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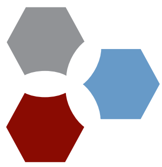

Viewpoint

# Patient Safety

Not so many years ago when this writer thought about patient safety it was related to issues such as elderly patients falling out of bed and physical assault on patients (or in some cases alleged assault by patients). Then, about 5 years ago, *MacLean's* magazine and the national newspapers also reported that as many as 24,000 Canadians were dying annually from medical errors. It was becoming apparent that when we talk and read about patient safety, the term needs to be expanded to include many different aspects of healthcare. For instance:

Patients are being compromised by hospital-acquired infections such as *C. difficile* and MRSA. So serious is the problem that spending time in a hospital or long-term care facility may be thought of as being a potential danger to the patient. Reviewing the news media in the last few years, I could not fail to note that there are many other examples where patient safety is at risk. For instance, medical laboratories, as well as some other types of patient diagnostic services, have been big news in the last several months. Errors in interpretation of some cancer tests by pathologists seem to be getting special attention. Authorities in Newfoundland, New Brunswick, and Ontario have each launched official inquiries into how misdiagnosis has occurred and how they may be prevented.

Diagnostic Radiology and Radiation Therapy have also come under scrutiny including the performance of a radiologist in Prince Edward Island. It seems that his rate of errors in reading radiology images was significantly higher than the acceptable limit. The erroneous interpretation of mammograms has long been a concern because what appears on the mammogram may show changes in the lung (not the breast) microanatomy which suggests that malignant tissue may be present, but similar changes may be benign. False positive and false negative results occur and a skilled radiologist is required if these types of errors are to be minimized. A few months ago, in a large teaching hospital in Ottawa, errors were made by a radiation technologist in the calibration of a therapy machine resulting in cancer patients getting a lower dose of radiation than was prescribed. This is being investigated.

Meanwhile, people who feel they have been harmed by various medications are suing the pharmaceutical industry. There have been several different publications that have claimed that some of the new, so-called "blockbuster" drugs are no more effective than the older generations. In the case of the drug Viox®  (Merck Frosst), it was withdrawn because it was associated with a significant increase in patient mortality. The blockbuster drugs are usually much more expensive than those they replace and, in many cases each one generates over a billion dollars in revenue annually.

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Securing a family doctor is difficult for many patients and examples of how ill people have suffered as a result are frequently cited in the news media. In some cases, those people who are fortunate enough to have a family doctor have found that the time spent with him/her seems to be too short. All of these observations have also been applied to the services provided by medical specialists. The lack of timely and effective care may well compromise patient safety. What presently happens when an error occurs that may have, or is known to have, compromised the safety of a patient's health? There have been several recent cases where the authorities seem to have responded to the problem by doing too little too late. Examples include the rampant problem of hospital-acquired infections.

Here are some examples of how the news media have presented the problems and the challenges:

- Dr. Charles Smith, until he was let go, worked for the Ontario Coroner's Office (OCCO). He was the senior forensic pathologist for deaths involving children. As a result of an increasing concern about some of Dr. Smith's interpretations of his autopsies, a commission chaired by Judge Stephen Goudge was set up. Serious errors in 20 cases resulted in parents and caregivers being wrongly convicted of killing children. Peter Wardle, a lawyer for some of the affected patients, accused the Coroner's Office of ignoring mounting evidence of Dr. Smith's incompetence. The College of Physicians and Surgeons of Ontario submitted that the Coroner's Office had failed to properly notify them of "practice or behavior following below acceptable standards". Dr. Smith subsequently worked for a time in another province as a surgical pathologist. He is said to have retired in British Columbia.
- In Newfoundland, between 1997 and 2005, over 1,000 women were tested to determine if their breast cancer was "estrogen sensitive". If the test was positive, then the patient would likely have benefited from treatment with the drug "Tamoxifin". Because some of the results were considered suspect by an oncologist, re-testing of the original tissue was performed in another province. As a result of this, 300 of the original results were considered faulty. An official inquiry was set-up to obtain more details. It seems that the laboratory that performed the original tests had temporarily suspended the test in 2003 because of problems. In an editorial published in the *Globe and Mail* newspaper, headlined "Tragedy of Errors", it concluded that "Our public institutions, including medical and scientific ones, need to be made accountable for

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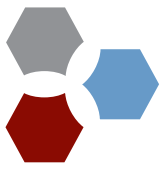



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doing quality work before the catastrophe ensues, rather than after".

- In New Brunswick, the Miramichi inquiry was set-up this year to evaluate the work done by a pathologist. Several thousand cases that involved this pathologist are being reviewed by an audit. The cases included investigations for breast and prostate cancer. An earlier review found that 18% of his reports were incomplete and that 3% were inaccurate. The inquiry heard of cases where both false positive and false negative results for cancer were reported.
- In Owen Sound, significant errors were said to have been present in 600 cases of a pathologist's work. An internal review found that his error rate on reports, including cancer, was 6%. "Acceptable error rate" was said to be 1%.

Accountability starts at the top.

In all of the inquiries cited above, staff shortages at all levels of laboratory medicine were said to be at least partly to blame for the problems. The president of the Canadian Association of Pathologists has echoed these concerns. But, Kurt Davis, Executive Director of the Canadian Society for Medical Laboratory Science, criticized the silence of pathologists throughout the 1990's in an interview published in the *Globe and Mail* as laboratories had major cuts to their budgets (*Globe and Mail*, Tuesday March 18, 2008). The same article noted three other cases where pathology errors had occurred.

In Montreal, women went through chemotherapy for breast cancer because of a wrong diagnosis. In Winnipeg, a pathologist was found to have made 50 errors in one year and in Vancouver, in 2004, a woman had her breast removed because of a misdiagnosis. In a large teaching hospital in Ontario, between November 2004 and November 2007, 326 patients were treated by radiation therapy for various types of skin cancer. It was discovered that an employee had improperly calibrated the radiotherapy equipment; the dosage of radiation was approximately 17% less than had been prescribed. The patients were notified 6 months after the error was noted. It was thought that none of the patients were at an increased risk, partly because the tumours in question are slow to grow and to spread. An outside expert in radiation oncology has been brought in to assess this matter.

In another centre, the reports by one radiologist on the mammograms of many patients were being re-assessed because of evidence of some misdiagnosis. Meanwhile, the pharmacology industry has been criticized for the way that many of the drugs that they have developed are marketed. Drug companies make a great deal of money; they often justify this on the very high costs associated with research and development (R&D). Recently a study was published which suggested that the industry spent as much on advertising and direct promotion to the medical profession as was spent on R&D. The continued success of the industry depends, in many cases, on the development, marketing, and effectiveness of the so-called "blockbuster drugs". Before a new drug can pass regulatory requirements, clinical trials are required and these typically take a few years to complete. However, after all of this, it sometimes happens that problems with a new drug are discovered only when it is released into the market. Only then will thousands of patients be taking the medication.

## What can be done to improve the situation?

The following list has examples of the policies, guidelines, and suggestions that have addressed the issue of patient safety.

- The Wikipedia – Web-based encyclopedia has a comprehensive review of the whole topic, including the issue of disclosing errors (http://en.wikipedia.org/wiki/Patient_safety)
- The Canadian Patient Safety Institute, in March of this year, published national guidelines on how medical professionals should inform patients when they have been harmed as part of their care (http://www.patientsafetyinstitute.ca/index.html)
- See also, Institute for Safe Medication Practices Canada (http://www.ismp-canada.org/index.htm)
- Several years ago the *Canadian Medical Association Journal* published a review of medical errors including discloser policies, see, CMAJ, Feb.20, 2001; 164(4)
- The Goudge inquiry, as part of its recommendations, has urged that the Office of the Chief Coroner's Office be revamped. These included a proposal that the forensic branch should be separated and that more forensic pathologists be recruited.
- The Canadian Association of Pathologists, the Canadian Medical Association, and the Royal College of Physicians and Surgeons are adopting national standards for some cancer tests. The immunohistochemisty tests, such as those you use to look for estrogen receptors in breast tissue, will be given special attention. In this regard, a timely abstract appeared in the College of American Pathologist's newsmagazine, *CAP Today*, "Role of advanced reagents in improving immunohistochemistry", February, 2008, page 93.
- It has been proposed that all patients' medical records should be electronically recorded. This would include doctor's orders and requests for diagnostic testing. In family doctors' offices, a computer program could, for instance, keep track of when each patient is due for further testing. It could also identify when the person is due to have the various age related screening tests, e.g. mammogram, PSA, and fecal occult blood test, etc.

In a future issue of *Advocate*, I will again review the news media to see what they are saying about how the shortage of family doctors and several of the medical and surgical specialties are being addressed, as well as the expanded role of the electronic medical record.

In conclusion, it seems to be clear that a major failure that resulted in almost all of the medical errors cited above is that there was all too often *a lack of accountability and that when the problem was recognized, the response was too little too late*. An editorial that appeared in the *Globe and Mail* on March 31, 2008 summed this up. It was titled "Accountability starts at the top". JLB ❖