TABLE OF CONTENTS

FROM THE EDITORS
3 Preface
S. McMullen, Editor-in-Chief

4 Editorial
T. Grennan, Executive Editor

EVIDENCE-BASED MEDICINE
6 Issues in the Design and Conduct of Randomized Trials in Surgery
M. Bhandari, P.J. Devereaux

CLINICAL REVIEW
14 Well-Differentiated Thyroid Carcinoma: A Review of the Available Follow-Up Modalities
T. Davids, A. Prebtani

BRIEF CASE
20 Gastric Carcinoma: An Unexpected Diagnosis
C. Hanley

HEALTH POLICY AND ECONOMICS
25 Getting Better Value for Money: The Use of Economic Evaluations in Several Surgical Subspecialties
S.N. Raza, J. Yousuf, K. Yousuf, S.D. Raza

29 Obesity: Implications for Health Care and Society
J. Braun, B. Heal

HISTORY OF MEDICINE
34 Public Health in Canada: Considerations on the History of Neglect
D. Yan

MEDICAL ETHICS
38 The Prescription Conundrum: Factors That Impact on Prescribing Practices
C. Costiniuk

MEDICAL EDUCATION
41 Selection of Medical Students at McMaster University A Quarter Century Later
H. Reiter, J. Rosenfeld, L. Giordano

MEDICAL CAREERS
46 Clinical Genetics: The Art and Science of Helping People Understand Their Genes
M. Carter

ALLIED HEALTH
49 Allied Health Care Professionals and Patient Care: When Should Physicians Refer?
J. Hunter-Orange, Usha Ramanathan, L.K. McLachlin-McDermid

CLINICAL QUIZ
56 How much do you know about Duchenne Muscular Dystrophy?
R. Nenshi, K. Strode

INSIGHT
60 Aunt Jane
J. Clement
Welcome, all, to the 2nd Issue

Sarah M. McMullen, BSc, MSc

Welcome, all, to the 2nd issue of the McMaster University Medical Journal.

The diversity of the articles in this issue is truly a tribute to that historically sought when selecting students for the undergraduate medical program here at McMaster University ...the diversity that allowed this former geologist to be sitting here typing the preface to a medical journal. For more on the history of selection of students at McMaster University, Reiter et al have provided some food for thought in this issue’s Medical Education section.

Before diving into our eclectic collage of contents, however, I hope everyone paused to admire this issue’s cover art. Sean de Souza, a promising young graphics artist at Sheridan College, is the brother of one of my classmates and MUMJ section editor; she had good instincts when she suggested we have him design our cover. His image is timeless, at once modern and sleek, yet calling to mind – with its stylized hourglass and antiqued tones- eras long passed, the ars longa of Hippocrates.

Headlining this year’s issue is our Evidence Based Medicine section, in which Bandhari and Devereaux artfully support the increased presence of EBM in surgical practice. Davids et al succinctly review the diagnosis, staging, prognosis and treatment of well-differentiated thyroid cancer, in addition to discussing the best methods available for follow-up. Continuing in the vein of nitty gritty medicine, Hanley provides us with a diagnosis not to miss, and Nenshi and Strode test our knowledge in this issue’s Clinical Quiz ...this being Mac, though, perhaps I should say “learning exercise” rather than “quiz”?! Regardless, learn and enjoy.

History and economics play large roles in this issue; Yan revisits some of the more recent tragedies in Canadian health care, and the role of politics and economics in the tumultuous history of public health in Canada. Raza et al review economic evaluations in health care decision-making, providing insight for those of us who sometimes scratch our heads when the topic arises. Heal and Braun consider the health and economics impact of what will hopefully become history sooner rather than later, the rising obesity epidemic.

“Innovative” is probably one of the most bandied-about words in our “Mac Speak” ... in keeping with our tradition of innovation and diversity in health care, Orange et al give us the first article in a brand new section for MUMJ, that of Allied Health; their article provides guidelines for physicians wanting to refer patients for multidisciplinary care and follow-up. Keeping future-focused, Carter provides insight into the up-and-coming world of Medical Genetics.

And finally, perhaps my favorite piece in this issue, is a touching “Reflection” written by recent McMaster graduate Dr Jennifer Clement; I hope you all read this and carry some of its wisdom with you in your back pockets.

This, the 2nd of what will hopefully be many issues of the MUMJ, has truly been a rewarding and insight-laden experience; may you all come away from this issue feeling the same way.

Thank you to all who made this happen.

Sarah M. McMullen
MUMJ Editor-in-Chief
A Call to Arms, of a Different Sort

J. Troy Grennan, BScN

In an article this past summer in *Harper's Magazine*, physician Ronald Glasser argues that society has grown complacent – or more precisely, “narcotized” into a sense of security – vis-à-vis its concern about the viability of public health as infrastructure and as a protective entity in general. Glasser ends his article with a diatribe against the American government’s exorbitant expenditures on the ‘fight against terrorism’, its missile defence system and the war in Iraq, and contrasts these with the inadequate funds put into the public health system, as well as the country’s more systemic problems. He closes abruptly, with a statement asserting that – given our foolishness and incompetence as a collective society in problem prioritization and fund allocation – perhaps we are not deserving of survival. “Perhaps”, he says, “it is simply time to die.”

Though clearly alarmist, one need not read very deeply into these statements to see that many of Glasser’s points ring true. Yes, perhaps a flimsily justified large-scale war of revenge for the 3,000 victims of 9-11, with a price tag of $4 billion a month, is problematic and warrants a re-examination of fiscal priorities. However, in making such claims one must be wary not only of the message conveyed, but the manner in which it is delivered. Alarmist threats, disruptive behaviour and exaggerated claims run the risk of undermining the credibility and effectiveness of the best-intentioned and sensible messages. An oft-repeated example of this is clearly demonstrated at ‘globalization protests’, where the unarguable and clear position of those concerned about the effect of global economic reform on the world’s most marginalized is completely erased by the brash and often bizarre actions of the violent protestor.

Now, some may wonder: what is the purpose of including this discussion of foreign policy and activism in this *MUMJ* editorial? Is there a point to be taken from all of this? More importantly, what – as medical students – should we be taking from this? Quite possibly, the most important message implicit in the above discussion is the need to concern ourselves with issues of advocacy and activism – in whatever form that may take – as well as an assurance that we do not become complacent or apathetic. Certainly, the implication here is not that medical students as a group are apathetic or not passionate about anything of substance. In fact, many medical students – and some may argue, especially those of us at McMaster – come to medical school from a life rich with interesting experiences and dedication to issues of social justice and otherwise. That being said, medical school can be a tremendously busy time – a time during which the ‘important things’ go by the wayside. All of a sudden, we are thrown into this world of limitless study, sleepless nights, and an integration of knowledge that will, for many of us, form the basis of our professional lives. In trying to make sense of this new world thrust upon us, we often feel like we have limited options in what we can take on. As a result, our priorities – and hence, our passions – change, and we dedicate ourselves to our new responsibilities.

Indeed, our lives change, with new responsibilities, the need for often radical time management and a re-evaluation of our priorities. On the other hand, there is also an argument that can be made about the position in which we are placed as medical students. Like it or not, physicians (and students, as future physicians) find themselves in a privileged position from many different standpoints – a privileged position from many different standpoints – a privileged position bringing with it responsibility extending beyond that of a direct health care provider. In fact, a variant of this idea has been formalized by the Canadian Medical Education Directions for Specialists (CanMEDS), a body of the Royal College of Physicians and Surgeons of Canada. Through work that has been spanning the past several years, the CanMEDS group has developed a model of core competencies for physicians based on societal needs. According to this document, the central role of the physician is that of medical expert, with the overlapping roles of communicator, collaborator, health advocate, manager, professional and scholar rounding out the remainder of these core competencies. Clearly, two salient points can be taken from this model. For one, these competencies do not necessarily fall nicely into the realm of what medical school dictates we must learn. Secondly – and despite the first point – many would agree that the roles outlined in the CanMEDS model are essential in order to be a minimally-competent physician, much less a ‘good’ physician.

All of this to make some very simple points: Most of us care deeply about many things lying outside of our ‘medical’ lives, and are forced to forgo some of these dedications as medical students. Being a competent or – even better still –
a good doctor necessitates the taking-on of roles that are not necessarily learned in standard medical education, such as health advocacy and efficient communication. Thus, for the sake of ourselves and our interests, as well as for the sake of our patients as they face the prospect – in the not-too-distant future – of having us as their health care providers, it is important that we continue to engage ourselves in the things that matter to us, as these will inevitably add invaluable tools to our arsenal of health care provision; tools that would arguably give us the skills necessary to fulfill the roles that society demands we possess.

As we cautiously make our way out into the world of medicine, and slowly build up our toolkit of the essentials with which to equip ourselves, the benefits of our ‘extra-curricular’ experiences and passions will become evident. Whether it be advocating on behalf of our homeless patient who has lost their health card, or using our political savvy to publicly challenge our government’s foreign policy, we will likely look back and know that multitudes of experiences helped us reach the point where we are able to accomplish what we accomplishing. Challenging what Glasser asserted in the abovementioned Harper’s Magazine article, perhaps we – as a collective society – are salvageable. Perhaps there is hope for us, that there is more for us to do. Perhaps it is simply not time to die.

J. Troy Grennan
MUMJ Executive Editor

Evidence-Based Medicine

Issues in the Design and Conduct of Randomized Trials in Surgery

Mohit Bhandari, MD, MSc, FRCSC
PJ. Devereaux, MD, FRCPC

ABSTRACT

Although surgeons may perceive that evidence-based medicine mandates a strict adherence to randomized trials, it more accurately involves informed and effective use of all types of evidence (from meta-analysis of randomized trials to individual case series and case reports), with particular emphasis on evidence from the medical and surgical literature, in patient care. With the escalating amount of available information, surgeons must consider a shift in paradigm from traditional practice to one that involves question formulation, validity assessment of available studies and appropriate application of research evidence to individual patients. Surgical investigators must endeavor to conduct methodologically rigorous trials, whenever possible, and be explicit and transparent in their reporting of methods and data. Herein, an overview of the issues involved in the design and conduct of surgical trials with an emphasis on randomization, concealment of allocation, blinding, type I and II errors and intention to treat analysis, is provided.

HIERARCHY OF RESEARCH DESIGN

In the hierarchy of research designs, randomized controlled trials (RCTs) represent the highest level of evidence (Figure 1). Randomization is the only method for controlling for known and unknown prognostic factors between two comparison groups; lack of randomization predisposes a study to potentially important imbalances in baseline characteristics between two study groups. The role of nonrandomized (observational) studies in evaluating treat-
ments is an area of continued debate: deliberate choice of the treatment for each patient implies that observed outcomes may be caused by differences among people being given the two treatments, rather than the treatments alone. Unrecognized confounding factors can interfere with attempts to correct for identified differences between groups. Nonrandomized trials have been reported to either overestimate or underestimate treatment effects when compared to results from RCTs.8,9 These considerations have supported a hierarchy of evidence, with randomized controlled trials representing the highest echelon of available evidence, followed by controlled observational studies, and finally, uncontrolled studies.10,11

**WHY SHOULD RANDOMIZED TRIALS BE UNDERTAKEN?**

Surgeons want to know if their procedures are effective, and although clinical observations provide important insights, they may be limited by lack of objectivity. This results from difficulties in integrating observations (e.g. taking into account variations in the natural history of a disorder), placebo effect, subtle but important effects of patient selection for one procedure versus another, a patient’s desire to please, and an expectation that more aggressive interventions are better interventions, and drawing inferences from them. As a result of these limitations, surgeons commonly rely on research evidence from a range of studies, including RCTs, to guide their clinical practice.

Observational studies populate the surgical literature; in contrast, RCTs are a much rarer find. When available, however, RCTs provide many advantages over an observational study, due mainly to the process of randomization which eliminates biases in the choice of treatment, facilitates blinding, and finally, represents our only means to control for unknown prognostic factors. Although cases exist in which observational studies have been shown to have effect estimates similar to those of RCTs, there are many cases where observational studies yield disparate results to those reported in RCTs. For example, an observational study of extracranial to intracranial bypass surgery suggested a “dramatic improvement in the symptomatology of virtually all patients” undergoing the procedure.12 However, a subse-

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**Table 1. Checklist for Assessing Quality of Reporting**

<table>
<thead>
<tr>
<th>Randomization</th>
<th>1 Yes</th>
<th>2 Yes</th>
<th>1 Partly</th>
<th>0 No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Were the patients assigned randomly?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Randomization adequately described?</td>
<td>1 Yes</td>
<td>2 Yes</td>
<td>1 Partly</td>
<td>0 No</td>
</tr>
<tr>
<td>Was treatment group concealed to investigator?</td>
<td>1 Yes</td>
<td>0 No</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total/4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Description of outcome measurement adequate?</td>
<td>1 Yes</td>
<td></td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Outcome measurements objective?</td>
<td></td>
<td>2 Yes</td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Were the assessors blind to treatment?</td>
<td></td>
<td>1 Yes</td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Total/4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Were inclusion/exclusion criteria well defined?</td>
<td>2 Yes</td>
<td>1 Partly</td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Number of patients excluded and reason?</td>
<td>2 Yes</td>
<td>1 Partly</td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Total/4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the therapy fully described for the treatment group?</td>
<td>2 Yes</td>
<td>1 Partly</td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Was the therapy fully described for the controls?</td>
<td>2 Yes</td>
<td>1 Partly</td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Total/4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Statistics</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Was the test stated and was there a p value?</td>
<td>1 Yes</td>
<td></td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Was the statistical analysis appropriate?</td>
<td></td>
<td>2 Yes</td>
<td>1 Partial</td>
<td>0 No</td>
</tr>
<tr>
<td>If the trial was negative, were confidence intervals of post hoc power calculations performed?</td>
<td></td>
<td>1 Yes</td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Sample size calculation before the study?</td>
<td></td>
<td>1 Yes</td>
<td>0 No</td>
<td></td>
</tr>
<tr>
<td>Total/4 (if positive trial)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total Score:</td>
<td>20 points (if positive trial)</td>
<td>21 points (if negative trial)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

quent large RCT demonstrated a 14% relative increase in the risk of fatal and nonfatal stroke in patients undergoing this procedure as compared to medical management. Given that most published interventions report moderate as opposed to large treatment effects, surgeons need to design, run and participate in RCTs, and when available, use these studies to guide clinical practice.

ASSESSING THE VALIDITY OF SURGICAL TRIALS?

One might propose that prior to applying the results of surgical trials to clinical practice, surgeons should be convinced that the results in these trials are valid. To provide an answer for orthopaedic surgery, a systematic review of published randomized trials in the Journal of Bone and Joint Surgery from 1988-2000 was performed. Two investigators independently conducted hand searches of the Journal of Bone and Joint Surgery over a twelve year period between 1988 and 2000. Randomized trials were identified by review of the methods sections of each of the studies. Discrepancies in identification were resolved by a consensus of the two reviewers. To further ensure that all randomized trials during the 12 year period were identified, an advanced PubMed search was performed using a journal search engine (Journal of Bone and Joint Surgery) and Year of publication. The Detsky quality index was utilized to score the methodology (Table 1). Briefly, this 14 item index contains questions which fall into the following categories: (1) randomization; (2) outcome measures; (3) eligibility criteria and reasons for patient exclusion (withdrawal/dropout); (4) interventions; and (5) statistical issues. Each of the 5 broad categories was given equal weight (4 points each). The final section on statistical analysis contains an extra question for negative or non-statistically significant trials. Thus, the total possible score for positive trial and negative trials is 20 and 21, respectively.

Of 2468 studies identified, 72 (2.9%) studies met all eligibility criteria. Two investigators each assessed study quality under blinded conditions and abstracted relevant data. A well-reported checklist was used to guide the assessment of study quality (Table 1).

The mean transformed score for overall study quality for the seventy two studies was 68.1 ± 1.6%. Sixty percent (43/72) of the randomized trials scored less than 75%. Drug trials had significantly greater mean quality scores than surgical trials (72.8% vs. 63.9%, P<0.05). It was encouraging to note that the sample of trials illustrated an increased interest in the conduct of randomized trials in orthopaedics over the past decade. The limitations in study design identified in the sample of trials could be addressed in future orthopaedic trials, if surgeons endeavor to (1) randomize patients with arbitrarily generated treatment schedules (computers); (2) use centralized computer randomization; (3) blind all those who can be blinded in a trial (i.e., patients, outcome assessors, data analysts, and caregivers); (4) limit the numbers of those lost to follow-up, and clearly document both losses to follow up and study withdrawals; and finally, avoid the risk of a Type II error (described below) by conducting an a priori sample size calculation to plan the number of patients that will be required for the study.

IS THE TRIAL RANDOMIZED?

While it may seem elementary to define what is meant by “randomization”, many clinicians remain unfamiliar with the rationale for random allocation of patients in a trial. Orthopaedic treatment studies attempt to determine the impact of an intervention on events such as nonunion, infection, or death - target outcomes or target events. Patient age, fracture severity, comorbid conditions, health habits, and a host of other factors typically determine the frequency with which a trial’s target outcome occurs (prognostic factors or determinants of outcome). If prognostic factors (both known and unknown) prove unbalanced between a trial’s treatment and control groups, the study’s outcome will be biased, either under- or overestimating the effect of treatment. Thus, through randomization, surgeons can achieve a balance between known and unknown prognostic factors between treatment groups.

WAS RANDOMIZATION CONCEALED?

Equally important is the concept of “concealment”, not to be confused with blinding, discussed below. Concealed randomization ensures that surgeons are unable to predict the treatment arm into which their next patient will be allocated. The most effective way to accomplish this is via remote, 24-hour telephone randomization service. Historically, treatment allocations in surgical trials have been placed in envelopes. While technically concealed, envelopes are easily tampered with; the following example illustrates this point.

In 1995, Hensen et al. (1996) undertook a randomized trial comparing open versus laparoscopic appendectomy. Logistically, the trial ran smoothly during the day, however, at night the attending surgeon’s presence was required for laparoscopic but not open procedures; in addition, the limited operating room availability rendered the longer laparoscopic procedure a nuisance. Reluctant to call in the consultant, and particularly reluctant with certain senior colleagues, the residents sometimes adopted a practical solution: when an eligible patient arrived, the residents ascertained which attending staff was on, in addition to the length of wait to access an operating room; then, depending on the situation, held the translucent envelopes up to the light. Once an envelope was found that dictated an open procedure, that envelope was opened. The first eligible patient in the morning would then be allocated to a laparoscopic appendectomy according to the passed-over envelope. If patients who present at night are sicker, the residents’ behavior would bias the results against the open procedure.

While an overwhelming proportion of orthopaedic surgical trials (97.5%) are described as randomized, less than half of these report concealed randomization (40.5%). In other
words, there is the possibility that investigators in the majority of trials (59.5%) could identify the treatment to which their next patient would be allocated.

Surgical trials cannot be completely blinded due to the relative impossibility of blinding surgeons (Figure 2); Devereaux et al. (2003) identified significant ambiguity when investigators use the term “double-blinding”: in a survey of 91 internists and researchers, 17 unique definitions of “double-blinding” were obtained.16 Moreover, hand searches of 200 randomized trials in five high profile medical journals (New England Journal of Medicine, The Lancet, BMJ, Annals of Internal Medicine and JAMA) revealed that authors using the term “double-blind” typically did not state which groups they blinded.16,17 Possible relevant targets of blinding in a randomized trial include physicians, patients, outcome assessors, and data analysts. Surgical trials can always blind the data analyst, almost always blind the outcome assessor, occasionally blind the patient, and never blind the surgeon. In our review of orthopaedic trials, outcome assessors were blinded only 44% of the time and data analysts were never blinded.13 However, at least two thirds of surgical trials could have the outcome assessors, patients, or data analysts blinded.

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WAS AN “INTENTION TO TREAT” ANALYSIS CONDUCTED?

Surgeons can also influence randomization by systematically omitting from the results those patients who do not receive their assigned treatment. Readers might, on first glance, agree that such patients who never actually received their assigned treatment should be excluded from the results. Some patients randomized to surgery never have the operation because they are too sick, or suffer the outcome of interest (such as stroke, deep venous thrombosis or myocardial infarction) before they get to the operating room. If investigators include such patients, who are destined to do badly, in the control arm but not in the surgical arm of a trial, even a useless surgical therapy will appear to be effective; the apparent effectiveness of surgery, however, will come not from a benefit to those who have surgery, but from the systematic exclusion of those with the poorest prognosis from the surgical group. More commonly, patients randomized to one surgical treatment arm do not receive the assigned treatment for technical reasons. Again, these patients are likely destined to have poorer outcomes. As a result, investigators exclude these patients from the analysis thereby losing the balance of prognostic factors achieved through randomization.4

The principle of attributing all patients to the group to which they were randomized represents the “intention-to-treat” principle (Figure 3). This strategy preserves the value of randomization, in that both known and unknown prognostic factors will be, on average, equally distributed in the two groups, thus the observed effect will be that due solely to the treatment assigned. When reviewing a report of a randomized trial, one should look for evidence that the investigators analyzed all patients in the groups to which they were randomized.

Some suggest that an intention to treat approach is too conservative and more susceptible to type II error due to increased biologic variability.18 The argument is that an intention-to-treat analysis is less likely to show a positive treatment effect, especially for those studies that randomized patients who had little or no chance of benefiting from the intervention. These critics argue that an efficacy approach to an analysis is more important than an effectiveness approach.

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ENSURING COMPREHENSIVE FOLLOW-UP

Ideally, at a trial’s conclusion, the investigators will be well-aware of the status of each patient with respect to the target outcome. Patients whose status is unknown are often referred to as being “lost to follow-up”. The greater the number of patients who are lost to follow-up, the more a study’s validity is potentially compromised; the reason for this being that patients who are lost often have different prognoses from those who are retained, and may disappear because they suffer adverse outcomes (including death) or because they are doing well and thus did not return to clinic for follow-up assessment.

When does loss to follow-up seriously threaten validity? The rules in this respect are misleading. Consider an hypothetical randomized trial in which 1,000 patients are entered into both treatment and control groups, and of whom 200 (20%) are lost to follow-up (100 in the treatment group and 100 in the control group). Treated patients have adverse outcomes at half the rate of the control group (200 versus 400), a reduction in relative risk of 50%. To what extent does the loss to follow-up potentially threaten our inference that treatment reduces the complication rate in half? If we assume the worst, that all treated patients lost to follow-up had the most unfortunate outcome, the number of adverse outcomes in the treatment group would be 300 (30%). If there were no adverse outcomes among the control patients who were lost to follow-up, our best estimate of the effect of treatment in reducing the risk of complications drops from 50% (1-200/400) to 25% (1-300/400). Thus, assuming the worst does change the estimate of the magnitude of the treatment effect. If assuming a worst case scenario does not change the inferences arising from study results then loss to follow-up is not a problem. If such an assumption significantly alters the results (as shown above), validity is compromised.

MINIMIZING ERRORS (ALPHA AND BETA ERRORS)

Trials of small sample size are subject to beta errors (Type II errors, mentioned above), in which the probability of concluding that there is no difference between treatment groups exists, when, in fact, there is a difference (Figure 4). Typically, investigators will accept a beta error rate of 20% (β=0.20), which corresponds with a study power (i.e., the ability of a study to conclude a difference when a real difference exists) of 80%. Most investigators agree that beta error rates greater than 20% (study power less than 80%) are subject to unacceptably high risks of false negative results.

In an effort to quantify the extent to which orthopaedic trauma trials were under-powered, 620 potentially relevant citations from Medline were reviewed, only 196 of which were randomized trials that focused upon adult fracture care.' Application of the eligibility criteria to the complete manuscripts eliminated 79 studies. Thus, a total of 117 randomized trials in orthopaedic trauma were included for the power analysis, in which 19,942 patients were randomized. Moreover, study sample sizes ranged from 10 to 662 patients (mean=95 patients, standard deviation = 79). The majority of trials involved treatment of hip fractures (34.2%). The mean overall study power among the 117 trials was 24.65% (range 2%-99%), and the Type II error rate for primary outcomes was 91%.

The power of a study represents the probability of concluding that there is a difference between two treatments when one actually exists.' Power (1-β) is simply the complement of the Type II error (β). Thus, if we accept a 20% chance of an incorrect study conclusion (β=0.20), we are also accepting that the correct conclusion will be obtained 80% of the time. Study power can be used before the start of a clinical trial to assist with sample size determination.' The power of a statistical test, typically, is a function of the magnitude of both the treatment effect (the designated Type I error rate, α), and the sample size (N).' When designing a trial, investigators choose the desired study power (1-β) and calculate the necessary sample size to achieve this goal. Most surgeons are less familiar with the concept of concluding that the results of a particular study are true when they are in reality due to chance (or random sampling error); this erroneous false positive conclusion represents a Type I or α-error (Figure 4). By convention, most studies in orthopaedics adopt an α-error rate of 0.05, thus, investigators can expect a false positive error about 5% of the time. Ideally, the rate of Type I error is based on one comparison between alternative treatment groups, usually designated as the primary outcome measure. In situations where no primary outcome variable has been determined, there is a risk of conducting multiple tests of significance on multiple outcomes measures. This form of data-dredging by investigators risks spurious false positive findings. Several techniques are available to adjust for multiple comparisons, such as the Bonferroni correction.'

| TRUTH |
|-------------------|-------------------|
| DIFFERENCE | NO DIFFERENCE |
| RESULTS OF THE STUDY | |
| DIFFERENCE | CORRECT CONCLUSION (1-β) | FALSE POSITIVE (α error or Type I error) |
| NO DIFFERENCE | FALSE NEGATIVE (β error or Type II error) | CORRECT CONCLUSION (1-β) |

Figure 4. Errors in Hypothesis Testing. See text for details.

Most readers are intuitively skeptical when one in a list of 20 outcomes measured by an investigator is significant (p < 0.05) between two treatment groups. This situation typically occurs when investigators are not sure what they are looking for and therefore test several hypotheses hoping that one may be true. It is therefore argued that studies generating a large number of measures of association have markedly greater probability of generating some false-
positive results due to random error than does the stated alpha level for individual comparisons.21,22

We conducted a review of randomized trials published within the last two years in order to determine the risk of Type I errors occurring among surgical trials in which the primary outcome was not explicitly stated;20 as such, we hand-searched four orthopaedic journals, six general surgery journals, and five medical journals to identify such trials. Information on outcomes and statistical adjustment for multiple outcomes was recorded for each study, and the risk of a Type I error was calculated for each study that did not explicitly state a primary outcome measure for the main statistical comparison. A total of 159 studies met the inclusion criteria for the study: 60 from orthopaedic journals, 49 from non-orthopaedic surgical journals, and 50 from medical journals. Of those trials that did not state a primary outcome measure, the risk of Type I errors (false positive results) in orthopaedic and non-orthopaedic surgery journals (mean: 37.3±13.3% and 37.6±10.5%, respectively) was significantly greater than medical journals (10.1±1.9%) (P<0.05).20

HOW PRECISE WAS THE ESTIMATE OF TREATMENT EFFECT?

The true risk reduction can never be known; all that is known is the estimate provided by rigorous controlled trials, and the best estimate of the true treatment effect is that observed in the trial. This estimate is called a "point estimate", a term that implies that although the true value lies somewhere close to it, it is unlikely to be precisely correct; investigators give the range within which the true effect likely lies by the statistical strategy of calculating confidence intervals.4

The 95% confidence interval (CI) is traditionally, albeit arbitrarily, used; it is defined as that range which includes the true relative risk reduction 95% of the time. The true RRR will seldomly be found toward the extremes of this interval, and the true RRR will lie beyond these extremes only 5% of the time - a property of the confidence interval that relates closely to the statistical level of "statistical significance" of p < 0.05.

REPORTING ALL THE FACTS: CONSOLIDATED STANDARDS OF REPORTING TRIALS (CONSORT)

In a recent effort to improve the reporting of RCTs, a group of methodologists and journal editors developed the consolidated standard of reporting trials (CONSORT) statement which was first published in JAMA in 1996 (25). CONSORT provides a checklist and flow diagram to guide authors in preparing RCT reports. The CONSORT checklist consists of 21 items that pertain mainly to the methods, results and discussion of a RCT report and identify key pieces of information necessary to evaluate the internal and external validity of the report.

The true benefit of a well-conducted randomized trial in surgery can only be realized when it has been reported in a clear and comprehensive manner. It has been shown herein that most reports of randomized trials in orthopedic trauma fail to provide the information necessary to judge study validity and to effectively apply the results to patient care.26 Over 70% of published trials met less than half of the CONSORT criteria. Even more striking is that less than 5% of studies present a summary measure of the magnitude of effect, such as a relative risk reduction or odds ratio, and less than 10% provide an estimate of precision, such as the confidence interval.

A well-designed, and well-reported, surgical trial should be able to answer each question asked in the CONSORT criteria. Adequate reporting of trials will only enhance readers’ understanding of what was actually accomplished, rather than what readers assume was done. Given the dramatic increase in randomized trials over the past decade, a well-reported study will enable investigators to adequately assess the validity, or believability, of published trials before deciding whether to apply their results to clinical practice. Moreover, when multiple trials on a similar topic exist, adequate reporting will enhance investigators’ abilities to decide whether statistical techniques to pool results across multiple studies (meta-analysis) might be appropriate.

CONCLUSION

Although surgeons, as other physicians, may perceive that evidence-based medicine mandates a strict adherence to randomized trials, it more accurately involves informed and effective use of all types of evidence (from meta-analysis of randomized trials to individual case series and case reports), with particular emphasis on the evidence from the medical and surgical literature, in patient care. With the escalating amount of available information, surgeons must consider a shift in paradigm from traditional practice to one that involves question formulation, validity assessment of available studies and appropriate application of research evidence to individual patients.

Surgical investigators must endeavor to conduct methodologically rigorous trials, whenever possible, and be explicit and transparent in their reporting of methods and data. Currently, the field of surgery is experiencing an exciting period of growth and innovation, fueled largely by a renewed enthusiasm for conducting high quality trials. The limitations of the surgical trials in the recent past will be effortlessly overcome by future investigators who endeavor to answer clinically important questions while respecting the need for scientific methodology in their quest for answers.

AUTHOR BIOGRAPHIES

Dr. Bhandari and Dr. Devereaux are both from the Department of Clinical Epidemiology and Biostatistics, McMaster University in Hamilton, Ontario. Dr. Bhandari’s salary was provided, in part, by a Detweiler Fellowship Award, Royal College of Physicians and Surgeons of Canada. Dr. Devereaux was funded by a Canadian Institutes of Health Research/Heart and Stroke Foundation scholarship.
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Well-Differentiated Thyroid Carcinoma: A Review of the Available Follow-Up Modalities

Taryn Davids, MD
Ally P.H. Prebtani, MD

ABSTRACT
Well-differentiated thyroid carcinoma (WDTC) is among the most curable of thyroid cancers. There is, however, a risk of local and regional recurrence that must be regularly monitored for, by using a variety of follow-up modalities. The purpose of this article is to briefly review the diagnosis, staging, prognosis, and treatment of WDTC, in addition to discussing the various available follow-up modalities such as: measurement of serum thyroglobulin (Tg) by either thyroid hormone withdrawal or recombinant human thyrotropin (rhTSH) stimulation; whole body scanning (WBS); ultrasound (US) examination; additional diagnostic procedures including chest X-ray (CXR), non-contrast Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET), Tc-99m bone scans; and reverse transcriptase polymerase chain reaction (rt-PCR). Through detailed discussion of the available follow-up methods, we conclude that conservative therapy (lobectomy plus isthmectomy) requires clinical examination, neck ultrasound, in addition to other imaging studies such as CT or MRI for follow-up; while total or near-total thyroidectomy with post-surgical ablation is best monitored using periodic measurement of Tg levels (in patients with no anti-Tg antibodies) by thyroid hormone withdrawal or rhTSH. For patients positive for anti-Tg antibodies, a new diagnostic tool - rt-PCR - may be warranted.

INTRODUCTION
Thyroid nodules are defined as discrete masses within the thyroid gland. Historically, the prevalence of thyroid nodules within the general population was estimated to be approximately 4-8%; however, with the advent of improved diagnostic imaging strategies such as ultrasound, that number is estimated to be closer to 50%. Thyroid nodules are classified as benign or malignant, with an associated malignancy risk of 5-10%. That being said, malignant thyroid tumors tend to be slow growing and indolent in nature, with a low potential for morbidity or mortality. The Canadian Cancer Society estimates that for the year 2003 there were 2,100 (550 male, 1,550 female) newly diagnosed cases of thyroid cancer and, of these, there were 180 deaths due to thyroid cancer (60 male, 120 female).

Malignant thyroid tumors are classified as well-differentiated thyroid carcinoma (WDTC), undifferentiated carcinoma, medullary carcinoma, thyroid lymphoma, or metastases. The content of this article focuses primarily on follow-up of WDTC, which comprises more than 80% of thyroid carcinomas and includes both papillary and follicular carcinoma subtypes. The histological variants of papillary thyroid carcinoma include encapsulated, follicular, tall cell, columnar cell, clear cell, hurthle cell, and diffuse sclerosing carcinomas; those of follicular thyroid carcinoma include minimally invasive, widely invasive, and hurthle cell carcinoma.

Thyroid cancers are two to four times more frequent in women than in men, and are rare in the pediatric population (<16 years old). The risk of malignancy increases with a history of irradiation to the neck; extremes of age (<20 & >60 years old); excess iodine intake (papillary carcinoma); positive family history; conditions such as Multiple Endocrine Neoplasia (MEN 2), Pendred syndrome (autosomal recessive syndrome characterized by sensorineural hearing loss and thyroid goiter), Gardner’s syndrome (familial adenomatous polyposis), and Cowden syndrome (multiple hamartomas); in addition to certain environmental exposures such as hexachlorobenzene and volcanic lava. Prognosis is based on the size, type and histology of the tumor; patient age; presence of metastases; extent of the tumor; and patient gender (males have a worse prognosis).
Table 1a. TNM Staging of Thyroid Carcinomas

<table>
<thead>
<tr>
<th>Stage</th>
<th>Tumor (T)</th>
<th>Nodes (N)</th>
<th>Metastases (M)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>&lt;2cm</td>
<td>No regional lymph node metastasis</td>
<td>No distant metastases</td>
</tr>
<tr>
<td>1</td>
<td>2-4cm (limited to thyroid)</td>
<td>N1a: metastases to level IV</td>
<td>Distant metastases</td>
</tr>
<tr>
<td>2</td>
<td>&gt;4cm (limited to thyroid)</td>
<td>N1b: metastases to unilateral, bilateral, contralateral cervical or superior mediastinal lymph nodes</td>
<td>Distant metastases</td>
</tr>
<tr>
<td>3</td>
<td>T4a: Any size, with extension beyond capsule to invade subcutaneous soft tissues, larynx, trachea, esophagus, or RLN</td>
<td>T4b: Tumor invades prevertebral fascia or encases carotid artery or mediastinal vessels</td>
<td>Distant metastases</td>
</tr>
<tr>
<td>4</td>
<td>Any T, Any N, M0</td>
<td>T1-3, N1a, M0</td>
<td>T4c: Any T, Any N, M1</td>
</tr>
</tbody>
</table>

RLN, recurrent laryngeal nerve; level IV, pre-tracheal, para-tracheal, and pre-laryngeal/delphian lymph nodes

Table 1b. Staging of WDTC

<table>
<thead>
<tr>
<th>Stage</th>
<th>&lt;45 years</th>
<th>&gt;45 years</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>Any T, Any N, M0</td>
<td>T1, N0, M0</td>
</tr>
<tr>
<td>II</td>
<td>Any T, Any N, M1</td>
<td>T2, N0, M0</td>
</tr>
<tr>
<td>III</td>
<td>T3, N0, M0</td>
<td>T3, N1a, M0</td>
</tr>
<tr>
<td>IVA</td>
<td>T1-3, N1a, M0</td>
<td>T1-3, N1b, M0</td>
</tr>
<tr>
<td>IVB</td>
<td>T4b, Any N, M0</td>
<td>Any T, Any N, M1</td>
</tr>
<tr>
<td>IVC</td>
<td>Any T, Any N, M1</td>
<td>Any T, Any N, M1</td>
</tr>
</tbody>
</table>

DIAGNOSIS

Diagnosis of WDTC typically involves palpation of a nodule, visualization by ultrasound, and a fine needle aspiration biopsy. Ultrasound examination aids in assessment of size, location, and characterization of the nodule (cystic, solid, or mixed), and identifies features associated with malignancy such as microcalcifications; irregular or microlobulated borders; vascularity; and finally, presence of marked hypoechogenicity of the thyroid. Fine needle aspiration (FNA) provides rapid cytological diagnosis, and may be performed blindly by manual palpation, or under direct vision via ultrasound guidance. It should be noted that follicular carcinoma and follicular adenoma are difficult to distinguish using FNA alone, as the sample is unable to demonstrate the invasion of vasculature, lymphatics, or capsule seen with follicular carcinoma in an en bloc resection. Nuclear medicine modalities that use radioactive iodine isotopes (I\(^{131}\)) are useful in the diagnosis of thyroid nodules when TSH is suppressed, and may uncover a hot nodule(s) (a nodule with increased radio-nuclear tracer uptake), which indicates a decreased likelihood of malignancy in that nodule. In contrast to hot nodules, 14-22% of cold nodules are found to be malignant. Finally, the use of second line modalities such as non-contrast CT scanning are useful in determining tumor extent, the presence of any lymph nodes, or invasion and/or compression of local structures. Early recognition and diagnosis of thyroid cancer is important, as a delay in treatment longer than a year significantly increases mortality rates.

STAGING

While there are many staging systems available for thyroid carcinoma, such as the AMES criteria (age, metastases, extent of primary cancer, size of tumor); the AGES criteria (age, grade of tumor, extent of tumor, size of tumor); and the MACIS (metastases, age, completeness of resection, invasion, size) systems, the TNM system is widely used for WDTC (Table 1). The National Thyroid Cancer Treatment Cooperative Study Registry composed a staging system that was based on age at diagnosis, tumor histology, size, multiple intra-thyroid foci, extra-glandular invasion, metastases, and tumor differentiation; five-year survival rates are presented in Table 2. On the basis of these staging systems patients are classified as either high risk or low risk. High-risk patients include some or all of the following characteristics: age under 16 or over 45 years; patients with certain histological subtypes (papillary histological subtypes: tall-cell, columnar-cell, diffuse sclerosing variants; and follicular subtypes: widely invasive, poorly differentiated, hurthle-cell); large tumor size; extra-capsular extension; lymph node metastases. As with all cancers, staging plays an important role when deciding on therapy.
Figure 1. Approach for the Follow-Up of Well-Differentiated Thyroid Carcinoma

TSH, thyrotropin; mo, months; Tg, thyroglobulin; WBS, whole body scan; CT, computed tomography; MRI, magnetic resonance imaging; FDG, fluorine-18 fluoro-deoxyglucose; PET, positron emission tomography; rt-PCR, reverse transcriptase polymerase chain reaction; T4, thyroxine; T3, triiodothyronine; rhTSH, recombinant human thyrotropin; CXR, chest x-ray.

Table 2. Five-year Survival Rates for the National Thyroid Cancer Treatment Cooperative Study Registry

<table>
<thead>
<tr>
<th>Stage</th>
<th>5-year survival rate (%)</th>
<th>Disease-free survival rate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>99.8</td>
<td>94.3</td>
</tr>
<tr>
<td>II</td>
<td>100</td>
<td>93.1</td>
</tr>
<tr>
<td>III</td>
<td>91.9</td>
<td>77.8</td>
</tr>
<tr>
<td>IV</td>
<td>48.9</td>
<td>24.6</td>
</tr>
</tbody>
</table>

TREATMENT

Thyroid cancer treatment generally consists of total, or near-total thyroidectomy either alone, or in combination with ablative radioactive iodine (I\textsuperscript{131}), external radiation therapy (for high risk patients), and post-operative suppression of thyrotropin (TSH) with concomitant synthetic thyroxine and triiodothyronine hormone supplementation. The decision to undertake total, near-total thyroidectomy, or lobectomy is a highly contentious issue in the arena of thyroid cancer management because the decision is often based upon the staging and extent of the tumor.\textsuperscript{4,5} The extent of surgical procedure must also be weighed against potential post-operative complications such as hypoparathyroidism and damage to the recurrent laryngeal nerve(s). Similarly, low-risk patients considering post-operative radioactive iodine (I\textsuperscript{131}) ablative therapy must consider possible side effects of large doses of I\textsuperscript{131}. Ablative doses are usually between 30-100mCi; however, high doses >200mCi are sometimes warranted for severe disease, and are associated with mild radiation sickness (headache, nausea, vomiting), radiation thyroiditis, radiation sialadenitis, in addition to tongue symptoms such as dry or
burning tongue, bone marrow suppression, pulmonary fibrosis, and the potential for gonadal damage and infertility. In general, very-low risk patients undergo limited surgery, low risk patients undergo surgery followed by radioactive ablation therapy, and high risk patients (patients with residual micro/macrosopic disease, elderly patients with large tumors, extra-thyroidal extension) are treated similarly to moderate risk patients with consideration of external beam radiation therapy, which decreases the rate of loco-regional recurrence. The most common side effects of external beam radiation are esophagitis, trachitis, neck fibrosis, and radiation-induced spinal cord necrosis. Patients who undergo near-total or total thyroidectomy, with or without ablative radioactive iodine therapy, are subsequently started on a dosage of thyroid hormone supplements sufficient to maintain TSH suppression < 0.1µgU/ml (high risk patients), or 0.1-0.4µgU/ml (low risk patients). The effective dose in adults is generally between 2.2-2.8µg/kg, a dose that prevents symptoms of hypothyroidism while minimizing adverse cardiac or osteoporotic effects. Finally, for patients with advanced disease that are not surgical candidates or are non-responsive to other therapies, chemotherapy can be used with the understanding that it is of limited therapeutic benefit, with few studies supporting its use.

**FOLLOW-UP**

While WDTC is among the most curable of thyroid cancers, it does carry a risk of local or regional recurrence that approaches 10-20 percent. It is, therefore, important to periodically monitor for signs of residual or recurrent disease using a variety of follow-up modalities. Presently, the most recognized screening tools include clinical assessment; measurement of serum thyroglobulin (Tg) by either thyroid hormone withdrawal or recombinant human thyrotropin (rhTSH) stimulation; I131 whole body scan (WBS); and ultrasound (US) examination. These modalities, when used either individually or in combination, have similar values for sensitivity and specificity.

**Serum Thyroglobulin (Tg)**

Serum Tg is a glycoprotein produced by both normal and neoplastic follicular thyroid tissue. In patients who have undergone total, or near total thyroid ablation, there should be no, or minimal, evidence of Tg. As such, routine monitoring of Tg levels using serum Tg immunoassay detects the presence of persistent thyroid tissue or the recurrence of disease. In monitoring serum Tg one must also assess the presence of anti-thyroglobulin antibodies, which are found in up to 15-25% of thyroid cancer patients, and interfere with Tg immunoassay by producing falsely low or undetectable serum Tg levels. Any increase in serum Tg concentrations in a patient following total thyroid ablation is considered suspicious and requires further evaluation with WBS and other imaging modalities.

**Table 3. Thyroglobulin Follow-Up Modalities**

<table>
<thead>
<tr>
<th>Modality</th>
<th>Method</th>
<th>Benefits/Consequences</th>
</tr>
</thead>
<tbody>
<tr>
<td>T4</td>
<td>6 week withdrawal</td>
<td>-free&lt;br&gt;↓ QOL</td>
</tr>
<tr>
<td>T4</td>
<td>3 week withdrawal</td>
<td>-free&lt;br&gt;minimal effect on QOL</td>
</tr>
<tr>
<td>T4→T3</td>
<td>T3x 4 weeks (from T4) then 2 week withdrawal</td>
<td>-cost of T3 x 2 weeks&lt;br&gt;↓ QOL</td>
</tr>
<tr>
<td>rhTSH</td>
<td>2x 0.9mg injections 24hrs apart (NO withdrawal)</td>
<td>-$1500&lt;br&gt;minimal side effects</td>
</tr>
</tbody>
</table>

TSH: thyrotropin; Tg: thyroglobulin; T3, triiodothyronine; rhTSH, recombinant human thyrotropin; QOL, quality of life.

**Thyrotropin Stimulation**

Tg production is stimulated by the discontinuation of thyroid hormone replacement therapy, which in turn stimulates TSH and production of Tg glycoprotein. A rise in the serum level of Tg > 2µg/L in low-risk patients, or >1µg/L in high-risk patients (as per staging and initial Tg level), indicates the presence of recurrent/residual thyroid disease. Measurement of serum TSH-stimulated Tg is accomplished by withdrawal of thyroid hormone thyroxine (T4) therapy for six-weeks, or triiodothyronine (T3) therapy for two-weeks. The six-week hormone withdrawal regimen is associated with prolonged periods of hypothyroidism, which results in significant morbidity, impaired productivity, and reduced quality of life (QOL). The hypothyroid state manifests itself with signs and symptoms such as fatigue, cold intolerance, weight gain, change in appetite, muscle cramps, amenorrhea, constipation, changes in sleep patterns, and changes in appearance. Attempts at rectifying the impact on quality of life include substitution of T4 with T3 therapy for 4 weeks with a subsequent two-week T3 withdrawal period; halving the dose of thyroxine; or a series of intramuscular injections of recombinant human TSH (rhTSH) (Table 3). Golger et al. (2003), investigated the adequacy of a three-week vs. traditional six-week T4 withdrawal regimen for the detection of elevated serum Tg levels; the study illustrates that the three-week hormone withdrawal regimen provides adequate Tg stimulation for the detection of recurrent disease, with minimal impact on QOL.

Recombinant human thyrotropin (rhTSH) represents an alternate approach to the stimulation of serum Tg and has been demonstrated to avoid the hypothyroid effects associated with T4 withdrawal. Two doses of 0.9mg of rhTSH are injected 24 hours apart, allowing the elevated serum TSH levels to stimulate the production of serum Tg (> 2µg/L in low risk patients, or >1µg/L in high risk patients), thereby, indicating the presence of any recurrent/residual thyroid disease. While patients experience no symptoms of hypothyroidism, minor side effects associated with rhTSH include mild nausea and headache.
Studies demonstrate that the sensitivity and specificity of rhTSH vs. thyroid hormone withdrawal in the detection of residual/recurrent thyroid cancer are similar (86% sensitive, 91-100% specific). While eliminating the negative effects of a hypothyroid state imposed by hormone withdrawal, the diagnostic use of rhTSH is associated with a significant increase in cost ($1,500) relative to the cost of thyroid hormone withdrawal (free). The difference in cost of rhTSH and thyroid hormone withdrawal has significant implications for patients who are not covered by a health insurer.

### Iodine-131 Whole Body Scan (WBS)

Iodine-131 whole body scanning (WBS) relies on thyroid tissue uptake of $^{131}$I in the presence of high serum TSH concentrations (>25 µU/mL). TSH stimulation occurs by either thyroid hormone withdrawal or by administration of rhTSH, and facilitates $^{131}$I uptake thus allowing nuclear imaging of residual/recurrent thyroid tissue. Patients are advised to avoid iodine-containing medications and foods one to two weeks prior to the study. Pregnancy, in women of childbearing age, must be ruled out prior to administration of $^{131}$I. WBS is performed 72 hours following the initial dose of 2-5mCi of $^{131}$I; this dose minimizes the possibility of thyroid stunning (interference with subsequent uptake of $^{131}$I for several weeks) seen with high doses of radioactive iodine. Scans are examined for the presence of any thyroid tissue uptake which is dependant on the ability of a tumor to concentrate and retain iodine, and is strongly associated with a high likelihood of persistent or recurrent thyroid carcinoma. While WBS alone has high specificity (100%) for the diagnosis of thyroid cancer, Pacini et al. (2003)6 reported sensitivities as low as 40%. Kasnar et al. (2003)6 report a false negative rate of 15%, and recent studies suggest WBS is minimally informative in patients with an undetectable serum Tg.6 Mazzaferri and Kloos (2001)8 evaluate the use of WBS in follow-up for WDTC, demonstrating that the imaging modality adds almost no diagnostic information to that provided by stimulated serum Tg; this study’s results are supported by those of Cailleux et al. (2000),18 who also suggest avoiding the use of WBS in light of its minimal contribution to the diagnosis of recurrent disease. Both studies emphasize the value of serum Tg stimulation as a tool for diagnosing recurrent/residual thyroid cancer. For the purpose of obtaining a control study, a WBS is performed 6-12 months after thyroid ablation. Following that, studies indicate that WBS is only recommended for the localization of the Tg production site in patients presenting with a rise in Tg concentration associated with TSH stimulation.2

### Ultrasound

High-resolution ultrasound of the neck is a simple follow-up procedure that provides information about the size, location, and features of small masses within the thyroid area. It also offers the advantage of obtaining FNA samples from suspicious lesions for further cytological examination. In a recent retrospective study by Pacini et al. (2003)6 rhTSH stimulation, WBS, and neck ultrasound was used to follow 340 patients who have undergone thyroidectomy and $^{131}$I ablation therapy. Results of neck ultrasound and WBS are compared (Table 4)6 and illustrate the following: rhTSH is highly sensitive in predicting the presence or absence of active disease; WBS has a low sensitivity; and, neck ultrasound is crucial in the detection of small local disease not detected by either Tg or WBS. In fact, when serum Tg is used in conjunction with ultrasound, the diagnostic sensitivity is increased from 85% to 96.3%.6

### Other Screening Tools

Additional diagnostic and follow-up procedures include chest X-ray (CXR), non-contrast Computed Tomography (CT) (contrast may interfere with subsequent $^{131}$I therapy), Magnetic Resonance Imaging (MRI), Positron Emission Tomography (PET), and even bone scans; these studies are warranted when metastatic disease cannot be localized by $^{131}$I imaging, often a result of metastases that fail to concentrate $^{131}$I, and an indication of a more aggressive clinical course. CXR, CT, MRI, and bone scans are relatively easy to obtain and are commonly used to localize tumors in the head and neck, chest and bones. Fluorine-18 fluorodeoxyglucose (FDG) PET scans represent a new non-iodine radionuclide-imaging tool able to detect recurrence or metastases with a high degree of sensitivity (80-90%) in patients whose bodies, for whatever reason, are unable to concentrate $^{131}$I. PET uses FDG to demonstrate enhanced glucose uptake expected from cancerous cells, thereby localizing the lesion.19

A relatively new molecular diagnostic screening tool includes using Tg mRNA as a tumor marker to detect the presence of cancer by making use of reverse transcriptase polymerase chain reaction (rt-PCR) technology. rt-PCR detects Tg mRNA in patients with normal functioning thyroid tissue, non-malignant thyroid disease, and in patients with residual/recurrent thyroid disease following surgical and ablative treatment. A prospective study by Grammatopoulos et al. (2003)12 examines 28 patients on TSH suppressive treatment and demonstrates that rt-PCR is a more sensitive and accurate, but less specific, diagnostic tool for the detection of Tg as compared to immunoassay in this patient population (Table 5).12 The primary benefit of rt-PCR is its use in patients with an elevated serum Tg, and positive anti-Tg antibodies, because it is able to detect Tg mRNA in the presence of anti-Tg antibodies.

---

**Table 4. Comparison of Diagnostic Accuracies of Different Tests in Detecting or Excluding Loco-Regional Disease**

<table>
<thead>
<tr>
<th>Test</th>
<th>Sensitivity%</th>
<th>Specificity%</th>
<th>PPV%</th>
<th>NPV%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Neck US</td>
<td>70</td>
<td>97.5</td>
<td>77.7</td>
<td>92.4</td>
</tr>
<tr>
<td>I$^{131}$ WBS</td>
<td>40</td>
<td>100</td>
<td>100</td>
<td>91</td>
</tr>
<tr>
<td>Stimulated Tg</td>
<td>78.2</td>
<td>100</td>
<td>100</td>
<td>98.6</td>
</tr>
</tbody>
</table>

US, ultrasound; I$^{131}$ WBS, iodine-131, whole body scan; Tg, thyroglobulin
Table 5. Comparison of Tg mRNA Assay with Tg immunoassay

<table>
<thead>
<tr>
<th></th>
<th>Tg mRNA</th>
<th>Tg immunoassay</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensitivity</td>
<td>93%</td>
<td>71%</td>
</tr>
<tr>
<td>Specificity</td>
<td>70%</td>
<td>80%</td>
</tr>
<tr>
<td>Accuracy</td>
<td>84%</td>
<td>75%</td>
</tr>
</tbody>
</table>

Tg mRNA, thyroglobulin messenger RNA

CONCLUSION

Well-differentiated carcinomas occur infrequently in the population and can be diagnosed easily with clinical exam, ultrasound, and FNA. They are among the most curable of cancers when treated with lobectomy, thyroidectomy, and iodine ablative therapy as indicated. The risk of recurrence, however, is considerable and is greater with certain histological variants, and the aforementioned prognostic indicators. As delayed detection and treatment of primary and recurrent/residual disease has a significant effect on mortality, it is important to provide adequate follow-up for patients post-operatively to prevent missed diagnoses. The follow-up of WDTC may differ based on the initial mode of treatment. For conservative therapy (lobectomy plus isthmectomy) $^{131}$I scans and measurement of serum Tg cannot be employed as remaining healthy thyroid tissue is left in situ and will produce positive results in all patients. Follow-up then relies on clinical examination, neck ultrasound, in addition to other imaging studies such as CT or MRI. If, however, treatment involves total or near-total thyroidectomy with post-surgical ablation, patients with no evidence of anti-Tg antibodies can be followed using periodic TSH stimulation by thyroid hormone withdrawal or rhTSH, to monitor any rise in Tg >2 µg/L in low risk patients, or >1 µg/L in high risk patients (as per staging and initial stimulated Tg). While a relatively new diagnostic tool, rt-PCR may have an important future role in patients who test positive for anti-Tg antibodies.

In general, following thyroid ablation, patients are maintained on a thyroid hormone supplement regimen at a level that maintains TSH suppression < 0.1µU/ml if high risk, and between 0.1-0.4 if low risk. This level not only suppresses TSH, but also prevents symptoms of hypothyroidism and minimizes any adverse cardiac and bone effects. A baseline $^{131}$I WBS is then obtained at 6-12 months following initial treatment to assess the presence of any residual thyroid uptake, and provide a control for any future scans. Following that, providing anti-Tg antibodies are negative, TSH stimulated serum Tg levels, by either thyroid hormone withdrawal or rhTSH, are measured at 6-12 month intervals depending on patient risk. Levels are then assessed one more time, after the initial 6-12 month follow-up, and then as necessary thereafter. This is considered, according to recent literature, as sufficient to detect residual/recurrent WDTC. Studies by Pacini (2003) and Cailleux (2000) indicate that an undetectable serum Tg, in the presence of TSH stimulation, is highly predictive of disease-free status. In conjunction with this, $^{131}$I and WBS, or ultrasound evaluation, can be employed as desired to further increase the sensitivity of Tg monitoring. With any rise in serum Tg >2µg/L (low-risk), >1µg/L (high-risk), further evaluation is warranted and can include WBS, US, CT, MRI, or PET to localize the presence/absence of thyroid tissue. The localization of recurrent/metastatic uptake may then lead to further ablative treatments with radioactive iodine, surgical intervention, external beam radiation, or chemotherapy as required.

ACKNOWLEDGEMENTS

The authors wish to thank Bosco Lui, Sonja Reichert, and Sarah McMullen.

REFERENCES

THE CASE

Mr. S is a 66-year-old man who recently presented to his family doctor with a one month history of epigastric pain and nausea. His pain was persistent, dull and increased with eating. He had never experienced this pain before. He had also had a few months’ history of weight loss and noticed a decreased abdominal girth, with his clothes fitting more loosely. He denied any dysphagia, changes in bowel movements, melena or hematochezia. He did not have a history of peptic ulcer disease or gastroesophageal reflux disease (GERD). His past medical history included coronary artery disease with a myocardial infarction in 1993, and a coronary artery bypass graft (CABG) six years prior. He had a 30-pack-year history of smoking, but had quit smoking ten years ago. He had also had a chronically low vitamin B12 level and received monthly injections. His current medications include metoprolol, atorvastatin and aspirin. He is married and has six children. He drinks alcohol only on special occasions.

What is the Differential Diagnosis from the Patient’s History?

Epigastric pain and nausea are non-specific symptoms that can generate a broad differential diagnosis. These diagnoses range from those that are benign and can be treated conservatively, to those that are malignant and require more aggressive intervention. The differential diagnosis at this time for Mr. S includes peptic ulcer disease or gastroesophageal reflux disease (GERD). His past medical history included coronary artery disease with a myocardial infarction in 1993, and a coronary artery bypass graft (CABG) six years prior. He had a 30-pack-year history of smoking, but had quit smoking ten years ago. He had also had a chronically low vitamin B12 level and received monthly injections. His current medications include metoprolol, atorvastatin and aspirin. He is married and has six children. He drinks alcohol only on special occasions.

Gastric Carcinoma: An Unexpected Diagnosis

Dr. Catherine Hanley, BSc(OT), MD

Gastroesophageal reflux or gastritis are certainly other diagnostic possibilities for Mr. S’s presentation. The pain of reflux is of a burning nature, can be worse at night and is exacerbated by irritants such as alcohol, aspirin and caffeine.3 Gastritis can also cause epigastric pain, and can be associated with these same caustic agents. GERD and gastritis can both cause nausea and vomiting in patients, but is not usually accompanied by weight loss. Both are best diagnosed by endoscopy, and often an improvement in symptoms with empirical treatment (H2 blockers or proton pump inhibitors), as well as lifestyle changes, can help to confirm the diagnosis.3

Considering an upper GI malignancy in the differential diagnosis – specifically an esophageal malignancy – one would typically observe the presence of varying degrees of dysphagia in these neoplasms. Gastric malignancy, on the other hand, often have episodes of postprandial pain (especially following fatty meals), and their pain usually begins abruptly and subsides gradually after a few minutes to several hours.1 Nausea and vomiting can occur during attacks of biliary colic, but not usually between attacks. Weight loss and anorexia are not common symptoms. Pain is episodic and usually localized to the right upper quadrant, but can be felt across the epigastrium and through to the back, or referred to the area overlying the scapulae. Liver enzymes, as well as leukocyte counts, are usually normal in patients with biliary colic. An ultrasound is the gold standard diagnostic test for cholelithiasis, with both a specificity and sensitivity of 95%.1

Pancreatitis is also on the differential diagnosis for Mr. S. In acute pancreatitis, signs and symptoms may include a very tender epigastrium with guarding, fever, nausea and profuse vomiting. Bloodwork often demonstrates a moderate leukocytosis, (usually not higher than 12,000/UL) as well as elevated amylase and lipase levels.1 In the case of chronic pancreatitis, one would expect Mr. S to be experiencing intermittent epigastric pain, as well as weight loss due to malabsorption.3 Further, abdominal ultrasound would potentially show pancreatic abnormalities. That being said, CT remains the best method to rule out chronic pancreatitis, as it has the greatest sensitivity for showing gland enlargement, atrophy, inflammation or calcification.3 Gallstones represent the most common etiology of pancreatitis, accounting for 60% of all cases. Alcohol consumption accounts for most of the remaining 40%.3

Gastroesophageal reflux or gastritis are certainly other diagnostic possibilities for Mr. S’s presentation. The pain of reflux is of a burning nature, can be worse at night and is exacerbated by irritants such as alcohol, aspirin and caffeine.3 Gastritis can also cause epigastric pain, and can be associated with these same caustic agents. GERD and gastritis can both cause nausea and vomiting in patients, but is not usually accompanied by weight loss. Both are best diagnosed by endoscopy, and often an improvement in symptoms with empirical treatment (H2 blockers or proton pump inhibitors), as well as lifestyle changes, can help to confirm the diagnosis.3

Considering an upper GI malignancy in the differential diagnosis – specifically an esophageal malignancy – one would typically observe the presence of varying degrees of dysphagia in these neoplasms. Gastric malignancy, on the other hand, often
presents with insidious upper abdominal discomfort, as well as nausea and weight loss (see Table 1). Other clues pointing to a gastric malignancy include anemia or positive fecal occult stool samples. Though a double contrast upper gastrointestinal series is 95% sensitive for diagnosing gastric carcinoma, endoscopy with biopsy remains the most sensitive method of establishing this diagnosis. Pancreatic malignancy is also included on the list of differential diagnoses for Mr. S, though patients usually present with pain, weight loss and jaundice. The best initial diagnostic test for pancreatic malignancy is a CT scan.

### Table 1. Presenting Symptoms of Gastric Cancer

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Weight loss</td>
<td>62%</td>
</tr>
<tr>
<td>Abdominal Pain</td>
<td>52%</td>
</tr>
<tr>
<td>Nausea</td>
<td>34%</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>26%</td>
</tr>
<tr>
<td>Melena</td>
<td>20%</td>
</tr>
<tr>
<td>Early Satiety</td>
<td>18%</td>
</tr>
<tr>
<td>Ulcer-type pain</td>
<td>17%</td>
</tr>
</tbody>
</table>

The case:

On examination, the patient appeared pale and there was some mild epigastric tenderness. No masses were palpated, and no peritoneal signs, such as acute generalized abdominal pain, rebound tenderness or guarding, were present. At this time, the family physician did bloodwork, specifically looking for *Helicobacter pylori*, while starting Mr. S empirically on triple therapy for *H. pylori* eradication (omeprazole, clarithromycin, metronidazole). He was then referred to a gastroenterologist for endoscopy.

When Mr. S’s bloodwork came back, it revealed the presence of *H. pylori* antibodies at a level of 50.9 U/mL (normal ≤ 15U/mL). However, there were no signs of anemia (hemoglobin 148g/L), and all other bloodwork, including liver enzymes, was normal. Serum amylase and lipase, as well as fecal occult blood testing were not done. An abdominal ultrasound showed no cholelithiasis or other abnormalities.

**How Significant is H. pylori?**

Studies have shown a consistent association between *Helicobacter pylori* and risk of gastric cancer. Those with *H. pylori* infection have a 3.6 to 18-fold higher risk of gastric carcinoma of the body or antrum of the stomach than those without infection. This association is seen largely with intestinal-type cancers and seems to be proportional to the serum levels of *H pylori* antibodies. Although the exact role of *H. pylori* in gastric carcinogenesis is unclear, it is associated with the development of chronic atrophic gastritis – a known precursor to gastric carcinoma (see Table 3).
amounts of blood. When an anterior gastrootomy was performed, a very large ulcer crater (greater than 10cm in diameter) was present on the posterior wall and had eroded through the stomach wall, into the splenic artery and pancreas (Figure 1). A partial gastrectomy and gastrojejunostomy were performed with clips being applied to both ends of the splenic artery lying in the bed of the ulcer (Figure 2). The ulcer bed included the pancreas, and the stomach had to be resected around the ulcer bed. During surgery, the splenic artery continued to bleed, sending Mr. S into hypovolemic shock, with a hemoglobin down to 30g/L and a platelet count of 3 x 10^9/L.

During the surgery, Mr. S arrested. He was given fresh frozen plasma and over 10 units of blood. Mr. S left the operating room three hours later in stable condition with a systolic blood pressure of 80mmHg.

**Why Did He Bleed?**

The differential diagnosis for upper gastrointestinal hemorrhage includes peptic ulcers, esophageal varices, gastritis and Mallory-Weiss syndrome. Uncommon causes include gastric carcinoma, pancreatitis and esophagitis. According to the Classification of Hemorrhagic Shock, Mr. S experienced a Class 4 hemorrhage, meaning greater than 40% (or 2000mL) of blood volume lost. He also developed a coagulopathy as his INR (which had been normal prior to surgery at 1.2) climbed to 4.3. This was likely due to massive blood loss (and thus platelet loss) as well as the dilution of clotting factors from his multiple red blood transfusions. In addition, shock can either cause or aggravate disseminated intravascular coagulation (DIC). Hypotension that leads to stasis can prevent normal circulating inhibitors of coagulation from reaching sites of microthrombi and DIC can be the result. With severe DIC, replacement of coagulation factors is accomplished through cryoprecipitate or fresh frozen plasma. Platelet transfusions can also be required as they were in the case of Mr. S.

**THE CASE**

Mr. S remained in the ICU for eight days postoperatively. His hemoglobin stabilized at 80g/L, and there was no further evidence of active bleeding. A gastrograftin study post-operatively demonstrated that much of the gastrograftin refluxed into Mr. S's esophagus and did not pass into the efferent loop of his anastomosis (Figure 3). The afferent loop of the gastrojejunostomy was identified on endoscopy, but not the efferent loop (Figure 3). The black, necrotic area of the stomach is around the ulcer bed. These edges were biopsied and adenocarcinoma was found on pathology.

There were two lesser omental lymph nodes sampled, and one of these positive for metastatic adenocarcinoma. Five greater omental lymph nodes were negative for malignancy.

**How is Gastric Carcinoma Classified?**

<table>
<thead>
<tr>
<th>Stage</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIA</td>
<td>T1 tumor invades lamina propria or submucosa (T1) without nodes</td>
</tr>
<tr>
<td>IIB</td>
<td>T1 tumor with metastasis in 7 to 15 lymph nodes (N2) or T2N1 or T3N0 (penetrates serosa)</td>
</tr>
<tr>
<td>IIIA</td>
<td>T2 tumor with N2 nodes or T3 tumor with N1 nodes or T4 tumor (adjacent structures)</td>
</tr>
<tr>
<td>IIIB</td>
<td>T3 tumor with N2 nodes</td>
</tr>
<tr>
<td>IV</td>
<td>T1-3 tumor with N3 or T4 tumor N1-3 or any T, any N M1 (distant metastasis)</td>
</tr>
</tbody>
</table>

As was the case for Mr. S, most patients with gastric carcinomas have tumors in the distal stomach (body and antrum). However, the incidence of proximal gastric malignancies is increasing. This appears to be correlated with an increase in the incidence of Barrett’s esophagus. The gold standard for diagnosing gastric malignancies is endoscopy, specifically when ulcerated lesions can be viewed and biopsied (Figure 3). Most gastric malignancies are adenocarcinomas. Advanced carcinomas, such as the one found in Mr. S, are the most common malignancy (35%) where a large tumor is found partly within and partly outside the stomach. Gastric adenocarcinomas can also be classified in terms of differentiation of cells; usually, the rate and extent of spread correlates with lack of differentiation. In Mr. S, his tumor cells were of the moderately differentiated,
intestinal glandular type, carrying with it a better prognosis than the diffuse-cell type. Three quarters of patients with gastric adenocarcinoma have metastases on initial presentation. The staging of gastric cancer is outlined in Table 2.

The mean age of diagnosis for gastric cancer is 63, and is twice as common in men as it is in women. In terms of specific precursor conditions to gastric carcinoma present in Mr. S, his pathology report showed chronic atrophic gastritis with intestinal metaplasia. As well, Mr. S had a chronically low vitamin B12 level – potentially indicating a diagnosis of pernicious anemia – which is also a precursor to gastric adenocarcinoma. It is not known whether Mr. S had a Schilling’s test as an investigation for pernicious anemia. Other factors that may have predisposed Mr. S to gastric cancer would certainly be his past history of infection with *H. pylori*, as well as a 30-pack-year history of cigarette smoking. Other risk factors and precursor conditions are listed in Table 3.

Although there has been an overall decline in the incidence of gastric cancer, it still remains the second most common cause of cancer-related death in the world. Unfortunately, patients with gastric cancer typically present once their condition has already metastasized. In terms of cure, the only option is resection. About 85% of patients are operable for this condition, and 50% of tumors can be resected. Surgically, the tumor should be removed with uninvolved margins, as well as an excision of regional lymph nodes. A Billroth I (partial gastrectomy and gastroduodenotomy) or II (partial gastrectomy and gastrojejunostomy) procedure is often performed (Figure 2). Gastric carcinoma is relatively resistant to radiotherapy and no survival benefit to radiotherapy alone after resection has been demonstrated. Adjunctive chemotherapy is also used in gastric cancer alone or to augment radiotherapy. Although it has been shown to reduce tumor mass in gastric cancer, as well as eradicating micrometastases along with radiotherapy after resection, large randomized trials have consistently shown that adjuvant chemotherapy offers no increased survival benefit over surgical resection of gastric carcinoma.

RESOLUTION

On post-operative day 11, Mr. S was very stable, mobilizing, passing flatus and bowel movements. His left upper quadrant fluid collection was drained percutaneously under radiologic guidance. At the time of writing, Mr. S remained in hospital six weeks after his admission, and continued stable. He was likely to have a jejunostomy feeding tube placed, as another surgery to repair his anastomosis would be difficult secondary to inflammation and necrotic tissue. Sadly, in patients like Mr. S with Stage 4 disease (T4, N1, M0), the five year survival rate is only in the range of 0-9%.1,5

ACKNOWLEDGEMENTS

Dr. R. A. Kessaram, General Surgeon, for his role in saving this patient’s life.

AUTHOR BIOGRAPHY

Catherine Hanley is a first year general surgery resident at McMaster University, having graduated from McMaster’s undergraduate medical program in the spring of 2004. She has a Bachelor of Science degree in Occupational Therapy which she received from the University of Western Ontario in 1991. She had been a practicing pediatric occupational therapist for many years before starting her medical training.

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Located in scenic Ottawa, Queensway Carleton Hospital is a patient and family-centred urban community hospital. Providing a broad range of progressive acute care services to the people of Ottawa and the Ottawa Valley, cornerstone programs include: Emergency, Childbirth, Geriatrics, Mental Health, Acute Rehabilitation, Medical and Surgical Services. With a strong focus on the future, QCH will soon be expanding and improving its setting, as a redesign and expansion of its facilities are currently underway to meet the needs of a fast-growing community.

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THE IMPORTANCE OF ECONOMIC EVALUATIONS IN MEDICINE

Research techniques for economic analysis are well-established,1 however, it was not until the early 1990s that the medical literature began to include many examples of such analyses. Given the scarcity of resources such as people, time, equipment, and knowledge, and in light of the ever-increasing demands placed on our healthcare system, caregivers are now being asked to consider cost in their clinical decisions in an effort to obtain greater value for money. As such, many professionals working in areas of health policy and health practice now require some understanding of health economic principles and methods.

In order to achieve such an understanding, three important and unique principles of economic evaluations must be considered:2 (1) Systematic Evaluations. Unless evaluations are performed in a systematic manner, identifying relevant alternatives to an intervention will be difficult. For example, when evaluating the outcomes of CO₂ laser resection of a laryngeal tumour, one must consider outcomes from currently available alternatives (i.e., radiation therapy, chemotherapy, and/or laryngectomy). (2) Study Perspective. The analysis must also consider which viewpoint makes the most sense in a given context. Though a treatment may seem unattractive from one perspective, the same may not be true when looking at outcomes from another vantage-point. Perspectives to consider include those of the patient, the institution providing treatment, the government paying for some (or all) of the treatment, and society. Consider using preoperative imaging in the surgical treatment of primary hyperparathyroidism: from the patient’s perspective, preoperative imaging results in more efficient localization of the offending parathyroid adenoma thus reducing the intraoperative time, in addition to minimizing both the surgical exploration to which the patient is subjected and the time spent under general anaesthesia. From a hospital standpoint, however, performing such imaging is expensive and time-consuming, and does not change patient-care management, therefore it is not as enticing. (3) Cost and Outcome Measurements. The ability to measure the costs and outcomes of alternative choices is critical for a meaningful economic evaluation. This is often important in the analysis of potentially novel screening methods. For example, in the evaluation of diabetic retinopathy screening by mydriatic indirect ophthalmoscopy using a slit lamp, the costs and outcomes of this screening method require comparison to the costs and outcomes related to diabetic retinopathy testing, diagnosis and treatment.3 Following the analysis, the ability to measure the magnitude of the effect of the ensuing decision (given a certain perspective) allows health economists to realize the opportunity cost of a decision, i.e. the cost of choosing to commit a certain amount of resources to a particular program over another.

HEALTH POLICY AND ECONOMICS

Getting Better Value for Money: The Use of Economic Evaluations in Several Surgical Subspecialties

S. Naweed Raza, MD
Junaid Yousuf, BSc
Kashif Yousuf, BA (Hons)
S. Daniel Raza

ABSTRACT

Health care economic analyses are becoming increasingly important in guiding health care resource allocation decisions. This paper defines the components of a full economic evaluation and highlights the four types of economic evaluations, using examples from surgical subspecialties, namely otolaryngology and ophthalmology. The economic evaluations discussed include (1) cost-minimization analyses; (2) cost-effectiveness analyses; (3) cost-benefit analyses; and (4) cost-utility analyses. The significance for clinicians of this focus on economics within the health care system is also addressed.
WHAT IS AN ECONOMIC EVALUATION?

Health care professionals often oversimplify the term “economic evaluation” due to a lack of understanding of what it encompasses. A recent study by Kezian and Yueh (2001) examined articles in several peer-reviewed otorhinolaryngology journals whose titles indicated different types of economic analysis, and reviewed both their use of terminology as well as established methodology guidelines. Of those reviewed, 53% of terms such as “cost-effective” were used incorrectly, and 60% confused “charge” (i.e., the price set by an institution) and “costs” (i.e., the true value of all resources consumed). Overall, the use of accepted definitions and research methods was inconsistent. This is an important finding as it demonstrates that even health care professionals who conduct economic evaluations often misunderstand and misuse economic terminology and methodology, which may in turn lead to incorrect conclusions among health care decision makers.

An economic evaluation is comprised of two key features (Table 1); it must deal with costs and consequences, and must also concern itself with a choice between alternatives. Therefore, any type of economic evaluation must identify, measure, value, and finally, compare the costs and the consequences of each alternative being evaluated. Without these characteristics, the analysis is considered a partial evaluation. A full economic evaluation, in contrast, takes into account both the costs and consequences of proposed alternatives, and is conducted using one of four different methodologies. In order of increasing complexity, these include (1) cost-minimization analysis; (2) cost-effectiveness analysis; (3) cost-benefit analysis; and (4) cost-utility analysis.2,5,6

### Table 1. Distinguishing Characteristics of Health Care Evaluations

<table>
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</tr>
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<td>Partial Evaluation</td>
</tr>
<tr>
<td>Costs only</td>
<td>Cost description</td>
<td>Cost-utility description</td>
</tr>
<tr>
<td>Cost-utility description</td>
<td>Cost-utility description</td>
<td>Cost-utility description</td>
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</tbody>
</table>


### 1. Cost-minimization analysis

Cost-minimization analysis represents the simplest of the four types of analyses, and compares at least two alternatives (diagnostic tools, preventive interventions, treatments, etc.). It is assumed that all alternatives have the same outcome, and as a result, it is not possible to compare just two alternatives. For instance, in evaluating two surgical procedures for a given illness, surgical outcomes may differ: one may cause significant post-operative morbidity secondary to pain, whereas the other may contribute more significantly to the patient’s time lost from employment. Complication rates in comparing various procedures can often be quite different. For this reason, cost-minimization analyses are quite restricted. Ultimately, the goal of the analysis is to find the treatment option that yields the lowest cost per patient treated; the analysis may consider various costs that the patient, institution, government, and society will face in light of the intervention, thus allowing one to determine which represents the least costly alternative.

A good example of how this type of analysis has been implemented within the field of ophthalmology is the comparison among different approaches to cataract surgery presented by Cresswell et al. (1996). Not surprisingly, the investigators were able to demonstrate similar clinical outcomes, but at a lower cost when the surgery was performed at an institution dedicated solely to cataract surgery versus a facility where all forms of ophthalmic surgery are conducted.

### 2. Cost-effectiveness analysis

Because the outcomes of different interventions are rarely the same, a method is required that incorporates the end-results of trials comparing these interventions; cost-effectiveness analysis represents an extension of cost-minimization analysis. The objective of conducting a cost-effectiveness analysis is to show the relative costs and consequences of alternative interventions for improving health. It measures the resources spent for a given endpoint, such as years of extended life, disability avoided, diagnosis or any other end result. Thus for example, in considering two different forms of cancer therapy, a cost-effectiveness analysis may compare the cost of extending a patient’s life by one year for each treatment.

Wilson et al. (2003) recently conducted a study examining the cost-effectiveness of intraoperative facial nerve monitoring in middle ear or mastoid surgery. The routine use of facial nerve monitoring is quite controversial, despite its utility in reducing the risk of iatrogenic facial nerve injury during neurosurgery. A major barrier to its acceptance is reportedly cost. To assess this further, comparisons were made between intraoperative facial nerve monitoring for both primary and revision middle ear or mastoid surgeries, facial nerve monitoring for revision surgeries only, and no monitoring for any of those surgeries. Taking into account patient outcomes and costs for each of the aforementioned groups, facial nerve monitoring has been shown to be cost-effective compared to no monitoring at all, leading Wilson et al. (2003) to recommend its routine use in order to reduce the risk of iatrogenic facial nerve injury during otologic surgery.
3. Cost-benefit analysis

In contrast to cost-effectiveness analysis, cost-benefit analysis represents a more universal way of performing an economic evaluation, in that this approach takes into account situations in which two alternatives may have multiple consequences, each of which may be of interest. Cost-benefit analysis measures both the costs and the outcomes of interventions in units of currency (e.g., dollars); that is to say, one can compare the cost of a treatment to the monetary benefits of improved survival (using income, or value of leisure time), with results often expressed as dollars spent for dollars gained. Although this type of economic evaluation is quite straightforward to interpret, there are often significant barriers with respect to translating health outcomes to dollar amounts. For example, it can be difficult to take into account the quality of life associated with a given health state.5

There have been relatively few cost-benefit analyses performed within the field of ophthalmology. However, Javitt et al. (1999) conducted a study addressing the cost-benefit of controlling retinopathy in Type 1 diabetes. In order to do this, a computer simulation model was designed to predict the medical and economic effects of applying currently accepted methods for the control of diabetic retinopathy. Over a period of 60 years, the model predicts that 72% of Type 1 diabetics will develop proliferative diabetic retinopathy and that 42% will develop macular edema. If treatments are delivered as recommended in current clinical trials, the model predicts a cost of $966 per person-year for vision saved from proliferative retinopathy, and $1,118 per person-year of central acuity saved from macular edema. This accounts for only one-seventh of the $6,900 average annual cost of Social Security Disability for those disabled with vision loss in the United States.

4. Cost-utility analysis

Cost-utility analysis brings outcome measures to a higher level by incorporating patient preferences to measure the value of the intervention. As a result, the term “value-based medicine” has been introduced by a group of researchers. This form of economic evaluation is perhaps the most complicated of the four methodologies, employing utility as a measure with which to value benefit by providing a numerical score that patients attach to individual states of health. As a result, utility is specific to an individual patient despite the fact that the clinical outcome may be the same for many patients.

Consider two patients who both suffer end-stage glaucoma, and have almost completely lost their eyesight. One is a truck driver and the other, a professional singer. When comparing the two, eyesight has much more value for the truck driver than for the singer, which translates into the truck driver having a higher degree of benefit from treatment than the singer, even though treatment outcomes are the same. Utility, therefore, is very case-specific.

Cost-utility analyses use Quality Adjusted Life Years (QALY) gained as the unit of measurement in order to gauge benefit. The advantage of using a QALY score as a measure of health benefit is that it encompasses both a reduction in morbidity (quality of life gained) and mortality (quantity of life gained). This form of analysis compares the QALY gained from two forms of treatment to their respective costs in dollars. The superior treatment is determined by whichever yields the greater QALY gained per case.

Many of the cost-utility analyses in the otorhinolaryngology literature pertain to the use of cochlear implants. One study by Wyatt et al. (1996) addressed the cost-utility of the cochlear implants in a group of Ontario residents. The study compared the health utility of 229 Nucleus 22-channel implant users and 32 cochlear implant candidates receiving medical treatment. Through methods described in the paper, the health utility of the implanted group was found to be greater than the group of people awaiting surgery by 0.204 (P<0.0001). Cost-utility calculations revealed that cochlear implantation costs were approximately $15,928 per QALY gained through surgical cochlear implantation. It was determined that since hearing loss reduces quality of life significantly, cochlear implants, which provide considerable improvements in hearing, largely improve the health utility of patients. Therefore, the cost of cochlear implantation per QALY provided is significantly lower than other medical interventions that do not improve health utility by the same degree.

IN SUMMARY

Health economic analyses ultimately aim to guide more efficient expenditure of healthcare dollars, and to permit stakeholders within the healthcare system to appreciate the value of a given intervention in light of the amount of expended resources. By conducting and understanding such analyses, physicians and other healthcare workers will be able to achieve greater value per dollar spent.

Unfortunately, many studies in the literature are confusing as they refer to any or all economic evaluation methods as cost-effectiveness analyses when, in reality, the analysis being conducted may either represent a cost-minimization, cost-benefit, or cost-utility analysis. Economic analyses are often complex and understanding them requires training that is not usually part of a standard medical education. As depicted by Keziran and Yuek (2001), investigators are not always aware that terms, such as “cost-effective”, have specific meanings. Since economic analyses are increasingly being used to inform healthcare management and policy decisions, it is becoming increasingly important that such studies are carried out using standard and well-defined terminology and research methods. Authors, reviewers, and readers must be aware of the fundamental components of an economic analysis, and the distinction between the four types of analyses in order to ensure that these studies are both conducted and interpreted appropriately.
ACKNOWLEDGEMENTS

The authors would like to thank Staff Advisor Dr. John Lavis, in addition to Dr. Greg Stoddart for their support and guidance in the preparation of this paper.

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INTRODUCTION

In the Canadian public health arena, the last 50 years have been witness to a host of non-communicable conditions replacing many infectious diseases as health care’s primary concern. Currently receiving a lot of media attention is the increasingly sedentary lifestyle of North Americans. High television ratings, video game sales and increasing computer usage, among other factors, help account for trends of physical inactivity among adults and their children.4,5 Compounding the problem of inactivity is that fast foods have become a mainstay of the North American diet, replacing more nutritious eating habits. As a result of these changes in lifestyle, obesity rates – both a national and global concern – will continue to rise, impacting on existing health care systems due to increases in the frequency and severity of debilitating chronic and/or fatal conditions such as diabetes, cardio- and cerebrovascular disease.2,6-11

In recent years, most indicators have pointed to better health and longer average life spans in industrialized countries than ever before.1,2,6-12 Canada has followed this trend, reporting a record life expectancy at birth of 79.2 years in 2003.12 Much of the credit for this is ascribed to improvements in science, medicine and technology. What is worrisome, however, is that current demographic trends may soon have an impact on life expectancy rates, thus limiting much of the progress made in the past half century. With respect to obesity, for example, it is well documented that many gains in fighting heart disease, diabetes and several forms of cancer will suffer regression if the obesity epidemic is not adequately addressed.9 Child and youth obesity rates continue to reach record levels, and without greater prevention efforts, health care systems will not have the capacity to address the needs of future populations.

The Problem

Cardiovascular morbidity, diabetes and cancers already represent substantial burdens on the health care system, and some predict that these will be the “big three” non-communicable diseases of the future. These three have particularly affected the industrialized world, severely impacting human health, and exposing the limits of current health care practices.2,6,13,14 As of 1999, approximately 1 in 3 adult Canadians suffered an increased risk of premature mortality or a combination of the following conditions due to excess body weight: cardiovascular disease (CVD), type-2 diabetes, stroke, hypertension, dyslipidemia, gallbladder disease, mental anxiety and various forms of cancer.2,15-23 As of 2000, approximately 10% of all mortality among those aged 20-64 is attributable to being overweight and obesity.24 Between 1994-2001, the number of obese adults in Canada, indicated by a body mass index (BMI) of 30 or
higher, rose from roughly 500,000 to almost 2.8 million, or approximately 15% of the total adult population.\textsuperscript{1,2} A study on economic impacts of obesity in Canada conservatively estimates that the cost of obesity exceeds $1.8 billion, or 2.4% of all annual health care expenditures for disease.\textsuperscript{2} This, along with a 2000-2001 survey indicating that 3.2 million, or 1 in 10 Canadians had unmet health care needs,\textsuperscript{1} confirms that obesity in Canada is helping strain the system beyond its limits.

As the aforementioned “big three” represent predominantly lifestyle diseases, increased prevention must become a priority. Though each has an identified genetic component, they can often be adequately controlled by healthy day-to-day habits including regular exercise and a proper diet.\textsuperscript{2,6,7} Obviously, if preventative measures are not improved over the immediate next decades, our health care system will become increasingly overburdened, putting further financial strain on already taxed governments. Indeed better prevention has long been promoted by health professionals and most recently, by extensive media coverage inspired by new research and renewed anti-obesity agendas undertaken by large public health organizations such as the World Health Organization and the US Center for Disease Control and Prevention. In addition to the media blitz about an obesity epidemic, overweight or ‘at-risk’ patients followed regularly by their family physicians are warned of potential health implications and encouraged to lead healthier lifestyles, all of which contribute to an improved general awareness of obesity-related consequences.

Countering these gains, however, are aggressive marketing campaigns by manufacturers of nutrient-poor foods and products associated with physical inactivity. Beyond advertising, artificial and junk foods are often priced lower than healthy eating options, making them a more convenient purchase for an individual or family on a limited financial budget. As obesity rates have continued to rise, preventative measures currently in place have been ineffective in countering external environmental pressures pushing the epidemic forward. In its most recent systematic review of interventions for preventing childhood obesity, the Cochrane authors assessed all programs targeting diet, lifestyle and physical activity concerning obesity between 1985-mid 2001, and inferred that no concrete conclusions could be drawn on the effectiveness of such programs as little quality evaluative data exists.\textsuperscript{25} A recent roundtable discussion on Obesity in Canada confirmed this conclusion by expressing concern for the lack of available evidence on the impact of interventions on obesity.\textsuperscript{26}

Children that grew up in the 1970s may be thought of as the inaugural fast food generation, the first group raised in an environment of ubiquitous and highly successful fast food marketing.\textsuperscript{27,28} In 2004, this fast food culture is so deeply entrenched as to be the norm. Combine this with increased access to physically inactive recreational choices, and an environment that virtually encourages obesity is created. Both childhood and young-adult obesity rates support these statements; the prevalence of child (aged 7-13 years) obesity continues to rise steadily, having already more than tripled from 5% of boys and girls in 1981, to 17% of boys and 15% of girls in 1996.\textsuperscript{1,2,3} Furthermore, it is well documented that overweight and obese children will likely remain overweight or obese throughout adulthood, severely impacting upon quality as well as length of life.\textsuperscript{3,6-9,13,29-31}

As today’s youth age, their latter years will be much different than those of the current population of senior citizens. At present, a newborn Canadian has a life expectancy of 79.2 years\textsuperscript{1} — a statistic based largely upon history, environmental conditions and scientific progress.\textsuperscript{12} Though there are exceptions, this mean age is likely to be met or exceeded by those in good health within an ideal weight range for their height. Correlations between child, adolescent and adult obesity with mortality indicate a substantial reduction in life expectancy when compared to the rest of the population.\textsuperscript{2,8-11,13,29-31} Large scale, long-term monitoring studies of obese populations have inferred life expectancy reductions in the 13 year range.\textsuperscript{8,9} When controlled for factors such as gender or smoking habits, individuals with a BMI of at least 30 continued to show a mean reduction in life expectancy of 7 years, and the probability of premature death has been demonstrated to increase with each unit of increase in BMI.\textsuperscript{8}

As mentioned previously, obesity has risen to the number two risk factor for cardiovascular disease, and becomes number one when considered in combination with cigarette smoking.\textsuperscript{23} While other leading risk factors such as genetics cannot be modified, it is possible for smoking and obesity to be addressed through preventative measures based on lifestyle and environmental channels. Aggressive anti-tobacco education and advertising, in combination with inflated taxes on cigarette purchases, have contributed to reductions in smoking rates, especially among youth.\textsuperscript{32,33} Though fast food, physical inactivity and certain advertising to children continue to feed the obesity epidemic, comparable campaigns to the tobacco fight have yet to be attempted in Canada against any of these factors.

**CONSEQUENCES OF INACTION**

When predicted years of life lost due to obesity are measured against normal life expectancy levels, an obese Canadian child or youth may have an adjusted life expectancy of approximately 66 years.\textsuperscript{1,8,9,12} The generation of the 1990s previously discussed will reach 65-70 by 2055-2065. If trends continue unimpeded, from these years onward the health care community will face a ‘double cohort’ of sorts, forced to accommodate significant numbers of patients from two different generations, each experiencing end stage complications. The population of elderly people in their 80s and 90s will be admitted as expected; however, they may be joined by record numbers of those in their 60s and 70s entering for end stage conditions associated with obesity. Should lifestyle changes not occur in young adult and child populations, and effective upgrades to care capacity and treatment options fail to be undertaken, current population trends will lead to one or more of the following consequences: (1) average lifespan and life expectancy rates will fall (discussed previously); (2) average quality of life will suffer with the increased risk of chronic disease and anxiety; and (3) further financial and logistical strains on our health care
system will ensue. While improved therapeutics will no doubt continue to be introduced, such strains will still prove significant without additional resources to handle a large increase in obesity related conditions in addition to a more numerous elderly population. If sufficient emergency funds are required, the unsavoury prospect of significant cuts to other sectors and social services looms large. This may not come to pass for many decades, therefore time remains for prevention efforts and improvements to services to adequately accommodate projected increases in need.

**WHAT CAN BE DONE?**

While innovative new anti-obesity strategies are required, perhaps a first step could build on conclusions from the Round Table Discussion on Obesity in Canada, and increase investment in program evaluations, which could facilitate the direction of limited resources toward those programs deemed successful. Development of pharmaceutical therapies must continue to be emphasized, and exist alongside innovative health legislation to curb emergent trends. Political resolve should be committed to employing a two-front approach, aimed firstly, at the implementation of effective policy and prevention campaigns to prevent weight gain, foster weight loss and prevent the re-gain of weight successfully lost. Secondly, these programs must complement gradual, smart and progressive upgrades to health care system capacity resources. Some of these initiatives are already underway as federal, provincial and territorial governments are currently working together to develop a Pan-Canadian Living Strategy to fight obesity and other major non-communicable diseases, which calls for innovative policy development, knowledge transfer, community development, infrastructure and public involvement.

Increased funding for health care is currently at or near the top of priority lists for all levels of government, which is an encouraging sign. The World Health Organization has called for broad legislative measures in their most recent draft policy on diet, physical activity and health, the most controversial of which is a proposed “fat-tax” intended to limit the consumption of food with high fat, salt and/or sugar content. While Canada has yet to declare a position on this matter, the idea of adopting pricing policies to affect consumption is not new as many nations have effectively altered consumption trends in this manner. A combination of taxing ‘bad’ foods, subsidising healthy foods and providing cash transfers (similar to GST-rebates) to low-income families to improve food purchases is likely to increase public practices associated with healthy eating. From a public health perspective the largest concern associated with a “fat-tax” appears to be the impact that rising food prices will have on low-income earners already struggling with day-to-day living. However, if curbing obesity rates is a priority issue, then a combination of effective marketing along with new pricing policies appears to be an excellent next step and a recommendation that should be taken very seriously. Taxing foods with high fat, sugar and salt contents will likely generate positive results; however, if such measures are taken they must co-exist with comparable rebates or other financial incentives to assist low-income families already struggling with the cost of food. To compensate for potential lost business revenue, extra cash levied from new taxes could be used to provide rebates and financial incentives for industry and manufacturers to provide and market healthier eating options.

Any new pricing policy, however, must be well planned and piloted, as was learned from the withdrawn food tax proposed by the Provincial Government of Ontario in early 2004, which called for extending the 8% provincial sales tax to all food purchases under four dollars. It did not specifically target items of poor nutritional quality, and no financial assistance was provided for low income earners or businesses anticipating lost revenue. These criticisms and others led to a public perception of the tax as strictly a cash grab, with little intent of fostering healthier eating habits. In a separate initiative, the incumbent Liberals also pledged to remove junk food vending machines from all schools. While such machines remain at the high school level, their movement may claim a partial victory as the Canadian soft drink industry has voluntarily agreed to withdraw carbonated beverages from all primary and middle schools in Canada by September 2004.

Other possible steps toward obesity prevention include passing legislation limiting marketing to children, allowing only those advertisements which pass a public health review board, an old idea which has previously been met with little success. While the Federal Government reformed the labelling of food items in 2003 with the introduction of standard Nutrition Facts tables to help individuals understand the nutritional content of food purchases, its effectiveness remains unclear and evaluative studies should be performed in the near future. Increased physical activity, especially in schools, should also be aggressively promoted through a curriculum with more mandatory physical education and fitness classes; more active adult lifestyles could also be promoted by making cities friendlier to cyclists and less convenient to automobile owners where public transit is accessible. Admittedly, each of these suggestions must be examined more thoroughly for cost-effectiveness and feasibility within the frameworks of current government mandates and commercial targets. Whether these or others are implemented, creative strategies must continue to be developed from collaborations between communities, governments, industry, health professionals and other interested parties.

**Conclusion**

Non-communicable diseases, such as those associated with obesity, have proven to be a great challenge and require a creative imagination to control. The growing epidemic has already reached record levels, driving the increases in numerous adverse health conditions, premature mortality, and augmented burden on health care systems. Curbing trends of rising obesity rates, particularly among youth, must be a priority. For this to occur there needs to be both strong public interest and rigorous political will to carry out aggressive education, prevention and healthy-living campaigns. Preventative efforts must co-exist alongside advances in medical research and progressive reforms in order to accommodate a potentially massive
increase in the number of health care users in the coming decades. Time is currently on our side, in terms of implementing reform and policies geared toward averting the potential downstream health care disaster; however, immediate joint actions from all levels of society must be initiated.

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Public Health in Canada: Considerations on the History of Neglect

Doris Yan, BASc

The growing concern over the state of public health in Canada has risen exponentially as numerous tragedies suggest that the system is failing. Examples include the transmission of the hepatitis C virus and the human immunodeficiency virus in contaminated blood products, which led to the Commission of Inquiry on the Blood System in Canada in 1997, and the *E. coli* 0157:H7 contaminated water sources in Walkerton, Ontario in 2000, which left 2300 people ill and seven dead. Most recently, during the SARS outbreak in 2003, Canada was witness to 438 probable and suspect cases, which included 44 deaths.

During times such as these, when many are reflecting upon Canada’s health care system, it becomes important to ask the questions: *How is it possible for these public health tragedies to have occurred, is Canada not a world leader in health and healthcare policy? Is health not one of Canada’s most prized national values? Where does the blame lie for the current public health system? And, how can we address the underlying issues that have ultimately led to this state of neglect?*

The answers to these questions are not simple. Consideration of Canada’s public health system requires consideration of the priorities upon which our healthcare system is based, as well as an understanding of population health in addition to the responsibilities of various levels of government. The interaction of these factors has contributed to the state of neglect in which we find our public health system. The lack of progress in the public health system needs to be addressed; however, until we are able to look into the past and understand from where we have emerged, we will never be able to shed light on how the decisions we make today will affect tomorrow.

**DEVELOPMENT OF THE HEALTH CARE SYSTEM**

Examining the priorities upon which our healthcare system is based, in addition to the division of responsibilities between the federal and provincial governments at that time, are the first steps in understanding our past.

At the time of Confederation, the federal government was minimally involved in the health of the people. Under the *British North America Act* (now known as the *Constitution Act, 1867*), provincial governments were responsible for social welfare, education, civil law and agriculture, whereas the federal government was given jurisdiction over aboriginal peoples, the armed forces, the RCMP, immigrants and refugees, and those living in the territories; health was formally declared a provincial responsibility in 1937 by the Supreme Court of Canada. Today’s structure, consisting of ten distinct provincial, and three territorial health systems, stems from the division of powers that occurred at Confederation. Over time, however, it became increasingly evident that provincial governments alone were unable to cover the rising costs of healthcare. As time progressed, the federal government began sharing in the costs of health care services.

Enacted in 1957, the *Hospital Insurance and Diagnostic Services Act* was the first national agreement in which all patients requiring acute hospital services would be covered by a publicly funded insurance plan; following this, the *Medical Care Act* in 1968 ensured the coverage of all physician services. The combination of the *Hospital Insurance and Diagnostic Services Act* and the *Medical Care Act* formed the basis of the *Canada Health Act* of 1984, which is still Canada’s federal legislation for publicly funded health care insurance. Under the *Canada Health Act*, federal cash contributions for “medically necessary hospital, physician and surgical-dental services” would be given to the provinces provided the insurance was comprehensive, universal, portable between provinces, publicly administered, and accessible to citizens of all provinces or territories regardless of socio-economic status. The Act also made provisions regarding extra-billing and user charges. Canada’s publicly funded health care system was founded on the basis of physician and medical services, and promoted health by placing the emphasis on the diagnosis and treatment of disease in the individual. This perspective is radically different from that which emerged in the middle of the 20th century.

**THE POPULATION HEALTH MODEL**

The population health, or health promotion model, recognizes that in addition to an effective health care system, there are non-medical determinants such as social and economic factors that play a critical role on the health of individuals and communities. The Constitution of the *World Health Organization*, recognized in 1945, stated “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity” and, “Governments have a responsibility for the health of their peoples which can
be fulfilled only by the provision of adequate health and social measures."5 Beginning with the publication of A New Perspective on the Health of Canadians in 1974 by then-Minister of Health Marc Lalonde, Canada has been a world leader in developing policies reflecting the population health model. The Lalonde report was influential in recognizing that in addition to an adequate healthcare system, factors such as human biology, lifestyle, and physical, social, and economic environments, play a crucial role in determining the health of individuals and populations.1

In 1986, Ottawa hosted the first International Conference on Health Promotion. The Ottawa Charter (Achieving Health for All) was subsequently developed to suggest specific actions needed to reach the 1978 Alma Ata Declaration goal of health for all by the year 2000.6 Salient points of this document include the recognition that “Health promotion is the process of enabling people to control over, and to improve their health. Health is... a resource for everyday life, not the object of living. Health is a positive concept emphasizing social and personal resources, as well as physical capacities.” 6

With this innovative understanding of health, it became clear that nations needed to look beyond hospital doors and physician services to both attain and maintain the health of their citizens. In Canada, governmental and non-governmental organizations adopted this perspective on health to develop policies and programs that help to create an environment conducive to attaining good health. In 1994, federal, provincial and territorial ministers of health officially endorsed this population approach to health in a report entitled Strategies for Population Health: Investing in the Health of Canadians.7 The documents cited above attest to the fact that Canada as a nation does recognize the importance of health promotion; however, the dubious success of these programs leaves much to be desired.

PUBLIC HEALTH AT THE FEDERAL LEVEL

If Canada is a world leader in healthcare and healthcare policy, how then is it possible for the public health system to have fallen into the current state of neglect? According to the National Advisory Committee on SARS and Public Health, total health spending in 2002 was $112.2 billion, whereas total public health expenditures in Canada from 2002 to 2003 ranged from only $2.0 to $2.8 billion.3 According to these figures, only 1.8% to 2.5% of total health expenditures was spent on public health. This seems counterintuitive when one considers the scope of public health practice itself.

By nature, the goals of public health - health promotion, health protection, in addition to illness and injury prevention - are incredibly broad. The expansive scope of public health practice leads to a lack of clear accountability by various levels of government. According to the Ottawa Charter:

The fundamental conditions and resources for health are: peace, shelter, education, food, income, a stable eco-system, sustainable resources, social justice and equity.

Good health is a major resource for social, economic and personal development and an important dimension of quality of life. Political, economic, social, cultural, environmental, behavioural and biological factors can all favour health or be harmful to it.6

Therefore, while the Constitution designates “health” as a provincial responsibility, many of the non-medical determinants of health, particularly political, economic and environmental factors, are under federal jurisdiction. Indeed, the federal government’s involvement in the nation’s health has increased since the time of Confederation. In 1993, Health Canada was born out of the reorganization of what was previously known as Health and Welfare Canada.1 Responsible for developing health policy, enforcing health regulations, promoting disease prevention and enhancing healthy living, Health Canada is the federal department responsible for helping the people of Canada maintain and improve their health.8 ParticipAction, the Dialogue on Drinking, the Canada Food Guide, the National Strategy to Decrease Tobacco Use in Canada and the Canadian Task Force on Preventive Health Care7 are some of the federal initiatives intended to promote the health of Canadians. While these programs have targeted specific areas of health in Canada as a whole, the structures of public health systems remain under provincial jurisdiction nationwide, thus each province has its own structure for fulfilling its public health mandate. While this allows local regions to identify their needs and determine their priorities, it also potentiates a fragmented infrastructure and lack of accountability.

In 2002, the Kirby report on The Health of Canadians called on the federal government for strong leadership to improve the state of public health systems in the various provinces and territories. “Fragmentation has resulted in a poorly coordinated or integrated health promotion infrastructure. More important, no health goals have been set nationally for health promotion...”7 In studying Ontario as an example, we can see more clearly some of the difficulties of the current public health system.

PUBLIC HEALTH AT THE PROVINCIAL LEVEL:
A LOOK AT ONTARIO

Established by urban and rural municipalities, Ontario has 37 public health units that represent the official agencies for administration of community health programs. In keeping with the population health model, these health units have a broad range of responsibilities including water, food and environmental safety; communicable disease control and surveillance; immunizations; maternal and child health; dental health for underprivileged groups; and, health promotion and population health assessment. While each municipality is able to determine its own priorities based on local needs, the provincial government mandates these fundamental responsibilities through a document called the Mandatory Health Programs and Services Guidelines.9,10

In early 2004, the funding formula for these public health programs was 50:50, meaning that a municipality would pay 50 per cent of the costs and the other 50 per cent would be covered by the province. Municipal governments made the decision as to which programs would be funded and how much funding each would be allocated.11 Once the municipal government determined a budget, the provincial government would then match the dollar amount. Money for community public health
programs is therefore in competition with other municipal services such as garbage and snow-removal. This arrangement clearly contributes to the deteriorated state of Ontario’s public health system, especially when many municipal governments find themselves in financial crisis. Furthermore, with local issues as their primary concern, municipal governments are less likely to make budget decisions based on what is happening elsewhere in the province. Therefore, a co-ordinated public health system is contingent on close communication between the Ministry of Health and Long-Term Care and each of the 37 public health units in the province of Ontario.

Tragedies such as Walkerton and SARS highlight the degree to which public health has been neglected; indeed, the Interim Report on SARS and Public Health in Ontario, released by the Campbell Commission, identifies Ontario’s central public health system as “broken”, “woefully inadequate”, ”unprepared, fragmented, poorly led, uncoordinated, inadequately resourced, professionally impoverished, and generally incapable of discharging its mandate.”

Support for the public health system is long overdue and, regrettably, the impetus for change has come from the tragic loss of human lives.

CONCLUSION: CHALLENGES FOR THE FUTURE

Understanding the history of neglect of Canada’s public health system requires an understanding of the priorities upon which our healthcare system is based, the evolution of the definition of health to include social determinants, and the complex nature of federal-provincial and provincial-municipal relationships. Early in Canada’s history, health was determined to be a provincial responsibility, which created a structural division in duties. As health care costs have soared well beyond the ranges affordable solely by provincial governments, the federal government initiated involvement through Medicare. Higher financial burdens and complex health care related issues have led to a blurring of federal and provincial health care roles. Also, the recognition in recent years that social determinants of health, including the global environment, also affect health, has increased the need for federal leadership in public health practices.

Recently, commitments have been made at the federal level for new public health funding for the establishment of a new Public Health Agency of Canada, and for the appointment of a Chief Public Health Officer for Canada. The challenge for the future will be in creating a new model for public health which encourages co-operation and communication between different governments, i.e., a model that is efficient enough to co-ordinate the efforts of the ten provincial and three territorial health systems yet allows enough flexibility for local needs to also be met.

Canada’s health care system was built upon a now outdated perspective that viewed health solely as the absence of disease; as such, health expenditures were, and will continue to be, focused on the treatment of acute diseases through physician and hospital services. As the federal 2002 Romanow report states:

For too long, Canada’s health care system has been overly focused on treatment rather than prevention. A central focus of primary health care must be on preventing illness and injury and helping Canadians stay healthy... there is evidence that current programs are dated. We also need to take steps to ensure that Canada is well prepared to face new and emerging problems resulting from globalization and the evolution of infectious diseases.

It is important to recognize that governments alone do not determine healthcare priorities. This emphasis on diagnosis and treatment, and the subsequent lack of focus on non-medical determinants of health, is perhaps an attitude held by the wider medical community. Implementation of health care policies cannot be accomplished without the partnership of medical professionals at large. How supportive are physicians of public health initiatives? How effective is health promotion education in medical schools? The challenge for the future is to develop a generation of physicians who will share in the pursuit of injury and illness prevention.

Finally, poor funding arrangements by provincial governments, as exemplified in Ontario, can lead to cuts in public health programs. Successful public health programs are not readily visible, and too easily are municipal funds allotted to other priorities when public health programs become undervalued. As exemplified by the tragic Walkerton case, cutting budgets for routine public health protection can be devastating when a public health emergency occurs. Fortunately, changes to public health funding are forthcoming. In Ontario, the Ministry of Health and Long-Term Care has committed to increasing the provincial share of public health costs from 50 per cent to 75 per cent by 2007. The challenge for the future will be to protect and advocate for public health programs through increased public awareness.

The underlying factors that have led to the state of neglect in Canada’s public health system are complex. Canada is indeed a world leader in health and health care policy, yet Canada’s state of public health can be blamed on our failure to recognize just how essential a strong public health system is to the functioning of our everyday lives. Federal, provincial and municipal levels of governments, the medical community and the general public all have a role to play in improving the public health system. By working toward a common vision of the future, one in which the health of the public is better protected and health tragedies prevented, it is hoped that the history of neglect may remain in the past.

ACKNOWLEDGEMENTS

The author gratefully acknowledges Dr. Christina Mills and Dr. John Last for reviewing the article and providing editorial contributions. She would also like to thank Vivian Sapirman, Sarah McMullen, Joy Liao and Alex Avila for their editorial assistance and support.

AUTHOR BIOGRAPHY

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The Prescription Conundrum: Factors That Impact on Prescribing Practices

Cecilia Costiniuk, BA, BSCPharm

ABSTRACT
The number of medications on the market is increasing at a dramatic rate. Physicians are expected to keep current so that they can prescribe the most appropriate medications for individual patients, at the same time considering novel agents for which the evidence may be limited. Physicians’ decisions can also be influenced by insurers, who stress cost containment, as well as patient impact. Specifically, many patients have taken on a more proactive role in their health care as they are well-informed, and often have high expectations for the health care they receive. In addition, whether real or perceived, pharmaceutical representatives attempt to persuade physicians to use specific products, and can exert influence over both basic and clinical research. Therefore, it is imperative that physicians, particularly those just entering the field, are made aware of the myriad of factors that can bias prescription choices.

CLINICAL PRACTICE GUIDELINES
Clinical practice guidelines are recommendations for physicians regarding the care and treatment of specific patient populations and ailments. Generally, these guidelines are based on a systematic review of evidence pertaining to a clinical issue, with emphasis placed upon the strength of that evidence. In these, recommendations are also typically provided for the management of patients. Of note, these recommendations are derived not only from evidence-based observations, but also from empirical observations and value judgments. In addition, these guidelines are only suggestions for care and not definitive rules (hence the term “guidelines”), as individual patient factors must be considered. Furthermore, although the name of a sponsoring agent does not guarantee quality, statements formally endorsed by respected bodies undergo intense scrutiny. Thus, strong incentives are provided to sponsoring agents to safeguard their reputation by having recent, evidence-based, comprehensive and well-reviewed guidelines. Finally, one must also keep in mind that not all physicians agree on what constitutes the most appropriate treatment for many conditions.

META-ANALYSES AND CLINICAL TRIALS
Randomized controlled, double-blinded, prospective trials are the gold standard for determining the effectiveness of any particular medication. However, not all medications have been
subjected to this type of investigation. Consequently, physicians must sometimes turn to studies of lesser methodological strength. Furthermore, meta-analyses, while having increased power, also have their limitations. For example, meta-analyses are retrospective and may be open to question vis-à-vis the inclusion of a specific study, the characteristics of which may skew the results of the analysis. Nevertheless, meta-analyses generally serve as condensed overviews of the best evidence available, thus saving a busy physician invaluable time.

As the emphasis on evidence-based medicine continues, one will frequently be confronted with evidence that casts doubt on the safety of commonly used medications. For example, in July 2002, the estrogen-progestin arm of the Women’s Health Initiative (WHI) intervention trial was terminated early when risks of treatment were found to be outweighing the benefits. Consequently, prescriptions for Hormone Replacement Therapy (HRT) in Ontario decreased by approximately 32% within one year of publication of the WHI trial data. The evidence also called for the revision of recommendations from the Canadian Consensus Conference on Menopause and Osteoporosis. This evidence also received significant media attention and provoked anxiety in many women who, in turn, needed their physicians to help them interpret what these results meant for them personally. This was entirely unexpected, as more than 20 non-interventional, descriptive trials had previously suggested that HRT was beneficial in the prevention of heart disease postmenopausally. This example illustrates how it is necessary for physicians to remain aware of the ever-changing consensus of prescription recommendations, as understanding of disease etiology and treatment develops.

**GENERIC VERSUS BRAND-NAME MEDICATIONS**

A twenty-year patent period is granted to brand-name product manufacturers. The intent of patent protection is cost recovery: the expectation is that the original manufacturers will be able to recover their costs incurred in research and development during this time. At the end of this period, significantly cheaper generic alternatives are permitted, and can thus be released into the market. In Canada, the Therapeutic Products Directorate (TDP) of Health has the task of approving generics based on bioequivalence and manufacturing quality. Nonetheless, nearly all Canadian provincial plans have either mandatory generic substitution or cover only the cost of the generic product. Consequently, patients are required to pay the difference in cost should they request the brand-name product. In the majority of cases, it is argued that these generic medications are interchangeable. However, based on the criteria for bioequivalence used in several countries, this does not hold true in many cases. For example, the criteria for bioequivalence for medications with narrow therapeutic indices (e.g., digoxin), and for those with high variability in their pharmacokinetics (e.g., proton pump inhibitors) may not be sufficient to ensure true bioequivalence. In addition, bioequivalence testing does not take into account certain individual patient factors, such as the high variability associated with genetic polymorphisms in drug-metabolizing enzymes.

**THE INFLUENCE OF THE PHARMACEUTICAL INDUSTRY**

Although there is evidence to suggest that physician prescribing habits can be influenced by the pharmaceutical industry, it is impractical for physicians to function entirely independent of the industry. Meeting with industry representatives provides physicians with a quick and efficient method to gather basic information about the new medications on the market. In addition, physicians may be given free medication samples that they can provide to their financially-disadvantaged patients. Although the industry representatives are in the market to sell products, *it is the physician who has the responsibility to critically assess all relevant product information.*

Since industry actually funds most drug development and assessment, it may demand ownership of results. In many cases, ‘negative’ results may not be reported. It is up to the individual researcher to ensure that he or she maintains ownership of the data and publication rights. It was the *Nancy Olivieri versus Apotex* case in the early 1990s that brought this issue to the attention of both the academic community and the public. Dr. Olivieri, a hematologist at the Hospital for Sick Children in Toronto, had signed a contract that gave her sponsor the right to prematurely end a trial with an experimental drug. The contract also demanded the right to control the release of particular information over a one year period. When Dr. Olivieri identified a risk involved with the treatment, and wanted to inform patients of this risk, the sponsoring company did not agree with her findings. As a result, they refused to allow her the right to inform the patients. Thus, although potential conflicts of interest merit careful and constant consideration, one must keep a balanced perspective and consider both the pros and cons of the relationship between physicians and the pharmaceutical industry.

**DIRECT-TO-CONSUMER ADVERTISING AND PATIENT PRESSURE**

Although permitted in the United States, prescription drug advertising directly targeted toward the public is currently prohibited in Canada. This protects the public from marketing influences and harm which could occur from using medications that are either unnecessary or inappropriate. Although some individuals may argue that direct-to-consumer advertising increases patient participation in the decision-making process and fosters patient-physician interaction, the current consensus among many Canadian physicians is that more advertising leads to more patient requests. The perception is that patients will likely pressure physicians to prescribe newer and more expensive medications, despite the fact that older and cheaper drugs may be as effective. Moreover, since advertised drugs tend to be newer, less information, especially that information garnered from research, is readily available regarding their risks and benefits, in particular their long-term effects. For instance, troglitazone (an oral hypoglycemic in the thiazolidinedione class and the first of its class marketed in the United States) was removed from the market after three years due to rare but severe hepatotoxicity, which was on occasion associated with...
fulminant liver failure and death; this toxicity had, obviously, not been evident initially.12 Furthermore, many advertisements for medications do not report misconceptions about the condition in question, or the treatment’s side effects or success rates.11

PATIENT FACTORS

Amidst all the factors involved in drug prescribing, the most important consideration is the individual patient. Physicians must take into account patient characteristics including age, race, body size and composition, co-morbidities and polypharmacy. There may also be significant variability associated with genetic polymorphisms in drug-metabolizing enzymes. For example, cytochrome P450 2C19 metabolises several psychoactive drugs, anti-epileptics and proton pump inhibitors. Similarly, the minimum effective plasma concentration of many psychoactive drugs varies considerably among patients.6

The advent of pharmacogenomics will enable physicians to tailor therapy to a patient’s unique biology, but it also will increase physician dependence on technology and raise a plethora of ethical issues.1

Patient financial status, preference, and beliefs are other factors that may come into play. Whether or not a patient has a drug plan may affect which medication the physician prescribes. In addition, a patient’s preference, especially in terms of dosing regimen, should be considered. For example, a patient wishing to quit smoking may prefer an oral medication, such as Zyban® (bupropion hydrochloride) to a nicotine patch. Finally, individual patient beliefs regarding health, illness and medications, as well as their relationships with health care providers, may influence compliance and, hence, patient outcomes.

Clearly, we are living in an age of pills. The number of medications on the market is increasing at a dramatic rate, and physicians are expected to keep current so that they can prescribe the most appropriate medications for individual patients. However, while patient factors are of paramount importance, physicians are restrained by government and insurance policies to contain costs, and often influenced by the pharmaceutical industry to prescribe newer and more costly medications. With the advent of direct-to-consumer advertising in several countries and patients taking a more proactive role in their health care, physicians may also feel pressure by patients themselves to prescribe certain medications, even though there may exist a paucity of evidence for these medications. Therefore, as future physicians, we must assume responsibility to critically assess all relevant medication information, and be cognizant of the various factors that can bias our prescription choices.

ACKNOWLEDGMENT

The author thanks Dr M. R. Buchanan for his suggestions, critical comments and support, and Shalini Nayar.

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Selection of Medical Students at McMaster University: A Quarter Century Later

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ABSTRACT
A quarter of a century has passed since the last update on the admissions process into the McMaster University Undergraduate Medical Program was published, and since that time, multiple external factors have slowly built pressure for reactive change. The external factors, discussed herein, have sprung from many areas including Canadian society; from the way in which Canadian physicians are defined; and, from the emergence of new philosophies at McMaster University. The Undergraduate Medical Program admissions process remained reasonably static until the escalating external stressors surpassed a threshold that could no longer be withstood, resulting in dramatic changes over a three year period, the swiftness of which belies the more gradual upsurge that occurred surreptitiously over the past 25 years. The intent of this article is to highlight those rapid changes in the admissions process within the appropriate historical context; we conclude with a new prescription for an approach to admissions, one that would be optimally responsive to as of yet unforeseen external stressors.

INFLUENCE ONE - CANADIAN SOCIETAL CHANGES

In 1978, nine years after McMaster University first admitted medical students, “Selection of Medical Students at McMaster University” was published in the Journal of the Royal College of Physicians of London. Since that time, striking changes have occurred, yielding dramatic influences on recent admission policies and philosophy. There have been three primary sources of change: (1) changes in Canadian society in general have irrevocably altered post-secondary education; (2) the objectives of achieving competence as a Canadian physician have been redefined on a national level; and (3) within McMaster University, old perspectives have been reshaped by changes in philosophy.

On a primary level, the admissions must reflect those influences. The corresponding adjustments to the admissions process may meet the needs of the time, however, in a more protracted view, the needs of a given time are, by definition, ephemeral. What is increasingly required is a dynamic admissions office; this paper will describe those three sets of influencing factors, and the rapidly changing face of McMaster University Undergraduate Medical Program to address the requirement of dynamism.

INTRODUCTION
In 1978, nine years after McMaster University first admitted medical students, “Selection of Medical Students at McMaster University” was published in the Journal of the Royal College of Physicians of London. Since that time, striking changes have occurred, yielding dramatic influences on recent admission policies and philosophy. There have been three primary sources of change: (1) changes in Canadian society in general have irrevocably altered post-secondary education; (2) the objectives of achieving competence as a Canadian physician have been redefined on a national level; and (3) within McMaster University, old perspectives have been reshaped by changes in philosophy.

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parate institutional blocks. More recently, university colleges (institutions devoted solely to distance education), and an amalgam of more loosely defined programs have further blurred the lines demarcating the borders of post-secondary educational institutions. The Association of Universities and Colleges of Canada presently catalogues these 93 public and private not-for-profit universities and university-degree level colleges across Canada, but its mandate does not extend to accreditation. For medical school admissions, the results have been twofold. Firstly, a small minority of courses or even programs described in university undergraduate calendars may not meet a sufficient level of rigor to make their students acceptable for medical school. More insidiously, and ultimately more corrupting, is the diluting effect on the university Grade Point Average (GPA). While still retaining much of its traditional strong reliability and predictive validity, the Grade Point Average risks becoming slowly degraded for critical endpoints such as the national licensing examination, the Licentiate of the Medical Council of Canada (LMCC) parts I and II. This worsening limitation is a more acute concern for those medical schools, like McMaster, that have traditionally eschewed the use of aptitude tests, such as the Medical College Admissions Test (MCAT). Despite its ability to predict LMCC outcome, concerns remain regarding financial cost to the applicant, advantages held by students with science vs. arts degrees, and the specter of correlations with rising socioeconomic status. The preference of medical school admissions offices would be to continue to derive reliable and valid cognitive data on applicants in a resource-cheap fashion, a preference less tenable over time if predicated purely on the GPA.

A second societal pressure impacting significantly on admissions has been the growing population, particularly with respect to an ever-expanding applicant pool. The general applicant pool for McMaster University Undergraduate Medical Program was approximately 2000 students vying for 100 available seats in 1990, 3000 students for 100 seats in 2000, 4150 students for 138 seats in 2004, and is projected at greater than 6000 in 2006, taking into account the “double cohort” effect on Ontario university undergraduate registration (the double cohort being the simultaneous high school graduation from grades 12 and 13 in 2000). The number of applicants, large compared to its Ontario counterparts, was driven by a lower minimal GPA of 3.00 for eligibility to apply, in addition to the lack of specific course prerequisites or the MCAT. Even ignoring fiduciary costs, the number of rater-hours of human resources required, utilizing the previously documented McMaster admissions system would be, respectively, 5000, 6500, 8200 and projected at 11,000. The lion’s share of rater-hours isdevoured by review of an Autobiographical Submission provided by each applicant, as independently read by raters representing faculty, student body and the community. Similar triumvirates of raters evaluate the 384 applicants invited for personal interview and simulated tutorial, these processes described in previous McMaster admissions article. The numbers of applicants interviewed was predicated on resource limitations, considering the approximately four hours of rater time per applicant for these processes.

The heightened level of competition attendant with the rise in applicant pool population has been expressed in increasingly negative terms. The temptation for fraud has increased commensurately; this had become most evident on the autobiographical submission, a measure whose control lay largely outside the hands of the admissions office. Further, there has been an increased predilection for prospective applicants to seek representation through legal counsel, steps that are well within their rights but are also reflective of the changing times. Such action has been further accelerated by differing interpretations of laws, like the Ontario Disability Act and the Personal Information Protection and Electronic Documents Act, which are so recent that clarification through ease law is still pending.

Finally, the reduction in transfer payments from the Canadian federal government to provincial governments has necessitated seismic changes in the methods of funding of provincial health and education. The resultant increases in tuition payments have forced medical school applicants to be shrewder purchasers. Ever vital endpoints such as likelihood of successful completion of LMCC parts I and II and placement in the residency program of choice assume an even greater relevance when the financial outlay for medical school has increased. In turn, the medical schools must become better recruiters, in hopes of ensuring that the admitted class has a high chance of success for those endpoints, a factor of self-interest well-described elsewhere. The need to “sell” the medical school, the university, and the city of Hamilton has prompted the Undergraduate Medical Program at McMaster University into significant upgrades of its recruitment efforts on interview dates. Examples of such endeavours include provision of greater interactions between present medical students and interviewed applicants, and familiarizing those applicants with the pervasive atmosphere of innovation in the medical program.

INFLUENCE TWO - THE CHANGING CANADIAN PHYSICIAN

From 1989 to 1998, the Government of Ontario, in conjunction with the Associated Medical Service and the five medical schools in the province, embarked on a project entitled “Educating Future Physicians of Ontario” (EFPO). One of the ensuing products became CanMEDS 2000, in which the Canadian physician would fit seven attributes – medical expert, communicator, collaborator, health care advocate, manager, scholar and professional. By January of 2003, these attributes were to be incorporated into all specialty training programs accredited by the Royal College of Physicians and Surgeons of Canada. As a result of these changes, the CanMEDS roles have now been applied to both the curriculum and the evaluation of all Canadian residency program trainees, with accreditation success of the programs
dependent upon their compliance with CanMEDS goals. All emerging Canadian physicians will be judged according to that paradigm. Similar efforts in the United States by the American Board of Medical Specialties (ABMS) and by the Accreditation Council for Graduate Medical Education (ACGME)\(^{18}\) have prompted suggestions to use similar personal quality attributes in an integrative fashion for medical school admission.\(^{14}\)

There is a certain appeal to the idea of transplanting assessment of personal qualities commensurate with long-term societal expectations of the physician to that pre-admission assessment of applicants. Nevertheless, a significant detraction of this nascent deliberation is the need to account for the differing curriculum and style of learning unique to each medical school; McMaster’s problem-based learning (PBL) undergraduate program nicely underscores this point.

**INFLUENCE THREE - McMaster University’s Changes in Philosophy**

Decisions are made based on some balance of evidence and faith. That balance was irrevocably altered at McMaster by the introduction of the concept of Evidence-Based Medicine (EBM) in 1992.\(^{19}\) Increasingly, the milieu of McMaster University has encouraged not only the more reactive assessment of evidence but the more proactive generation of evidence on which to predicate decisions. Where evidence is lacking, faith may yet rule decision-making, however, given the palpable aura of EBM at McMaster, there is a much decreased level of acceptability toward the conditions of “lack of evidence” when a more proactive approach is possible.

The incident that first argued for a more proactive approach occurred in 1989. The subsequent chain of events occurred simultaneously, and seemingly independently, with the rise of EBM at McMaster. A failure rate nearly four times higher than the national average on the LMCC part I occurred simultaneously, and seemingly independently, with the rise of EBM at McMaster. A failure rate nearly four times higher than the national average on the LMCC part I led to the institution of the Personal Progress Index (PPI), a reactive assessment of evidence but the more proactive generation of evidence on which to predicate decisions. Where evidence is lacking, faith may yet rule decision-making, however, given the palpable aura of EBM at McMaster, there is a much decreased level of acceptability toward the conditions of “lack of evidence” when a more proactive approach is possible.

The incident that first argued for a more proactive approach occurred in 1989. The subsequent chain of events occurred simultaneously, and seemingly independently, with the rise of EBM at McMaster. A failure rate nearly four times higher than the national average on the LMCC part I led to the institution of the Personal Progress Index (PPI), a regularly administered multiple choice examination, with accompanying performance feedback.\(^{20}\) The PPI demonstrated reliability and predictive validity for LMCC success. Further, there was a subsequent rise in LMCC part I success to exceed the national average in recent years, as students adjusted their learning approach based upon the feedback provided. The obvious improvement in the LMCC endpoint facilitated the movement toward the installation and validation of further reliable evaluation tools for McMaster medical students. These have included the Objective Structured Clinical Examination (OSCE) to assess clinical skills,\(^{21}\) the Critical Reasoning Exercise (CRE) to assess higher taxonomic cognitive abilities,\(^{22}\) clinical encounter cards to assess clerkship level skills,\(^{23}\) and most recently, Minimal Observations Often (MOO) to test performance in tutorial.\(^{24}\) Each has demonstrated reliability, with predictive validity in large part pending.

These changes did not occur in a vacuum; they occurred with the sequential Chairmanship of the Undergraduate Medical Program by Assistant Deans of the time, in partnership with the Program for Educational Development and its later incarnation, the Program for Educational Research and Development. Such alliances are not unique; similar collaborations applying the pursuits of psychology and psychometry to the betterment of medical school education occur elsewhere; rather, the uniqueness of said alliance at McMaster has been the extent and rapidity with which it has brought on transformation of the medical program.

One area of potential transformation lay in the area of program admissions. The same psychometric principles used in evaluating medical school students could be used in evaluating medical school candidates. Indeed, data was slowly accumulating regarding the limitations of the evaluation instruments in place for admissions. A literature review by Salvatore (2001) demonstrated the paucity of evidence in support of any extant measure of personal qualities,\(^{25}\) conclusions largely seconded by a later, separate review.\(^{14}\) Using McMaster data, Kulatunga-Moruzi (2002) not only confirmed that only GPA and MCAT were predictive of success on LMCC part I and II,\(^{26}\) but also that a McMaster-interviewed cohort deemed less strong than the admitted class was still sufficiently strong to do as well on the LMCC.\(^{27}\) The general literature on personal interviews provided concerns regarding reliability due to rater bias\(^{28}\) and content specificity.\(^{29}\) Save for two studies on tutorial evaluation,\(^{24,30}\) no reliable measures had been shown for tutorials conducted in problem-based learning medical schools. Significantly, both of these studies depended heavily on frequent repeat measures. This low level of confidence on the ability of the simulated tutorial to reproducibly distinguish between applicants was further evinced by an internal unpublished McMaster study, which illustrated a test-retest reliability in four separate domains on the simulated tutorial that ranged from 0.09 to 0.18. Inter-rater reliability of the autobiographical submission was reasonable for the full applicant pool at 0.6426, though this dropped to 0.45 for the interviewed pool. The lack of oversight of the autobiographical submission, given its provision by applicants outside of university controls, provided even greater concerns.

Similarly, the literature on the personal interview has been mixed. While students’ personal qualities are of vital concern for all medical schools, it represents an even greater concern for a PBL-based program like McMaster. Yet, literature reviews conducted at McMaster\(^{25}\) and elsewhere\(^{14}\) demonstrated the lack of reliable and valid tools for assessment of personal qualities, a conclusion supported by internal McMaster data. Despite being the most popular assessment of personal qualities by medical schools,\(^{25}\) the personal interview was limited by inter-rater reliability\(^{28}\) and content specificity.\(^{29}\) Even on the cognitive side, ground was being lost by diluting effects on the GPA, compounded by the absence of another cognitive measure such as an aptitude test. Further, the increased numbers of applicants had made personal qualities assessment using resource-intensive autobiographical submission, personal
interview and simulated tutorial less sustainable, and concomitantly, increasing competition was raising concerns regarding the legitimacy of non-centrally controlled instruments (ABS). Interestingly, the growing size of the applicant pool not only generated part of the problem, but also contributed to the supernatant which was awaiting the nidus for change.

THE NIDUS FOR CHANGE

In response to individual concerns regarding admissions across the program within the Faculty of Health Sciences, a faculty-wide retreat was arranged to address the issues at hand. In advance of that retreat, collaborative interaction occurred between members of the Admissions Committee, Evaluation Committee and PERD under the auspices of an OSCE research working group. An OSCE-style admissions process was theorized, with separate, sequential measures across a wide variety of domains, through many short interview stations. It would have the potential to address both concerns of inter-rater reliability and content specificity. Resource allocation worries were ameliorated, curiously, by the knowledge that a very large number of rater-hours were already being used for admissions, such that the “Multiple Mini-Interview” (MMI) would in fact be more efficient. From OSCE research working group to retreat, to the formation of an MMI working group, to preliminary study and larger studies, the potential process of MMI crystallized, with impressive study results that provided validation. Reliability results of the three completed MMI studies to date are robust, averaging 0.75,31,32 markedly superior to other measures of personal qualities. Early validity results demonstrated the ability of the MMI to predict for OSCE performance of medical students.33 Increased efficiency would allow a marked increase in the number of applicants who could be interviewed; exit surveys supported the acceptability of the process on the part of both applicants and raters.31b

Meanwhile, a separate phenomenon was noticed, one with a potentially dramatic impact. Of the 3600 applicants to McMaster in 2003, only the top third in overall GPA for the entire pool were admitted, despite the use of cognitive and personal quality scores in equal measure. Two factors contributed to this realization. First, for the 138 seats available, there are bound to be at least many individuals superb in personal qualities in any randomly chosen group of 1200, no less so in the 1200 students with the highest GPAs. Regardless of how strong the personal qualities of applicant 1201 may be, there are sure to be at least 138 candidates with higher GPA and with equally strong personal qualities. Second, the lower reliability of pre-MMI measures of personal qualities was due to the greater contribution of error in those measurements. That random noise in those measures militated against their ability to hold their own against the more reliable cognitive measures. Apparently, the relatively unreliable personal quality measures, when added to reliable cognitive measures, had succeeded in somewhat diluting, but not counterbalancing, those reliable measures. Thus, despite any beliefs to the contrary, only those thousand or so applicants with the strongest cognitive records stood any real chance of medical school admission in the province. The only way to counterbalance the reliable cognitive measures would be with the implementation of reliable personal quality measures, to as large a proportion of the applicant pool as possible. Enter the Multiple Mini-Interview, and expansion of the interviewed pool to as great a number as this new, more resource-efficient measure could sustain.

CONCLUSION: THE ROLE OF DYNAMISM

As the significant changes in Canadian society, the Canadian physician, and McMaster philosophy illustrate, the admissions office has been forced to maintain responsiveness. This is no mean task. Ponderous administrative endeavours accumulate increasing momentum over time. Adjusting policies and procedures becomes difficult, and only became possible in the scenario described above because of the confluent, severe changes being brought to bear from external sources. Even with internal administrative facilitation, three years were required to move from identification of the challenges faced, through theorized solutions, research study completion, and administrative implementation. The challenges were forced to crisis proportions before radical action occurred. While responsiveness is credible, a reactive policy will always be faced with a stiffer climb than a proactive policy. A relentless research agenda increases the likelihood that new options are theorized when challenges have not yet grown large, and reduce the lead-time between crisis identification and solution implementation. It may be sufficient to respond to the issues of the days -more laudable still to seize that day.

AUTHOR BIOGRAPHIES

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Lynn Giordano is the Associate Registrar, Admissions at McMaster University; she is presently the Vice-Chair of the Standing Committee on Undergraduate Admissions for the Ontario Universities’ Registrars’ Association and is a member of the McMaster Undergraduate Medical Program Admissions Committee.

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**MCMaster University**

**Faculty of Health Sciences**

**Department of Psychiatry and Behavioural Neurosciences**

We are a multidisciplinary department consisting of 51 full-time and 145 part-time MD and non-MD faculty working within a unique regional network of psychiatric services that integrates two general hospitals, a 24-hour psychiatric emergency service, a primary care mental health program, a community of psychiatric agencies, and outreach services for children, adults and the elderly. This rich array of resources has allowed us to develop and maintain a vigorous and integrated academic environment that spans multiple clinical teaching sites.

Areas of academic excellence within the Department include mood, anxiety and women’s health (Regional Mood Disorders Program, Anxiety Treatment and Research Centre, Depression Information & Resource Education Centre (DIRECT), Women’s Health Conumers Clinic, Brain-Body Institute) child psychiatry, epidemiology and population mental health (Canadian Centre for Studies of Children at Risk), evidence-based psychotherapy training, and innovative models of mental health care delivery.

The Department is committed to achieving and maintaining excellence in teaching and innovative educational program development, excellence in research and, through collaboration with our Hospital partners, creative modes of clinical service delivery.

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**Phone (905) 522-1155 extension 3498 Fax (905) 540-6533**
Clinical Genetics: The Art and Science of Helping People Understand Their Genes

Melissa Carter, MSc

When I tell people that I want to be a clinical geneticist when I am finished my medical training, usually I get a puzzled look – and not only from lay people. Fellow medical students, residents, and even some of my attending physicians are taken by surprise that such a specialty exists. One of my supervisors even told me that since I have such a good rapport with patients, it is a shame that I will be spending the rest of my life in a lab. Well, that couldn’t be farther from the truth! This article will describe the roles played by clinical geneticists; it will also outline the training processes and special qualities required for the job. Finally, it will provide a brief description of a typical work environment for a physician working in this capacity.

ROLES OF THE CLINICAL GENETICIST

**Diagnostician and Genetic Disease Management Consultant**

Clinical geneticists are experts in inherited diseases. They diagnose genetic diseases, chromosomal anomalies, and dysmorphic syndromes. Their patients range from expectant couples to neonates, and from children with developmental delay to adults with cancer or neurodegenerative disease. Most of the conditions diagnosed by clinical geneticists cannot be cured, but accurate diagnosis often has major implications for prognosis, management, family planning and psychological acceptance. For example, a couple whose unborn child has been diagnosed with Trisomy 18, an invariably fatal chromosomal disorder, may choose to either: (a) end the pregnancy; or (b) emotionally prepare for the birth of a severely handicapped child with a short life expectancy. A diagnosis of Marfan syndrome, a connective tissue disorder which puts the patient at increased risk for aortic dissection, will ensure regular monitoring by a cardiologist and appropriate lifestyle choices. A young woman known to carry the BRCA1 gene, which predisposes to breast and ovarian cancer, may choose to have her children early and undergo elective oophorectomy, as well as having frequent breast examinations and yearly mammograms.

**Genetic Counselor**

Contrary to popular belief, clinical genetics is a patient-centered specialty, in that clinical geneticists spend a great deal of time with each patient. A typical new patient encounter will include a full medical history, detailed family history, physical examination, and lengthy discussion about the genetic basis of the disease or condition in question. An important aspect of a clinical geneticist’s job is genetic counseling; this means explaining genes and chromosomes, how a particular disease occurs or is inherited, and the implications for diagnosis, treatment and prognosis, to both the patient and the patient’s family.

**Information Resource for Patients and Physicians**

Clinical geneticists must keep up-to-date regarding the genetic tests that are available to their patients. With genetic testing becoming simultaneously more available and more complex, the results of these tests must be carefully explained to families at length. Patients can become inundated with media hype about genetic testing, and clinical geneticists help them separate fact from fiction. They can also be a valuable resource to other physicians, who may not be familiar with the less common genetic conditions; geneticists are consulted by family doctors, obstetricians, internists, pediatricians and neurologists, to name just a few.

**Dysmorphology “Detective”**

Patients are referred to clinical geneticists for many reasons, a common one being to seek genetic or chromosomal causes for developmental delay. The clinical geneticist is trained to recognize dysmorphisms (differences in the physical appearance of a person that arose during fetal development); dysmorphisms can be as subtle as low-set ears or widely spaced eyes, or as obviously manifest as a cleft lip or extra digits. Particular combinations of dysmorphisms can sometimes be found in unrelated people with the same underlying condition. For example, people with Down syndrome, a common chromosomal condition in which there is an extra chromosome 21, typically have similar features including upslanting eyes, flat facial profile, short stature, single palmar crease, and a wide gap between the first and second toes.
Risk Assessor
Clinical geneticists are like medical actuaries in that they estimate the disease risk posed to an individual or their offspring. Sometimes this is straightforward, as for conditions that are inherited in an autosomal recessive pattern. For example, cystic fibrosis is a serious lung disease that is only present when a child inherits a mutated gene from both parents; a couple with one affected child thus has a 25% recurrence risk (i.e., the chance that they will have another affected child with subsequent pregnancies). Increasingly, however, patients and clinicians are requesting risk estimates for such non-Mendelian, multifactorial diseases as Alzheimer’s disease, epilepsy and schizophrenia, for which no one single gene is likely to be the cause.4

Researcher
Research is an important part of clinical genetics; geneticists will commonly publish case reports of interesting patients or families.3 Because so many of the diseases that geneticists see are rare, reviewing scientific literature is an important part of the job.3,6 They may also be involved in molecular, epidemiological, psychosocial or other types of research. Clinical geneticists will often adopt an area of special interest, and will focus much of their research in that area. For example, Dr. Margaret Nowaczyk, head of clinical genetics at McMaster, is the leading Canadian authority on Smith-Lemli-Opitz syndrome, a disorder of cholesterol biosynthesis.7 Dr. Victoria Siu of the University of Western Ontario is studying genetic disease in the Amish Mennonites.8 Dr. Michael Hayden of the University of British Columbia heads a laboratory investigating the role of genes in the development of Huntington disease and premature heart disease;9 he is also the Editor-in-Chief of the scientific journal Clinical Genetics.10

BECOMING A CLINICAL GENETICIST
Currently there are two training routes for those interested in a career in clinical genetics. The Royal College of Physicians and Surgeons offers a five-year training program in medical genetics.11 This is a residency program to which you apply directly from medical school. Medical genetics residency programs are currently offered at six institutions across Canada: University of British Columbia, University of Calgary, University of Manitoba, McGill University, University of Ottawa, and University of Toronto.11 A second option is fellowship training under the Canadian College of Medical Genetics (CCMG).12 Most people who have gone this route have completed a pediatric residency first, but other specialties (such as internal medicine or obstetrics and gynecology) are also applicable.3 This option also takes a minimum of five years – for example, three years of pediatric training followed by two years of clinical genetics fellowship.3

What is residency in Clinical Genetics like?
Dr. Linlea Armstrong is a recent graduate from the medical genetics residency program at Children’s Hospital of Eastern Ontario in Ottawa; she found that residency in medical genetics was very diverse, including rotations through pediatrics, internal medicine and obstetrics during the first two years, with the last three years spent focusing on clinical genetics. “You have a chance to shape a good deal of your five-year curriculum yourself – for example, spending some time on a research project”, says Dr. Armstrong. On the down side, since the existing programs have only one or a few residents at one time, there is comparatively little formal teaching relative to a larger program.13 That being said, however, clinical genetics residency programs are growing. For example, the University of Toronto program currently has seven residents training under the Royal College. Dr. Sarah Nikkel, a clinical geneticist at CHEO, completed the medical genetics residency at the University of Manitoba; she feels that although the call requirements are not as onerous as in some other specialties, there is a significant knowledge base that needs to be mastered, as genetics touches on every single body system at every stage of the life cycle. Dr. Nikkel states, “learning the genetics of how these things occur...is fascinating.”14

What qualities are required to succeed as a Clinical Geneticist?
A strong interest and background in genetics are obvious assets. Research experience is also an asset, but is certainly not required.3 Communication skills are of utmost importance, as geneticists must convey complex scientific information in a simplified manner to patients, as well as being able to communicate with other physicians, scientists, and members of the genetics team. Compassion and empathy are required, as geneticists often must give distressing news about prognosis to their patients and deal with strong emotions such as grief, guilt, and anxiety. Also required are sensitivity and respect for the rights of individuals to make their own reproductive choices based on religious and cultural beliefs.

Where do Clinical Geneticists work?
Most geneticists in Canada work in hospitals and are affiliated with an academic centre. This obviously limits the geneticist as to where they can live and practice. Most centers have salaried physicians versus fee for service, as the numbers of patients seen by clinical geneticists are few compared to other specialties.15 Starting salaries are usually around $150 000 per year, and range from $120 000 to $270 000 per year.3,14,16 According to Dr. Nikkel, currently the job market for clinical geneticists in Canada is very good. “There are lots of jobs available, and many centres are expanding their genetics services [with the increasing demand].” Currently, there are 42 cities offering Clinical Genetics services across Canada.17

WHAT DO CLINICAL GENETICISTS ENJOY MOST ABOUT THEIR JOB?
Dr. Sandra Farrell is a McMaster medical graduate and head of clinical genetics at Credit Valley Hospital in Mississauga. “The opportunity to continuously be stimulated to learn is the one of the most positive aspects. Since we don’t see an individual disorder very often and because the literature is so rapidly
Like all careers in medicine, the only way to know if clinical genetics is truly for you is to spend some time in a clinical genetics department. Dr. Nikkel gives this advice to students considering a career in clinical genetics: “Consider the type of patients you like seeing. If you like adrenaline rushes, this is not the career for you. However, if you like to learn new things everyday, taking the time to research and spending time with patients, this is a good choice.”

Table 1. Job Description for a Clinical Geneticist

<table>
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<tr>
<th>Roles</th>
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<tr>
<td>• Diagnostician and Genetic Disease Management Consultant</td>
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<td>• Genetic counselor</td>
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<td>• Information resource for patients and physicians</td>
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<td>• Genetic risk assessor</td>
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<tr>
<td>• Dysmorphology “Detective”</td>
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<td>• Researcher</td>
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<tr>
<th>Education</th>
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<tr>
<td>• M.D.</td>
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<tr>
<td>• Royal College residency program in Medical Genetics (5 years) or</td>
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<tr>
<td>• Pediatrics or other residency program (3 plus years), followed by</td>
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<tr>
<td>a 2 year fellowship in Clinical Genetics</td>
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<tr>
<th>Skills and Qualities</th>
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<tbody>
<tr>
<td>• Strong interest in genetics</td>
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<tr>
<td>• Excellent communication skills</td>
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<tr>
<td>• Compassion, empathy</td>
</tr>
<tr>
<td>• Sensitivity to cultural and religious issues</td>
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<table>
<thead>
<tr>
<th>Income</th>
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<tr>
<td>• Usually salaried</td>
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<tr>
<td>• $120 000 to $270 000 in Ontario; may vary by province and experience</td>
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<tr>
<th>Further Information</th>
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<tr>
<td>• Canadian College of Medical Geneticists website: <a href="http://www.ccmg.medical.org">www.ccmg.medical.org</a></td>
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<tr>
<td>• Canadian Association of Genetic Counsellors: <a href="http://www.cage-accg.ca">www.cage-accg.ca</a></td>
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<tr>
<td>• Canadian Residency Matching Service website: <a href="http://www.carms.ca">www.carms.ca</a></td>
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ACKNOWLEDGEMENTS

The author would like to thank Dr. Sandra Farrell, Dr. Linlea Armstrong, and Dr. Sarah Nikkel for all of their help. A special thanks to Dr. Margaret Nowaczyk for proof-reading the manuscript and for being a superb mentor to the author.

AUTHOR BIOGRAPHY

Melissa Carter is a recent graduate of the McMaster MD Program (Class of 2004). She has a Master’s degree in genetics and plans to become a clinical geneticist.
INTRODUCTION

Medical students, residents and licensed physicians are constantly striving to do what is best for patients by providing optimal care in a timely, caring and evidence-based fashion. In many instances, the physician is limited in what he or she can provide to patients and must rely on the education, training and experiences of a wide variety of allied health care professionals who make up the interdisciplinary health care team (see Table 1). In order for physicians to make appropriate allied health care referrals, they must have a solid understanding of the roles, responsibilities and scopes of practice of the various health care professionals available to their patients.

However, there is growing concern that medical school curricula lack appropriate education regarding the roles, responsibilities and expertise of other health care professionals. In fact, evidence from research done in the last 20 years has suggested that interdisciplinary education within medical curricula is either weak or absent altogether. In 1982, a survey examining the incorporation of ‘inter-professional education’ in Canadian and American medical curricula found that fewer than 30% of the 105 responding schools had incorporated formal interdisciplinary training into their programs. Furthermore, only 15% of those training programs were mandatory.

Unfortunately, no current comparable literature exists. However, in April 2000, the Ontario Chairs of Family Medicine and the Council of Ontario University Programs in Nursing issued a statement that “some programs have tried to bring together students in their first year of professional training, but the difference between student profiles can prevent effective integration.” They also concluded that “the current practice system fragments the education of health care professionals and does little to engender collaboration when students progress into the working environment...students have never experienced the benefits of collaborative care.”

With the increase in patient care complexity, the aging population and lack of time and resources, physicians must become familiar with the various health professionals available to assist them, but there has been much controversy as to when interdisciplinary education should be introduced to the health professional. Hall and Weaver – researchers from the University of Ottawa with an interest in inter-professional education – suggest there is no optimal time for interdisciplinary education to begin. Conversely, the Ontario Chairs of Family Medicine and the Council of Ontario University Programs in Nursing suggest that, “interdisciplinary education should be mandatory for all professional education programs before practice.” In ac-
dance with this statement, one can assume that education early on in a physician’s training will enhance that physician’s familiarity with the allied health professions. Regardless of timing, knowledge and familiarity on the part of physicians of how these professionals contribute to patient care are essential. This article will discuss the utility of five of the most commonly encountered allied healthcare professionals: physiotherapy, occupational therapy, speech-language pathology, dietetics and social work. It will also provide a brief review of their roles, as well as general guidelines suggesting when it may be appropriate for medical students, residents and practicing physicians to refer for consultation.

OVERVIEW OF SELECTED ALLIED HEALTH PROFESSIONALS

Physiotherapists

Physiotherapists are registered health care professionals who are experts in movement and rehabilitation. The Physiotherapy Act (1991) states that physiotherapy practice is “the assessment of physical function and the treatment, rehabilitation and prevention of physical dysfunction, injury or pain; to develop, maintain, rehabilitate or augment function; or to relieve pain.”5 Physiotherapy practice is generally focused on treating dysfunction in three main body systems: the musculoskeletal system, the nervous system and the cardio-respiratory system. More specifically, sub-disciplines in physiotherapy include neurology, burns, pediatrics, geriatrics, orthopedics, ergonomics, sports medicine and amputee rehabilitation.6

In order to practice physiotherapy in Canada, the therapist must hold a university level Bachelor’s degree.7 However, existing regulations regarding the required entry-level education are changing. In June 2001, the National Physiotherapy Advisory Group issued a statement expressing that the preferred entry-level education for physiotherapy practice in Canada was a Master’s level degree. By 2010, the Advisory Group predicts that Canadian universities will only offer physiotherapy education at the Master’s level, and that this will become the required level of education for entry to practice.7

Once a degree has been obtained, the therapist must pass a set of national certification exams and register with the profession’s provincial regulatory board, the College of Physiotherapists. Further, many physiotherapists participate in specialty-specific continuing education programs, once they are registered, to improve their practice skills.

Physiotherapists may choose to practice in a variety of settings, including clinical practice, academic research and professional leadership. In reality, most physiotherapists practice in a clinical, patient-care setting often focusing on a specialty discipline.6 The subspecialties determine not only the setting, but also the demographics of the patient population as well. For example, a physiotherapist working in respiratory therapy may work with children who have undergone lung transplant or older patients with chronic obstructive pulmonary disease (COPD). As such, a physiotherapist often works with patients of all ages and a variety of different pathologies.6

Regardless of the specialty in which the physiotherapist chooses to work, the accompanying responsibilities are fairly standard. The therapist takes an appropriate history and performs a physical examination. Following this, an assessment of the patient’s condition is made based on the physical examination and relevant laboratory tests. Finally, a plan and appropriate treatment is initiated. Treatment options usually include electrical modalities, exercise, manual therapies and education. By using these treatments, the physiotherapist’s role is to “improve quality of life through maximizing a patient’s movement and functional ability.”6 Whether it is a child with cystic fibrosis needing respiratory conditioning or a geriatric patient living with arthritis, the physiotherapist facilitates independence and confidence in a patient’s ambulatory and functional abilities.
Physiotherapy is an autonomous profession, meaning that a patient usually does not require a physician’s referral in order to be treated by a physiotherapist. However, there are some cases when a physician’s referral is necessary; for instance, if the patient is in hospital or is being treated in an OHIP-funded outpatient clinic. Regardless of how a referral should take place, physicians should be encouraged to consult a physiotherapist when they believe a patient may benefit from their services (see Table 2).

Due to the diverse nature of physiotherapy practice, it is impractical and beyond the scope of this paper to summarize the effectiveness of each area of physiotherapy practice. The Cochrane Collaboration has published a number of meta-analyses clearly outlining the effectiveness of physiotherapy as a beneficial adjunct to primary care in a wide variety of patient populations such as those with cystic fibrosis, cerebral vascular accidents, stress incontinence as well as a variety of musculoskeletal disorders.8,9,10 Physiotherapy has been shown to be effective in clearing lung secretions, improving independence in activities of daily living, as well as reducing stress incontinence in the aforementioned populations. Although physiotherapy as a profession is grounded in evidence-based practice, more methodologically sound data is required to demonstrate the unequivocal value of the various physiotherapy specialties.

Table 2. When do I refer to a Physiotherapist (PT)?

- Restoration of muscle strength and joint mobility after injury, surgery or neurological disease
- Education regarding pre-natal and post-natal care and activity
- Pelvic floor strengthening for urine incontinence
- Mobilizing patients after periods of inactivity or de-conditioning
- Manual chest therapy to aid in secretion clearance in patients with lung pathology such as pneumonia.
- Respiratory therapy to increase strength of respiratory muscles and increase ability to breathe in patients with chronic lung diseases.
- Education and exercise training for patients following cardiac diseases such as myocardial infarction in order to increase functional capacity.
- Movement and motor control re-education after traumatic brain injury, spinal cord injury or stroke.
- Education regarding the use of mobility devices such as walkers, canes, crutches and wheelchairs.
- Assessment of physical readiness for work or sports
- Osteoporosis prevention via exercise training
- Pain relief via modalities, exercise and mobilizations.

Table adapted from the Ontario Physiotherapy Association (2004), http://www.opa.on.ca

Occupational Therapists

Occupational therapists (OTs) are registered health care professionals who assist their patients in “developing or maintaining life roles and activities at home and in the community, when one’s ability to function independently has been challenged by accident, handicap, emotional problems, developmental difficulties or disease.”11 Typically, the main areas of focus for OTs and their patients are self-care, productivity and leisure, with emphasis on the interaction between the person, their environment and their occupation. The World Federation of Occupational Therapy (WFOT) defines occupational therapy as “the treatment of physical and psychiatric conditions through specific activities to help people reach their maximum level of function and independence in all aspects of daily life.”13

In order to practice as an OT in Canada, one must have graduated from either an occupational therapy educational program accredited by the Canadian Association of Occupational Therapists (CAOT), or a non-Canadian occupational therapy educational program recognized by the World Federation of Occupational Therapists. Candidates must also successfully pass the CAOT Certification Examination upon graduation. Most university programs across Canada are now at a Master’s level, requiring an honours undergraduate degree from any discipline with some prerequisites, prior to commencing a Master of Science in Occupational Therapy. As of 2008, CAOT has mandated Masters level entry for all new graduates.14

Occupational therapists work in a wide variety of settings, with patients of all ages and abilities. In hospitals, schools, outpatient clinics and treatment centres, private practices, long-term care facilities, community-based settings and industry, OTs use a “variety of assessment and treatment techniques to address goals developed with the client.”11 OTs are concerned with the ‘occupation of all individuals in society’ and use the term ‘occupation’ to refer to the activities one does on a daily basis,12 whether that involves a premature, 30 week-old neonate in the NICU with feeding difficulties, a 76 year-old gentleman with Parkinson’s Disease who lives in a nursing home, or a 42 year-old administrative assistant with Carpal Tunnel Syndrome who is struggling to meet her deadlines. ‘Occupation’ is what clearly guides occupational therapy practice. Ultimately, the goals of assessment and treatment involve maximizing occupation, overall function and improvement of quality of life of both individual and groups.12 Over the past several decades, the scope of practice of the OT has greatly expanded to provide a more valuable contribution to overall patient care (see Table 3).

Table 3. When do I refer to an Occupational Therapist (OT)?

- Assessment and training regarding activities of daily living (ADLs) (i.e., bathing, dressing, feeding) or instrumental activities of daily living (IADLs) (i.e., banking, groceries, driving)
- Prescription of assistive devices to assist with ADL’s, IADL’s, walkers, wheelchairs
- Discharge planning for transition from hospital or care facility to home
- Prescription of mobility devices, such as walkers & wheelchairs
- Evaluation and modification to physical environments such as a client’s home, work or school
- Counseling regarding work and return to work issues and ergonomic assessments
- Design and fabrication of hand splints/foot orthoses
- Issues regarding chronic medical conditions, which may have an impact on day-to-day function
- Psychosocial integration & life skills teaching in those with mental illness or developmental delay
- Issues regarding positioning, feeding in infants and children
- Assessment and treatment of children with school-related issues & or developmental delay
- Cognitive and perceptual rehabilitation in acquired brain injuries
Occupational therapists worldwide are responding to the need for evidence-based literature to evaluate outcomes of interventions they provide. The Cochrane Collaboration has published numerous meta-analyses which have demonstrated the value, contribution and efficacy of occupational therapy services to a variety of diverse populations ranging from those with a mental health condition, to those living with physical and/or cognitive disabilities.\textsuperscript{15,16,17,18} There is a continuous call for further methodologically sound research involving randomized controlled trials in order to continue to evaluate specific occupational therapy interventions.

**Speech-Language Pathologists**

The ability to convey thoughts and emotions is a crucial aspect of human culture. A lack of proper attention to communication as well as swallowing disorders can lead to serious long-term consequences with respect to socialization, literacy, academic achievement, and overall development.\textsuperscript{19} Speech-language pathologists (SLPs) work to alleviate these problems in patients and comprise an integral part of the allied healthcare team. The Audiology and Speech-Language Pathology Act (ASLPA) (1991) describes the scope of practice for speech-language pathology as the “assessment of speech and language functions; the treatment and prevention of speech and language dysfunctions or disorders; and the development, maintenance, rehabilitation or augmentation of oral motor or communicative functions.”\textsuperscript{20}

In order to practice, speech-language pathologists must complete professional training at the Master’s or Doctoral level. Following this, provincial certification requirements must be met. The College of Audiologists and Speech-Language Pathologists of Ontario (CASLPO) has developed a Quality Assurance Program ensuring that SLPs are regulated professionals who are held accountable to CASLPO. Further, it is mandated under the Regulated Health Professions Act (1991) and the Audiology and Speech-Language Pathology Act (1991) that SLPs are required to deliver safe, competent and ethical services.\textsuperscript{20}

In general, a speech-language pathologist diagnoses and treats ‘communication disorders’, a term encompassing speech, language, voice, fluency, hearing, and cognitive-communicative disorders.\textsuperscript{19} SLPs assess language disorders with the goal of improving the individual’s ability to understand as well as convey messages, both oral and written. With other professionals such as OTs, speech-language pathologists assess and treat cognitive-communication disorders. This involves helping patients improve reasoning, problem solving, memory and organizational skills so that the individual is able to interact in social situations. SLPs can also improve articulation and fluency in those who stutter, and with respect to dysphagia, the SLP assesses whether a person is at risk for choking or aspiration.\textsuperscript{19,21} Overall, SLPs are responsible for providing counseling to patients about their condition, as well as how to best cope with it. From a research standpoint, speech-language pathologists have the opportunity to participate in the development of new approaches in the treatment of communication and swallowing disorders.\textsuperscript{21} SLPs also play an important role in the lives of those who are non-verbal through the development and prescription of communication methods and devices. Due to the diverse nature of their clientele, from infants to the elderly, SLPs work in a variety of different settings such as hospitals, child development centres, rehabilitation centres, as well as home care and governmental agencies.\textsuperscript{19,21,22}

As evidenced by the speech-language pathologist’s scope of practice, there are many opportunities for physicians and physicians-in-training to integrate the services of SLPs into the care of a patient (see Table 4). Children who are slow to speak or patients with declining communicative abilities due to a progressive neurological disease, for instance, can benefit from the services of a speech-language pathologist. Additionally, patients with receptive (comprehension) or expressive language difficulties can be referred to SLPs.\textsuperscript{19,21,22} SLPs can also provide care to address the specific concerns of the individuals who are deaf or have developmental disabilities. By closely working with the patient’s school teacher(s), SLPs can help create appropriate classroom programs. SLPs can also initiate voice restoration procedures, or introduce alternative forms of communication for the patient who has undergone a laryngectomy due to cancer.\textsuperscript{21}

<table>
<thead>
<tr>
<th>Table 4. When do I refer to a Speech-Language Pathologist (SLP)?</th>
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<tbody>
<tr>
<td>• Child with delayed language skills</td>
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<tr>
<td>• Child/adult with expressive or receptive communication difficulties</td>
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<tr>
<td>• Adult who has expressive and/or receptive disorders following a stroke or other brain injury</td>
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<tr>
<td>• Child/adult who is hard-of-hearing or who may be deaf</td>
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<tr>
<td>• Persons with developmental or learning disabilities</td>
</tr>
<tr>
<td>• Persons requiring augmentative and alternative communication</td>
</tr>
<tr>
<td>• Child/adult who has a chronically hoarse voice, or who loses his/her voice for periods of time</td>
</tr>
<tr>
<td>• Child/adult with swallowing difficulties</td>
</tr>
<tr>
<td>• Persons/community groups etc. needing education on coping with communication and swallowing disorders</td>
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</table>

Table adapted from Canadian Association of Speech-Language Pathologists and Audiologists (2004). http://www.caslpa.ca\textsuperscript{22}

It is evident that SLPs can contribute greatly to the scope of care offered by the allied health care team. To further establish the necessity for including SLPs in the care and management of patient, there are ongoing evidence-based evaluations of speech and language therapy interventions. Recently, a study by Law et al (2003) examined the efficacy of speech-language interventions for children with primary speech language delays and disorders.\textsuperscript{23} This meta-analysis revealed that the interventions resulted in a positive effect for those with expressive language difficulties. Other researchers are currently investigating the efficacy of direct speech and language interventions aimed at improving communication skills of children with cerebral palsy.\textsuperscript{24} Thus,
the results of these and other studies should encourage physicians to include SLPs in the care of patients who have language and communication issues.

**Registered Dieticians**

Registered dietitians are allied health care professionals who are “highly educated in the sciences related to foods and human nutrition and are trained to apply their knowledge in a variety of settings.”25 More specifically, the *Dietetics Act* (1991) clearly defines the scope of practice of the registered dietician as, “the assessment of nutrition and nutritional conditions and the treatment and prevention of nutrition-related disorders by nutritional means.”26 The American Dietetics Association (ADA) refers to the services provided by a registered dietitian as medical nutrition therapy.27

In order to practice as a registered dietitian (RD), one needs to successfully complete an undergraduate university program in food and nutrition followed by an accredited internship of at least 35 weeks in duration.25 Following formal education and internship, RDs must pass a competency exam in order to practice in Canada. As with other regulated healthcare professions, only those who are registered with the College of Dietitians of Ontario can use the titles Dietitian, Registered Dietitian, or other abbreviations. The title ‘Nutritionist’ is not a protected title by Ontario law; therefore only those who use the designation ‘Registered Dietitian’ are regulated and have achieved standards set forth by the College of Dietitians of Ontario.25

Registered dietitians work in a wide variety of settings, similar to other allied health care professionals. Registered dietitians and physicians work closely together in the neonatal intensive care units, nurseries, pediatrics, and both medical and surgical wards. RDs can commonly be found in hospital wards, where their responsibilities center around the ongoing assessment of an individual’s nutritional and metabolic status through the monitoring of fluids, electrolytes and overall health status. Premature neonates, individuals with eating disorders, the elderly, and those with both acute and chronic diseases are a few of the patient groups who can benefit from the services of a registered dietitian (see Table 5). Health promotion and disease prevention are also a large part of dietetic practice. Registered Dietitians are commonly consulted for primary prevention regarding healthier dietary choices in order to decrease the risk of heart disease, cancer and diabetes. Dietitians can also be found in the community through Community Care Access Centres (CCACs) and public health units in Ontario. They offer healthy eating information and resources, run various nutritional programs for both groups and individuals, and devise public health protocols regarding health and nutrition. Industry and businesses employ dietitians to assist with the development of food products and to manage food preparation and distribution.28

Over the past several years, there has been an increased call for evidence-based practice within the dietetics community in order to justify the value and contribution of the profession to patient care. In 1998, the ADA formed a Health Services Research Task Force to examine both the effectiveness and outcomes of medical nutrition therapy provided by registered dietitians. Much literature has been published, however “inadequate specification of the nutrition care process and the lack of common definitions for nutrition care and its outcomes” have been major barriers.29 In the *Journal of the American Dietetics Association*, Ron Smith a registered dietitian, states that “anecdotal summaries of patients’ responses to medical nutrition therapy are no longer sufficient to justify the benefit. Everyone understands that a proper diet is critical to good health.”27 The development of a model for effective nutrition care has been put forth with the aim of “linking nutrition care to positive outcomes”.29 Currently, the profession is working on demonstrating and justifying that registered dietitians are the best providers of medical nutrition, that services provided by RDs improve the quality of life of patients, and that RD services are cost efficient.27

**Table 5.** When do I refer to a Registered Dietician (RD)?

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<th>Conditions</th>
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</thead>
<tbody>
<tr>
<td>Assessment and treatment of nutrition-related conditions</td>
</tr>
<tr>
<td>Ideal body weight recommendations</td>
</tr>
<tr>
<td>Caloric and dietary needs advice</td>
</tr>
<tr>
<td>Recommendations of foods that facilitate swallowing</td>
</tr>
<tr>
<td>Need for special diets (i.e. renal, cardiac and diabetic patients)</td>
</tr>
<tr>
<td>Specific dietary modifications that need to be made as a result of a disability or general medical condition</td>
</tr>
<tr>
<td>Total Parenteral Nutrition (TPN) formulas and schedules for patients who are unable to eat by mouth</td>
</tr>
</tbody>
</table>


**Social Workers**

While it is difficult to define social work, the concepts underlying social work are easier to explain. A key component of social work is the “person-in-environment” perspective, which highlights the need for the care of a person in the context of environmental influences such as support networks, personal beliefs, social customs and societal laws.30 The idea of a bi-directional relationship existing between a person and society is termed ‘social functioning’. Social work is a framework that is concerned with the social well-being and functioning of individuals at the individual, family, community, national and international levels.30

The education required to become a social worker is strictly regulated. The 4-year Bachelor of Social Work (BSW) degree at a university accredited by the Canadian Association of Schools of Social Work is required for generalists. However to practice in different sub-specialties, a Master of Social Work (MSW) is usually required. Those interested in teaching, research, or social policy administration can pursue post-graduate study leading to a Doctorate degree. There are regulations and a code of ethics, guiding the conduct and practice of social work, and these principles are an important aspect of the social worker’s education.30,31
Understanding the components of social work helps one appreciate the specific roles and responsibilities of the practitioners in this field. Though social workers are commonly viewed as those who work with the homeless, the unemployed and street youth, this perception is only partly true. For example, social workers can influence community and social planning, such as unemployment insurance, old age pension, and other large scale programs. Moreover, social workers are capable of working in a wide variety of settings such as family services agencies, psychiatric hospitals, school boards, welfare administration agencies, federal departments, and even private practice. In essence, social workers empower individuals, via certain practice methods, to identify and use problem-solving skills to improve their social situation (see Table 6).

Since physicians also strive to educate and empower their patients, there are many opportunities for collaboration between the two professions (see Table 7). As a physician, if one suspects child abuse or neglect, a social worker employed by a child welfare agency can be called in to investigate the case. In such a situation, the social worker has the ability to take immediate, protective action, such as recruiting foster parents or placing the child in protective care. As a physician, one may also encounter, for instance, an aggressive and truant student. In this case, social workers, with their expertise in mediation and management, may add much-needed skills to the healthcare team. Though sometimes seem as though social workers are only consulted in dire cases such as abuse, this is certainly not true. Social workers can be enlisted when there is a need for interventions such as parent-child counseling or marriage counseling. Older adult patients, as well as individuals with physical or mental illnesses, may also benefit from having a social worker acting as a link between them – the individual – and community resources, often as a transition from hospital to home or to a long-term care facility. This allows the individual to become integrated into the social structure of his or her community, and ensures that the individual has access to necessary healthcare resources.

There have been studies investigating the benefits of social work practice methods. For example, researchers have evaluated the positive effects of case management for people with severe mental disorders, and have compared the benefits of counseling therapy over medication therapy of patients in a primary care setting, and have assessed the increased effectiveness of group-based teenage parenting programs in improving psychosocial outcomes of the parents and their children. However there is a serious need for methodologically sound projects to firmly establish the need for including social workers in the allied health care team.

### CONCLUSION

Due to the aging population, and the concomitant problems arising from this – namely that of increasingly complex patient presentations, together with the rising incidence and prevalence of chronic illnesses – the focus of health care is shifting. Physicians are now required to look beyond pharmacological solutions and emphasize overall functioning and quality of life for their patients. More emphasis is being placed on the need for health care to be comprehensive and holistic, thus requiring the expertise of allied healthcare professionals in order to adequately address the needs of current patient populations. In fact, in his November 2002 report entitled “Commission on the Future of Health Care in Canada”, Roy Romanow highlighted the need for enhanced collaboration between the healthcare system and social work.

### Table 6. Common practice methods used by Social Workers

<table>
<thead>
<tr>
<th>Case management</th>
<th>Psychosocial therapy</th>
<th>Community resource co-ordination</th>
</tr>
</thead>
<tbody>
<tr>
<td>Child protection assessments*</td>
<td>Psychotherapy*</td>
<td>Developmental social welfare</td>
</tr>
<tr>
<td>Client-centered therapy</td>
<td>Social casework</td>
<td>Grassroots mobilization</td>
</tr>
<tr>
<td>Clinical social work*</td>
<td>Social group-work</td>
<td>Neighborhood and community organizing</td>
</tr>
<tr>
<td>Crisis management</td>
<td>Client advocacy</td>
<td>Political and social action</td>
</tr>
<tr>
<td>Discharge planning</td>
<td>Network skills training</td>
<td>Social planning</td>
</tr>
<tr>
<td>Family and marital therapy*</td>
<td>Class action social work</td>
<td>Social policy analysis and development</td>
</tr>
</tbody>
</table>

*Restricted practice activities – practice methods that are exclusive to social workers who have received specialty training, and who are regulated by provincial statutes

Adapted from original table published in the National Scope of Practice Statement, Canadian Association of Social Workers, [http://www.casw-acts.ca](http://www.casw-acts.ca)

### Table 7. When do I refer to a Social Worker (SW)?

<table>
<thead>
<tr>
<th>Situation</th>
<th>Which social worker do I refer to?</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Possibility of domestic violence, child abuse, or child neglect</td>
<td>Social worker associated with a child welfare agency</td>
</tr>
<tr>
<td>• Adoption issues</td>
<td>Social worker associated with a child welfare agency</td>
</tr>
<tr>
<td>• Young or adult offenders</td>
<td>Social worker specializing in the correctional field; Classification officers; Probation officers; Parole officers</td>
</tr>
<tr>
<td>• Marital problems; parenting problems</td>
<td>Social worker in private practice, or, social worker in health and community service centers</td>
</tr>
<tr>
<td>• Social-welfare problems</td>
<td>Social worker in private practice, or, social worker in health and community service centers</td>
</tr>
<tr>
<td>• Rehabilitation of the elderly, or those with physical or mental disabilities</td>
<td>Social worker associated with a general or psychiatric hospital</td>
</tr>
</tbody>
</table>

Adapted from Canadian Association of Social Workers (2002), [http://www.casw-acts.ca](http://www.casw-acts.ca)
this by emphasizing the importance of “getting the right mix of skills from an integrated team of healthcare providers to deliver the comprehensive approaches to health care that Canadians expect.”35 Unfortunately, many medical schools fail to adequately educate future physicians on the various roles and responsibilities of other health care professionals, and how they can serve as adjuncts to contemporary medical practice.2,3 Recognizing this, the preceding discussion has served to highlight the value, contribution and scope of practice of five key health care professions which are commonly involved in the management of patients in both hospital and community settings. The professions of physiotherapy, occupational therapy, speech-language pathology, dietetics and social work have been described and general guidelines for physician referral have been outlined. Ultimately, it falls to physicians to familiarize themselves with the wide variety of professionals who are available to them, in order to ensure that their patients are receiving holistic and comprehensive health care. Clearly, the trend is now moving towards inter-professional teamwork and collaborative practice in order to optimize outcomes and improve the quality of life of current and future patients.

ACKNOWLEDGEMENTS

The authors would like to thank our Faculty Editor, Professor Penny Salvatori, as well as Derek Orange, Troy Grennan and Sarah McMullen for their valuable editorial contributions.

All three authors contributed equally to the writing and development of this article.

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REFERENCES

How much do you know about Duchenne Muscular Dystrophy?

Rahima Nenshi, BA
Kelly Strode, BSc

WHAT IS DUCHENNE MUSCULAR DYSTROPHY?
Muscular dystrophies are a group of diseases characterized by the following obligate criteria:
1) They are primary myopathies.
2) Degeneration and death of muscle fibers occurs at some stage in the disease.
3) They have a genetic basis.
4) They follow a progressive course.

Duchenne muscular dystrophy (DMD) is one of the most common hereditary neuromuscular diseases, affecting all races and ethnic groups. One of every 3,500 live infant boys will be born with DMD. Duchenne first described the characteristic clinical features in 1861 after seeing boys with progressive weakness, hypertrophy of the calves, intellectual impairment and proliferation of connective tissue in muscle.

Precise diagnosis of DMD is crucial, as it carries both genetic and prognostic implications. Once a diagnosis of DMD is made, appropriate management may be instituted and family members may be screened for the dystrophic mutation. As well, advances in molecular genetics are providing new means of evaluating patients with this condition. Appropriate awareness and treatment of the cardiovascular and respiratory aspects of DMD also allow for a better prognosis for DMD patients. As the pathogenesis of DMD includes many systemic complications, promoting an interdisciplinary approach to these patients' care will help maximize their quality of life.

This quiz is designed to evaluate your knowledge of DMD. Answers along with explanations are located at the end of the quiz.

1) DMD is most commonly inherited in the following pattern:
   a) Autosomal dominant
   b) Autosomal recessive
   c) X-lined recessive
   d) Sporadic mutation

2) What role does dystrophin play in the muscle cell?
   a) Dystrophin works to increase the ability of actin and myosin to bind together.
   b) Dystrophin is a transport protein that helps control the intracellular environment of the myocyte.
   c) Dystrophin works to link the cytoskeleton with the extracellular matrix.
   d) None of the above.

3) Which of the following is true of female carriers of the dystrophin mutation?
   a) Creatine Kinase (CK) levels are elevated in 80% of carriers.
   b) CK levels are highest between the ages of eight and twelve.
   c) Clinically apparent muscle weakness occurs in 2.5 - 20% of female carriers.
   d) All of the above.

4) Most patients with DMD exhibit clinical signs of muscle weakness between:
   a) 0-2 years
   b) 2-5 years
   c) 5-7 years
   d) 7-9 years

5) The pattern of weakness that predominates in the early stages of DMD is:
   a) Proximal muscles and lower extremities.
   b) Distal muscles and upper extremities.
   c) Proximal muscles and upper extremities.
   d) Distal muscles and lower extremities.

6) Which of the following is NOT a common finding on physical exam?
   a) Trendelenburg (waddling) gait
   b) Pseudohypertrophy of calves
   c) Hyperreflexia
   d) Lumbar lordosis
7) **Pseudohypertrophy is characterized by:**
   a) An initial increase in number of muscle cells to compensate for the degenerating muscle cells.
   b) Local interstitial edema.
   c) An increase in muscle bulk to compensate for proximal muscle weakness.
   d) An initial increase in the size of muscle fibers, followed by an increase in muscle volume due to deposits of fat and connective tissue.

8) **All of the following tests are helpful in diagnosing DMD except:**
   a) Pelvic X-Ray
   b) Electromyography
   c) Serum levels of muscle enzymes
   d) Muscle Biopsy

9) **Associated conditions of DMD include:**
   a) Tendon and muscle contractures
   b) Kyphoscoliosis
   c) Intellectual impairment
   d) Obesity
   e) All of the above

10) **Patients with DMD have sensory disturbances and autonomic dysfunction:**
    a) True
    b) False

11) **Which of the following therapies is recommended for treating select DMD patients?**
    a) Oxandrolone
    b) Azathioprine
    c) Cyclosporine
    d) Prednisone

12) **The most common cause of death in DMD patients is:**
    a) Arrhythmia secondary to cardiomyopathy
    b) Cardiorespiratory insufficiency and its ensuing complications
    c) Heart failure
    d) Toxicity from muscle fiber breakdown products

13) **What is the most likely life expectancy of someone with DMD?**
    a) 20-25 years old
    b) 30-35 years old
    c) 35-40 years old
    d) 15-16 years old
ANSWERS

1) C  DMD is an X-linked trait. It is located in the Xp21 region and encodes the protein dystrophin. Seventy percent of cases are male offspring of female carriers of the gene mutation. However, up to 30 percent of cases are new mutations.

2) C  Dystrophin is an essential component of the dystrophin-glycoprotein complex (DGC) and links the cytoskeleton with the extracellular matrix. The DGC strengthens the sarcolemmal membrane and protects it against mechanical injury during contraction. The absence or decreased level of dystrophin in DMD patients weakens and disrupts the sarcolemmal membrane, thus allowing calcium entry and an ensuing process which causes muscle fiber necrosis.

3) D  Carrier detection of at-risk females is possible after the detection of a DNA deletion or duplication in an affected family member. Although mild (three times the upper limit of normal), elevations in CK are noted in up to 80% of female carriers. Most carriers of the dystrophin mutation are asymptomatic, and those symptomatic carriers often present with higher CK levels. Female carriers will demonstrate highest CK levels between eight and twelve years of age.

4) B  Patients born with DMD will be normal at birth and will often achieve all normal motor milestones in infancy. Walking is often delayed in DMD patients, and the first clinical signs manifest around age two or three, when the child finally begins to walk. Patients usually exhibit marked clumsiness and instability, and parents often complain that their child has frequent falls. The child may also have difficulty puckering their lips or may be less able to change their facial expressions. By age eight, the child has difficulty walking up stairs and by the age of twelve, most DMD patients are in a wheelchair.

5) A  The pattern of weakness in DMD first begins in the pelvic girdle muscles then extends to the shoulder girdle. Weakness is more predominant in proximal muscles and, and this is reflected in the child’s compensation for weakness in the pelvic and shoulder girdles. One of the classic signs demonstrating this compensation is Gower’s sign. To stand up, the child rolls from his back to his stomach, pushes himself up on all fours and then “walks” up his legs and thighs with his hands until he’s in standing position.

6) C  Deep tendon reflexes remain normal or are decreased in patients with DMD. Ankle jerks are relatively preserved until the terminal stages, while the knee jerk reflex is less brisk than the ankles by age six, but is eventually lost. As well, it is common to find a stronger brachioradialis reflex compared to either the biceps or triceps reflex. A waddling gait and lumbar lordosis typically result from proximal muscle weakness.

7) D  Muscle biopsy of DMD patients demonstrates degeneration and regeneration of muscle fibers, isolated hypertrophic fibers, and significant replacement of muscle by fat and connective tissue. Muscle fiber necrosis and subsequent fibrous changes are intertwined with the inflammatory response, which also causes the initial enlargement of individual muscle fibers. However, the calves appear large due to an increase in deposits of fat and collagen, not due to the inflammatory response or an increasing number of muscle fibers.

8) A  Elevated serum levels of creatinine kinase and a muscle biopsy revealing minimal dystrophin are diagnostic of muscular dystrophy; however muscle biopsy remains the gold standard. Biopsy reveals the pathological process that involves both the consequence of the genetic mutation and the involvement of the immune system: there is a decrease or absence of dystrophin (<3% of the normal dystrophin [<365 U/L] concentration) as determined by immunocytochemistry. CD8+ and macrophages are also found, both of which contribute to the eventual destruction of the cell. An electrodiagnostic consultation from a neuromuscular specialist is important to exclude motor neuron or peripheral nerve disorders.

9) E  With the atrophy of muscle fibers resulting in weakened muscle strength, the pressure on joints shifts. There are two common complications due to the lack of muscular support: contractures and scoliosis. More than 95% of children with DMD will develop scoliosis, which progresses at a rate of approximately 10 degrees for each year that a child is in a wheelchair. Varying degrees of intellectual impairment are found in DMD patients, though rarely a child presents with average or above average intelligence. Obesity is a frequent problem because of the decreased ability to move therefore a decreased use of calories. This lowers the child’s caloric requirement to a point where even a normal diet can lead to obesity.

10) B  Patients with myopathies do not have sensory disturbances or autonomic dysfunction as the peripheral nerves and the autonomic nervous system are spared.

11) D  The pathophysiology of DMD is driven by the lack of the protein dystrophin which, in the normal person, contributes to the strength and longevity of muscle cells. Although the lack of dystrophin ‘weakens’ the cell, the final stage in the death of the cell involves an inflammatory response, whereby the immune system recognizes the damaged cell, then proceeds to destroy it. A recent study by Griggs et al. (1993) has shown that the use of immunosuppressants can slow the rate of muscle atrophy and its associated weakness, at least in the short term.

This prospective double-blind study examined the effects of prednisone on DMD patients. Compared to placebo, those randomized to high dose prednisone (1.5 mg/kg/d) showed significant improvement in walking, standing, lifting weights, and arising from a supine to standing position. These benefits appeared within 10 days and peaked by three months. However, significant side effects included weight gain, hypertension, behavioural changes, growth retardation and cataracts. Prednisone at lower doses (75 mg/kg/d) is therefore recommended for ambulatory DMD patients older than 5 years. Immunosuppression with azathioprine has been shown to improve clinical function in children with DMD, however due to rare reports of myopathies associated with other drugs (e.g. statins), its use remains controversial. Pilot studies with
oxandrolone, an anabolic steroid, have shown improved quantitative muscle strength with fewer side effects. However, this effect only lasted for 6 months. As DMD has a high incidence in all populations, there is a significant amount of ongoing research investigating novel therapies to improve the morbidity and mortality of the disease.

12) B

In the adult phase of DMD, scoliosis, weakened respiratory muscles, inactivity and obesity compromise both lung expansion and function. By age 14, the patient’s vital capacity can be reduced to up to half of the original vital capacity. The muscle weakness also limits the cough reflex, thus predisposing the patient to pneumonia. Cardiomyopathy is a common feature in DMD patients, occurring in a significant percentage of patients. Together, these respiratory and cardiac complications eventually lead to cardiorespiratory insufficiency.

13) A

Although DMD is a relatively common disease, there have been few breakthroughs in the treatment and management of these patients. Historically, DMD patients lived on average, until their late teens, and rarely past the age of 20. With the recent recognition of DMD’s cardiopulmonary complications and the availability of more respiratory support, patients now live to approximately 20 – 25 years, and sometimes beyond that. At the moment, however, the prognosis continues to be poor, with minimal functional ability and death before age 30.

ACKNOWLEDGEMENTS

The authors express their gratitude to Dr. Anthony Levinson and to Dr. S. Baker for their time and feedback.

AUTHOR BIOGRAPHIES

Rahima Nenshi and Kelly Strode are both in their final year of the McMaster Undergraduate MD Program.

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“Stem cell transplantation involves harvesting of a patient’s own pluripotent bone marrow cells and subsequent reestablishment of the marrow following high-dose toxic chemotherapy for advanced cancer. This modality has been used in the treatment of recurrent breast cancer, but recent meta-analyses of the results have failed to show any significant survival benefit.”¹

When I read the above sentences, they stopped me in my tracks. My aunt died after a long, arduous battle with breast cancer that ended in the early months of 1998. Jane was young and she had only three years of relapse from her disease, so our whole family was hopeful when she was accepted into an experimental trial involving stem cell transplantation; we hoped for a cure from her recurrent breast cancer. Jane spent weeks in isolation in a downtown Toronto hospital with central lines and visitors wearing masks because any exposure to germs would have been devastating, as her immune system had been decimated by the treatment. She suffered not only from the lack of physical contact, but from pain and an incredibly dry mouth that no amount of Popsicles could right. Toward the end of her life, she struggled to breathe as the cancer had metastasized to her lungs. Yet, in two sentences those truths were somehow re-written, overlooked; she became a part of a trial, a ‘poor outcome’. Jane was wonderful and fought hard to win against a devastating disease, and nothing about her experience was captured in those few short, aseptic sentences I read.

Since I stumbled across this text while preparing for my licensing board exam, I have had a hard time putting it out of my head. Medicine is so odd and nothing I experienced could have prepared me for the juxtapositions that I have encountered in medical school. Medicine is all about people; we call them patients. Yet when learning medicine, much time is spent pouring over books and trying to remember facts and details that may or may not be relevant, or even true, several years from now. While my readings occasionally save me from some small humiliations in morning rounds, they do very little to help me console or counsel a family about how to struggle through the death of someone they love. They do even less to help prepare me for dealing with my own feelings and emotions when patients that I am caring for die. I have often found that there is a disparity between what I read in medical textbooks and what I see when working with real people, and part of medicine is, I think, learning to meld the two realities together into a workable truth. Having said that, I was forcibly struck by how little of my aunt’s life and death was captured by the scant phrases that I read. I keep thinking that another medical student will read those lines and not give the words a second thought simply because they are not personal to them, just as I was not affected by so much of what I have read thus far.

For the past three years I have been reading about diseases; some are mild and some fatal, but textbooks, wonderful things that they are, often fail entirely to capture the people behind the patients. When pouring over clinical details, diagnosis and treatment options, it is far too easy to forget, or not even realize how dryly and inadequately these lists and trials summarize personal experiences and struggles. While Evidence-Based practices bring many things to the diverse field of medicine, one aspect it does not offer is any information about the individual and how his or her life is affected by our interventions. How many sentences exactly like the one above had I read about countless other diseases? But, one hit close to home, stopping me and forcing me to think about what I read in a new light, and I hope that will last throughout my career.

I have a picture in my room of Jane reading to her daughter and me when we were children; it was taken long before she knew she would die from breast cancer, and it is a much better testimony to her life than any summary about her experience that could be found in the medical literature.

AUTHOR BIOGRAPHY
Jennifer Clement is a recent graduate of the McMaster University MD (Class of 2004).

REFERENCES
Bayshore HealthCare is a national, Canadian owned care provider serving people in their home as well as in hospitals and care facilities.

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- A complete address to whom correspondences should be addressed including email, telephone and fax
- Three to ten key words describing the text

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