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Guardians of the Work Ethic

As Nova Scotia's economic situation becomes more difficult, it becomes necessary to understand and re-examine the motives of both physicians and patients towards work. The actual "work ethic" of his Province will be central to our future success as we are forced to become more self reliant. Donald Savoie, Executive Director of the Canadian Institute for Research and Development, University of Moncton, recently wrote "Increasingly, development economists look to the population, its history, and its culture and work ethic (of an area) as a key to a competitive economy".

Indications are that even if those on our unemployment lists in Nova Scotia are genuinely seeking work, the number of those who just don't wish to work is increasing steadily for various reasons. Being over-educated for jobs available, mothers wishing to be at home with children, availability of only boring work or work of lesser pay than meets expectations, are all some of the reasons.

We, as physicians, are drawn daily into the work place of our patients with a surprising and ever increasing array of forms, most of which are to substantiate the fact that a worker cannot carry on in his/her job. It rapidly becomes obvious that workers are not trusted to make their determination of fitness for work and hence their appearance in our offices. Physicians have been made the guardian of the work place, with an increasing role of a policeman in many occupations. At a time when so many are dissatisfied with their work, this has become an increasing burden that is frustrating and wasteful as well as frightening. In many instances, objective evidence will aid us in assessing ability to work but at least as often, ability to work is dependent on motivation or the work ethic of the person. This ethic is difficult to evaluate and even more difficult to change.

G.R. Smith, in *JAMA*, states, "Work disability after a first myocardial infarction has proved to be especially problematic because there is currently a puzzling discrepancy between the progress made in keeping patients alive and that made in getting patients back to work after the event. In the past thirty years, there have been major advances in reducing the mortality associated with an acute myocardial infarction but the percentage of patients disabled by this disease, has not been substantially reduced". In the case of heart disease, the amount of anxiety and the stigma attached to it may help explain the motivation of the worker. However, it is difficult in cardiac cases and in many other situations to document the number of hours, days and even years of disability we are legitimizing that is really not deserved. It is equally difficult to document how much effort we as professionals spend in sorting and identifying the legitimately ill from the undeserving for occupational purposes. In these times of manpower planning, a good research project would be helpful.

In an age when the work ethic is being challenged, the physician is made to be judge and jury for a large number of unhappy workers seeking pay for no work. Considering our "have not" status as a Province, perhaps we should examine the work ethic more closely at a time when increasing self reliance and entrepreneurial spirit will be necessary, as the political structure of this country changes. Certainly physicians themselves tend to follow the "protestant work ethic" in practice if not philosophically. The ethic, first elaborated by Max Weber in "The Protestant Ethic and the Spirit of Capitalism" presents the thesis that modern capitalism arose out of an association between Calvinistic concern for moral obligation and the pursuit of economic success. The ethic of unceasing commitment to one's worldly calling followed a religious conviction that also allowed the most efficient accumulation of capital. This is a very apt description of many physicians lives, currently, and in the past.

Physicians financial success often becomes the subject of envy by many of our population who completely ignore the hard work and number of hours needed to gain such wealth. Physicians seem out of step as they utilize the "reward for work" system in the daily practice of medicine. It will be interesting to examine our productivity change if salaries are introduced in any significant way in the future. Salaried patients seem in the majority of people seeking sick time disability. Independent workers in small businesses or anyone on the equivalent of the fee-for-service do not seem to take up much time seeking paper excuses.

The lack of trust in workers to make their own determination of fitness for work is an acknowledg-

ment of problems within the system. Profit sharing, Japanese management techniques, a more paternalistic attitude to workers and incentives, might help in large enterprises but we have few such large industries. In the case of Nova Scotia individual self reliance will be essential and exploiting opportunities crucial.

Many doctors would welcome a comfortable salary with benefits, as opposed to continuing fee-for-service, working less time and less financial incentive. Self-actualization with less status seeking and more living for "now" may be mentally healthy but can our society afford the lifestyle? In fact, there would be many services not performed by newly salaried physicians, to be performed by other physicians or others in the health care team, probably salaried also. This may be desired by many to facilitate expanded occupational opportunity, status and income but there certainly is little evidence available that it would be cheaper. Studies that used nurse practitioners as cheaper replacements for doctors were limited, flawed and done ten years ago. Certainly, the experimentation with health maintenance organizations or health service organizations going on in this country using salaried physicians will prove interesting and should be watched closely. In fact, the work ethic is elaborated by Weber and connected to Calvinistic Theology may be out of date. Perhaps it is a luxury to work in a society that has many other alternatives. However that reality in Nova Scotia has not yet arrived. Nova Scotia may have to look back in its history to rediscover and promote a strong work ethic. Physicians should be able to help; we never lost the work ethic in the first place. □

J.F.O'C.



CORRECTION

Please note that unfortunately the Cover of our April Issue contains a number of errors. This issue was VOLUME 70 not 69 as shown and it was NUMBER 2 not 4 as shown. Also this issue did not deal with the topic of Quality Assurance.

The Editorial Staff apologizes for any inconvenience these errors may have caused our subscribers and members.

Editor

Pathology of Valvular Heart Disease in Adults in Nova Scotia

ANALYSIS OF SURGICALLY REMOVED VALVES

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299 surgically removed cardiac valves at the Victoria General Hospital, Halifax, Nova Scotia, were studied. All were removed from adult patients from November 1985 to November 1989. Valves were separated into four groups: Mitral alone: 139; mitral plus aortic: 56; aortic alone: 54; and prosthetic: 50. The mitral was the most frequently excised valve. Women constituted the majority of the patients in every group. The majority of the mitral valves removed had non-rheumatic process. Marked myxoid degeneration dominated the findings in 39% of the cases of non-rheumatic mitral valves; the majority of these valves of this subgroup had insufficiency as the clinical dysfunction. Most cases of the aortic alone group had stenosis as the clinical dysfunction and calcification as the dominant feature. The most interesting finding of this study was the frequency of cases of mitral valves with marked myxoid degeneration.

MATERIAL AND METHODS

Two hundred and ninety-nine surgically removed heart valves at the Victoria General Hospital, Nova Scotia, Canada, were studied. All valves were removed from adult patients during a four-year period, from November, 1985, to November, 1989. The clinical information used was that available to us on the pathology requisition form. Most specimens studied were comprised of pieces of valves; therefore, the diagnoses were not only based on gross but also on microscopic findings. Decalcification and hematoxylin and eosin stain were routinely done in all cases. Special stains such as Masson's trichrome, Alcian blue, Gram, PAS, Giemsa, etc., were done when needed.

The gross examination of the specimens included valve weight, degree of fibrous thickening, degree of calcification, status of cordae tendinae, status of portions of papillary muscles, and presence of vegetations. Other morphological findings such as commissural fusion, valve perforation, number of cusps, or measurements, as recommended by Waller were not reliable due to the fragmented condition in which most valves were received.¹ The presence of fibrosis, inflammatory infiltrate, microorganisms, granulation tissue, myxoid degeneration, hyalinization and calcification were evaluated under light microscopy. Valves were separated into four groups: 1) mitral valves, 139; mitral plus aortic

valves, 56; aortic valves, 54; and prosthetic valves, 50. Valves in each group were divided according to their functional status, either stenotic or insufficient. The etiology for each valve was divided into either rheumatic or non-rheumatic, the latter group was subdivided into myxoid and non-myxoid degenerative subgroups.

RESULTS

Data are summarized in Table I. The mitral valve was the most frequently excised valve. Women constituted the majority of patients in every group. The mean age was 70 years, and patients were in the fifth decade or older, except in the mitral valve group, where there were young adults.

TABLE I

SUMMARY OF THE 299 HEART VALVE SPECIMENS

Valve	No.	Sex		Age (average and range)
		Male	Female	
Mitral only	139	59	80	70 (30-85)
Mitral plus aortic	56	19	37	68 (57-85)
Aortic only	54	20	34	72 (57-86)
Prosthetic	50	19	31	71 (57-87)

Mitral Valve

A total of 139 were studied (Table II). Thirty-eight had a rheumatic and 101 had a non-rheumatic etiology. Degenerative valves accounted for 78% of the non-rheumatic group and for 56% of the total group. The degenerative group was divided into valves showing predominantly myxoid changes (myxoid degeneration subgroup), and valves showing predominantly other changes (calcification, fibrosis, hyalinization, etc.), rather than myxoid change ("Non-myxoid degeneration" subgroup). Calcification, fibrosis and hyalinization were frequent microscopic findings in the non-rheumatic valves (>50%). Inflammatory infiltrate was present in 35% of cases. In the vast majority of cases, the infiltrate was constituted by lymphocytes and a few plasma cells, except in the cases of endocarditis and in several cases of recent myocardial ischemia, where neutrophils were also seen. Vegetations were present in two cases of bacterial endocarditis. Myxoid changes were present in 58% of cases. 36% of the 38 cases of rheumatic valves, and 66% of the non-rheumatic group showed myxoid changes. The mean age for patients with myxoid changes in their valves was 69 years (range 57-86 years). The more frequent occurrence of myxoid changes in the non-rheumatic group was due, predominantly, to a high incidence of these changes in heart valves with

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clinical regurgitation (Table III). To further investigate this point, we separated the mitral valves showing myxoid changes as their main pathologic finding and correlated them with their clinical dysfunction (Table III). Mitral valves with severe myxoid changes stand out as a separate group associated with mitral regurgitation. No rheumatic valves showed severe myxoid changes.

TABLE II

PATHOLOGY OF 139 SURGICALLY REMOVED MITRAL VALVES	
A. Rheumatic = 38.	B. Non-rheumatic = 101
	• Degenerative Valve = 78
	Myxoid (39)
	Non-myxoid (39)
	• Ischemia = 15
	• Endocarditis = 5
	• Trauma = 2
	• Cordal rupture = 1

TABLE III

ANALYSIS OF MYXOID CHANGES AND CLINICAL DYSFUNCTION OF MITRAL VALVES			
I) All mitral valves with myxoid changes			
A) Rheumatic = 27	B) Non-rheumatic = 66		
Stenosis = 4	Stenosis = 6		
Regurgitation = 6	Regurgitation = 58		
Both = 1	Both = 2		
II) Mitral valves with "myxoid degeneration"			
A) Rheumatic = 0	B) Non-rheumatic = 39		
	Stenosis = 4		
	Regurgitation = 34		
	Both = 1		

Mitral and Aortic

Twenty-eight surgical specimens (Table VI), containing both mitral and aortic valves, were studied. The percentage (47%) of valves of rheumatic origin is higher in this group than in any other group. When we look at the mitral valves in this group, we see that 11 (40%) had rheumatic disease. This percentage is much higher than that seen for the Group I (mitral valves only), where rheumatic disease explained only 27% of the cases. The majority of both valves (80%) showed calcification, but again we separated some into myxoid and non-myxoid degeneration groups under the same considerations given in Group I (mitral group), for the purpose of comparison. Three valves showed myxoid degeneration, 11 were pure insufficient valves, as supposed to stenotic or combined dysfunction (80%) seen in the rest of the valves.

Aortic Valve

Fifty-four aortic valves were studied (Table V). Most cases (48) were stenotic, and only 6 were insufficient. All stenotic cases and one insufficient showed calcification. Three valves showed severe myxoid changes, had no calcification, and were clinically insufficient. Myxoid changes were also present to a lesser degree in another 30 cases. Hyalinization (35 cases) and fibrosis (25 cases)

were frequently seen in calcific valves, but the dominant feature was calcification. Most aortic valves had calcification as a major component of their pathology (92%).

TABLE IV

ANALYSIS OF 28 SPECIMENS CONTAINING MITRAL PLUS AORTIC VALVES			
	Mitral	Aortic	Total
A) rheumatic	16	11	27
B) Non-rheumatic	12	17	29
Calcific	4	5	9
Myxoid degeneration	2	2	4
Non-myxoid degeneration	5	4	9
Endocarditis	1	2	3
Bioprosthetic	0	4	4

TABLE V

ANALYSIS OF 54 SURGICALLY REMOVED AORTIC VALVES	
Diagnosis	No. of Cases
— Calcific	16
— Degenerative	22
— Congenital bicuspid	8
— Valvulitis	2
— Rheumatic disease	2
— Graft	1
— Myxoid degeneration	3

Prosthetic

Fifty valves (Table VI) were studied — 24 mitral and 26 aortic. Changes such as hyalinization (40%), fibrosis (27%) and calcification (40%) were seen less frequently than in native valves. However, a foreign body-type of chronic inflammatory infiltrate was frequently (55%) seen at the stent. Twenty-eight valves had a grossly recognizable defect (tear, perforation, dehiscence of ring) that explained the malfunctioning. Endocarditis was proven in only one case, this frequency is not higher than that seen in the three previous groups.

TABLE VI

ANALYSIS OF 50 PROSTHETIC VALVES		
Diagnosis	Mitral	Aortic
Degenerative	18	18
Lipid deposits	0	2
Thrombosis	4	4
Endocarditis	1	1
Foreign body	1	1

COMMENT

The results indicate that the majority of patients whose valves were studied had a non-rheumatic disease (78%). However, rheumatic valves were still frequently seen (22%). Even though calcification was present in only 41 (50%) of aortic valves, this is considered to be low

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Focus on Malignant Melanoma

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The term 'melanoma' derives from the Greek roots *mela* meaning black and *oma* meaning tumour. Public interest and medical attention has been riveted by this 'black tumour' in recent years because of a reported dramatic increase in its incidence worldwide. While the magnitude of the 'melanoma epidemic' has undoubtedly been exaggerated by the media, epidemiologic evidence does indeed lend credence to the reported rise in its incidence. This has been attributed in part, to depletion of the ozone layer, the earth's natural ultraviolet filter, by environmental pollutants, thus admitting increased amounts of carcinogenic solar radiation to the atmosphere. That factor has been compounded by behavioral trends, which under the influence of a fashion industry enamoured by suntanned idols, have resulted in increased sun exposure. However, the deleterious link between skin cancer and ultraviolet radiation is now well established and, in the current age of enlightenment, sun protection has become the vogue.

FACTS AND FIGURES

Though estimates vary, increases in the annual incidence of malignant melanoma worldwide have ranged from 3 to 9% per year over the past several decades.¹ In the USA, there has been a 7% increase in the yearly incidence of that disease since 1980. Figures released by the American Skin Cancer Foundation indicate that in 1990, approximately 600,000 new cases of skin cancer were diagnosed in the U.S. and that melanoma accounted for approximately 32,000 (5.3%) of these. Furthermore, of an estimated 8,800 deaths due to skin cancer in that year, roughly three-quarters were attributable to malignant melanoma. Earlier diagnosis and more effective management of melanoma have resulted in better outcomes and since the 1940s survival rates for this disease have improved by approximately 10% per decade. Despite this however, the disproportionate rise in incidence rates has resulted in escalating mortality (eg. 1/100,000 in the 1950's to 2.5/100,000 in the 1990s).

Light skinned individuals, with high levels of sun exposure, are at most risk of developing malignant melanoma. The disease is uncommon in dark skinned races and rare in Negroes where it shows a predilection for involvement of mucous membranes, subungual

areas and volar skin.² A person's chance of developing malignant melanoma increases with advancing age.³ Approximately 0.3 to 0.4% of cases occur in prepubescent children, 2% occur in patients less than 20 years of age, and 50% develop in persons under the age of 55. In 1990, the estimated average lifetime risk of an individual in the US developing melanoma was 1 in 120.

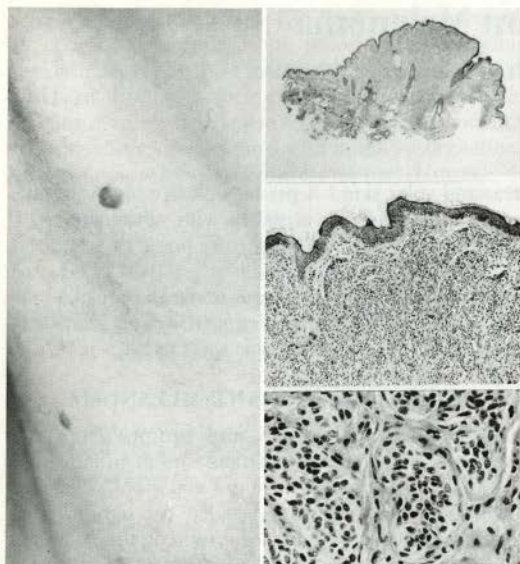
DIAGNOSIS OF MALIGNANT MELANOMA

Because early diagnosis and prompt complete excision of a malignant melanoma result in cure of a potentially fatal disease, there is a major onus on those involved in health care to be alert for signs of this disease. Furthermore, public education on this subject is crucial, both from the point of view of prevention and early detection. Briefly, features of a pigmented skin lesion which should alert one to the possibility of malignant melanoma and serve to distinguish it from common acquired nevi or benign moles include: size (>6mm, by convention); irregularity in shape typified by notched borders; poor circumscription; variability in pigmentation; and recent change (Figs. 1, 2, 3, 4). Furthermore, the clinical spectrum of these lesions is broad and can range from a flat pigmented patch to an ulcerated nodular growth. Other cutaneous neoplasms which can share these clinical characteristics include pigmented seborrheic keratoses, pigmented basal cell carcinomas and some congenital nevi. Hence these are not infrequently mistaken for malignant melanomas by clinicians. In essence, any skin lesion which raises a suspicion of melanoma, on the part of patient or physician, should be removed and submitted for histopathological evaluation. There can be no justification for following such lesions, without intervention.

While keen clinical acumen is vital in the detection of malignant melanoma, microscopic examination constitutes the cornerstone of diagnosis. Melanocytic neoplasms frequently present a diagnostic conundrum for pathologists and hence it is vitally important that a suitable biopsy specimen be submitted. Just as evaluation of the overall architecture of the lesion 'in vivo' has been stressed, estimation of size, symmetry, and circumscription at the histopathological level is crucial to diagnosis.⁴ In the arena of melanocytic lesions, in contrast to other human neoplasms such as lymphomas, assessment of cytological features is of secondary value. For these reasons, the optimal diagnostic specimen for submission to pathology is a complete excisional biopsy with narrow margins. This, in addition to assisting accurate diagnosis, allows estimation of the true depth of the lesion from the outset and provides guidance as to the appropriate definitive surgical approach.

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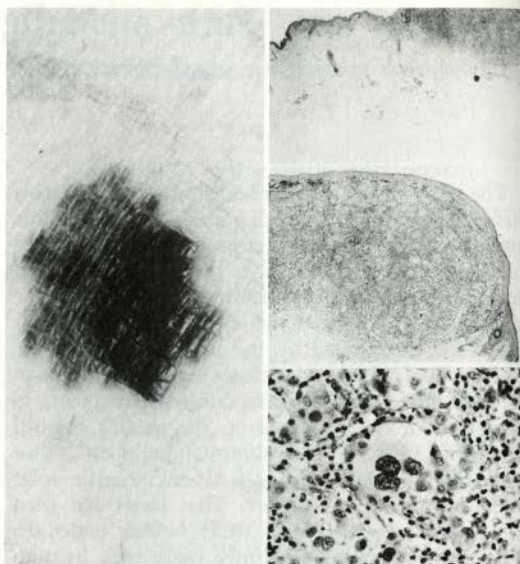


1a

1b

Fig. 1a. Small, symmetrical, dome-shaped papule on the neck, characteristic of a benign nevus (mole).

Fig. 1b. Low, medium and high power views of corresponding histopathological section of such a lesion.

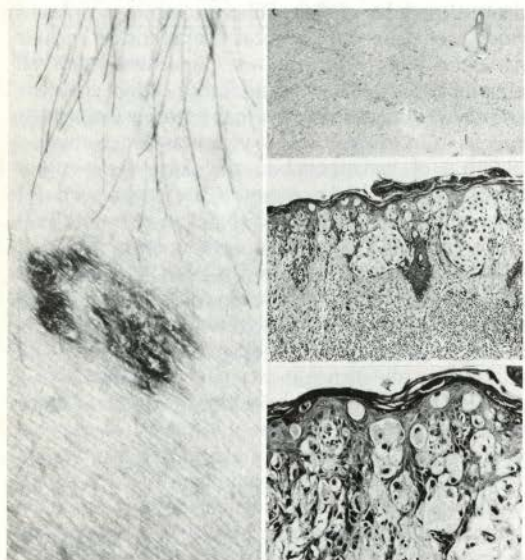


2a

2b

Fig. 2a. Malignant melanoma, typified by raised and flat components with an irregular notched periphery.

Fig. 2b. The asymmetry of such a lesion is also evident on histopathological sections at low magnification, while higher power views display cytological atypia.

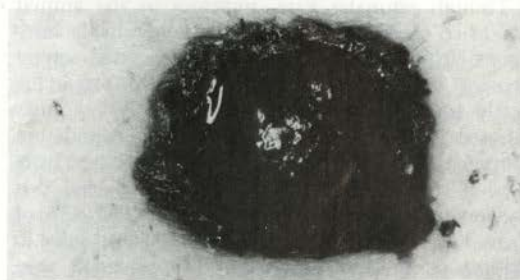


3a

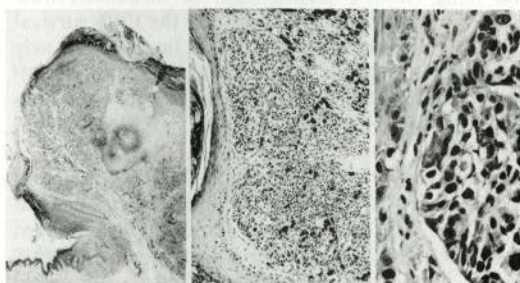
3b

Fig. 2a. Irregular, flat pigmented macule with notched borders representing a non-invasive malignant melanoma.

Fig. 2b. Histopathologically, this type of lesion is characterized by a florid poorly circumscribed proliferation of melanocytes (pale cells), which is confined to and partially replaces the epidermis.



4a



4b

Fig. 4a. Nodular malignant melanoma with ulcerated, glistening surface.

Fig. 4b. Microscopically, an asymmetrical, ulcerated polypoid neoplasm, composed of melanocytes, mirrors the clinical appearances.

In normal human skin, melanocytes are dotted along the basal zone of the epidermis in an approximate ratio of 1:5 with intervening keratinocytes.⁵ Their function is to produce melanin pigment which confers protection from the damaging effects of solar radiation. Chronic solar damage produces melanocytic hyperplasia, thus increasing the melanocyte:keratinocyte ratio. This feature is readily evident in facial skin of the elderly. As in many examples of human malignancy, hyperplasia provides fertile soil for the development of neoplasia (endometrial hyperplasia and endometrial carcinoma, adenomatous hyperplasia of colonic mucosa and colonic cancer, mammary duct hyperplasia and breast carcinoma).

Melanomas represent an uncontrolled, but initially localized, proliferation of melanocytes which have undergone malignant transformation and possesses the ultimate capability of killing the patient. Morphologically, this event is recognisable by attending to the pattern or silhouette of the neoplasm (Figs. 1, 2, 3, 4). In brief, it is characterised by a broad, poorly circumscribed, asymmetrical melanocytic proliferation which begins at the dermoepidermal junction and, in contrast to that of benign melanocytic nevi, often displays intraepidermal spread (Fig. 2b). With time, the lesion extends into the dermis in a similarly disorganized fashion where there is a potential for lymphatic and vascular invasion. Cytological features of malignancy may or may not be present and are of only secondary diagnostic value.

The majority of cutaneous malignant melanomas arise *de novo*⁶, although a certain percentage occur in association with pre-existing nevi, notably congenital nevi. A small proportion of melanomas as a whole arise from melanocytes of the uveal tract and represent the most common primary intraocular tumour in adults. Malignant melanomas have also been reported to develop primarily in a variety of internal organs but in that setting it is difficult to disprove metastatic disease from a regressed cutaneous primary. Furthermore, soft tissue tumours such as clear cell sarcoma, epithelioid malignant schwannoma and pigmented (melanocytic) schwannoma, share features in common with malignant melanoma and may in fact represent variants of that disease.⁷ In tumour histopathology, melanoma is considered to be 'the great mimic' and is traditionally considered in the differential diagnosis of any undifferentiated malignant neoplasm. Fortunately, the advent of sophisticated immunohistochemical techniques and electron microscopy now allow accurate identification of such lesions.

PROGNOSIS AND MANAGEMENT OF MALIGNANT MELANOMA

The prognosis in cases of malignant melanoma is directly related to the clinical stage of disease (Table I). This may be localized (stage 1); associated with regional lymph node involvement (stage 2); or include generalized metastatic disease (stage 3). In instances of localised

disease (stage 1), the outcome hinges on tumour thickness (Breslow measurement) and the depth of dermal involvement (Clark's level). These factors are evaluated microscopically. Stage 1 melanomas are divided into minimum, low, medium and high risk groups, based on tumour thickness, (Table II). In general, lesions <1.5 mm in thickness have a good prognosis and are associated with a five year survival of >87%.²

TABLE I

CLINICAL STAGING SYSTEM FOR MALIGNANT MELANOMA

Stage	Clinical	Pathological
I	Localized disease	Regional lymph nodes devoid of metastatic tumour
II	Enlarged regional lymph nodes	Microscopic evidence of metastatic disease in regional lymph nodes
III	Distant metastases	Histological confirmation of distant metastases

TABLE II

PROGNOSIS OF CLINICAL STAGE 1 MELANOMA BASED ON TUMOUR THICKNESS

Risk Category	Melanoma Thickness (mm)	5 Yr. Survival (%)
Minimum	<0.76	96-99
Low	0.76-1.50	87-94
Intermediate	1.51-4.0	66-77
High	>4.0	<50

Complete surgical excision represents the cornerstone of management in cases of malignant melanoma. Formerly, it was customary to carry out wide local excision of the lesion with 5 cm margins on all sides. However this usually resulted in a disfiguring scar and its validity was questioned by authors such as Ackerman in his paper entitled "How wide and deep is wide and deep enough?"⁸ A more conservative surgical approach has now gained acceptance and this is usually tailored to tumour thickness. It now appears that a 1 to 2 cm margin is adequate for melanomas less than 2 mm thick and resection margins greater than 3 cm are not of value even for melanomas of greater thickness.² The approach to regional lymph node dissection in cases of clinically uninvolved nodes is controversial.^{9,10} However dissection is recommended when lymph node involvement is suspected.

In the setting of metastatic disease a number of chemotherapeutic agents have been employed, with palliation in mind, but these have met with limited success. At the present time, dacarbazine (DTIC: dimethyl triazeno imidazole carboxamide) is the most extensively studied single agent and is regarded as the most effective.¹¹ However, responses have been partial and of short duration. Better responses have been obtained with combination chemotherapy but these have to be weighed against the significant morbidity associated with this mode of therapy.¹² Finally, it should be noted that melanoma is one of the malignancies which can remain dormant for prolonged periods and

metastatic disease can occur 10 years or more after the initial presentation. For this reason, prolonged follow-up is mandatory both from the point of view of patient care and statistical evaluation of outcome.

CONCLUSION

Knowledge of the factors which predispose to malignant melanoma should stem the rising incidence of this disease and education concerning early recognition will allow for less radical curative surgical techniques and improved survival. Furthermore, advances in the surgical and chemotherapeutic management of this lesion and continuing medical research also offer scope for optimism. In the latter regard, a number of forms of immunotherapy are currently under investigation and these may serve to enhance the natural host response to the tumour without incurring undue morbidity.^{13,14} However at this time, malignant melanoma remains a challenging problem for patient, clinician and pathologist alike and only continuing and devoted research in the field will serve to unlock the secrets of this fascinating neoplasm. □

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Continued from page 72.

and probably represents our tendency to submit the least calcified areas. Calcific bicuspid valves only explained 8 of the 82 aortic specimens; this is much lower than what others have found, and probably reveals the predominantly elderly population included in this study.² The high frequency of our aortic and mitral annular calcifications probably reflects the increase in longevity as well.

One hundred valves showed myxoid changes of varying degrees. These changes were more frequently seen in mitral (93%) than in aortic (14%) valves. These percentages are higher for mitral and much lower for aortic valves than those found by Kern *et al.*, who found myxoid changes to be the same (73%) for both valves.³ Thirty-nine of the 100 cases showing myxoid changes were considered to be predominantly affected by this histopathological change. Mitral valve was the only one showing marked myxoid degeneration and, with the exception of four cases, they all had insufficiency as clinical dysfunction. Although not stated in our pathology requisition form, these valves likely represent cases of mitral valve prolapse, which would agree with other studies which report myxomatous change as the dominant course of removed insufficient mitral valves.^{3,4} □

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Molecular Diagnosis of Human Cancers

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PROTO-ONCOGENES AND ONCOGENES

In the human genome there exists groups of genes referred to as proto-oncogenes, and they are involved in normal cell proliferation and development/differentiation. However, when they are inappropriately expressed (by mutation, translocation, etc.), their protein products lead to the neoplastic state. This activated form of the gene is called an *oncogene*. To date there have been approximately 50 different oncogenes identified in various human cancers (also called *dominant oncogenes*). Inappropriate expression is the result of spontaneous or induced mutation. The mutation lesions most often characterized in oncogenes are either: 1) a point mutation or small deletion in the coding sequence, thus producing a hyperactive oncogene product that is made in normal amounts; or 2) an amplification of a single oncogene sequence that results in a high level of expression of the normal protein; or 3) chromosomal rearrangements leading to overexpression of the gene or production of an activated fusion protein.

Proto-oncogenes have been classified according to either the biochemical activity of the protein product or the cellular location of the product. Many of the proto-oncogenes are involved in a cascade for signal transduction from the outside cell-surface (proliferation signals such as growth factors) through the cytoplasm, to the nucleus. Activation of any oncogenes in this signal transduction cascade may result in abnormal proliferation and/or differentiation.

Identification of Mutations in Oncogenes

The most widely used system for detecting molecular changes in genes is based upon the standard techniques of agarose gel electrophoresis, Southern blotting and hybridization (Figure 1). DNA is isolated from the patient's white blood cells and then enzymatically cleaved into a wide range of sizes. The DNA molecules can be sized/separated by electrophoresis through an agarose gel. The DNA molecules are denatured to become single standard and transferred into a filter paper. This later process is accomplished by placing the paper directly on the gel and pulling the DNA out of the gel and onto the paper by capillary action (Southern

blotting). The paper, containing the immobilized single-stranded DNA, is then placed in a bag along with the radioactively labelled single-stranded DNA probe of interest. The probe hybridizes to complementary single-stranded DNA sequences immobilized on the filter, which is then exposed to x-ray film. Only the DNA molecules that are homologous to the labelled probe will anneal together on the paper. This radioactive complex will expose the x-ray film and will be seen as a discrete band. If the original enzymatic cleavage of the DNA cut the molecule once, then two bands will appear.

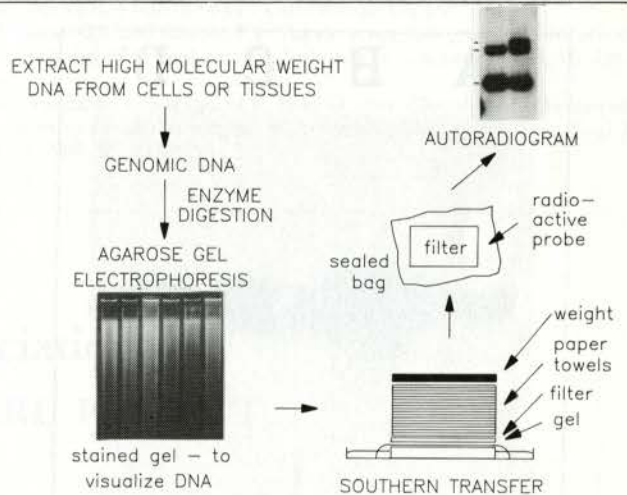


Fig. 1 Agarose gel electrophoresis, Southern blotting, and probe hybridization.

A recent addition to these techniques is the ability to amplify specific DNA sequences with a method called polymerase chain reaction (PCR). This technique uses synthetic pieces of specific DNA to amplify a larger sequence to as high as 100,000-fold. Subsequent to the amplification a specific mutation can be analyzed from very small amounts of tissue. Using these techniques, and others, there now exists a large body of data defining some parameters for the molecular diagnostics of human cancer.^{1,2} A few examples are discussed below.

Neuroblastoma

Neuroblastoma is a highly malignant tumor of postganglionic sympathetic neurons that presents during childhood, and it is the most common solid tumor in children.

It has been found that between 20 and 50% of human primary neuroblastomas have an amplification of the *N-myc* oncogene.^{3,4} Gene amplification is a process where the gene duplicates itself with the amplification ranging

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from 3 to 300-fold extra copies of the gene. It has been determined that the magnitude of amplification correlates with advanced disease stage. Seeger *et al.* reported that amplification of *N-myc* was detected in 13% of Stage II tumors, 65% of Stage III tumors and 49% of Stage IV tumors, while no duplication of *N-myc* was detected in Stage I or Stage IV-S tumors.⁴ Additionally, the estimated progression-free survival at 18 months was 70%, 30%, and 5% for patients whose tumors had 1, 3 to 10, or more than 10 *N-myc* copies, respectively. These data suggest that genomic amplification of *N-myc* may play a key role in determining the aggressiveness of neuroblastomas. Figure 2 shows the results of a Southern blot using DNA isolated from a neuroblastoma from a patient at The Izaak Walton Killam Hospital for Children in Halifax, N.S.

N-MYC AMPLIFICATION IN HUMAN NEUROBLASTOMA

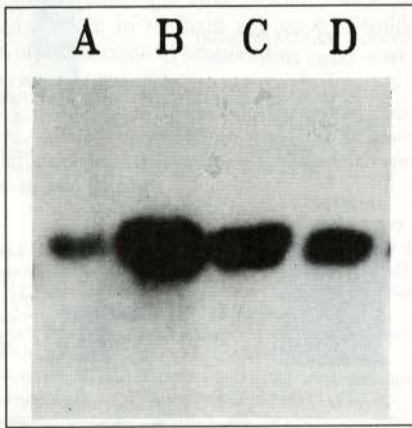


Fig. 2 The results of a Southern blot using DNA isolated from unaffected normal human tissue (lane A) and from a human neuroblastoma (lanes B, C, D). Lane B contains 1/2 the amount of DNA run in lane A; and lane C contains 1/4 and lane D contains 1/8th the amount of DNA in lane A. The results demonstrate that the patient's neuroblastoma has an *N-myc* amplification greater than 10 fold.

Chronic Myelogenous Leukemia (CML)

CML is a cancer of the pluripotent stem cell and is associated with a consistent chromosomal translocation.

CML is an example of a translocation-mediated oncogene activation. This occurs in leukemia patients with a t(9;22) translocation; also called a Philadelphia translocation (Ph⁺). The Ph⁺ translocation activates the *abl* proto-oncogene by shifting it from chromosome 9 to 22, where it recombines with part of the *bcr* gene (breakpoint cluster region). The new *abl-bcr* gene sequence codes for a highly active *abl* protein, leading to abnormal proliferation function. While this mutation is not detected by cytogenetic methods, the use of *abl* and *bcr* molecular probes are a very sensitive means to detect

aberrations in these genes. Alterations in these genes is considered a critical adjunct diagnostic test for the classification and diagnosis for CML.

Follicular and Diffuse Large-Cell and Mixed-Cell Lymphoma

Cloning the breakpoint of a specific translocation in a patient with a hematologic malignancy led to the isolation and characterization of a B-cell lymphoma/leukemia oncogene (*bcl-2*). Subsequently, rearrangement of the *bcl-2* oncogene has been reported in most patients with follicular lymphoma and in some patients with diffuse large-cell lymphoma. Yunis has recently reported that *bcl-2* rearrangement has an important prognostic value in these patients.⁵ He reported that *bcl-2* rearrangement was found in 56% of patients with follicular lymphoma having a large-cell component and in 35% of patients with diffuse lymphoma having a large-cell component.⁵ Patients without a *bcl-2* rearrangement usually had a prolonged and complete clinical remission following chemotherapy. However, patients with *bcl-2* rearrangements often had a partial response or no response to therapy and a shorter survival. These findings suggest that most patients with these lymphomas can be divided into important subgroups by a simple Southern blot analysis of the *bcl-2* oncogene, regardless of other risk factors or histopathology.

Immunoglobulin-Gene Rearrangements Applied to Diagnosis of Lymphoid Neoplasms

Rearrangements of the immunoglobulin (Ig) and T-cell receptor (TCR) genes have been used as markers of lineage, clonality, and stage of differentiation in B and T cell neoplasms.⁵⁻⁷ Ig rearrangements in B cells, and TCR rearrangements in T cells, are specific normal events in their differentiation. Therefore, a specific rearrangement of these genes indicates a tumor lineage and clonality. Since the rearrangements occur sequentially in normal cell differentiation, they have been used to analyze the stage of differentiation of lymphoid tumors. These molecular techniques are useful adjuncts to immunologic and karyotypic analysis.

TUMOR SUPPRESSOR GENES

There is a growing body of evidence that the expression of the parameters of neoplasia depends not only on the expression of genes that actively contribute to the neoplastic phenotype (the oncogenes) but also on the loss of expression of genes that act to maintain the normal phenotype, the cancer suppressor genes.^{8,9} Since both alleles at a given genetic loci must either be lost or inactivated by mutation to produce a functionally deficient expression, this type of oncogene acts as a recessive. These data are consistent with the knowledge of hereditary syndromes with a predisposition to neoplasia, e.g. neurofibromatosis, Beckwith-Wiedemann syndrome. It has been found that tumors

developing type-1 familial multiple endocrine neoplasia as a result of the inactivation of both alleles of a suppressor gene mapped to the long arm of chromosome 11.¹⁰

The loss or inactivation of alleles can be determined by karyotype analysis, Southern blotting and DNA sequencing. A suppressor gene is usually suspected when a chromosome deletion is found at an unusually high percentage of time in a specific tumor type; such as the case of the loss of 3p in renal cell carcinomas and small cell carcinoma of the lung, and the loss of 11p in bladder carcinoma.

The best studied example of a suppressor gene function is found in retinoblastoma in children. Patients with inherited retinoblastoma (RB) carry a mutation in one of the RB alleles in germ line cells. A tumor develops when the remaining normal allele is inactivated by mutation or loss. The RB gene has been cloned, and recently reported that the RB gene product suppresses cell growth by acting as a cell cycle regulator element. Thus, it can be seen that very little information is known about the function of the numerous suspected anti-oncogenes. Obviously, this is an area of active research interest, with the possibility of dramatic effects on cancer prevention and treatment. □

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An Appreciation

DR. WILLIAM EARL POLLETT

"What ever he did was done with so much ease, in him alone was natural to please. . ."

Dr. William Earl Pollett died after a brief illness at the Victoria General Hospital on October 27, 1990.

He graduated in medicine from Dalhousie University in 1934, following which he practised in New Germany, N.S. He then did post graduate studies at the University of Edinburgh, Scotland, obtaining a fellowship in general surgery in 1943. The following three years was spent as a surgeon with the British army in the rank of major.

In 1946, Dr. Pollett returned to Halifax and was appointed to the medical faculty Dalhousie University as lecturer in surgery and to the staff of Victoria General, Halifax Children's and Halifax Infirmary Hospitals where he practiced surgery and family medicine until his retirement.

Earl had many interests in medicine and community life. He was past president of the Halifax Medical

Society, the Halifax Children's Hospital and a valued associate editor of the *Nova Scotia Medical Bulletin*. He was also past president of the St. George Society and an elder of St. Matthew's United Church. He was a member of the Ashburn Golf Club and an avid golfer. He was honoured by the Canadian Medical Association in 1979 by election to senior membership.

Dr. Pollett was highly considered by all whom know him. He was admired by students as a teacher of surgery where he displayed sound adjustment and skill. To his patients he was a father figure and competent physician and to his colleagues a courteous and true gentleman.

Earl will be much missed by the medical community and all who knew him.

My sympathy is extended to his family members.

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Mammographic Localization of Non-Palpable Breast Lesions in a Cape Breton Regional Referral Centre

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In recent years a large number of double-blind trials of screening mammography have appeared in the literature. Only in the past couple of years, however, has it become clear that the benefits of such programmes may, in fact, result in improved mortality from this disease. In Sydney, xeromammography has been available for more than 10 years. However, on a clinical level the reports emanating from these studies were rarely clear enough, or specific enough, to demand biopsy based simply on their findings. Consequently, clinicians were justifiably disinclined to commit their patients to excisional biopsies based on these reports. However, early in 1988 a state-of-the-art mammographic machine was arranged through special funding for the Sydney Community Health Centre in Sydney, Nova Scotia.

Shortly thereafter, the improved visualization of breast tissue began to result in a different type of report being issued by the radiologists. For the first time they were descriptive of lesions visualized, and very specific recommendations regarding biopsies. One of them (R. S. Dunn) became aware of a significant change in clinical surgical practice as a result of these reports. Clearly, a number of the biopsies specifically recommended by mammography for non-palpable lesions were turning out to be positive. Although there is no universal screening programme set up in Cape Breton, nonetheless a large number of women have been referred to increasing numbers to the mammography unit for screening purposes, and also for assessment of the "symptomatic breast". It was in order to determine the relative effectiveness of this type of referral pattern, and to gauge the predictive value of our reports, that the current data were reviewed and presented below.

MATERIALS AND METHODS

Radiological Review

5,050 mammographic examinations performed from March 1988 until October 15, 1990 were reviewed. Sixty-three of the reports issued during that time period advised excisional biopsy (Table I). Data present on the requisition forms included age of the patient, the referral pattern, family history of cancer of the breast, age of menarche, and parity (Table II). (The biopsy results were also available, but broken down simply into benign and malignant, and will be presented).

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TABLE I
AGE DISTRIBUTION (N=500)

Age Group	No.	%
20-29	24	4.8
30-39	122	24.4
40-49	155	31.0
50-59	103	20.6
60-69	62	12.4
70-79	27	5.4
80-89	7	1.4

TABLE II
INFORMATION FROM REQUISITION FORMS

	No.	%
Family History of Cancer of Breast (N = 500)		
Positive History	159	31.8
Negative Family History	333	66.6
Data Not Recorded	8	1.6
Age at Menarche (N = 500)		
Age 10-14	398	79.6
Age 15-18	95	19.0
Not Recorded	7	1.4
Parity (N = 500)		
0	62	12.4
1-2	195	39.0
3-4	152	30.4
5 & Over	91	18.2
Previous Breast Surgery (N = 500)		
Positive	114	22.8
Negative	385	77.0
Missing Data	1	0.2
Was Cancer Detected? (N = 114)		
Positive	19	16.4
Negative	92	79.3
Missing Data	5	4.3
Reason For Study (N = 500)		
Baseline	103	20.4
Asymptomatic	71	14.2
Symptomatic	327	65.4
Action Based on Mammography (N = 71)		
Biopsy	9	12.6
Follow-up Mammography	50	70.4
Biopsy + Follow-up Mammography	4	5.6
Finer Views	8	11.2

Because of the nature of the referral pattern to the radiologist, a number of important facts are never available — specifically, whether or not there was any

palpable lump either prior to the mammogram or on subsequent re-examination after the physician had received the report. Also, many of the patients are referred to the mammographer because of "symptoms". On close examinations, most of these turn out to be simply diffuse mastodynia, without palpable lumps, which is common throughout the female population and often of very dubious clinical significance. Some of these, however, probably do fall into a group where there were, in fact, palpable thickenings in the area subjected to mammography.

Since one of the great potential strengths of mammography is to detect cancer of the breast before it becomes palpable, it was important to compare this kind of data to a clinical surgical practice where this variable was definably known. Consequently, a series from one surgical practice, consisting of a 12-month follow-up from May 1, 1989 until April 30, 1990, is presented. The age range of these patients, which total 18 in number, are presented in Table III. All of these patients were carefully examined to be certain there was no palpable lesion. If there was a clear recommendation by the mammographer to do the biopsy, then the procedure outlined in Table IV was followed. As indicated in that table, a definitive surgical procedure was usually not carried out under the first anesthetic because of the early nature of a number of these lesions. The pathologist frequently requested the opportunity to do paraffin sections of these very early lesions to be certain of the many nuance of the pathological details. For example, the lesion might have multifocal areas present, or there might be areas of locally invasive tumor not originally visualized on the frozen section.

TABLE III

AGE DISTRIBUTION
(patients followed May 1, 1989 to April 30, 1990)

30-39	2
40-49	6
50-59	3
60-69	5
70	2

Results

a) Radiological Study

Of the 63 biopsies recommended by the radiologist, 46 percent, or 29, had some type of malignancy diagnosed and 54 percent, or 34, had benign tissue. These were not further broken down in this study. Table V indicates the distribution in various age groups, benign vs. malignant diagnoses.

b) Surgical Results

Of the 18 patients subjected to biopsy based on the mammographic findings only, over the one year period, 9 were benign (6 were diagnosed as fibrocystic disease, and 3 of atypical hyperplasia only). The results of those patients having malignant diagnoses are listed in Table VI — 3 were in situ, and 6 invasive. Two of these

patients at the time of biopsy had obvious small carcinomas. All the rest simply had areas of fairly unremarkable tissue which might have ordinarily been passed off as fibrocystic change in terms of gross examination. The stage at diagnoses is listed in Table VII.

TABLE IV

PROCEDURES FOLLOWED

1. Routine Pre-Op
 - CXR
 - CBC / ALK PHOS
2. Mammographic Localization in Xray
 - Kopan Wire
 - Homer Hook
3. To O.R. and Excisional Biopsy, General Anesthetic
4. Specimen to Xray for Confirmation
5. Wake Patient or Rebiopsy (2/18)

TABLE V

BIOPSY RESULTS

Total Number	Malignant	Benign
63	29 (46%)	34 (54%)

Biopsy Results by Age		
Age Group	Malignant	Benign
30-39	2	1
40-49	10	9
50-75	17	24

TABLE VI

TYPES OF MALIGNANCIES

	In Situ	Invasive	
Lobular	1	Lobular	1
Intraduct, Multi	1	Intraduct, Multi	1
Intraduct, Single	1	Intraduct, Single	3
	3	Tubular	1
			6

For purposes of comparison, we have included 21 patients, which in the same surgical practice over the same time period had cancers of the breast diagnosed by palpation. In the mammographic group, as far as we could determine, all of these patients were Stage I. There were no palpable lymph glands. We have to accept that a number of these, because of the very early nature of the

TABLE VII

STAGE AT DIAGNOSIS

Method of Diagnosis	Stage			
	I	II	III	IV
Mammogram	9	—	—	—
Palpation	10	8	2	1

lesions, did not have axillary lymph node dissections, and there remains the mathematical possibility that some of these could have had micrometastases here.

In the palpation group, however, there were clearly more advanced stages in many of these patients, with less than 50 percent being Stage I, and the rest Stage II, III, and IV.

The surgical management of the patients is presented in Table VIII. In the group with non-palpable lesions, tylectomy alone was felt to be adequate in 44 percent; whereas a quadrant with node dissection or mastectomy with node dissection was carried out in the remainder. All of those dissections revealed negative lymph nodes, and radiotherapy was only added in one patient who had a medially based small cancer less than 0.9 cm in diameter.

TABLE VIII

TYPES OF SURGICAL MANAGEMENT

Procedure	Mammography	Palpation
Tylectomy	4 (44%)	2 (9%)
Quadrant + Nodes	1 (12%)	5 (17%)
Mastectomy + Nodes	4 (44%)	14 (74%)
	9	21

By contrast, the group picked up by palpation had a variant of tylectomy and quadrantectomy in 7 of 21, or 26 percent, with the bulk requiring modified radical mastectomy. Table IX illustrates the numbers of patients requiring adjuvant treatment. As might be predicted from the advanced stage of those picked up by palpation, there was a variety of adjuvant therapies required in this group with over 50 percent advised to have radiotherapy, chemotherapy, or hormonal therapy. Only one of the patients picked up by mammography alone required adjuvant radiotherapy.

TABLE IX

PATIENTS REQUIRING ADJUVANT TREATMENT

	Mammography	Palpation
Radiotherapy	1	3
Chemotherapy	—	4
Hormonal	—	4
	1	11

DISCUSSION

There exists a voluminous literature regarding the natural history of breast cancer and the possible effect of early detection of small cancers on this natural history.¹ Many of these papers refer to some classic studies; such as the H.I.P. Study of New York, the B.C.D.D.P. Study from the United States, and the extensive literature regarding randomized screening trials from Sweden. All these studies have reported a statistically significant reduction in overall mortality of breast cancer due to mass screening. There remain major differences of opinion regarding effectiveness of screening in young

age groups, and older age groups, and other details of the screening process. All these studies emphasize that although mammography screening can lead to a significant improvement in breast cancer survival, the degree to which any programme achieves potential gain will depend on the technical quality of the study, the interpretive expertise of the radiologist, and the screening frequency. The role of the pathologist and the surgeon as members of the team cannot be overemphasized.

Although there has been participation by Nova Scotia centres, such as Dalhousie University, in the Canadian Breast Screening Study, there is as yet no universally adopted mammography screening programme in place in Nova Scotia. Nonetheless, mammographic machines exist in various centres around Nova Scotia, and we believe it is important to look at some of the results on a strictly clinical basis and see what kind of effect this may be having on general surgical practice.

We believe that the predictive value of the mammographic reports in our study, being close to 50 percent, compare very favorably with the literature. In many centres a predictive value of 20 percent would be expected, and has been considerably less than this in areas of the United States.² There is a fairly large literature building up on the expertise in needle localization and fine needle aspiration in an effort to try to reduce the numbers of needless biopsies, and to bring the ratio of benign to malignant biopsies more into the line of a 1 to 1 ratio. The subject is well reviewed by Evans & Kaid in 1989.³ This does require a special pathological interest and training and, where biopsies are being kept down to a predictive value of 50 percent, may not be cost effective. As discussed by Kopans, "precise needle placement, optimal aspiration technique, experienced cytologists, and a large institutional data base, is required for any physician who considers relying on information gained from fine needle aspiration".

The significance of the minimally invasive cancer of the breast, or localized in situ disease, is still a subject of some controversy. It seems clear that some of these lesions never do translate into clinically significant cancer of the breast. However, at least some of these mammographically identified lesions do turn out to be small invasive carcinomas, and no doubt are better removed at an early stage. Whatever the true value in removing all of these lesions may be, it does seem clear that most of these women will be benefited by having this area of tissue removed.

The enthusiasm of clinicians in their ability to identify these lesions and to remove them must be tempered with the reality of some of the negative effects of an active screening and biopsy programme. These include the increasing levels of anxiety engendered among women requiring these mammograms, repeat mammograms, and continued reminders of the possibility of developing cancer; the inordinate numbers of negative biopsies that are performed in some areas of the

world; the frequency of interval cancers; and the uncertain significance of the diagnosis of carcinoma in situ which occurs in up to 40 percent of cancers in some screening programmes, and which occurred in 33 percent of this small series. Some authors warn that when all causes of death are considered, the absolute numbers salvaged by screening mammography may be smaller than originally anticipated, and the cost may be higher.

The application of widespread screening programmes requires considerable thought to avoid unexpected consequences in our particular medical system. Most areas of the Province would have difficulty coping with the sudden increase in the numbers of biopsies that would be required should all female patients be screened; increased costs would doubtless be felt throughout the health care system. A major concern that we would express regarding the volumes of mammograms that would be generated by a walk-in clinic where patients are not referred by a physician, is that the quality of the radiological reporting may suffer. If the volumes of examinations are high and the compensation for reporting them is low, and the patients present without proper referral from a family physician, then the overall benefits to the patients may be more difficult to predict than in other published studies. The results of the programme recently set up by the Department of Health, in Halifax, will be of great interest.

SUMMARY

Whatever the merits of the various arguments, pro and con, the reality is that patients and their family physicians are requesting more and more mammograms, and increasing numbers of referrals to general surgeons are occurring because of that abnormal mammogram report. This is in part based on better technology and more precise reporting by radiologists as to which lesions should be removed. In Cape Breton, our regional referral centre is quite some distance from the nearest academic institution, yet a considerable

change is taking place in referral patterns over the past five years because of this technology.

In the year reported in this study, in one surgical practice, 18 referrals based solely on abnormal mammographic findings occurred. All were biopsied and 9 patients had some type of malignancy, for a predictive value of 50 percent. The overall predictive value for all positive mammograms performed (March 1988 to October 1990) is 46 percent.

This improved technology then, plus the increasing number of referrals, are resulting in significant numbers of impalpable cancers of the breast being detected and surgically excised. As we move towards true regionalization for the delivery of medical care throughout Nova Scotia, improved cooperation between surgeons, radiologists, and pathologists should lead to further improvement in the results that may be obtained from the application of this technology. □

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Gestational Trophoblastic Disease Registry

UPDATE 1989

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A total of 34 new patients were entered into the Nova Scotia Gestational Trophoblastic Disease Registry and Surveillance Program in 1989. Thirteen patients were confirmed to have benign hydatidiform mole (HCG titres return to normal with no treatment other than the original D&C); four patients developed NMGTD; sixteen patients had partial (incomplete) mole; one patient was diagnosed with placental site trophoblastic tumor. (Table I)

TABLE I

1.	Benign GTN
	A. Hydatidiform Mole
2.	Malignant GTN
	A. Non-metastatic (NMGTD)
	1. Persistent Hydatidiform Mole
	2. Invasive mole
	3. Choriocarcinoma
	B. Metastatic GTN (MGTD)
	1. Good prognosis, low risk
	2. Poor prognosis, high risk
	a) Initial urinary HCG titre > 100,100 IU/24 hr. or serum HCG titre > 40,000 mIU/ml
	b) Duration of symptoms > 4 months
	c) Liver or brain metastasis
	d) Previous chemotherapy
	e) Disease following term pregnancy

PRESENTATION

Ultrasound plays a major part in the diagnosis of the hydatidiform mole. Of the 17 patients referred to the registry (including benign and non-metastatic disease) all 17 patients had ultrasound determinations performed. Fifteen ultrasounds were positive for hydatidiform mole. Two patients who had negative ultrasound examinations were subsequently found to have a molar pregnancy. These two patients were diagnosed following uterine curettage for the following: non-viable pregnancy (1), missed abortion (1). This represents a false negative rate of 11.76 for ultrasonography.

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GLOSSARY:

HCG — Human Chorionic Gonadotrophin (Amerlex-M serum Beta sub unit assay)

NMGTD — Non-metastatic gestational trophoblastic disease

MGTD — Metastatic gestational trophoblastic disease

BENIGN HYDATIDIFORM MOLE

Of the 13 patients confirmed to have hydatidiform mole, 7 patients had titres return to normal in 6-10 weeks. HCG titres in four patients returned to normal in 10-12 weeks. One patient had titres which took 16 weeks before gradually returning to normal and one patient was non-compliant in follow up.

Three patients were referred to the registry by pathologists, 9 patients by gynaecologists and 1 patient by her family physician.

The median age of these 13 patients was 26 years. The primary presenting symptom was abnormal vaginal bleeding which occurred in 9 patients. Five patients were noted to have a uterus large for their dates, while two patients had a uterus smaller than the normal. One patient had ovarian enlargement, 1 patient experienced excessive nausea and vomiting and 1 patient presented with anaemia <10. Two patients had no symptoms related to their disease.

Malignant Gestational Trophoblastic Disease

A. Nonmetastatic (NMGTD)

1) Persistent hydatidiform mole

Four patients developed nonmetastatic gestational trophoblastic and required adjunctive chemotherapy to eradicate their disease.

Two patients had HCG titres which initially began to fall. After approximately 4 weeks the HCG titre started to rise. Both patients were treated with 2 courses of the Methotrexate with Leucovorin regimen. HCG titres had returned to normal (three consecutive negative titres) 2 weeks following the second course of treatment for one patient and six weeks for the other patient.

The third patient, who had a post D&C HCG titre of 122,768, had titres begin to fall initially, but after six weeks had climbed to 104,254. She was treated with two courses of Methotrexate with Leucovorin regimen. Again HCG titres started to fall but after four weeks began to climb. Four courses of the Actinomycin D regimen were administered at two

weekly intervals. HCG titres had returned to normal two weeks following the last course of Actinomycin D.

The fourth patient whose titres also started to fall, but began to rise at the four week mark, received 2 courses of the Methotrexate with Leucovorin regimen, alternating with one course of the Actinomycin regimen. HCG titres were normal on completion of the last course of treatment.

Follow up to date has been uneventful.

2) *Invasive mole*

No cases of invasive mole registered in the 1989 year.

3) *Choriocarcinoma*

No cases of choriocarcinoma registered in the 1989 year.

B. Metastatic gestational trophoblastic disease

1. or 2. No registered cases in the 1989 year

Follow-up case study

The following case study is presented for your information.

This 21 year old patient, gravida 0 para 0, was diagnosed in December, 1988 with a hydatidiform molar pregnancy. The Beta sub unit HCG titre prior to D&C was 354,526 and following D&C was 5143. Weekly HCG titres were continued, gradually falling to negative titres in January, 1989. Monthly HCG titres were initiated for 12 months. Oral contraception was refused, but an alternate form of birth control was agreed upon.

In May, 1989, the patient informed the registry that she and her husband had made a decision to discontinue HCG follow up. There was no further contact until six months later, when the patient contacted the registry with a request to have an HCG titre done. She had been attempting pregnancy without success.

The HCG titre result was 12 and continued to rise, climbing to 75 when seen by the registry in late January. Pregnancy was ruled out. Vaginal ultrasound confirmed a mass in the fundal area of the uterus. D&C and laparoscopy were performed. The endometrial curettings were strongly suggestive of trophoblastic disease.

Two courses of the chemotherapy regimen, EMACO, was administered and tolerated poorly. The HCG titres continued to rise and a repeat transvaginal ultrasound showed an increase in the size of the uterine nodule. An exploratory laparotomy with an abdominal hysterectomy was performed in March, 1990. Final pathology review in Boston confirmed the diagnosis of placental site tumor.

HCG titres returned to normal and follow up has been uneventful to date.

THE INCOMPLETE OR PARTIAL MOLE

In 1981 a study to evaluate the clinical significance of the partial mole (hydatidiform degeneration) was begun.

To date 70 patients with partial mole have been followed by the registry. Dr. I. Zayid of the Dr. D.J. MacKenzie Diagnostic Centre has reviewed the pathology of 68 of these patients. Two patients were lost to follow up.

Of these patients, 49 had HCG titres which returned to normal in ten weeks or less; 8 patients had titres which took 10-14 weeks before returning to normal, 10 patients entered the study late (8 to 11 weeks, 1 at 18 and 22 weeks) and their titres were normal at entry. One patient was non-compliant with HCG follow up.

Follow up for the 70 patients has been uneventful and ranged from five to twelve months (sixty patients) one to two months (seven patients).

In 1989, 16 patients were diagnosed with partial (incomplete) mole.

Eight of these patients had titres return to normal in 4-10 weeks; six patients had titres which took 10 to 14 weeks before returning to normal; one patient entered the study late at 18 weeks with normal titres and one patient was non-compliant with HCG follow up.

These 16 patients had a median age of 28 years. Six patients were referred to the registry by pathologists, 9 referred by gynaecologists and one patient was referred by her family physician.

Eleven of the 16 patients followed in 1989 experienced vaginal bleeding, 1 complained of abdominal pain and 4 patients had no symptoms. One patient had spontaneous passage of molar tissue. The size of the uterus was smaller than dates in 6 patients; larger than dates in one patient. Uterine size was appropriate for dates in 8 patients and there was no record on 1 patient. Thirteen of the 16 patients had ultrasound examinations performed. Ten of the 13 ultrasounds were not diagnosed as a mole.

The registry will continue to recommend 6 months of follow up with HCG titres for the patient with partial mole. This decision is based on recent literature which suggests that 5-9% of patients with partial mole will develop persistent gestational trophoblastic disease. (*Obstetrics and Gynaecology*, Natural History of the Partial Molar Pregnancy, Vol. 66, No. 5, 1985).

TABLE II
EXPERIENCE OF THE TROPHOBLASTIC DISEASE
REGISTRY IN 1989

1. Benign GTD	
A. Hydatidiform mole	13
2. Malignant GTD	
A. Nonmetastatic (NMGTD)	
1. Persistent hydatidiform mole	4
2. Invasive mole	0
3. Choriocarcinoma	0
B. Metastatic GTD (MGTD)	0
Partial mole	16
Placental Site Trophoblastic Tumor	1
TOTAL	34

TOTAL EXPERIENCE — GESTATIONAL TROPHOBLASTIC DISEASE REGISTRY

A total of 458 patients (partial mole excluded) have been registered by the Nova Scotia Gestational Trophoblastic Disease Registry as of December, 1989. (Table III)

TABLE III

TOTAL EXPERIENCE (Excludes Partial Mole)

	1965-75	1976-80	1981-85	1986	1987	1988	1989
Nova Scotia	40(12)	108(15)	72(14)	18(1)	12(1)	11(2)	9(3)
New Brunswick	8(6)	31(2)	46(8)	5(3)	3	8(2)	6(2)
Prince Edward Island		4(0)	9(0)	0	2	2	2
Newfoundland		15(4)	39(5)	0	2	2	1
St. Pierre		1(0)					
Total number of patients — 458							
Total requiring Rx (in parenthesis) 75 or 16.37%							

Benign Gestational Trophoblastic Disease

Hydatidiform Mole

Three hundred and seventy-seven patients were confirmed to have benign hydatidiform mole requiring no treatment other than the original D&C. (Table IV)

TABLE IV

1. Benign GTD	
A. Hydatidiform mole	377
2. Malignant GTD	
A. Nonmetastatic (NMGTD)	
1. Persistent hydatidiform mole	58
2. Invasive Mole	0
3. Choriocarcinoma	3
B. Metastatic GTD (MGTD)	17
Non gestational choriocarcinoma	1
Placental site trophoblastic lesion	1
Placental site trophoblastic tumor	1
TOTAL	458

Malignant Gestational Trophoblastic Disease

Nonmetastatic (NMGTD)

Fifty-eight patients developed persistent nonmetastatic gestational trophoblastic disease. Three of these patients developed historically confirmed choriocarcinoma. (Table V). All 58 patients remain alive and well.

Metastatic Gestational Trophoblastic Disease

Seventeen patients developed persistent metastatic disease. Six of these had histologically confirmed choriocarcinoma. (Table V) Four of the patients with metastatic choriocarcinoma died. Three were diagnosed following a normal pregnancy and died either of advanced disease or complications of chemotherapy. The fourth patient, who presented with choriocarci-

noma etiology unknown, had a 2½ year remission between the time of her original treatment and recurrence. She was treated extensively with chemotherapy but expired in 1987. The remaining 13 patients with MGTD remain alive and well.

Non-gestational choriocarcinoma

One patient presented with non-gestational choriocarcinoma. This patient's case history was published in the 1987 registry report. Her HCG titres are now done once every three months and remain normal.

Placental Site Trophoblastic Lesion

Follow up has been uneventful.

Placental Site Trophoblastic Tumor

This patient's case history is presented in this report.

TABLE V

CHORIOCARCINOMA (confirmed histologically)

	Metastatic	Nonmetastatic
Post Ectopic	1	
Post molar pregnancy		1
Post normal pregnancy	4 (3 died)	1
Etiology unknown*	1	
Post hysterectomy — DUB**		1

*recurrent choriocarcinoma - expired 1987

**positive pregnancy test

Five patients remain alive and well.

FOLLOW-UP RECOMMENDATIONS

Between 15-20% of the patients who have had a molar pregnancy will require adjunctive chemotherapy or an occasional patient will require surgery to eradicate their disease. For this reason follow-up with HCG titres is essential. Registration with the Trophoblastic Disease Registry is recommended for all cases and can be made by writing to:

N.S. Gestational Trophoblastic Disease Registry,
Room 5054, Ambulatory Care Center,
Victoria General Hospital,
Halifax, N.S. B3H 2Y9
or by phone (902) 428-2263
or fax (902) 428-3765

ACKNOWLEDGEMENT

Our sincere thanks for the continued support of the patients, physicians and pathologists.

The follow up protocol for patients with gestational trophoblastic disease as recommended by the Nova Scotia Gestational Trophoblastic Disease Registry is as follows:

Continued on page 94.

The Pitfalls of Health Goal Setting

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This paper is dedicated to my colleague and friend, the late Dr. James Fan.

The purpose of this paper is to critically appraise the philosophy and process of health goal setting. It focuses on issues to be addressed at the early stages of the process.

Goal setting, needs assessment and the specification of objectives, form a crucial interdependent triad of initial steps in strategic planning. In health and health care planning, the benefits of goal setting are threefold. First, goals and objectives provide guidelines for a unified direction and prioritization of program development. Secondly, goals may lead ultimately to the formulation of healthy public policy. Thirdly, the establishment of goals is inextricably linked with the ongoing evaluation of these and the means to achieve them. The process therefore allows for future challenges to the status quo.

Since 1974, when the *Goal-setting Strategy* was first proposed in the Lalonde Report, the international trend has been one of acceptance of the need for health goal setting.¹ However, the value of health goal setting is, at this time, theoretical. No evidence supports the contention that the articulation of health goals measurably improves a population's health. The health goal setting process itself may be viewed as an expensive population-based intervention. In health care, an intervention should be subjected to evaluation. Should the same standard of proof be required for the goal-setting exercise? What are reasonable expectations of improved outcomes relative to the effort and resources expended?

HISTORICAL OVERVIEW

The 1974 report by Marc Lalonde, *A new perspective on the health of Canadians*, is internationally acclaimed as a landmark paper.¹ It represents the first national attempt to focus planning efforts on healthy people and healthy environments rather than on medical care services. It stressed that improvements in the health status of industrialized nations were more likely to arise from changes in lifestyle, environment and biology, rather than changes to the health care delivery systems. The report stated two objectives, using five strategies. The *Goal-setting Strategy* was ground-breaking. Goals, to be stated in quantitative terms with a time limit, were

to provide a united sense of direction for those in the health field. In 1977, the Thirtieth World Health Assembly adopted a resolution specifying the main social goal of governments and the World Health Organization (WHO).² The resolution became known as *Health for all by the year 2000*. In 1979, the *Global Strategy for Health for All by the year 2000* was adopted and Member States of WHO were invited to formulate their own strategies.² Monitoring and evaluation of the strategies were to be integral parts of the managerial process for national health development.

In the decade following the Lalonde Report, several industrialized nations produced documents detailing health goals, objectives and targets. In 1979, the United States Department of Health, Education and Welfare presented a report on health promotion and disease prevention, followed in 1980 by national objectives.^{3,4} In 1984, a strategy for the European Region was developed by the WHO.⁵

In 1986, a second Canadian document identified three national health challenges: *Reducing inequities, Increasing the prevention effort, and Enhancing people's capacity to cope*.⁶ It focused on community development and healthy public policy, and emphasized the social, economic and collective determinants of lifestyles rather than personal behaviour. Three Canadian provinces subsequently produced health goals. Québec produced health goals twice, in 1986 and in 1989.^{7,8} Ontario and New Brunswick produced goals in 1989 and 1990 respectively.^{9,10}

ISSUES CONCERNING HEALTH GOAL SETTING

Four important issues concerning health goals need to be addressed at the early stages of health goal development. First, the approach to goals needs to be determined. Secondly, the scope of evaluation must be planned. Thirdly, it must be decided whether or not to include priorities and an implementation plan. Finally, the process of goal setting must be determined.

The Approach to Goals

In the health field, the term 'goal' has come to be defined as a broad statement of desired, but not necessarily attainable change. An 'objective' is a more specific statement of intent, in measurable form. A 'target' defines the amount of change desired and the date by which it is to be achieved. The hierarchy of scope, effort and measurability is evident. The reader is referred to the Webster Dictionary definition of 'intention' where an extensive hierarchy is presented.

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Health goals may relate to health, determinants of health, major causes of disease and death, risk factors for disease, risk conditions, life stages, population groups, health care, or, health promotion and disease prevention. The use of life stages has fallen into disfavour because health in the later life stages cannot be dissociated from previous life stages.

In the United States, *Healthy People* (1979) presented five goals based on life stages and 226 disease prevention and health promotion objectives.⁴ *Healthy People 2000* presents three health goals: *Increase the span of healthy life for Americans, Reduce health disparities among Americans, and Achieve access to preventive services for all Americans.*¹¹ To achieve these goals, 298 objectives were elucidated in 22 priority areas.

Québec produced formal goals and objectives as well as a comprehensive health and health care strategic plan in 1989.⁵ The three goals were: *Adding years to life, adding health to life, and Adding well-being to life.* The 20 objectives were priorities, focusing on disease, risk factor and risk condition reduction, and health and environment enhancement.

The Premier's Council on Health Strategy presented Ontario with five goals: *Shift the emphasis to health promotion and disease prevention, Foster strong and supportive families and communities, Ensure a safe, high quality physical environment, Increase the number of years of good health for the citizens of Ontario by reducing illness, disability and premature death, and, Provide accessible, affordable, appropriate health services for all.*⁹ No objectives or priorities were stated in this document. New Brunswick's five health goals are substantively identical to those of Ontario.¹⁰

Clearly, the number of goals and their scope are important interrelated choices. The group of goals aims at comprehensiveness in health planning. Too many goals make planning and implementation unwieldy; too few may lead to an overly-broad scope not easily translated into action. Pre-existing reports on health, federally-endorsed priorities or intersectoral concerns may influence the approach to goals. In the end, the choice of approach is a reflection of the goal setters' philosophy of health and health care.

Measurement and Evaluation

Health, health status and health indicators are the basic building blocks for goal development. All three terms are problematic. The WHO's definition of health is utilized in many goal documents. Health is "a state of complete physical, mental, and social well-being, and not merely the absence of disease or injury".¹² The WHO identified nine pre-requisites for health: peace, shelter, food, education, income, a stable eco-system, sustainable resources, social justice and equity. Health appears to be polarized as an either/or situation. Effectively, fourteen criteria must be satisfied to meet the definition. In real life, health is a continuum with great variability in the cut-off between health and unhealth.

Clearly, a utopian definition of health is a liability for the term 'health status'.

'Health status' and 'health indicators' are misnomers relative to each other. In general, knowledge of the collective well-being of a population is gleaned through the use of data such as morbidity, mortality and disability. Health status is typically measured by disease-related indicators. Knowledge of a population's health status is therefore indirect, and the inverse of the burden of disease. Health status may be measured by alternative means such as periodic health surveys. However, the instruments and/or methodology regarding non-traditional indicators are not yet fully developed. Thus, objectives and targets which are health-related as opposed to disease-oriented may be very difficult or impossible to measure.

Mechanisms for the evaluation of discrete goals and objectives as well as the evaluation of the goals exercise must be planned. The non-measurability of discrete objectives compounds the difficulty of evaluating the goals exercise. For example, the midcourse review of the United States health objectives for 1990 revealed that 48% were likely to be accomplished, 26% were unlikely to be met, and there was an absence of data on the remaining 26%.¹³ The success or failure of the goals exercise of the United States is unclear. Were the objectives appropriate? Was the effort expended sufficient to achieve them, especially in hard-to-reach populations? Were the effects proportionate to the effort? How should priorities be weighted in the evaluation? Finally, was 'health' improved as a result of the articulation of goals?

Priorities and Implementation

The establishment of priorities and the development of an implementation plan are not necessarily included in health goals documents. Resources and the nature and size of jurisdictions in part dictate the desirability of undertaking these tasks. Integrating these aspects of planning in the goals document may render the health plan visibly concrete and immediately feasible for communities.

The Process

The goal setting process may involve extensive consultation among health and other professionals, or may aim at widespread public participation, or may combine the two. In Ontario, the goals were selected by the Premier's Council on Health Strategy, based on three reports commissioned by the government of Ontario, primarily "Health for all Ontario".¹⁴ The latter was an extensive research work, providing needs assessment, seven health goals, thirty objectives, strategies and follow-up mechanisms. The process for arriving at the goals in this document involved numerous organizations and individuals, health professionals, and experts in health goals, over a seven-month period.

In Québec, the Rochon Commission report and the Québec Health Survey provided background informa-

tion and needs assessment for the 1989 goals exercise.⁸ Departmental consultations enabled more than 2000 persons to comment. Methods to achieve the objectives were to be determined by the regional authorities with public participation.

The goal setting process to arrive at *Healthy People 2000* in the United States involved twenty-two expert working groups, regional and national hearings, review by a consortium of three hundred national organizations, including the American Public Health Association, the Institute of Medicine of the National Academy of Sciences, federal health agencies and the fifty state health departments. Public review and comment involved more than ten thousand people.¹¹

The cost, effort and amount of time invested in the goal setting process must be realistic relative to the population size, number and types of jurisdictional levels. Striking a balance between public participation and experts' advice is analogous to the means used for the development of public policy. In most situations, policy is made by our representatives. Only exceptionally is the referendum employed. The liberal use of the referendum would cripple efficiency and would undermine our representatives' mandates.

A second caveat to inviting broad public input is that participants may represent, but not be representative of, their community. The disenfranchised or unmotivated segment of the population may benefit little from the health education value of the process. On the other hand, lack of meaningful public participation in the goal setting process may translate into lack of ownership and action vis-à-vis the goals.

If the term 'goal' is viewed as at the philosophical end of the hierarchy of 'intention', then it may be valid to adopt goals established by a similar jurisdiction. (Objectives and targets clearly relate to a specific jurisdiction and population, and are not transferable). Adoption of another jurisdiction's health goals may result in a lack of ownership of the goals. However, adopting goals could enable a focusing of effort and resources on the establishment of provincial health objectives and priorities, and the development of an implementation plan. It could also provide a basis of comparison for evaluation purposes.

For example, Nova Scotia could adopt the health goals stated by New Brunswick. The history of commonality of purpose, as evidenced by the Council of Maritime Premiers, and the socio-economic similarity of the two provinces suggest that this approach would be valid. Some aspects of epidemiological methodology could be coordinated. Evaluation would be strengthened in both provinces.

The goal setting process itself may be considered an important health promotion and community development activity. Since the days of Lalonde, the process has evolved into a veritable industry, replete with expert advisors. The "Cadillac-model" process is not dissimilar to a population-based consensus conference. For a small province, such complexity may represent disproportion-

ately large demands on scarce resources. On the eve of goal setting, perhaps Nova Scotia can borrow from the wisdom of another great Canadian, Herbert Marshall McLuhan, Lalonde's equal as visionary and international trend setter. In 1967, McLuhan's *The medium is the message* was a thunderclap in the communication field.¹⁵ In the health field, is the health goal process now the message?

The critical appraisal of health goal development begs a final remark. Numerous determinants of health reside outside the domain of the Ministry of Health. The success of goals, objectives and targets therefore presumes a high level of intersectoral cooperation and coordination, as well as meaningful public participation. Sustaining this in the long term is no small order.

So, should Nova Scotia have health goals? Yes, for the reasons stated in the introduction. The Lalonde Report had concluded on a powerful note: "In the end — by individuals, by society and by governments — choices must be made". Choices must also be made at the outset, regarding the philosophy and process of health goal setting which would best serve Nova Scotia. □

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Laparoscopic Cholecystectomy

INITIAL EXPERIENCE WITH 50 CASES

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Laparoscopic cholecystectomy is gaining wide acceptance and enthusiasm among the general surgeons in North America. We present our experience with the first fifty patients who underwent a laparoscopic cholecystectomy. All patients with biliary colic and acute cholecystitis were included, including those with morbid obesity as well as scars in the upper half of the abdomen. There were no mortality, intra-operative or post-operative complications. Post-operative hospital stay was 24 hours in 90% of the patients. Our initial experience clearly demonstrates the major advantages this procedure has over the conventional cholecystectomy. We believe it should be the procedure of choice for any patients who present with gallbladder pathology and all surgeons who deal with biliary tract surgery should be familiar with this procedure.

Since its introduction in Europe by Dubois in 1987,¹ and in North America by Reddick in 1988,² laparoscopic cholecystectomy is gaining very rapid and wide acceptance all over this continent. Earlier enthusiasm for Extra Corporeal Shock Wave Lithotripsy of biliary tract calculi is wearing off. Indeed, this is a procedure which treats the acute problem and gets rid of the stone but leaves a diseased gallbladder intact. It is evident that even if this treatment might have proved successful, removal of the diseased gallbladder will still be the treatment of choice in these patients.

Laparoscopic cholecystectomy is a definitive treatment for symptomatic cholelithiasis because it removes the cause — the gallbladder. The initial results reported by the pioneers of this procedure in Europe and in the United States were very good and the advantages over the open technique were quite obvious. Since these initial reports, several hundred laparoscopic cholecystectomies have been performed by various groups which confirmed the earlier results of major advantages over the open cholecystectomy, mainly, a very short hospital stay, early return to normal activity and minimal pain to the patient.

PATIENTS, MATERIALS AND METHODS

From January 1991 to March 1991, fifty patients had the benefit of a laparoscopic cholecystectomy by the same surgeon at the Glace Bay General Hospital. There were forty-one women and nine men, ranging in age from 25 to 82 years. Indications for laparoscopic

cholecystectomy are the same as for a standard cholecystectomy. All patients with biliary colic without any exceptions were candidates for this procedure. Contrary to previous series no patient was excluded, whether he was obese, had previous upper or lower abdominal surgery or had an acute cholecystitis.^{1,3,4}

Under general anesthesia, after creation of the pneumoperitoneum either with the verres needle or, if the patient had multiple previous operations, using the open laparoscopic technique with the Hasson trocar, the intra-abdominal pressure was constantly monitored and was maintained around 14-15 mm of mercury. Including the trocar through which a 10 mm laparoscope was inserted, a total of three to four punctures were used. If the three-puncture technique was used, one 5 mm trocar was inserted in the anterior axillary line 5 cm below the costal margin and another 10 mm trocar was inserted just below the xiphoid bone. If the four-puncture technique was used an additional 5 mm trocar was inserted in the anterior mammary line, two fingers width from the costal margin as described by Reddick and associates² and by Zucker and associates.⁵

The cystic duct and the cystic artery are both dissected free and the cystic artery is doubly clipped and sectioned, the cystic duct is clipped and an operative cholangiogram is done using a ureteral catheter No. 5 French, which is introduced in the abdominal cavity through a Jelco No. 14.

We tend to do an operative cholangiogram in all patients with small stones, even if the pre-operative ultrasound report shows a normal common bile duct. Each patient is submitted to an intra-operative cholangiogram except patients who have an acalculous cholecystitis or solitary stones which measure 1 cm and more.

The gallbladder is removed from its liver bed, using the hook cautery and spatula cautery and it is extracted through the umbilical incision. The reason we do this is because if ever the stone is too big and we have to enlarge the incision, a peri-umbilical incision is almost never visible post-operatively and is associated with minimal pain even if we extend the incision significantly. The biggest stone we extracted through the umbilicus was 4 cm in diameter and the patients who had enlargement of the incision did not have more post-operative pain than other patients who had only 1 cm incisions.

RESULTS

Seven patients had acute cholecystitis, 42 had chronic cholecystitis and one patient had the upper half of her gallbladder completely intra-hepatic with the fundus of the gallbladder extruding through the upper surface 3

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cm from the anterior edge of the liver. This necessitated a hepatotomy with the cautery and the gallbladder was successfully removed laparoscopically.

An *acute cholecystitis* was defined as patients who had pain which was not responsive to a regular dosage of narcotics, leukocytosis, and ultrasonographic as well as operative findings of gallbladder wall more than 5 mm in thickness. Five patients had undergone previous lower abdominal surgery with midline incisions below the umbilicus for hysterectomy or cesarean section. Two patients had previous vagotomy and pyloroplasty. In these two cases, adhesions were very dense between the duodenum and the gallbladder and their dissection was quite tedious but both of them could be done successfully laparoscopically.

No intra-operative complications occurred. Two patients had the procedure completed by standard surgery. The first was an 82 year old patient who presented with a very florid, acute cholecystitis. Ultrasound showed ultrasonographic evidence of acute cholecystitis and the common bile duct was normal. He was admitted and placed on conservative medical treatment but on the second day, he experienced an acute exacerbation of his pain and he was taken immediately to the operating room. A laparoscopic cholecystectomy was done and the dissection of the gallbladder was successful but the intra-operative cholangiogram showed multiple intracholedochal stones. We decided to convert the procedure to proceed with a choledocholithotomy and not to take a risk and leave stones and to try an extraction with ERCP.

The second was a 65 year old obese patient who also presented with acute cholecystitis. The anatomy was very distorted because of the acute inflammation and the gallbladder could not be grasped without puncturing and we decided to convert the procedure for safety reasons. This was the only case which had to be converted for inability to dissect the gallbladder hilum, although most of the others were more acutely inflamed and the gallbladder wall was more thickened. The maximum size of the wall of the gallbladder was 9 mm and this was in a patient who was managed successfully by the laparoscopic technique. Five of the patients were grossly obese and this did not change the outcome of the procedure.

Including the time to create the pneumoperitoneum and to close the skin incisions, the total operating time varied from 15 minutes to a maximum of 50 minutes, with more than 90% of the cases being completed between 25 and 35 minutes. The variation depended on the size of the patient, the difficulty of dissecting the gallbladder, if it was in an acute phase, and whether or not an intra-operative cholangiogram was performed. Only two cases took more than one hour. One of them was an acute cholecystitis in a grossly obese patient and the other one was the first ever performed in the hospital, where no one was familiar with the instruments.

We believe that it is very important to keep the

operating time as short as possible within the range of safety, because this will decrease the incidence of complications. Ninety percent of the patients were discharged 24 hours after the completion of their surgery. The patients kept longer were those who had other concomitant medical problems, and those who were more than two hours drive from the hospital. Pain medication was minimal post-operatively with most of them getting codeine by mouth for the first day. The post-operative complication rate was 0%. After their surgery, patients are seen in the out-patient department at one week and in the office at one month.

DISCUSSION

The first surgeon to proceed with a laparoscopy was Jacobaeus from Stockholm in 1910 using a cystoscope.⁶ The gynecologists were the first to use a laparoscope to proceed with intra-abdominal procedures and Palmer was the first in 1962 to proceed with a laparoscopic-tubal fulguration. It was Semm in 1974 who started to use laparoscopy for salpingectomies, ovariectomies, myomectomies and ovarian cystectomies.⁷ The first digestive procedure that was done by the laparoscope was in 1982 by Semm.⁸

In 1987, in Lyon, Mouret was the first one to proceed with a laparoscopy cholecystectomy on a human, but the first two series that were published were by Perissat in Bordeaux and Dubois in Paris. This technique appears to be the surgeon's response to the introduction of Extra Corporeal Shock Wave Lithotripsy which is not applicable to more than 30% of the patients. Most of the time, it takes between six months to a year to dissolve all the calculi and is expected to have 10-15% recurrence rate per year.⁹ Consequently, the expense associated with repetitive procedures and the need for prolonged administration of agents with their side effects to prevent recurrent formation, makes this approach less attractive.

In certain cities such as Nashville, Tennessee, where the first laparoscopic cholecystectomy was done in the United States in 1988, this technique has made Shock Wave Lithotripsy completely disappear. Judging from the earlier results, it will make it disappear in the rest of North America as well as the rest of the world. As far as its advantage over the open technique, these are obvious and the potential benefits were recognized very early: rapid disappearance of pain, if every pain exists; no danger of wound dehiscence; minimal scarring is left; a very short hospital stay and a much faster recovery period. We believe that every hospital and surgeon who treat biliary tract disease should become familiar with this technique which is rapidly spreading throughout Canada. Most patients are now requesting this procedure and all the patients who are having it done are very satisfied post-operatively. Patients who have had previous open surgery found a remarkable difference in their recovery.

Another area where we believe laparoscopic cholecystectomy had made the decision for surgery much easier

are patients who have acalculous disease. These patients go through multiple investigational procedures, with everything normal but they still have typical biliary tract and gallbladder symptoms. Traverso *et al.* reviewed the clinical outcome of sixty patients who had recurrent biliary colic treated by elective open Cholecystectomy.¹⁰ All had a normal oral cholecystogram as well as normal ultrasounds. He concluded that a precise history of biliary colic is the best predictor in selecting patients with acalculous gallbladders for cholecystectomy.

In the last four years we have had six patients who had typical biliary colic and who were treated by cholecystectomy, after eliminating other abdominal pathologies by multiple investigations, and the pain disappeared completely in all of them. Another two patients were offered the cholecystectomy with a clear understanding that this operation might not clear their symptoms in at least 10% of the time as Traverso has proved. These patients refused the operation but, when we started doing the laparoscopic cholecystectomy and with the persistence of their symptoms, they came on their own for this procedure. We believe that if these patients are offered laparoscopic cholecystectomy rather than the open technique, their decision, one way or the other, will be made much easier.

Another area of controversy which might be changed with the appearance of laparoscopic cholecystectomy is the patient with asymptomatic cholelithiasis. So far it is generally accepted that these patients should not undergo cholecystectomy with some exceptions. With the advent of a procedure like laparoscopic cholecystectomy, there are doubts in our minds that this statement will remain valid, mainly regarding the young patients, and studies should be carried out to answer this question. As Davis has clearly demonstrated by leaving an asymptomatic patient unoperated, we are producing an older and sicker patient population which will come much later on for cholecystectomy with the doubling of complications and a much higher cost.¹¹ In Dubois series, 28% of the patients were asymptomatic and this could represent the beginning of the change.¹

In view of our extremely low morbidity and the feasibility of this procedure in all the patients who presented with biliary colic, we recommend laparoscopic cholecystectomy as the procedure of choice for all patients with gallbladder disease. Laparoscopic surgery is quickly becoming a safe, well tolerated and effective means of dealing with many other intra-abdominal pathologies. At the Glace Bay General Hospital we are also using this technique to perform appendectomies, ulcer surgery and Nissen's Funduplication. However, proper training in this procedure is highly recommended because of the potential complications that could follow inappropriate techniques. In addition, there are specific complications related to the laparoscopy itself, mainly, CO₂ gas embolism. However, this can be kept almost non-existent with maintenance of pressure less than 15 mm of mercury.¹² □

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GESTATIONAL TROPHOBLASTIC DISEASE REGISTRY

Continued from page 87.

After hospital discharge

- a) HCG weekly until three consecutive normal values are achieved. Then . . .
- b) HCG monthly for one year. Pregnancy is permissible after 6 months of normal titres. If pregnancy is suspected an ultrasound is indicated for early confirmation.

If chemotherapy was required for low risk trophoblastic disease follow-up is as follows:

- a) HCG weekly until three consecutive normal values are obtained. Then . . .
- b) HCG monthly for one year. Then . . .
- c) HCG once every three months for one year. Pregnancy is permissible after one year of normal titres. If pregnancy is suspected an ultrasound is indicated for early confirmation.

If chemotherapy was administered for high risk trophoblastic disease follow-up is as follows:

- a) HCG weekly until three consecutive normal values are obtained. Then . . .
- b) HCG once a month for two years. Pregnancy is permissible after two years of normal titres. Once again, if pregnancy is suspected an ultrasound is indicated.
- c) HCG once every three months for the third year.
- d) HCG titres once every six months for the fourth year.
- e) Yearly thereafter. □

Notes on Being a Physician and Patient at the Same Time

T. Neville Elwood,* MB

Halifax, N.S.

Thursday night, July 26, 1990; 10 pm: left Juliet's, where she had invited us to have dessert — delicious raspberry pie as only she can make it — and I noticed my left foot was causing me to limp.

Thursday night: pain in the left foot kept me awake for a long time. It radiated from the MCP joint of the left hallux. I turned various ways in the bed, seeking a position where there was no weight on the great toe. Sleep eventually came, and I woke early, refreshed, and not tired, but the pain still there if a thought about it.

Friday morning: I loaded the car preparing to take M away for the weekend, and I tossed in some aspirin. She remarked on how much was packed into the car, and there were heavy planks lifted onto the roof rack. I was favouring the right foot, and avoiding weight on the tenderness of the left foot.

Friday afternoon: we drove a leisurely 99 miles to *Ecum Secum*. Then bedtime came but no sleep! I had taken two aspirin at 5 pm, two again at 9, and would rise and take two more at 4-hour intervals. By midnight this would be more than I had ever taken in my life. In bed this position was tried, then that, in an effort to place no weight on the foot. Tossing and turning brought no relief. The flame seemed to burn hotter. The hours passed, vacuous thoughts raced around; my fingers kept rising to the pinna feeling for tophi; I wondered what I, a teetotaler and of generally abstemious habits, had done to deserve this. In 40 years of medicine I had never diagnosed a case of gout; did it come as severely as this? with onset so sudden? without warning? Did it show no respect for a family with no history of joint disease? Did it strike a person universally considered — by all save his wife — of mild temper and manners, more interested in playing a Mozart Sonata or reading Old Testament history, than in the fleshpots of excessive living . . . sleep eventually came. I awoke refreshed and not tired, and thought this odd.

Saturday morning: Chris came to paint the cellar. I had lifted the paint a few feet from the car to the cellar floor on Friday, but today there was no lifting for me. I instructed him and left him. M and I sat in various places, where a kindly tree cast its shadow on the lawn, but walking for me was hobbling, with the left foot at right angles to its usual sagittal plane, so that all the weight was carried on the heel, and the foot not required to flex. The least pressure on the ball of the foot was unpleasant, and if in walking on the lawns a root or an unevenness caused pressure, and slight flexing of the

joint, I was brought up with a start. Limping in this way I got as far as the river bank — say 100 feet.

Saturday afternoon: I lay down for an hour. Then on rising found it so uncomfortable that I lay down again. No movement, passive or active, was possible in the joint. It was easy to avoid using its agonists and antagonists, but some movements necessary to adjust body posture called for unconscious synergistic leg movements that extended the small joints of the foot. Such sent signals straight to the pain centres in the thalamus — and on to the cortex. Specially efficient communication seemed to come from the extensor hallucis longus; it apparently wanted to help in every movement of the leg, the thigh, the pelvis and points north of it.

Saturday night: the least touch on the gouty joint was now so heavy that I considered abandoning the gentlemanly habits of a lifetime and sleeping with the foot protected with its shoe. However as time slowly wore on, swelling developed around the joint, and when the shoe was painfully removed its seams had pitted the oedema. The swelling centred around the MCP joint, the skin's ordinary wrinkles smoothed out, and the whole a pleasing plum shade of red. As for bedclothes the least weight of a summer sheet was intolerable.

Again sleep eluded me until the light began to dawn and, when I awoke a few hours later, I felt refreshed. The flame was burning high and there was no joy in putting the foot on the ground. I stayed in bed, with a persistent and irrational dread that something was going to fall on the foot.

How could this patient have managed without M! M packed the car, and brought it to the door. When all was ready I limped from the bed to the passenger seat. Pain at this stage was constant, with exacerbations at intervals of 20-30 minutes that made me wince. Always there was an apprehension that in moving the foot it would bang

EDITOR'S NOTE

Doctors are probably liable to the same range of tragedies as most people, although they and their families are known to frequent medical facilities much less than the ordinary population.

The insight gained as doctors become patients can be unique and valuable. Contributions to "The Doctor as a Patient" column are welcomed and encouraged.

*Ophthalmologist, 1483 Carlton Street, Halifax, N.S.

against some confining part of the car. At one stage I held the foot up, steadying it against the dash; the free part of the foot, throbbing mildly, was vibrating in tune with the motor's internal combustions. The fine passive movement of the vibration did not seem to affect the pain level. I thought about saccadic movements.

At Musquodoboit Harbour M phoned Phillip, a colleague and old friend, who most kindly met me on his driveway, brushed aside my Sunday apologies, "You couldn't possibly intrude on me!", he said, took one look and smiled. "Gout: I've got just the remedy". He had been pruning his hedge while waiting for me and was carrying garden shears. I said, "Sure. Use the shears, I'm ready to have it amputated!". 75mg of Phillip's Indocid®, taken at 7 pm produced a noticeable change in 22 minutes, and an hour later at home relief. By 11 pm there was no pain, the area could be touched, and already the mind wondered what all the fuss had been about. □

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To the Editor:

CAROTID ENDARTERECTOMY REINSTATED

On February 22, 1991 at the annual stroke meeting of the American Heart Association, a Clinical Alert was released stressing the effectiveness of carotid endarterectomy. Newspapers and TV networks publicised these findings the following day.

NASCET investigators, through The National Institute of Neurological Disorders and Stroke, released the same clinical alert three days later. Their main findings were that "... over 24% of medical patients, but only 7% of surgical patients, had experienced fatal or non-fatal ipsilateral stroke at 18 months. This result yields an absolute risk reduction of 17% ($p < 0.001$). Furthermore, carotid endarterectomy was beneficial in the prevention of any stroke of any severity in any territory". The study also found that the benefit of surgery persisted for at least 30 months. The investigators concluded that "carotid endarterectomy is highly beneficial for patients with recent hemispheric, transient ischemic attacks or non-disabling strokes and ipsilateral high-grade (70-99%) stenosis.

The carotid endarterectomy study had been highly publicised by the media prior to its initiation. At the time, I questioned whether press involvement would produce a bias on patient selection and reduce referrals for surgery.^{1,2} That is the operation could be condemned before any results were available. I based this conclusion on the small number of patients enrolled in the study because of decreased referrals.² Thus many patients may have been denied the benefit of carotid endarterectomy in the above setting.

Since the trial was announced by NASCET, the number of patients referred for surgery at our hospital decreased by 30% the first year, 40% the second year and 60% on the third year. Since we did not participate in the trial, it appears that this decrease was due to uncertainty of the benefits of surgery, by referring to physicians.

It is now clear that the benefits of carotid endarterectomy are so superior to medical therapy in the above mentioned group that a clinical alert was needed to prevent a significant number of fatal or disabling strokes. It is urgent that all physicians, faced with a patient presenting with transient ischemic attacks or a non-disabling stroke, consider surgery as the therapy of choice.

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Current Topics in Community Health

Selected by: Dr. Lynn McIntyre
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COORDINATING HEALTHY PUBLIC POLICY

The Epp Report, *Achieving Health for All: A Framework for Health Promotion* recommended three implementation strategies to address the health challenges of reducing inequities, increasing prevention and enhancing coping.¹ These strategies were the fostering of public participation, strengthening community health services and coordinating healthy public policy. The coordination of healthy public policy was the subject of critical review in a recent monograph written by a behavioural science research group and published by Health and Welfare Canada.² The report makes interesting reading for those who become confused at times by the jargon and the rhetoric of health promotion.

What is Healthy Public Policy?

The research base in the area of coordinating healthy public policy reveals a wide variety of definitions. Conceptual ambiguity exists concerning such issues as the difference, if any, between healthy public policy, public health policy and health promotion policy.

Healthy public policy is best defined as "public policy for health". Public policies for health have been characterized by Milio as "ecological in perspective, multisectoral in scope, and participatory in strategy".^{3,4} Thus, healthy public policy incorporates a broad vision of health, crosses traditional departmental and ministerial boundaries, and involves dialogue between the policy makers and the "public" recognizing that there is no such thing as a homogeneous public.

Healthy public policy suggests a new way of thinking about health and government policy that is participatory, multisectoral, and ecological. In this way, healthy public policy is an overarching notion that links policy sectors through a concern for health. It has been identified as a primary strategy for health system reform.^{1,5}

The Role of Coordination

Efforts to place health explicitly on the agenda of policy makers in traditionally non-health areas demands collaboration and will almost certainly generate intra- and inter-organizational conflict. Policies that concern, for example, nutrition, housing, defence and recreation all have an impact on preventing health problems or actually enhancing the health status of the population. It is necessary, however, to ensure that a measure of coordination exists between the various types of policies and policy-making bodies in this wider health domain,

so that they reinforce, rather than undermine, one another.

Recent Canadian multisectoral approaches involving healthy public policy initiatives in the areas of smoking, drug use and traffic safety are excellent examples of coordination crossing both sectoral and jurisdictional lines.

The Policy Process

Healthy public policy can be seen as a complex process in a changing social, economic and political environment. It must confront the power of vested interests while remaining committed to public participation, and it must resolve the contradiction between effective coordination and the decentralization that wide participation would entail.

Healthy public policy requires new arrangements between and within organizations which facilitate communication and cooperation. Intersectoral coordination occurs primarily at the provincial levels, while the constitutional separation of powers between the federal and provincial governments often requires interjurisdictional coordination.

Milio suggests that three approaches to healthy public policy predominate, a *targeted* approach, a *policy planning structures* approach, and a *participatory structures* approach.³

Targeted approaches aim at specific areas of policy such as food and nutrition or cardiovascular disease. Policy planning structures approaches are those in which mechanisms for intersectoral planning and policy development are developed. Examples would be an interministerial committee. The participatory structures approach addresses the need for widespread public participation in the policy process such as through public consultations. It is also possible to combine these approaches.

Whatever the approach used, policy development, according to Siler-Wells, involves five consecutive stages: The process begins with a problem or need; policy, involving goals and aims, is formed to address the problem; following policy formation, strategic planning for implementation is undertaken which translates the goals and intent of the policy into a formula for action; the formula for action is put into practice through the policy implementation step, thereby achieving the final step; a solution to the problem.⁶

Many in the healthy public policy field emphasize the importance of "vision" and "shared values" as a basis for the development and implementation of initiatives. "Visioning processes" are used to facilitate healthy

public policy development. The "Healthy Cities" movement is an example.⁷

Goals are the ends to which public policy is directed and goal-setting is another component of the policy process that is widely advocated and, to some extent, realized as in the Quebec Report, *Objectif Santé*,⁸ and the Ontario report, *Health for All Ontario*.⁵ The relationship between somewhat abstract goals, more concrete objectives and behavioural or organizational outcomes lead logically to policy initiatives.

Problem Identification

To understand how a problem becomes defined as a policy issue requires attention to agenda-setting, which is the process of how issues are included and how priorities get established in policy-making.

Dror concludes that less is known about agenda-setting than other features of policy-making.⁹ He does suggest some possible issues affecting agenda setting, such as the 'politics of the day' driving out more basic issues, mass media influences, the delay of controversial and unpleasant items and the personal idiosyncrasies of senior decision makers and their advisors. These features of actual agenda setting contravene such requisites of high quality policy-making as the timing of decisions, the need for multiple, open-ended problem formulations, and some correlation between agenda items and the main objective problems facing a policy.

Participation

Enhancing public participation is one of the guiding principles of healthy public policy.¹⁰ Yet participation has many forms. Arnstein describes a ladder of participation which extends from non-participation through tokenism to citizen power, but then defines true citizen participation as the redistribution of power that enables have-not citizens to be included, for instance, in determining how tax resources are allocated, how information is shared and how goals and policies are set.¹¹

The literature suggests that to strengthen citizen participation, a distinctive power base must be developed, perhaps from an identifiable local constituency or from representation of relevant grass roots community organizations.¹² In this view, measures need to be taken to make citizens more confident in their own abilities and more comfortable with decision-making responsibilities.¹³ Citizens "should develop personal skills, organizational capabilities and lobbying strategies to build effective citizens groups to institutionalize themselves into the policy-making process".¹⁴ Milio characterizes this notion as "capacity building", ie, building the capacity of citizen organizations to participate in policy-making and of government to incorporate them.⁴

The Implementation Conundrum

Healthy public policy is considered to be a fundamen-

tal strategy to promote health and is integral to health system reform. Recognition of pressing issues in health has been followed in most countries by the establishment of planning machinery.¹⁵ Standing planning bodies are often set up to assist the policy-makers in analyzing issues and formulating policy proposals. (The Nova Scotia Provincial Health Council is such a body.)

In the policy process, implementation traditionally has been considered to be primarily administrative and distinct from policy formulation. *Policy* is the decision regarding what to do, *implementation* is getting it done. For all its emphasis on planning and envisioning a desired future, the field of healthy public policy is on the verge of the "implementation conundrum: a framework of goals and plans but little in the way of achieved outcomes".⁶ Siler-Wells contends that the implementation conundrum consists of three barriers: a universal fear of change; inadequately developed social change technologies; and the failure to plan for implementation.⁶

Implementation of healthy public policies can utilize "top-down" or "bottom-up" approaches. The essential ingredient of the *top-down approach* is that it starts with a policy decision, often a statute, made by central governmental officials, and thereby makes its way into the system.

The *bottom-up approach*, on the other hand, is concerned with policy implementation as actually realized. It therefore emphasizes the discretion of the 'street level bureaucrats' on whom the responsibility for implementation of policy and programs rests.¹⁶ As opposed to the top-down focus on formal organizational hierarchies, communication and control mechanisms, policy is determined by explicit or implicit bargaining between policy formulators and the policy implementors from different organizations.¹⁷ Policies are not fully implemented by a single organization, then, but by an implementation structure or policy network of individuals within public and private organizations.¹⁸

As one might expect, one of the issues in coordinating healthy public policy is the tension between "top-down" and "bottom-up" approaches to policy development and implementation.^{19,20}

Barriers to Healthy Public Policy

There are a variety of barriers to coordinating healthy public policy. These include inexperience in working on a multisectoral basis and vested interest groups which may resist the opening up of policy-making to new stakeholders such as the elderly, the unemployed, members of minority groups and so on.

An important barrier is lack of political will. Competing interests, such as those of industry and those of the public health sector, provide another significant barrier to coordinating healthy public policy. The distribution of powers in Canada's federal system may also inhibit or complicate multisectoral action.

Meeting the criterion that healthy public policy involves public participation in policy development and

implementation also poses a challenge. How the media deal with initiatives in health promotion and healthy public policy can work to facilitate or inhibit implementation.

In examining these barriers, Milio suggest that the central issue facing healthy public policy is how to enhance the feasibility of placing health criteria on the agendas of policy makers who have previously not considered health part of their domain.^{3, 4} This implies new roles for many stakeholders including the recognition that individuals not previously considered as stakeholders in the health domain ought to be considered as such.

The coordination of public policies is supposed to make it easier for people to live healthy lives and make healthy choices. "It is often said that health is too important to be left to a Ministry of Health".¹⁹ What is meant is that the health care sector alone is unable to meet the challenge of achieving equity in health.

Coordinating and implementing healthy public policies are social processes which involve developing and channelling human motivations, the creation of social institutions, modifying the relationship between the individual and societal institutions, and mobilizing groups to action. The literature is insufficient to direct us on how we can manage this complex social process. Perhaps Milio is correct; she insists that we need to "learn by doing".²¹ □

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OBITUARIES

Dr. William W. Bennett, (83) of Bridgewater, N.S. died on May 8, 1991. Born in Newfoundland he received his medical degree from Dalhousie Medical School in 1933. He established a practice in Bridgewater in 1934, was a senior staff member at Dawson Memorial Hospital from 1934 to 1967, and served on the board of directors of Maritime Medical Care. He is survived by his wife, a son and three granddaughters. The *Journal* extends deepest sympathy to his family.

Dr. Charles J. David, (53) of Dartmouth, N.S. died on May 21, 1991. Born in India, he received his medical degree in Bombay, India in 1962. He was an Associate Professor of Psychiatry at Dalhousie University and past Clinical Director of a psychiatric unit at the Victoria General Hospital. He is survived by his wife, a son and three daughters. The *Journal* extends sincere sympathy to his wife and family.

Dr. Joseph F. Cantwell, (75) of Kingston, Ontario died on May 23, 1991. Born in Newfoundland, he received his medical degree from Dalhousie Medical School in 1949. He practised in Halifax until his retirement in 1978. He was involved with sports medicine: football, hockey and boxing. He was the first elected President of the Canadian Academy of Sports Medicine and the Medical Director of the first Canada Summer Games. He is survived by his wife, a daughter, and two sons. Sincere sympathy is extended to his family.

"A man cannot do himself a better service than to acknowledge error, for it shows a plain nature and does much to intenerate* wrath."

Samuel Johnson (1709-1984)

*intenerate — "to make tender, soften, mollify"

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