in Ontario in 1996, only 1% of cardiac patients who should have been reported to the Ministry if Canadian

Cardiovascular Society (CCS) guidelines were followed were in fact reported, indicating widespread non-compliance with the legislation amongst physicians who care for cardiac patients. Furthermore, a calculation of theoretical benefit using the *Risk of Harm* formula found that, at those reporting rates, less than 1 death or serious injury was being prevented each year. When one considers the broader context (929 people were killed on the roads in Ontario that year), the effect of mandatory reporting legislation in reducing death and injuries on the roads appears to be negligible. Given that only 1.4% (13 of 929) of road fatalities in Ontario in 1996 were attributed to a driver with *any* medical illness, the relative gains in the hypothetical situation of 100% physician compliance would appear to be modest at best, and an estimated 72,407 cardiac patients would lose their licenses. Compared to any other intervention in terms of "number needed to treat", mandatory reporting legislation would appear to be extremely ineffective.

Nevertheless, there appears to be a societal expectation that drivers with potentially incapacitating medical illnesses be restricted in some way from driving. However, society accepts that driving is inherently risky. We accept this risk in order that we may live the kind of lifestyle that driving makes possible. The ultimate question then becomes, *what level of risk is society willing to tolerate?*

The Nature of Risk and Risk Assessment

The theologian Reinhold Niebuhr once wrote that politics is "a twilight zone where ethical and technical issues meet." That characterization certainly applies when risk enters the political

arena. How are risks perceived? How are risks described? How are risks assessed? How are

risks managed? Ethical and social issues are entangled with technical issues in all these

questions, yet with respect to determinations of fitness to drive, the ethical and social issues

remain largely in the twilight zone.

That is not as it should be because risk is not exclusively a scientific or technical concept. In

fact, social scientists regard risk perception as a social or cultural concept:

> Concerns about risk may depend less on the nature of the danger
> than on the observer's political and cultural biases. It is the
> social system, the world view, the ideological premises of a
> group or a society that shapes perceptions of risk. According to
> anthropologist Mary Douglas, a leading proponent of this view,
> beliefs about risk are embedded in a complex system of beliefs
> and values. Judgments about risk are a social comment. The
> concepts of accountability, responsibility, and liability that
> pervade debates about risk are in effect political statements
> expressing points of tension and value conflicts in a given
> society. (Dorothy Nelkin, *The Language of Risk*, Sage
> Publications, 1985, p. 16)

Two features of our society frame how the risks associated with fitness to drive are perceived

and assessed. One is the official view that driving is a privilege rather than a right. That view

makes sense insofar as it emphasizes the responsibilities that attach to a potentially hazardous

activity and the authority of the state to revoke the privilege to drive when those responsibilities

are not fulfilled. The view that driving is a privilege granted by the state follows from the

second feature: the conviction that the most fundamental tenet of morality and law is the duty not

to harm others. John Stuart Mill's famous "harm principle" in *On Liberty* (Currin V. Shields,

ed., Bobbs-Merrill, 1956 [1859], p. 13) allows the state to restrict the liberty of its citizens only

when the exercise of that liberty threatens to harm another, not when the exercise of that liberty

threatens to harm oneself. The latter is, in Mill's view and in the view of many others,

unjustified paternalism. Medical ethics likewise begins with the fundamental injunction to avoid

harming others: *primum non nocere*.

These two features provide a moral rationale for the legal requirement that doctors report patients

who suffer from conditions that may make it dangerous for them to operate a motor vehicle.

Framing the issue in terms of just these premises is too narrow and too circumscribed, however,

because harm judgements must be comparative. There are two options for patients with

conditions that might make it risky for them to operate a motor vehicle – stop driving and

continue driving -- and there are potential harms associated with both. Yet the prevailing

depiction of the fitness-to-drive issue is one-sided: it focuses only on the harms that might be

caused to others by allowing a patient to continue to drive and ignores the harms that might be

caused to patients by not driving. The harms imposed on patients whose licences are suspended

can be genuine and serious, though. Driving can be essential to having or sustaining important

dimensions of life – earning a livelihood, buying groceries, or maintaining social interactions

with others, for example. Depriving people of such opportunities also can produce substantial

harm, so when, given the social and economic circumstances in which we live, driving is

necessary for a good life, it seems to be more than just a revocable privilege even if it cannot be

deemed a full-fledged right.

A defensible, comprehensive approach to decision making about fitness-to-drive needs to

recognize that the issue involves a comparative harm judgement that is imbued with social and

cultural beliefs and values. There is a standard formula for analyzing risk, according to which

risk is a function of two variables: the severity of the harm that could result and the probability

that that harm would result. Serious physical and mental injuries and death are, of course, the

most severe harms one can suffer. But the risk associated with those harms must be appraised in

terms of the probability of their occurrence to obtain a rational evaluation of the magnitude of the

risk. The potential harms for persons who are not permitted to drive are less catastrophic than

severe physical injuries and death, but that does not mean they are not serious. Losing a job and

social isolation also can have momentous consequences. The risks associated with these harms

likewise must be appraised in terms of the probability of their occurrence, which might be

greater than the probability of harms to others. More remote harms also must be considered; for

example, a deterioration in the physician-patient relationship because the patient withholds vital

information for fear of being reported. Decisions about fitness to drive need to be made on the

basis of a comprehensive risk assessment that considers not just the severity of the potential

harms but also the probability of those harms and that compares the resulting risks to others

posed by allowing patients to continue to drive with the risks to patients themselves posed by

prohibiting them from driving.

In addition, a comprehensive risk assessment must attend to the social and cultural influences on

how risks are identified, characterized, and appraised. What is it about our society and our

political and legal institutions that explains why the risks considered relevant to decisions about

fitness to drive have been so limited and one-sided?   Moreover, in a society that prizes scientific

objectivity, there will be a bias towards risks that are tangible, immediate, and, most importantly,

quantifiable. In tort law, for instance, damages are much easier to calculate when the loss is

economic (foregone wages and benefits for a civil servant with twenty years on the job, say) and

much harder to calculate when the compensation is for pain and suffering, loss of sexual

relations, or the death of an infant. When only those harms that can be "objectively" measured

in some fashion or another are considered, no matter how arbitrary or haphazard that

measurement might actually be, the danger is that nonquantifiable, intangible, seemingly

amorphous harms are ignored, even though they might reflect fragile, important values such as

emotional well-being and the maintenance of family or social relationships.

Given that risk assessment must be comprehensive and comparative, what policies and

procedures should govern decision making about fitness to drive? How does one design a

process that generates all the relevant information, that appreciates the intrinsic vagueness,

uncertainty, and incommensurability of the information, and that allows judgements about fitness

to drive to be made in a fair, rational, and expeditious manner? Those procedural questions

about institutional design are the practical outcome of a substantive analysis of the nature of risk

and risk assessment. A determination of the role that physicians rightfully and responsibly

should play in the process of reviewing fitness to drive can be made only if the comprehensive,

comparative nature of risk assessment is recognized and policies and procedures congruent with

that recognition are adopted.

The cogency of this analysis of the nature of risk and risk assessment presupposes that the ethical

and social issues inherent in both should be brought out of the twilight zone. One might think

that that assumption is uncontroversial: policy-making should be open and transparent. That is

the theory. The practice is different, however. The literature on the allocation and rationing of

scarce medical resources, for example, emphasizes how attractive it is for decision makers at the

"macro" level to evade accountability for the budgetary decisions they make. The consequence

is that overt responsibility for difficult decisions is forced down the hierarchy of decision making

until that hierarchy terminates with the front-line worker; in this case, the doctor at the bedside.

Similarly, if it is in the self-interest of "macro" level decision makers to devolve overt

responsibility for decisions about fitness to drive to physicians, do they have any reason for

wanting to bring the ethical and social dimensions of those decisions out of the twilight zone?

And if not, is there any hope that those decisions will be recognized as involving more than

clinical or technical considerations and that policies and processes for making those decisions in

a fair, rational, and timely manner will be implemented?

Issues which require further clarification

1. How many motor vehicle accidents are caused by patients with cardiac disease who have had a sudden, incapacitating event? That is, what is the scope of the problem?

This is one of the most fundamental questions to consider in the mandatory physician reporting

debate. If we were able to identify and remove from the road all cardiac patients who are

destined to cause an accident because of sudden incapacitation, how many injuries and how

much property damage would be prevented? How many lives would be saved?

Available data suggest that sudden cardiac incapacitation at the wheel poses a very small risk to

public safety. Sudden driver illness causes only 0.9 to 2.1 of every 1000 road accidents (3-5). In

Ontario in 1996, only 825 of 384,453 (0.2%) collisions and 13 of 1367 (0.9%) fatal collisions

were caused by drivers with a "medical-physical defect" (8). It is unclear what proportion of

these events was cardiac in nature. Furthermore, it is unclear whether the driver deaths were the

result of the incapacitating event or the consequence of the MVA. In 2001, the most recent year

for which data are available in Ontario, 474 (0.1%) of 316,167 "property damage" collisions, 491

(0.4%) of 102,519 "personal injury" collisions, and 20 (1.6%) of 1251 fatal collisions were

attributed to a driver with a "medical physical defect"(9). In comparison, 5650 (1.8%) 0f 316,167

"property damage" collisions, 3073 (3%) of 102,519 "personal injury" collisions, and 204 (16%)

of 1251 fatality collisions were attributed to a driver who had been impaired by alcohol or drugs.

The driver involved was determined to be "normal" in 79% of all collisions. External, non-

driver related factors such as excessive speed and poor road conditions were found to be

responsible for the majority of accidents in which the driver's condition was normal. Indeed,

excessive speed has been identified as the strongest risk factor for mortality in motor vehicle

accidents (10).

The State of Utah initiated a project in the 1990's entitled, *Evaluating Drivers with Medical*

Conditions in Utah. This study compared the citation and accident rates of drivers with medical

conditions to those of drivers without medical conditions in the years 1992-1996. Over 20,000

patients with cardiovascular conditions were compared to over 30,000 age and sex-matched

controls without cardiac illness. No differences in citation and accident rates were found for at-

fault accidents (11). .In contrast, patients with vision problems, neurologic diseases, psychiatric

diseases, epilepsy, and diabetes did have higher citation and accident rates compared to age and

sex-matched controls.

Recognizing the limitations of these data, it nevertheless would appear that removing all cardiac patients who are destined to have an MVA because of sudden incapacitation would, in fact, have a negligible impact on the overall problem.

2 . Of the patients who do have a sudden, incapacitating event behind the wheel, how many had been previously diagnosed with a disqualifying condition? That is, how many would have been identified by a physician reporting scheme?

This is also a very important question. Is it realistic to expect that we can actually prospectively identify, with accuracy, those patients who are destined to have a motor vehicle accident? How wide do we have to "cast the net" to identify these patients and prevent them from driving?

Based on incidence and prevalence data, a Canadian study of the Ontario mandatory reporting experience in 1996 estimated that approximately 72,000 cardiac patients in Ontario would have had their driving privileges suspended that year if current guidelines were followed (7). Given the low rate of accidents caused by sudden incapacitation, the number of suspensions required to prevent one event would be extraordinarily high. The number needed to treat to prevent one death or serious injury would be even higher. These considerations also assume that all drivers experiencing a sudden cardiac incapacitation at the wheel would have been among these 72,000, "high risk" suspended patients. Of course, it is probable that many patients who experience a sudden incapacitation secondary to cardiac disease while driving would have been patients with "low risk" cardiac conditions. Myerburg (12) points out that while the *incidence* of sudden death is highest in patients with a left ventricular ejection fraction less than 30%, the *proportion* of all

sudden cardiac deaths in the US attributed to this population is only 1/3. Twice as many sudden

cardiac deaths occur in people who do not have this "high risk profile".

In Finland and in Vaud, Switzerland, investigators found that sudden illness of the driver

accounted for only 1.5-3.4% of all traffic deaths. They also found that these incapacitating

events would have been difficult to foresee. In most such instances, the sudden incapacitation at

the wheel was the patient's first medical event (13). Therefore, most of these patients would not

have had their licenses suspended under any mandatory reporting scheme.

Buttner at al (14) evaluated the consequences of natural death while driving in 147 drivers over a

15 year period. The majority of these events resulted in only minor injuries and minor property

damage. These investigators concluded that sudden death at the wheel is rare and that medical

screening can not be expected to be an effective way to reduce these events.

3. *Of patients with license suspensions, or with a recommendation not to drive, how many*

continue to drive anyway? That is, what is the efficacy of the intervention?

While there are little data of this sort relative to cardiac patients per se, the evidence which does

exist is troubling. Maas et al (15) administered an anonymous questionnaire to 104 patients

referred for assessment of syncope, all of whom had received advice not to drive. Over the

subsequent year, three reported that they had had another syncopal episode while driving. Only

7 of the 104 had stopped driving on their own accord after the first syncopal episode and only 2

additional patients had stopped driving on the recommendation of the physicians. At a second

interview 3-6 months later, all of the remaining patients (95) had continued to drive, even though

79% recalled being advised not to drive. One of these 95 patients had a recurrent syncopal

episode while driving but it did not result in an accident. These results indicate that medical

advice not to drive will be ignored by many patients.

Salinsky et al (17) found that a mandatory reporting environment, paradoxically, may actually

put more unsafe drivers on the road. Patients with epilepsy were asked by anonymous

questionnaire whether they would tell their physician about a breakthrough seizure in an

environment of mandatory physician reporting of patient fitness to drive. The study reported that

72% of currently-driving patients would report a breakthrough seizure to their physician in such

an environment compared to the 96% that would report a breakthrough seizure to their physician

in the absence of mandatory physician reporting In this scenario 28% of patients would not only

continue to drive but would also be inadequately treated because of their failure to disclose

breakthrough seizures to the physician; thereby actually increasing the risk to other road users.

Other studies have also suggested that mandatory physician reporting may hinder optimal patient

management (18-23).

Lee et al (24) have provided data indicating only 25%-28% of drivers with epilepsy who

experienced a seizure reported their episode to a physician because of a fear of being reported to

licensing authorities. Given that substantial numbers of these patients indicated they would also

continue to drive despite license suspension,, these authors suggested that mandatory reporting

statutes are both discriminatory and destructive and should be repealed. As Bornemann (20)

stated, "When the practice of medicine or law creates a regulation without full regard for its

consequences in the lives of those affected, more harm may result than the good which was intended".

4. How many patients with cardiac disease need to be removed from driving in order to save one accident or one life? That is, what is the "number needed to treat"?

This question was addressed, in part, above. Although we do not know the "number needed to treat", it is certainly very high. This means that the vast majority of drivers who are ordered not to drive would not have been destined to have a dangerous event behind the wheel. Better risk stratification data are clearly required.

5. What are the consequences to the physician-patient relationship and the quality of care when physicians report their patients to the Ministry or other regulatory authority? That is, what are the costs of the intervention to the physician-patient relationship?

As described above, the physician-patient relationship and the patient's subsequent quality of care may be diminished under a mandatory reporting system. These harms need to be quantified and fully integrated into the overall risk-benefit assessment. In particular, the possibility that a mandatory reporting environment may actually contribute to an increased risk to other road users should be addressed.

6. What are the economic, social, and health impacts on patients whose licenses are suspended for medical reasons? That is, what are the costs of the intervention to the patient?

We know that patients whose driving privileges have been restricted for medical reasons have a diminished quality of life and decreased employability (18, 20, 23, 25-27). However, little data exist on the economic impact and health status changes that result from mandatory reporting. These data are required to properly balance the advantages, disadvantages, and risks of mandatory reporting of patient fitness to drive.

7. How much do governments with mandatory reporting legislation spend annually on the identification, suspension, and evaluation of medically unfit drivers? That is, what are the costs of the intervention to society?

Virtually all medical interventions which are shown to be of benefit are subjected to a cost effectiveness analysis to assess the overall worth of the intervention. A typical way to express cost effectiveness data is in terms of "cost per year of life saved". In order to assess cost, investigators will need, in addition to all of the information discussed above, data relative to the costs of managing the mandatory reporting environment.

8. Does a mandatory reporting system remove more unfit drivers from the roads than simple physician advice to the patient to do so? That is, what is the incremental benefit of the intervention?

It is unclear whether or not advice by physicians not to drive is superior, equivalent, or inferior to mandatory reporting because of the complexity of all the contributing factors discussed above.

The authors of a Canadian study (7) have suggested that many physicians make "private pacts" with their patients not to drive. While legal advice has strongly discouraged physician non-compliance with mandatory reporting legislation, many physicians appear to be ignoring this advice. In Canada, regional differences in reporting requirements provide an opportunity for assessment of the impact of reporting requirements on road safety.

9. Do drivers with cardiac disease impose limitations on themselves? That is, do they change their driving behaviour intuitively to reduce overall risk?

The *Risk of Harm Formula* recognizes that the time spent behind the wheel is one component of the assessment of risk. While some drivers may pose a high risk *per kilometer driven,* they may mitigate this risk by reducing the distance driven or time spent behind the wheel. Other changes in driving behaviour may also favourably affect the risk. Such patients may drive only in familiar areas; may avoid highway driving, may drive at reduced speeds, and may refrain from driving on days when they are not feeling well. A restricted licensing program was evaluated in Saskatchewan (28) wherein patients with some medical conditions were permitted to drive under limited circumstances. That study reported that at-fault accident rates decreased by 12.8% after the program was implemented and calculated that license restrictions likely averted up to 816 accidents and 751 traffic violations over a 7 year period.

10. How does the risk posed by drivers with cardiac illness compare to that posed by other definable groups? That is, do drivers with cardiac illness pose a greater risk that other,

apparently, acceptable drivers including young and elderly drivers, drivers who work shift

work, drivers who eat or drink while driving, and drivers who use cell phones?

This final question addresses fundamental questions of consistency and justice. Do we hold

drivers with some medical illnesses to a higher standard than other groups? Consider, for

example, the finding (29, 30) that women *with* epilepsy have lower accident rates than men

without epilepsy. Nevertheless, men without epilepsy are permitted to drive, while women with

epilepsy often cannot. Smoking increases the relative risk of a motor vehicle accident by a factor

of 1.5 (31). Being younger than the age of 25 years increases the relative risk of a motor vehicle

accident by 1.93 (32). Being prone to migraine headaches increases the risk by a factor of 2.5

(33, 34). Having diabetes or, being an elderly individual receiving treatment with a tricyclic

antidepressant drug are associated with relative risks of 1.78 (26) and 2.3 (35), respectively.

A number of the issues considered above were addressed in a prospective, anonymous

questionnaire based study of patients in the Antiarrhythmics Versus Implantable Defibrillator

(AVID) trial. These patients all had potentially-life threatening ventricular tachycardia or

ventricular fibrillation and would have been prohibited from driving a motor vehicle by all

current guidelines regarding driving privileges. Of the patients who had been driving prior to

their index episode of ventricular tachycardia or ventricular fibrillation, 57% had resumed

driving within 3 months, 78% within 6 months, and 88% within 12 months (36) regardless of

physician advice to the contrary. Neverthelss, the motor vehicle accident rate in these patients

was only 3.4% per patient year (only 11% of which were preceded by symptoms of a possible

arrhythmia). This rate compared favorably to the motor vehicle accident rate of 7.1 percent in the general American driving population. This study found no evidence of a relationship between the duration of abstinence from driving after an episode of ventricular tachyarrhythmia and the risk of a motor vehicle accident.

Conclusions

Important questions regarding the ethics, efficacy, cost, and efficiency of mandatory reporting remain unresolved.

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General Recommendation # 1:

The Panel recommends further research to examine the efficacy and cost-effectiveness of mandatory and discretionary physician reporting systems; as well as the economic, social, health and quality of life impact of such systems on drivers with cardiac disease and other potentially disqualifying medical conditions.

General Recommendation # 2:

The Panel recommends that regulatory agencies in jurisdictions where physician reporting is compulsory should work towards an open, transparent, accountable, and timely driver evaluation process to minimize the negative impact on drivers whose licenses are under review or suspension.

MANDATORY PHYSICIAN REPORTING

Legal Considerations

Introduction

All Canadian provinces and territories have enacted some form of legislation regarding physician reporting of a patient who is believed to be unfit to drive a motor vehicle. In some jurisdictions this duty is mandatory, in others, it is discretionary. In either case, the duty to report represents an exception to the normal rules in respect of physician-patient confidentiality. In each jurisdiction, some form of statutory protection is provided to physicians while fulfilling their obligations to report, although conditions may apply for the protection to be applicable.

This section of the paper provides a legal perspective, comparing each of the Canadian jurisdictions in respect of reporting requirements, physician protection and production of medical reports. The legal principles in respect of standard of care and causation are outlined, and case law from both mandatory and discretionary jurisdictions is canvassed. Brief mention is made of the federal provisions of the *Aeronautics Act,* which provide for mandatory reporting of patients who are deemed unfit to pilot an aircraft. Lastly, provincial guidelines and application of applicable medical guidelines and standards are examined for their impact on standard of care issues.

Alberta *	British Columbia	Manitoba	New Brunswick	Newfoundland	Northwest Territories
Discretionary for MD *Motor Vehicle Administration Act*, s. 14(2) Mandatory for patient to report change in medical condition s. 14(1)	**Mandatory** *Motor Vehicle Act*, s. 230(2)	**Mandatory** *Highway Traffic Act*, s.157(1)	**Mandatory** *Motor Vehicle Act*, s.309.1(1)	**Mandatory** *Highway Traffic Act*, s.174.1(2)	**Mandatory** *Motor Vehicles Act*, s.103(1)

Nunavut	Nova Scotia	Ontario	Prince Edward Island	Quebec	Saskatchewan	Yukon
Mandatory *Motor Vehicles Act (Nunavut)* s.103(1)	**Discretionary** *Motor Vehicle Act,* s.279(7)	**Mandatory** *Highway Traffic Act,* s.203(1)	**Mandatory** *Highway Traffic Act,* s.233(1)	**Discretionary** *Highway Safety Code*, s.603	**Mandatory** *Vehicle Admin. Act,* s.94(1)	**Mandatory** for physician *Motor Vehicle Act,* s.17(3) Mandatory for patient s.17(1) and (2)

* In Alberta, the College of Physicians and Surgeons discourages the practice of reporting only when the patient may not be reliable. It takes the position that "only by routinely reporting all failed medical standards for the operation of a motor vehicle, will public responsibility for this important preventive health program become widely accepted."

Only three provinces in Canada provide for discretionary reporting: Alberta, Nova Scotia and Quebec.

While the wording in each statute may differ, the language from Ontario's *Highway Traffic Act* is a good example of the language of mandatory reporting sections across Canada.

Section 203(1) of the Act provides:

> "Every legally qualified practitioner shall report to the Registrar the name, address and clinical condition of every person sixteen years of age or over attending upon the medical practitioner for medical services who, in the opinion of the medical practitioner, is suffering from a condition that may make it dangerous for the person to operate a motor vehicle."

Provincial statutes differ as to whether the medical reports produced in compliance with these

statutory requirements are privileged as follows:

Alberta	British Columbia	Manitoba	New Brunswick	Newfoundland	Northwest Territories
not addressed	not addressed; subject to the provisions of the access to information legislation	privileged s. 157(7)	not addressed	privileged s. 174.1(3) not admissible in evidence at trial except to prove compliance s. 174.1(4)	confidential s. 313

Nunavut	Nova Scotia	Ontario	Prince Edward Island	Quebec	Saskatchewan	Yukon
confidential s. 313	not privileged; subject to access to information legislation	privileged s. 203(3)	privileged s. 233(3)	not admissible in court s. 606	privileged s. 94(3); not admissible except to show that report was made in good faith	not addressed

In the reporting context, where a document is prescribed by statute to be privileged, the report

given by the physician in respect of his or her patient is privileged and for the information and

use of the registrar and/or the medical review committee only. In some jurisdictions, the reports

are not privileged or the use is restricted to limited situations such as evidence that the reporting of the medical condition was made in good faith or to confirm compliance.

In respect of penalties, while the Ontario legislation provides no specific penalty for failure to report a medically unfit patient, there is a general penalty provision at section 214(1) of the *Highway Traffic Act* as follows:

> "Every person who contravenes this Act or any regulation is guilty of an offence and on conviction, where a penalty for the contravention is not otherwise provided for herein, is liable to a fine of not less than $60 and not more than $500."

While there are no reported circumstances where a physician has been convicted of an offence under the provision for failure to report, there are other "penalties" for failing to report, including prosecution under a regulatory statute, professional discipline, or civil liability.

Applicable Legal Principles - Civil Liability

Civil actions brought against physicians for a failure to report are based on principles of the law of negligence. Negligence is conduct which falls below the standard of reasonable care accepted in the community. For a finding of negligence in a medical negligence context, two aspects must be proven. First, that the physician breached the requisite standard of care, and secondly, that this breach was the cause of the defendant's damages.

Standard of Care

The conduct of a physician must be assessed against the conduct of a prudent and diligent physician placed in the same circumstances.[1] Put another way:

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[1]*Lapointe* v. *Hopital le Gardeur*, [1992] 1 S.C.R. 382

"Every medical practitioner must bring to his task a reasonable degree of skill and knowledge and must exercise a reasonable degree of care. He is bound to exercise that degree of care and skill which could reasonably be expected of a normal, prudent practitioner of the same experience and standing, and if he holds himself out as a specialist, a higher degree of skill is required of him than of one who does not profess to be so qualified by special training and ability."[2]

Causation

Liability in negligence cannot be found unless the alleged damages are caused by the negligent conduct.

There are two leading decisions of the Supreme Court of Canada that provide guidance on the issue of causation.

Causation is established where the plaintiff proves to the civil standard (balance of probabilities) that the defendant caused or contributed to the injury.

In *Athey* v. *Leonati*[3], the Supreme Court of Canada confirmed that the general test for causation (general, but not conclusive) is the "but for" test, which requires the plaintiff to show that the injury would not have occurred but for the negligence of the defendant. Where the "but for" test is inconclusive, the courts have recognized that causation is established where the defendant's negligence "materially contributed" to the loss. Notably, the Court held that the presence of other non-tortious contributing causes does not reduce the extent of that liability. Therefore, loss

[2]*Crits et al.* v. *Sylvester*, [1956] 1 D.L.R. (2d) 502, affirmed 5 D.L.R. (2d) 601

[3][1996] 3 S.C.R. 458

cannot be apportioned according to the degree of causation where it is created by both tortious and non-tortious causes.

In *Snell* v. *Farrell*[4] the Supreme Court of Canada held that causation need not be determined with scientific precision. The Court acknowledged that, in many medical negligence cases, the facts lie within the knowledge of the defendant physician, and very little affirmative evidence on the part of the plaintiff will justify the drawing of an inference of causation in the absence of evidence to the contrary. In any event, the legal or ultimate burden rests with the plaintiff.

Case Law from Mandatory Reporting Jurisdictions

There are few reported cases interpreting the scope and application of statutory reporting requirements.

In an Ontario decision, *Ferguson Estate* v. *Burton*[5]*,* the defendant experienced an epileptic seizure and lost consciousness while driving. His car crossed the median and struck a car driven by the plaintiff, who was killed. His estate sued the defendant and his employer. The defendants subsequently brought a third party claim against the driver's physician who treated him prior to the accident for failing to report the driver's medical condition to the Registrar of Motor Vehicles.

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[4][1990] 2 S.C.R. 311

[5](1987), 50 M.V.R. 197 (Ont. H.J.)

The defendant suffered from an arteriovenous malformation that, the evidence suggested would lead to a 20% chance of the defendant experiencing sudden unconsciousness. He had suffered no seizures involving loss of consciousness in the two and a half years prior to the accident. Five months before the accident, he had an abortive seizure without loss of consciousness. The physician believed that the defendant's medication, Dilantin, was controlling the epilepsy. However, the defendant did not always take his medication and on the day of the accident he had neglected to take it.

The action against the physician was dismissed because the court was not satisfied on the balance of probabilities that the physician failed to treat and advise his patient in accordance with the standard expected of an ordinary family physician at the relevant time. The court arrived at its conclusion based, in part, on the fact that the physician had discussed with his patient beforehand the three conditions that had ultimately contributed to the accident. Accordingly, it was held that there was no breach of the CMA guidelines, particularly the duty to warn the patient not to drive. Lastly, there was no evidence that the patient's licence would have been suspended if the doctor had reported his patient's condition. The trial judge found that had an investigation been conducted by the appropriate licencing authorities, in the circumstances, they would not have suspended the defendant's licence.

In another Ontario decision, *Toms* v. *Foster*[6]*,* the issue of reporting temporary conditions was examined. The defendant driver suffered from cervical spondylosis and caused an automobile accident which seriously injured the plaintiffs, a motorcyclist and his passenger. The

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[6](1994), 7 M.V.R. (3d) 34 (Ont. C.A.)

defendant's physicians (a general practitioner and a neurologist who had attended the driver prior to the accident) did not report his medical condition to the Registry of Motor Vehicles as required by the *Highway Traffic Act*.

At trial, the court found the doctors liable and awarded substantial damages to the plaintiff. On appeal, the physicians' argued that the obligation to report under the statute was not mandatory but rather a matter of discretion for the doctor. One physician argued that he believed the defendant's condition to be temporary and that he could be trusted not to drive if so advised. The physicians conceded that they both knew at the time of the accident that the defendant was unfit to drive.

The Court of Appeal dismissed the appeal and held that the reporting obligations under the *Highway Traffic Act* were mandatory and made no exceptions for temporary versus permanent conditions, or whether a patient could be trusted not to drive. The court held that suspension would have been probable had the doctors reported the defendant's condition to the Registrar. Further, the court held that the duty of physicians to report is a duty owed to members of the public and not just to the patient.

The Ontario Court of Appeal also upheld a finding of liability against physicians in *Spillane* v. *Wasserman*[7] in which a fatal motor vehicle accident occurred involving a cyclist and the defendant truck driver. The defendant driver suffered from seizures known to his physicians, who failed to report his condition.

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[7](1992), 42 C.C.L.T. (2d) 267 (Gen Div.; affirmed (1998), 41 C.C.L.T. (2d) 292 (C.A.)

The evidence at trial established that the doctors were both aware or should have been aware that the defendant suffered nocturnal seizures as well as daytime seizures on a fairly regular basis. The trial judge further concluded that the doctors failed to run blood tests on a routine basis on drugs prescribed in order to confirm control and compliance.

The court held that the physicians were held liable for failure to report under the statute as well as a failure to follow the minimum CPSO and CMA standards. Further, it was held to be insufficient to state that the patient was "a normal compliant patient because he did not fit the pattern of a non-compliant one". At trial, the court held the physicians 40% liable for the damages in negligence.

The Court of Appeal upheld the finding of liability, but reduced the apportionment of the physician's liability to 5% on the basis of the patient's own deliberate conduct, failing to report some seizures, neglecting to take medication, and falsifying his licence renewal application.

In *Lax* v. *Denson et al*[8]*,* the plaintiff sued the defendant physician for his own injuries sustained in a motor vehicle accident which occurred ten days following his discharge from a psychiatric hospital. It was alleged that his licence would have been suspended if his condition had been reported by his physician.

The action was dismissed at trial on the basis that, even if the licence had been promptly revoked, it was unlikely that knowledge of revocation would have been communicated to the

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[8](1997), 32 O.R. (3d) 383 (Gen. Div.)

plaintiff by the date of the accident. The defendant doctor's medical expert testified that from the period of December 1987 to December 1993, the average delay between the reporting of the information and confirmation of its receipt was 88 days. Therefore, it was held that in these circumstances, the failure to report did not cause or contribute to the accident.

Case Law from Discretionary Reporting Jurisdictions

In the Alberta decision of *Wenden* v. *Trikha*[9], the confidentiality dilemma as between the patient and physician was considered. This action arose as a result of injuries sustained by the plaintiff in a motor vehicle accident caused by the defendant. The defendant was a student who suffered from a medical disorder and who had voluntarily admitted himself to the hospital on several occasions. He had been released on the basis of good progress and that his condition was controlled with medication. The day prior to the accident the defendant voluntarily admitted himself but left the next day in a vehicle. The plaintiff brought an action against the defendant driver, the hospital and the psychiatrist who treated him.

The court found the defendant driver fully responsible. The hospital and the psychiatrist were held to have discharged the duty of care owed to the defendant or to any third party.

In the reasons for judgment, brief reference was made to section 14(2) of the *Motor Vehicle Administration Act*[10], which allows for the discretionary reporting of medical information. The trial judge simply stated that he did not consider that this statutory provision affected the

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[9](1991), 116 A.R. 81 (Alberta Court of Queen's Bench); affirmed (1993), 135 A.R. 382 (Alberta C.A.); [1993] 3 S.C.R. ix (application for leave to appeal dismissed)

[10]R.S.A. 1980 c.M-22

question of to whom a duty of care was owed in this case. He went on to briefly explain the

implications of the section, stating that it did not impose a duty to report, but that it did deal with

the confidentiality problem from a liability point of view as between the patient and physician.

Aeronautics Act

The *Aeronautics Act*[11] prescribes mandatory reporting requirements at section 6.5(1) as follows:

> "Where a physician or an optometrist believes on reasonable grounds that a patient is a
> flight crew member, an air traffic controller or other holder of a Canadian aviation
> document that imposes standards of medical or optometric fitness, the physician or
> optometrist **shall**, if in his opinion the patient has a medical or optometric condition that
> is likely to constitute a hazard to aviation safety, inform a medical adviser designated by
> the Minister forthwith of that opinion and the reasons therefor."

The Act provides protection for the physician or optometrist for anything done in good faith in

compliance with the section[12], and further, information provided under the section is

privileged.[13]

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[11]R.S.C., 1985, c.A-2

[12]Section 6.5(4)

[13]Section 6.5(5)

Physicians who report disabilities pursuant to the Act cannot be compelled to testify. Section 6.5(5) provides a limited medical privilege applicable to both civil and criminal proceedings because of the wide ambit of the language used, "any legal, disciplinary, or other proceedings".[14]

Statutory Reporting Obligations, Guidelines and Medical Standards

Most Canadian jurisdictions rely upon the CMA guidelines "Determining Medical Fitness to Drive - A Guide for Physicians" as a guide to determine when a driver's license should be suspended and restored.

The *Motor Vehicles Acts* of the Northwest Territories and Nunavut are the only jurisdictions in which there is express reference to "prescribed guides or codes". Section 103(2) of the statutes provide:

> "For the purposes of satisfying subsection (1), a medical practitioner may adopt the recommendations contained in prescribed guides or codes that have been prepared to assist medical practitioners in determining if a person is unable to operate a motor vehicle in a safe manner because of a physical or mental disability or disease."[15]

Few jurisdictions, including British Columbia, possess their own guidelines in respect of physician reporting. The "Guide to Determining Medical Fitness to Drive a Motor Vehicle" was prepared by the British Columbia Medical Association. While the final responsibility for determining medical fitness is with the Superintendent by statute, great weight is placed on the recommendations of the B.C. Medical Association outlined in the

[14]*R.* v. *Schmiemann* (1991), 126 A.R. 124 (Alberta Prov. Ct.)

[15]Motor Vehicles Act, R.S.N.W.T. 1988, c.M-16

Guide in determining the medical fitness of the individual in question. The suspension decision is subject to review procedures outlined in the Guide.

Does breach of a statutory obligation to report result in automatic civil liability? The Supreme Court of Canada has addressed this question and has held that civil consequences of a breach of statute should be subsumed in the law of negligence. Further, it has held that the notion of a tort of statutory breach giving a right to recovery merely on proof of breach and damages should be rejected, as should the view that unexcused breach constitutes negligence *per se,* giving rise to absolute liability. However, it is also clear that proof of statutory breach, causative of damages, may be evidence of negligence. Further the statutory formulation of the duty may afford a specific and useful standard of reasonable conduct.[16]

Where the duty of a health professional is prescribed by statute, the failure to perform the duty may constitute actionable negligence.

In addition, some provincial regulatory Colleges specifically set out policies to address the reporting issue. For example in Ontario, the CPSO policy #10-00 provides that the reporting requirement pertains not only to ongoing patients of the physician, but also to anyone "attending upon the medical practitioner for medical services", which includes those individuals seeing a physician for industrial or third-party exams/assessments. The report must be in writing and sent to the Medical Review Section of the provincial

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[16]*Canada* v. *Saskatchewan Wheat Pool,* [1983] 1 S.C.R. 205

Ministry of Transportation. Although the Act does not specify a time period in which the report must be made, it should be done as soon as possible.

Does a physician face civil liability for failing to comply with Provincial legislation, a college policy or CMA guideline which provides for mandatory reporting? A physician's failure to comply with a mandatory reporting obligation under a statute may result in potential quasi-criminal liability under the statute. A physician's failure to comply with a college policy may result in disciplinary proceedings taken by the college. However the breach of a statute or breach of a college policy or other professional guideline does not necessarily automatically result in civil liability.

The statutory formation of the duty may afford a specific and useful standard of reasonable conduct to be applied by the court.

In determining civil liability, courts frequently refer to practice guidelines and standards in determining that a physician has met a reasonable standard of care.

While conformity with common practice and recognised professional guidelines will generally exonerate physicians of any complaint of negligence, there are certain situations where the standard practice itself may be found to be negligent. However, this will only be where the standard practice is fraught with obvious risks such that anyone is

capable of finding it negligent, without the necessity of judging matters requiring diagnostic or clinical expertise.[17]

Further, the fact that the professional has followed the practice of his or her peers may be strong evidence of reasonable and diligent conduct, but it is not determinative.[18]

It appears that courts have been willing to give considerable weight and to apply guidelines such as those formulated by the Canadian Medical Association in determining the scope of a physician's obligation to report. While these guidelines are not determinative, unless a court finds that the guidelines are themselves unreasonable, they will be given considerable weight in determining whether a reasonable standard of care has been met by the physician.

Conclusion

Physicians are facing ever increasing legal obligations to report patients who they believe are unfit to drive. While the obligations may vary slightly from one jurisdiction to the other, the majority of Canadian jurisdictions provide for mandatory reporting. In all jurisdictions, a physician who fails to report in circumstances where the physician is of the opinion that the driver is suffering from a condition that may make it dangerous for the patient to operate a motor vehicle faces potential quasi-criminal liability, civil liability and/or college disciplinary proceedings.

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[17]*ter Neuzen* v. *Korn*, [1985] 3 S.C.R. 674

[18]*Roberge* v. *Bolduc*, [1991] 1 S.C.R. 374

The current statutory provisions and professional guidelines leave little room for the exercise of discretion on the part of the physician and do not provide the physician with the ability to make judgments depending on his/her assessment of a patient's compliance with verbal instructions not to drive and/or to address temporary conditions. Unfortunately, current statutory requirements and professional guidelines do not address the reality of lengthy delays in the review process by provincial licencing bodies nor the lengthy delays that occur prior to a license being suspended or the delays in reinstatement, which extend the period of suspension well beyond what is reasonably required.

General recommendation # 3:

The Panel recommends that physicians practicing in mandatory reporting jurisdictions recognize that current legislation indicates that the physicians' duty to report patients who may be unsafe drivers supersedes the physicians' duty to an individual patient. Physicians are encouraged to err on the side of caution when considering the fitness of cardiac patients to drive.

IMPLEMENTATION

With the proliferation of practice guidelines for many diseases and conditions, it is becoming increasingly difficult for physicians to stay abreast of the current body of medical knowledge. In an effort to reach as many physicians as possible, members of the Panel will actively execute an *implementation strategy* over the coming year and beyond, to disseminate this report, to foster and encourage research and to create an environment in which the recommendations can be easily accessed. The implementation strategy includes:

1. Presentation of the Executive Summary and Main Document at the 2003 Canadian Cardiovascular Congress.

2. Incorporation of feedback and approval of the Executive Summary and Main Document by the Canadian Cardiovascular Society (CCS) membership and Council.

3. Completion of the full manuscript and submission for peer-reviewed publication.

4. Distribution of the Executive Summary and Main Document to provincial and territorial regulatory authorities and to the Canadian Council of Motor Transport Administrators (CCMTA).

5. Distribution of the Executive Summary and Main Document to the Canadian Medical Association (CMA) to allow for integration into the CMA guidelines.

6. Development of a Power Point presentation for use by educators.

7. Distribution of a printed handbook for distribution to the CCS membership and provincial and territorial regulatory authorities; posting of the final version of Power Point slides and pdf's in downloadable version on the CCS website.

8. Establish contact with the Family Medicine and Internal Medicine communities to facilitate distribution of guidelines.

9. Engagement of stakeholders to facilitate research initiatives.

General Recommendation # 4:

The Panel recommends the development of a longitudinal strategy to maximize the dissemination and implementation of these guidelines and to foster research in this area.

SUMMARY TABLE OF RECOMMENDATIONS

- **Where more than one set of circumstances or conditions co-exist, the more restrictive recommendation prevails, unless stated otherwise.**

- **These guidelines are intended to assist decision makers regarding the fitness of cardiac patients to drive, and are not intended to diminish the role of the physician's clinical judgment in individual cases.**

I. **CORONARY ARTERY DISEASE**

	Private Driving	**Commercial Driving**

1. Acute coronary syndromes

ST elevation MI	1 month after discharge	3 months after discharge
Non-ST elevation MI with significant LV damage*	1 month after discharge	3 months after discharge
Non-ST elevation MI with minor LV damage*		
- If PCI performed during initial hospital stay	48 hours after PCI	7 days after PCI
- If PCI not performed during initial hospital stay	7 days after discharge	30 days after discharge
Acute coronary syndrome without MI (Unstable angina)		
- If PCI performed during initial hospital stay	48 hours after PCI	7 days after PCI
- If PCI not performed during initial hospital stay	7 days after discharge	30 days after discharge

2. Stable coronary artery disease

Stable angina Asymptomatic coronary artery disease	No restrictions	
PCI	48 hours after PCI	7 days after PCI

3. Cardiac surgery for coronary artery disease

CABG surgery	1 month after discharge	3 months after discharge

NOTES:

* Minor LV damage is classified as an MI defined only by elevated troponin $\pm$ ECG changes and in the absence of a new wall motion abnormality. Significant LV damage is defined as any MI which is not classified as minor.

Notwithstanding any of the foregoing recommendations, angiographic demonstration of 50% or greater reduction in the diameter of the left main coronary artery should disqualify the patient from commercial driving, and 70% or greater should disqualify the patient for private driving, unless treated with revascularization.

CAD: coronary artery disease; LV: left ventricle; MI: myocardial infarction; PCI: percutaneous coronary intervention; CABG: coronary artery bypass graft

II. DISTURBANCES OF CARDIAC RHYTHM, ARRHYTHMIA DEVICES and PROCEDURES

1. VENTRICULAR ARRHYTHMIAS

	Private Driving	Commercial Driving
VF (no reversible cause) Hemodynamically unstable VT	6 months after event	Disqualified
VT or VF due to a reversible cause*	No driving until/unless successful treatment of underlying condition	
Sustained VT with no associated impairment of consciousness; LVEF < 30%	3 months after event	Disqualified
Sustained VT with no impairment of consciousness; LVEF ≥ 30%; ICD has not been recommended	4 weeks after event Satisfactory control	3 months after event Satisfactory control
Nonsustained VT with no associated impairment of consciousness	No restriction	

VF: ventricular fibrillation; VT: ventricular tachycardia; LVEF: left ventricular ejection fraction

*Examples include, but are not limited to, VF within 24 hours of myocardial infarction, VF during coronary angiography, VF with electrocution, VF secondary to drug toxicity. Reversible cause VF recommendations overrule the VF recommendations if the reversible cause is treated successfully and the VF does not recur.

2. PAROXYSMAL SVT, AF or AFL

	Private Driving	Commercial Driving
With impaired level of consciousness	Satisfactory control	
Without impaired level of consciousness	No restriction	

Drivers should receive chronic anticoagulation if clinically indicated (AF/AFL)
SVT: supraventricular tachycardia; AF: atrial fibrillation; AFL: atrial flutter

3. PERSISTENT or PERMANENT AF or AFL

	Private Driving	Commercial Driving
Adequate ventricular rate control; no impaired level of consciousness	No restriction; chronic anticoagulation if clinically indicated	

AF: atrial fibrillation; AFL: atrial flutter

4. SINUS NODE DYSFUNCTION

	Private Driving	Commercial Driving
No associated symptoms	No restriction	
Associated symptoms (sick sinus syndrome)	Disqualified until successful treatment	

5. ATRIOVENTRICULAR (AV) and INTRAVENTRICULAR BLOCK

	Private Driving	Commercial Driving
Isolated first degree AV block	No restriction	
Isolated right bundle branch block (RBBB)		
Isolated left anterior fascicular block		
Isolated left posterior fascicular block		
Left bundle branch block (LBBB)	Fit to drive if no associated impairment of level of consciousness	Fit to drive if no associated impairment of level of consciousness; and no higher grade AV block on an annual 24 hour Holter
Bifascicular block		
Second degree AV block; Mobitz I		
First degree AV block + bifascicular block		
Second degree AV block; Mobitz II (distal AV block)	Disqualified	
Alternating LBBB and RBBB		
Acquired third degree AV block		
Congenital third degree AV block	Fit to drive if no associated impairment of level of consciousness	Fit to drive if no associated impairment of level of consciousness; QRS duration $\leq$ 110 msec; and no documented pauses $\geq$ 3 seconds on an annual 24 hour Holter

If a permanent pacemaker is implanted, the recommendations in Section 6 (below) prevail

6. PERMANENT PACEMAKERS

	Private Driving	Commercial Driving
All patients	* Waiting period 1 week after implant * No impaired level of consciousness after implant * Normal sensing and capture on ECG * No evidence of pacemaker malfunction at regular pacemaker clinic checks	* Waiting period 1 month after implant * No impaired level of consciousness after implant * Normal sensing and capture on ECG * No evidence of pacemaker malfunction at regular pacemaker clinic checks

7. IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (ICDs)

	Private Driving	Commercial Driving
Primary prophylaxis, NYHA Class I-III	4 weeks after implant	Disqualified†
A primary prophylaxis ICD has been recommended but declined by the patient	No restriction	
Secondary prophylaxis for VF or VT with decreased level of consciousness; NYHA Class I-III	6 months after event*	
Secondary prophylaxis for sustained VT with no associated cerebral ischemia; NYHA Class I - III	1 week post implant, in addition to the appropriate waiting period for the VT (see Section II(1)	
Any event resulting in device therapies being delivered (shock or ATP), in which level of consciousness was impaired, or the therapy(ies) delivered by the device was/were disabling	Additional 6 month restriction	

* The 6 month period begins not at the time of ICD implant, but rather at the time of the last documented episode of sustained symptomatic VT, or syncope judged to be likely due to VT or cardiac arrest.

Note: For patients who have a bradycardia indication for pacing as well, the additional criteria under Section II (6) also apply.

All patients must be followed from a technical standpoint in a device clinic with appropriate expertise.

† ICDs may sometimes be implanted in low risk patients. Individual cases may be made for allowing a commercial driver to continue driving with an ICD provided the annual risk of sudden incapacitation is felt to be 1% or less

8. OTHER

	Private Driving	Commercial Driving
Brugada's syndrome; Long QT syndrome; Arrhythmogenic Right Ventricular Cardiomyopathy (ARVC)	*Appropriate investigation and treatment guided by a cardiologist *6 months after any event causing impaired level of consciousness	Disqualified†
* Catheter ablation procedure * EPS with no inducible sustained ventricular arrhythmias	48 hours after discharge	1 week after discharge

VF: ventricular fibrillation; VT: ventricular tachycardia; EPS: electrophysiology study; SVT: supraventricular tachycardia; AF: atrial fibrillation; AFL: atrial flutter; ECG: electrocardiogram; ATP: antitachycardia pacing

† Inherited heart diseases may sometimes be identified to pose a very low risk to patients. Individual cases may be made for allowing a commercial driver to continue driving despite the diagnosis of one of these diseases, provided the annual risk of sudden incapacitation is felt to be 1% or less.

III. SYNCOPE

	Private Driving	Commercial Driving
Single episode of typical vasovagal syncope*	No restriction	
Diagnosed and treated cause e.g. permanent pacemaker for bradycardia	Wait 1 week	Wait 1 month
Reversible cause e.g. hemorrhage, dehydration	Successful treatment of underlying condition	
Situational syncope with avoidable trigger e.g. micturition syncope, defecation syncope	Wait 1 week	
- Single episode of unexplained syncope - Recurrent (within 12 months) vasovagal syncope	Wait 1 week	Wait 12 months
Recurrent episode of unexplained syncope (within 12 months)	Wait 3 months	Wait 12 months
Syncope due to documented tachyarrhythmia, or inducible tachyarrhythmia at EPS	Refer to Section II	

* No restriction is recommended unless the syncope occurs in the sitting position, or if it is determined that there may be an insufficient prodrome to pilot the vehicle to the roadside to a stop before losing consciousness. If vasovagal syncope is atypical, the restrictions for "unexplained" syncope apply.
EPS: Electrophysiology study

IV. VALVULAR HEART DISEASE

1. Medically treated valvular heart disease

	Private Driving	Commercial Driving
Aortic stenosis	* NYHA Class I or II * No episodes of impaired level of consciousness	* Asymptomatic * NYHA Class I * AVA $\geq$ 1.0 cm(2) * EF $\geq$ 35%
* Aortic regurgitation * Mitral stenosis * Mitral regurgitation	* No episodes of impaired level of consciousness * NYHA Class I or II	* No episodes of impaired level of consciousness * NYHA Class I * EF $\geq$ 35%

2. Surgically treated valvular heart disease

	Private Driving	Commercial Driving
*Mechanical prostheses * Mitral bioprostheses with non-sinus rhythm * Mitral valve repair with non-sinus rhythm	* 6 weeks after discharge * No thromboembolic complications on anticoagulant therapy	* 3 months after discharge * No thromboembolic complications * Anticoagulant therapy * NYHA Class I * EF $\geq$ 35%
* Aortic bioprostheses * Mitral bioprostheses with sinus rhythm * Mitral valve repair with sinus rhythm	* 6 weeks after discharge * No thromboembolic complications	* 3 months after discharge * No thromboembolic complications * NYHA Class I * EF $\geq$ 35%

NYHA : New York Heart Association; AVA: Aortic valve area; LV: left ventricle; NSVT: nonstained ventricular tachycardia; EF: ejection fraction

V.   <u>CONGESTIVE HEART FAILURE, LV DYSFUNCTION, CARDIOMYOPATHY, TRANSPLANTATION</u>

	Private Driving	**Commercial Driving**
NYHA Class I	No restriction	EF $\geq$ 35%
NYHA Class II		
NYHA Class III		Disqualified
* NYHA Class IV * Receiving intermittent outpatient or home inotropes * Left ventricular assist device	Disqualified	
Heart transplant	* 6 weeks after discharge * NYHA Class I or II * On stable immunotherapy *Annual reassessment	* 6 months after discharge * Annual assessment * EF $\geq$ 35% * NYHA Class I * Annual non-invasive test of ischemic burden showing no evidence of active ischemia

LV: Left ventricle; NSVT: nonsustained ventricular tachycardia; EF:ejection fraction

VI.   <u>HYPERTROPHIC CARDIOMYOPATHY</u>

	Private Driving	**Commercial Driving**
All patients	* No episodes of impaired level of consciousness	* LV wall thickness < 30 mm * No history of syncope * No NSVT on annual Holter * No family history of sudden death at a young age * No BP decrease with exercise

BP: blood pressure; LV: Left ventricle; NSVT: nonsustained ventricular tachycardia

DEFINITIONS

MET (metabolic equivalent): One MET is the resting oxygen consumption in the seated position and is equivalent to 3.5 mL/kg/min

Private driver: A driver who drives less than 36,000 km/year or spends less than 720 hours/year behind the wheel; who drives a vehicle weighing less than 11,000 kg; and who does not earn a living by driving.

Commercial driver: Any licensed driver who does not fulfill the above definition of a private driver.

Waiting period: the time interval following onset of a disqualifying cardiac condition, initiation of a stable program of medical therapy, or performance of a therapeutic procedure (whichever is applicable) during which driving should generally be disallowed for medical reasons.
- Recurrence of the disqualifying condition or circumstance during this time resets the waiting period.
- If more than one waiting period would apply, the longer one should be used, except where stated otherwise.

Satisfactory control (for SVT, AF, or AFL which are associated with cerebral ischemia)**:**
- Of SVT: successful radiofrequency ablation of the substrate, plus an appropriate waiting period (see Section II(8)); or a 3 month waiting period on medical therapy with no recurrence of SVT associated with cerebral ischemia during this time.
- Of AF/AFL: a 3 month waiting period after appropriate treatment during which there have been no recurrences of symptoms associated with cerebral ischemia. If AF is treated with AV node ablation and pacemaker implantation, or if AFL is treated successfully with an isthmus ablation (with proven establishment of bidirectional isthmus block), then the appropriate waiting periods in Section II(8) apply.
- Of sustained VT with an LVEF greater than or equal to 40% and no associated cerebral ischemia: successful ablation of the substrate plus a one week waiting period, or pharmacologic treatment plus the appropriate waiting period defined in Section II(1).

Sustained ventricular tachycardia: Ventricular tachycardia having a cycle length or 500 msec or less and lasting 30 seconds or more or causing hemodynamic collapse

Nonsustained ventricular tachycardia: Ventricular tachycardia $\geq$ 3 beats; having a cycle length of 500 msec or less and lasting less than 30 seconds; without hemodynamic collapse.

Appendix A

Risk of Harm **Formula Derivation**

The risk of harm (RH) to other road users posed by the driver with heart disease is assumed to be directly proportional to the following:

- time spent behind the wheel or distance driven in a given time period (TD)

- type of vehicle driven (V)

- risk of sudden cardiac incapacitation (SCI)

- the probability that such an event will result in a fatal or injury-producing accident (Ac)

Expressing this statement as Formula 1:

$$RH = TD \times V \times SCI \times Ac$$

Fewer than 2% of reported incidents of driver sudden death or loss of consciousness have resulted in injury or death to other road users or bystanders (1-4). In Formula 1, therefore, Ac = 0.02 for all drivers.

There is evidence that loss of control of a heavy truck or passenger-carrying vehicle results in a more devastating accident than loss of control of a private automobile (5). Truckers are involved in only about 2% of all road accidents but in approximately 7.2% of all fatal accidents (5). In Formula 1, if V = 1 for a commercial driver, then V = 0.28 for a private driver.

There is no published standard or definition of what level of risk is considered acceptable in Canada even through this is crucial in the formulation of guidelines based on the probability of some event occurring in a defined time period. It was necessary, therefore, to develop such a standard.

For several years, the guidelines of the Canadian Cardiovascular Society, the Canadian Medical Association, and the Canadian Council of Motor Transport Administrators have permitted the driver of a heavy truck to return to that occupation following an acute myocardial infarction provided that he or she is functional class I with a negative exercise stress test at 7 metabolic equivalents, has no disqualifying ventricular arrhythmias and is at least 3 months post infarct. On the basis of available data, however, such a person cannot be assigned a risk lower than 1% of cardiac death in the next year. The risk of sudden death would be lower than this but would be at least partially offset by the risk of other suddenly disabling events such as syncope or stroke. For such a person, SCI is estimated to be equal to 0.01 in Formula 1.

It may be assumed that the average commercial driver spends 25% of his or her time behind the wheel (5). Thus, in Formula 1, TD = 0.25. As indicated above, V may be assigned a value of 1 for commercial drivers and Ac = 0.02 for all drivers. Substituting into Formula 1:

$$RH = TD \times V \times SCI \times Ac$$
$$= 0.25 \times 1 \times 0.01 \times 0.02$$
$$= 0.00005$$

Allowing such a driver on the road is associated with an annual risk of death or injury to others of approximately 1 in 20,000 (0.00005). This level of risk appears to be generally acceptable in Canada.

A similar standard may be applied to the driver of a private automobile. The average private driver spends approximately 4% of his or her time behind the wheel (TD = 0.04) (6). As indicated above, for such a driver, V = 0.28 and Ac = 0.02. The acceptable yearly risk of sudden death or cardiac incapacitation for such a person would be calculated as follows:

$$RH = TD \times V \times SCI \times Ac$$
$$0.00005 = 0.04 \times 0.28 \times SCI \times 0.02$$
$$SCI = 0.223$$

Thus, the private automobile driver with a 22% risk of sustaining an SCI in the next year poses no greater threat to public safety than the heavy truck driver with a 1% risk.

Finally, for the commercial driver who drives a light vehicle, such as a taxicab or delivery truck, V = 0.28 and TD = 0.25, placing them at a risk between that of the private driver and the tractor-trailer driver.

(*Adapted with permission from the Canadian Journal of Cardiology*)

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Appendix B

<u>Regulations governing reporting of medically unfit drivers and protection for physicians</u>

Jurisdiction	Reporting	MD protection for reporting	Legislation
Alberta	Discretionary	Protected	Motor Vehicle Administration Act, R.S.A. 1980, c. M-22
British Columbia	Mandatory if the unfit driver has been warned not to drive but continues to do so	Not protected	Motor Vehicle Act, R.S.B.C. 1986, c. 318
Manitoba	Mandatory	Protected	Highway Traffic Act, S.M. 1985-1986, c.3-Cap.H60 (consolidated to Feb, 1998)
New Brunswick	Mandatory	Protected	Motor Vehicle Act, R.S.N.B., c. M-17, 1973 as amended by S.N.B. 1994, c. 4, s. 6
Newfoundland and Labrador	Mandatory	Protected	Highway Traffic Act, R.S.N. 1990, cH-3 as amended by S.N. 1992, c. 26, s.1
Northwest Territories	Mandatory	Protected, unless acting maliciously or without reasonable grounds	Motor Vehicles Act, R.S. N.W.T. 1988, c. M-16
Nunavut (currently applying NWT legislation)	Mandatory	Protected, unless acting maliciously or without reasonable grounds	Motor Vehicles Act, R.S. N.W.T. 1988, c. M-16
Nova Scotia	Discretionary	Protected	Motor Vehicle Act, R.S.N.S. 1989, c. 293
Ontario	Mandatory	Protected	Highway Traffic Act, R.S.O. 1990, c. H.8
Prince Edward Island	Mandatory	Protected	Highway Traffic Act, R.S.P.E.I. 1988, cH-5
Quebec	Discretionary	Protected	Highway Safety Code, C-24.2
Saskatchewan	Mandatory	Protected	Vehicle Administration Act, S.S. 1986, c. V-2.1 as amended by the Highway and Vehicle Statutes Amendment Act 1996, c.29, s. 35
Yukon	Mandatory	Protected	Motor Vehicle Act, R.S.Y. 1986, c. 118

Source: CMA Guidelines for Fitness to Drive, 2000

Canadian Cardiovascular Society Consensus Conference 2003

Assessment of the Cardiac Patient for Fitness to Drive and Fly

Flying Subgroup Final Report

"Fly" subgroup: David Ross (chair), Vidal Essebag, Francois Sestier, Chris Soder, Claude Thibeault, Michael Tyrrell, Andreas Wielgosz

Introduction

This section of the report deals with the fitness of people with cardiovascular disease to fly on commercial airlines and some related topics including recommendations for DVT prophylaxis during flight and the effects of airport screening devices on defibrillators and pacemakers. It specifically does not deal with the fitness of aviation personnel to perform their duties which is subject to recently revised Transport Canada guidelines. Those interested can view the Transport Canada guidelines at **http://www.tc.gc.ca/CivilAviation/Cam/TP13312-2/cardiovascular/menu.htm**.

In most instances, the recommendations that follow are based on opinion, not data as there is none available. They are derived, largely, from a consensus developed by a working group from the Canadian Cardiovascular Society and published in 1998 (1).

Additional guidelines for ill passenger travel may be found at the Aerospace Medical Association website at **www.asma.org**.

Air Travel and Cardiovascular Patients

Travel by commercial airlines is undertaken by people with cardiovascular disease both for their own personal enjoyment and in order to receive treatment for their cardiac condition. Air travel imposes both general stresses on these patients including travelling through crowded airports, transporting luggage etc. as well as specific stresses related to the aircraft environment.

Stresses specific to the aircraft environment include lowered humidity, relative confinement in a cramped space and most importantly reduced barometric pressure while in flight. In addition, patients are relatively inaccessible to medical care for the duration of the flight.

I) Effects of Altitude:

Cabin pressure in modern pressurized aircraft ranges from 0-8,000' above sea level (ASL). Normal jet flights longer than 1 hour maintain cabin pressure of 7-8,000'. This results in arterial pO2 of 55-60 mm Hg and an arterial saturation of ~90% in people with normal lung function as this partial pressure lies on the flat portion of the oxyhemoglobin dissociation curve. Individuals with cardiorespiratory disease often have sea level arterial partial pressures of oxygen less than 95 mm Hg and may have a dramatic reduction in oxygen saturation in flight as they fall on the steep part of the curve.

Any passenger with a partial pressure of arterial oxygen less than 70 mm Hg at sea level requires supplemental oxygen during air travel (2). Supplemental oxygen for in flight use

must be prearranged with the carrier in advance and requires a prescription. Patients may not use their own oxygen as it is considered a hazardous material.

The other significant effect of a reduction in cabin pressure is the expansion of gases (ie pneumothorax). At 10,000' the volume of a gas will increase by 50% compared to sea level, at cabin pressures commonly encountered during airline travel gas will expand by approximately 30%.

Table I. Indications For Oxygen During Commercial Airline Flights

1. PaO_2 less than 70 mm Hg at sea level
2. Angina CCS Class III symptoms
3. Heart failure NYHA Class III symptoms
4. Cyanotic congenital heart disease
5. Pulmonary hypertension / right heart failure

II) Recommendations for Specific Cardiovascular Conditions

1) Angina Patients:

Clinicians are should consider exercise testing patients with known coronary artery disease to determine their functional level prior to advising on air travel.

a) Patients with stable angina controlled by medical therapy can travel by commercial aircraft without difficulty.

b) Patients with Functional Class IV angina should not travel by commercial aircraft.

c) Patients presenting with unstable angina which is stabilized in hospital may travel the next day to a tertiary care centre on a commercial aircraft only if accompanied by a physician with an attached ECG monitor / defibrillator, appropriate medication and on supplemental oxygen.

2) Post MI Patient:

Clinicians should consider performing a symptom-limited exercise test on post-MI patients to determine functional capacity and exclude residual ischemia prior to advising on air travel.

a) Patients should not travel by commercial aircraft until all complications resulting from a myocardial infarction are controlled appropriately including postinfarction angina, arrhythmia, heart failure, and hyper or hypotension. Ideally, patients should wait six to eight weeks following a MI before elective flying.

b) A patient may be allowed to travel by air after an uncomplicated MI and a normal cardiac stress test with a Bruce protocol greater than six metabolic units.

c) A patient with a more significant myocardial infarction not meeting the above criteria who needs to be repatriated or transferred to a tertiary hospital for revascularization may travel by commercial aircraft if accompanied by a physician with an attached ECG monitor / defibrillator, appropriate medication and is on supplemental oxygen.

3) Heart Failure Patients:

a) Patients with medically controlled Functional Class I or II heart failure may travel by commercial aircraft.

b) Those with Class III symptoms require supplemental oxygen. Patients with isolated right heart failure may travel by air. Those undertaking long flights may benefit from supplemental oxygen to reduce the effects of hypoxemia on pulmonary artery pressures.

4) Valvular Heart Disease Patients:

a) Patients with medically controlled Functional Class I or II symptoms may travel by commercial aircraft.

b) Those with Functional Class III symptoms require supplemental oxygen. Consideration should be given for supplemental oxygen for those with concomitant pulmonary hypertension.

5) Congenital Cardiac Patients

a) Patients with medically controlled Functional Class I or II symptoms may travel by commercial aircraft.

b) Those with Functional Class III symptoms require supplemental oxygen. Consideration should be given for supplemental oxygen for those with concomitant pulmonary hypertension.

c) Cyanotic heart patients require supplemental oxygen (PaO_2 < 70 mm Hg). As they may be prothrombotic they should follow the recommendations listed in Section III.

5) Cardiac Surgery Patients:

a) Coronary bypass patients can fly four days after surgery for short trips (less than 2 hours) if their hemoglobin is greater than 90 gm/l. If the patient is going on a long trip and may experience jet lag and extended relative hypoxia he or she may fly seven days after surgery only if symptoms are well controlled and the hemoglobin is higher than 90 gm/l. Postoperative patients are at increased risk for deep vein thrombosis and those anticipating very long flights should be considered for prophylaxis (see section III).

b) Valve patients with Functional Class I or II can fly under the same criteria as coronary bypass patients.

c) Patients whose hemoglobin is less than 90 gm/l and who wish to avoid transfusion should receive supplemental oxygen for the duration of the flight.

d) All postoperative patients require a chest xray prior to flight to exclude the presence of a residual pneumothorax.

6) Therapeutic Intervention Patients:

a) Angioplasty patients may fly the day following an uncomplicated procedure if they are asymptomatic. A patient undergoing angioplasty following an uncomplicated MI may fly according to the guidelines for uncomplicated MI. If the procedure was unsuccessful or there are complications, treat as complicated MI.

b) Patients receiving other percutaneous interventions such as device closures of ASD's may fly the day following the procedure.

7) Patients with Arrhythmias or Post-Arrhythmia Management Procedure:

a) Patients with supraventricular arrhythmias may travel the next day following an electrophysiology study or cardiac ablation if the arrhythmia is well controlled. Because of the recent venous instrumentation, however, advice in Section III should be followed. Patients with supraventricular tachycardia, atrial fibrillation or flutter whose arrhythmias are well-controlled with either conservative therapy or pharmacologic treatment may fly without restriction.

b) Patients with ventricular arrhythmias may travel 48 hours after a diagnostic or therapeutic procedure, if the arrhythmia is well controlled. Patients with uncontrolled hemodynamically significant ventricular arrhythmias (severe presyncope or syncope) should not travel by commercial aircraft until the episodes are brought under satisfactory control.

c) Patients who have undergone the implant of a pacemaker, ICD, or insertable loop recorder (ILR) may generally be permitted to fly 1 day after the implant, provided that there was no pneumothorax associated with the implant procedure, and that the device is functioning normally and has been programmed to the optimal parameters.

d) Patients with an implanted cardioverter defibrillator (ICD) may fly on commercial aircraft provided they have not had a therapeutic intervention from the device (antitachycardia pacing or shock) associated with severe presyncope or syncope in the past month.

Functional Classification

Class I: No functional limitation. Patient is able to achieve 7 METs without developing symptoms or objective evidence of cardiac dysfunction .
Class II: Mild functional limitation. Able to achieve 5-7 METs.
Class III: Moderate limitation. Working capacity 2-4 METs.
Class IV: Severe impairment. Symptoms at rest. Working capacity less than 2 METs.

MI: Myocardial infarction; MET(metabloic equivalent): one MET is the resting oxygen consumption in the seated position and is equivalent to 3.5 ml/kg/min

III) Indications for DVT Prophylaxis with Air Travel

Despite media reports, it has only been recently that there has been some scientific data to

support the association between long aircraft flights and the risk of venous

thromboembolism. The data that does exist supports this association only for very long

flights of 12 hours duration or longer where the incidence of asymptomatic DVT may be

as high as 5-10% (3). While shorter flights may also predispose to venous thromboembolism, there is no data to support this conjecture.

The risk of developing DVTs is related both to flight related factors (duration) and to patient-specific factors. Several common cardiovascular conditions would place patients at increased risk including previous venous thromboembolism (VTE), recent major surgery and congestive heart failure.

Three major classes of interventions may reduce the risk of DVT during long flights: general supportive measures, compressive stockings and pharmacological agents (ASA, low molecular weight heparin, and coumadin). There is direct evidence from randomized prospective trials that demonstrates that compressive stockings reduce the risk of travel associated VTE by 95% (3,4). Support for the use of ASA and LMWH is less direct and is primarily from data on postoperative patients where ASA reduces the risk of DVT by approximately one-third (5) and LMWH by about three-quarters (6). One randomized prospective study showed that one dose of LMWH, but not ASA , almost completely prevented the development of DVT following a long flight (7).

Low molecular weight heparin (4-5,000 anti Xa units) is available in prefilled narrow-bored needles and may be self-injected into the subcutaneous fat of the thigh or abdominal wall.

Recommendations for DVT Prophylaxis with Long Duration Air Travel

1) All Travellers:

1) Avoid stasis, move around cabin, isometric calf exercises
2) Avoid dehydration by drinking water and avoiding alcohol and caffeinated drinks

2) Moderate Risk:

healthy people age > 75, women > 45 taking estrogen containing hormone replacement therapy, pregnant and postpartum women, people up to age 45 who are heterozygous carriers of mutations for Factor V Leiden and Prothrombin gene mutation, varicose veins, heart failure, myocardial infarction within previous 6 weeks, recent lower limb trauma within 6 weeks (8,9).

1) Below knee graduated pressure stockings should be considered (placed before departure)
2) If elastic stockings not used, ASA 160-325 mg 4 hours prior to departure.

3) High Risk:

history of previous VTE, recent major surgery (within 6 weeks), active malignancy, gross obesity or marked immobility due to neuromuscular or cardiorespiratory disease, people age >45 with deficiencies of antithrombin, protein C or protein S, people age >75 with cardiac or pulmonary disease (8,9)

1) Below knee graduated pressure stockings placed before departure.
2) If elastic stockings not used, LMWH (4,000-5,000 anti Xa units) injected subcutaneously 2 hours before departure.

In individuals considered very high risk, pressure stockings should be combined with LMWH.

IV) Airport Security screening, AICDs and Pacemakers:

Archway style security metal detectors (those used in airport terminals, courthouses, and some schools) detect metal objects by utilizing an electromagnetic field. This type of security system should not affect the operation of implantable cardioverter-defibrillators (ICDs) or pacemakers. Metal detectors in compliance with the National Institute of Law Enforcement and Criminal Justice (NILECJ) standards generate relatively small amplitude magnetic fields, which are unlikely to affect cardiac rhythm devices.

Independent testing performed on ICDs and pacemakers from various manufacturers showed no device inhibition, inappropriate detection, or reprogramming by any of the units during a slow walk-through (10-15 seconds). Remaining in the archway for longer periods should be avoided.

A hand held detector wand has the potential to temporarily inhibit an ICD or pacemaker's output. Passing the wand over the ICD or pacemaker may result in a brief pause in the patient's heart rhythm. This pause may or may not be felt by the patient, and would be extremely unlikely to be harmful. More frequent movement of the detector wand over the ICD or pacemaker has the potential for causing increased interference with device operation. If a hand held detector wand must be used, it should not be passed over the device area more than once every five seconds. This will minimize the potential for interference with device operation.

An ICD or pacemaker patient walking through an archway metal detector may set off its alarm because the device is enclosed in a metal housing. Because the detector cannot determine the nature of detected metal objects, the patient may need to undergo a hand search for clearance. The patient should inform security personnel that he/she has an implanted cardiac device, present their identification card, and be prepared for alternative search methods.

V) Medical Resources On Commercial Aircraft

1) Emergency Medical Kit

Transport Canada requires all commercial aircraft with more than 100 passengers to carry
the following items in an emergency medical kit. This is the minimum requirement and
airlines may have additional items in the kit. Transport Canada is currently reviewing the
drugs on the list and will (probably) add some more in the future. The kit contains a
report form and physicians should complete this after the event.

Items	Quantity
a) Sphygmomanometer	1
b) Stethoscope	1
c) Syringes (sizes necessary to administer required drugs)	4
d) Needles (sizes necessary to administer required drugs) and safe disposal method (amended 2000/12/01)	6
e) 50% dextrose injection, 50cc	1
f) Epinephrine 1:1000, single dose ampoule or equivalent	2
g) Diphenhydramine HCl injection, single dose ampoule or equivalent	2
h) Nitroglycerin (2000/12/01)	10 tablets or equivalent (amended 2000/12/01)
i) Basic instructions for use of the drugs in the kit.	

2) Automatic external defibrillators

There is increasing evidence that automatic external defibrillators result in successful
resuscitation of 27 to 50% of people experiencing non-traumatic cardiac arrest on board
aircraft (2) or at airports (9). Some airlines already have these devices on onboard and the
US will require all commercial aircraft with at least one flight attendant to carry an
automated external defibrillator by April 2004. Some airlines only permit trained flight
attendants to operate the devices as volunteering physicians may be unfamiliar with the
equipment.

There are no plans, at present, to make defibrillators mandatory on Canadian registered aircraft.

VI) Physician liability when advising patients on the safety of flying

(The reader is also directed to the *Aeronautics Act* section in the *Mandatory Reporting – Legal Considerations* section of the "Driving" document.)

Three situations are addressed: Good Samaritan, direct patient involvement and remote assistance.

Good Samaritan is defined as attending to a passenger in need on a volunteer, ad hoc basis, where no prior patient-physician relationship existed. There may be two concerns, one of liability by acting and the other by not volunteering to act. The former is governed by law while the latter is more likely to be addressed by medical licensing bodies, ie the respective provincial Colleges.

There is no precedent of a physician who acted in good faith on board an aircraft as a Good Samaritan being successfully sued for malpractice. However, there is one example in case law of a successful suit against a physician, which was not related to air travel. The legal position on Good Samaritan behaviour is that the physician takes the usual measures expected of a licensed physician. If a physician has serious reservations about providing assistance either because of a lack of necessary skills or by being impaired eg due to fatigue, drugs or alcohol, that physician has the right to withdraw their service. Any mishap while impaired could result in a loss of protection in the courts.

Physicians are expected to respond to a call for assistance. Recognizing such a moral duty, a provincial College may look unfavourably on a physician who refuses assistance, considering such behaviour unprofessional. That such a refusal finds its way to a court of law is unlikely.

Direct patient involvement arises when a patient is advised about medical fitness to fly, such advice occurring in a sanctioned doctor-patient relationship. In such cases, a physician is liable for any related adverse outcome. As long as the advice given was reasonable and reflected customary practice, such a physician can expect to be indemnified by the Canadian Medical Protective Association. Where guidelines exist, they provide a benchmark for the appropriateness of the advice that was offered.

Remote assistance relates to management advice that is offered for a passenger with whom the physician, typically on the ground, is not in direct contact. This can apply either to a patient known to the physician or to a new case. For example, a physician may be asked to provide management advice for a patient being transported to a hospital or a medical opinion may be offered about the advisability of air evacuating a patient from a remote location such as a foreign country.
In such cases, the physician assumes some responsibility, usually shared with any other parties, that may be involved, eg those attending to the patient directly. The advice rendered should reflect reasonable practice. Proper documentation particularly of the information that is made available is of paramount importance in legal defence.

Information should be requested by fax or at least notes of any telephone conversations should be made.

Physicians involved in telehealth, providing routine medical advice for flying passengers, should check with their respective licensing authorities about the validity of their practice beyond the named jurisdiction.

SUMMARY TABLE OF RECOMMENDATIONS
I.

Table I. Indications For Oxygen During Commercial Airline Flights

1. PaO$_2$ less than 70 mm Hg at sea level
2. Angina CCS Class III symptoms
3. Heart Failure NYHA Class III symptoms
4. Cyanotic congenital heart disease
5. Pulmonary hypertension / right heart failure

II. *Recommendations for Specific Cardiovascular Conditions*

Condition	New York Heart Association Functional Class	Travel by Commercial Airline
Angina pectoris	I and II	No restriction
	III	Supplemental oxygen required
	IV	Only if medically necessary and accompanied[1]
Post MI	I	6-8 weeks
	II-IV	Only if medically necessary and accompanied[1]
Heart Failure	I and II	Unrestricted
	III	Supplemental oxygen required

Valvular disease	I and II	Unrestricted. Supplemental oxygen suggested if pulmonary hypertensive
	III	Supplemental oxygen required
	IV	Only if medically necessary and accompanied[1]
Congenital	I-II	Unrestricted, supplemental oxygen if PaO_2 <70 mmHg
	III	Supplemental oxygen required
	IV	Only if medically necessary and accompanied[1]
Post CABG / Valve surgery	I-II	4 days post surgery if flight < 2 hours 7 days post surgery if longer flights and Hb $\geq$ 90 gm/l
Therapeutic Intervention – PTCA / ASD closure	I-II	1 day post procedure If PTCA following MI follow MI guidelines
Arrhythmia / Post-arrhythmia procedure	I-II I-II I-II III-IV	Well-controlled supraventricular arrhythmias – unrestricted 1 day post procedure for supraventricular arrhythmias 2 days post procedure for ventricular arrhythmias uncontrolled hemodynamically significant ventricular arrhythmias should not fly by commercial aircraft
Post pacemaker /ICD/loop recorder implant	I-II	1 day post implant if no pneumothorax, device functions normally and is programmed appropriately
ICD Patients	I-II	1 month following last intervention from device associated with severe presyncope / syncope

1 Accompanied by physician with attached ECG monitor/defibrillator, oxygen and appropriate medication

MI: myocardial infarction; CABG: coronary artery bypass graft; PTCA: percutaneous transluminal coronary angioplasty, ASD:

atrial septal defect; ICD: implantable cardioverter defibrillator

Functional Classification

Class I: No functional limitation. Patient is able to achieve 7 METs without developing symptoms or objective evidence of cardiac dysfunction .
Class II: Mild functional limitation. Able to achieve 5-7 METs.
Class III: Moderate limitation. Working capacity 2-4 METs.
Class IV: Severe impairment. Symptoms at rest. Working capacity less than 2 METs.

III. *Recommendations for DVT Prophylaxis with Long Duration Air Travel[1]*

Flight < 12 hours – all travelers	Avoid stasis, move around cabin, isometric calf exercises Avoid dehydration, alcohol and caffeinated drinks
Flight > 12 hours – low risk	Avoid stasis, move around cabin, isometric calf exercises Avoid dehydration, alcohol and caffeinated drinks
Flight > 12 hours – moderate risk Healthy people age > 75, women > 45 taking estrogen containing hormone replacement therapy, pregnant and postpartum women, people up to age 45 who are heterozygous carriers of mutations for Factor V Leiden and Prothrombin gene mutation, varicose veins, heart failure, myocardial infarction within previous 6 weeks, recent lower limb trauma within 6 weeks (8,9)	Avoid stasis, move around cabin, isometric calf exercises Avoid dehydration, alcohol and caffeinated drinks Below knee graduated pressure stockings If elastic stockings not used, ASA 160-325 mg 4 hours before flight[2]
Flight > 12 hours – high risk History of previous VTE, recent major surgery (within 6 weeks), active malignancy, gross obesity or marked immobility due to neuromuscular or cardiorespiratory disease, people age >45 with deficiencies of antithrombin, protein C or protein S, people age >75 with cardiac or pulmonary disease (8,9)	Avoid stasis, move around cabin, isometric calf exercises Avoid dehydration, alcohol and caffeinated drinks Below knee graduated pressure stockings If elastic stockings not used, low molecular weight heparin (4,000-5,000 anti Xa units subcutaneously) 2 hours before flight

1 Literature supports 12 hours as threshold for risk of developing thromboembolism but many would consider 9 hours long haul

2 Data for efficacy of ASA is inconclusive

ASA: acetylsalicylic acid

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