

**ACCIDENTAL EXPOSURE OF PREGNANT PATIENTS TO IONIZING RADIATION  
DURING RADIATION THERAPY PLANNING AND TREATMENT**

**IN BRITISH COLUMBIA CANCER CENTERS**

**by**

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## **Abstract**

This project was an interdisciplinary study of a specific medical error - inadvertent radiation therapy (RT) in the treatment of female cancer patients during early pregnancy in British Columbia. RT is very damaging to the fetus during the first trimester of pregnancy and this is a very undesirable adverse event (or medical error). I explored why this error could occur by reviewing the types and causes of medical errors in general and then studying potential errors specific to RT planning and treatment. I created and administered a questionnaire of all health care professionals (HCPs) in cancer centers across British Columbia to assess if this error had occurred. I also asked if HCPs thought this error was a significant problem and asked for their opinions regarding solutions. I examined the potential for HCP legal liability as a result of this error and existing Canadian case law regarding the inadvertent use of teratogenic agents in early pregnancy. I examined different methods for gathering data about and documenting medical errors in general and then specifically for this particular problem. I looked at the barriers to improving patient safety and how the risk of making this medical error could be reduced. As a result of my work, policy has been changed in all British Columbia Cancer Centers. A program now exists which involves check lists, signage and patient education to address this problem.

## Preface

A part of this research was published in articles which required approval by the University of British Columbia ethics review board.

The research outline, the questionnaire and ethics proposal were written by Dr. Karen Goddard (100% contribution). Dr. Rob Olson, Dr. Scott Tyldesley, Dean Mary Anne Bobinski, Dr. Alannah Bergman, Ming Fong and Rosie Vellani checked the content of the proposal and survey for accuracy and relevance. The publications arising from this research were written into manuscript form by Dr. Julianna Caon (70% contribution), Dr. Rob Olson (10% contribution) and Dr. Karen Goddard (20% contribution). The results were analysed by Dr. Rob Olson (90% contribution) and Dr. Karen Goddard (10% contribution).

## List of Publications

1. Caon J, Olson R, Tyldesley S, Bergman A, Bobinski M, Fong M, Ma V, Vellani R, **Goddard K**. Assessing the risk of inadvertent radiation exposure of pregnant patients during radiation therapy planning and treatment in British Columbia. Practical Radiation Oncology, Practical Radiation Oncology, Volume 2, Issue 3, Pages 179-185, July 2012.  
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2. Olson R, Caon J, Tyldesley S, Bergman A, Bobinski M, Fong M, Ma V, Vellani R, **Goddard K** National Survey of Health Care Providers' Views on the Risk of Inadvertent Exposure of Pregnant Patients to Ionizing Radiation in Canadian Radiotherapy Departments, accepted for publication in Journal of Radiation Oncology December 2011. In press.

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## **Dedication**

To Patrick, Rachael and Hannah.

# **1 Introduction**

This thesis and the subject of my research was entirely my own original idea and motivated by personal and professional experience.

## **1.1 Thesis Hypothesis:**

- Female cancer patients were at risk of receiving inadvertent radiation therapy (RT) in early pregnancy (a type of medical error) at BC Cancer Agency Clinics throughout British Columbia (BC), Canada.
- This risk existed because of human error and the lack of any formal mechanisms in place to check if patients were pregnant (such as a mandated communication about this risk, written patient education materials, signage or a check list) prior to radiation therapy.
- Though this was likely to be a rare event, this medical error was very undesirable as RT has the potential to seriously damage a developing fetus.
- Because of the medical consequences, the possibility of legal liability existed for Health Care Practitioners (HCPs) in BC Cancer Agency radiation oncology departments if this medical error was made.
- A research project would help to establish how often inadvertent exposure of a pregnant patient to radiation therapy had previously occurred in BC and study the circumstances around this adverse event. The research would involve asking HCPs

working in radiation oncology departments about their experiences and opinions using a survey. Publication of the results of this survey would be likely to raise awareness of this problem and drive the development of a Provincial program to prevent the inadvertent exposure of pregnant patients to radiation therapy.

## **1.2 Background**

I work as a full time clinical radiation oncologist specializing in the therapy of pediatric cancers, adult sarcomas and adult lung cancers. Some time ago I cared for a woman who had been attempting to conceive for more than 5 years before I met her. She had developed an abdominal sarcoma which had been surgically resected and now required adjuvant post-operative radiation therapy (RT) to reduce the risk of locally recurrent disease. She was just about to have a CT scan to plan a course of high dose abdominal RT, when she casually remarked that she had not had a menstrual cycle for 6 weeks. She said “wouldn’t it be ironic if I had finally managed to become pregnant!” I immediately sent her for a blood test which confirmed that she was indeed pregnant. Had she said nothing, I would have most likely given treatment that would either have destroyed or profoundly damaged her unborn foetus. The thought was terrible.

Later, as a patient myself, I had a chest X-ray at the Vancouver General Hospital. I noticed large signs in English and Cantonese prominently displayed on the walls of the radiology department warning patients to “Tell a staff member if you think you might be pregnant!” I had never seen a sign like this in any Canadian radiation oncology department. Why did we not have these notices in a department where we were giving far higher doses of radiation?

Finally, I was discussing my experience of almost inadvertently irradiating a pregnant woman with a group of colleagues and it became obvious that my experience was not unique. Many of

them had almost treated a patient or had in fact treated a patient in early pregnancy, not realizing that the patient was pregnant. At the time, I was reading a book by Atul Gawande “The checklist manifesto<sup>1</sup>” which outlined the use of checklists to reduce the morbidity and mortality for patients undergoing surgery in hospitals around the world. It occurred to me that a checklist integrated into routine radiation oncology practice with other measures (such as signage and patient education materials) might help to address the risk of inadvertent treatment of pregnant patients with high dose RT and help to ensure that female cancer patients were screened.

This project documents my efforts to change this situation and to explore the medical, legal and ethical ramifications of this particular medical error and medical errors in general.

### **1.3 Thesis Outline**

Chapter 2 documents the potential for damage to the fetus from radiation therapy in early pregnancy (when it may not be obvious that the patient is pregnant) and why preventing this situation is so important.

Chapter 3 examines medical error in the broader context of general medical practice together with the overall frequency of medical errors and the different types and classifications of medical errors. The types of errors that can occur specifically within the practice of radiation oncology are described. Professional groups, regulatory bodies and individuals have introduced measures to reduce the risk of medical errors and these are next documented with specific reference to the WHO study which involved Atul Gawande<sup>2</sup>. Different countries have used different approaches to reduce the frequency of medical errors and the relative merits of these programs are discussed.

Chapter 4 explores the legal and ethical ramifications for a HCP involved in medical error. The elements of medical negligence are explored and relevant Canadian Case law. I have explored medical error in terms of the legal concept of negligence, causation and injury in pregnancy (wrongful life and wrongful birth) duty of care and fiduciary duty. There is no existing Canadian case law regarding the inadvertent exposure of a pregnant woman to ionizing radiation therapy. Therefore, I have examined relevant case law involving other teratogenic agents - drugs prescribed in early pregnancy. These Canadian cases involved three different medications known to cause fetal damage in early pregnancy, namely Phenytoin (otherwise known as Dilantin, a medication used to prevent seizures), Coumadin (otherwise known as Warfarin, an anticoagulant agent used to prevent blood clots) and Accutane (a retinoic acid derivative used to treat acne). In all three cases, infants were born with significant congenital damage as a result of maternal drug ingestion of these drugs during early pregnancy.

I have explored the concept of “Duty of Care” and the origins of this concept in relation to fiduciary duty. Increasingly patients are managed by teams of HCPs. I explore individual HCP responsibility within the team and where duty of care lies in terms of existing Canadian case law.

Once an error has occurred there is the duty to disclose the event to the patient. The last section of Part III discusses ethical and legal issues around disclosure of medical error.

Chapter 5 outlines the research project that I led to assess the incidence of inadvertent radiation exposure of patients in early pregnancy in Cancer centers across British Columbia (BC). I organized an online, anonymous questionnaire for HCPs working in all the different BC Cancer Agency Cancer clinics to document this problem. I also asked HCPs if they felt that current

clinical practise was safe and what measures could be taken to reduce the risk of this medical error. I present the results of the research.

Once the survey results were available, under the guidance of the BC Cancer Agency, Vancouver Program Radiation Oncology departmental head, Dr. Mohammed Khan there was enormous enthusiasm for developing a program which included many different measures (including a check list, patient education materials and mandated improved communication about this risk between HCPs and patients) to prevent inadvertent exposure of pregnant patients to ionizing radiation. A screening policy is now in place for female patients who need to have radiation therapy and has been integrated into clinical practice. I outline the elements of this program.

Chapter 6: In conclusion, I review my thesis and the Provincial program introduced to reduce the risk of this particular adverse event. In general terms, I discuss measures that are currently underway to improve general patient safety in Canadian radiation oncology centers. I also discuss the Canadian legal framework and how this may affect the reporting of medical errors.

One of my radiation oncology colleagues recently pointed out these measures are unlikely to ever completely prevent a pregnant patient from being treated inadvertently. That may be true, but awareness of this problem is the first step towards reducing the risk of this adverse event happening. Showing due diligence and a willingness to try to improve the system is an important component of professionalism. We have a duty of care to always work towards improving patient safety.

## **2 Radiation Therapy: Effects in Early Pregnancy**

Every year approximately ten thousand women who are potentially fertile, receive therapeutic radiation therapy (RT) in Canada as a component of their cancer treatment. Health problems that necessitate RT in younger women include early stage breast cancer, lymphomas, soft tissue sarcomas, brain tumors and benign intracranial arteriovenous malformations<sup>3-5</sup>. It is possible that some of these women may actually become pregnant - either around the time of diagnosis or at some point during their RT planning and treatment.

RT can be very damaging to the developing fetus<sup>6,7</sup>. The risks are greatest in the first trimester during organogenesis, when it may not be at all obvious that a patient is pregnant. Congenital malformations and significant neuro-developmental delay are associated with radiation exposure in early pregnancy. Brain development is most sensitive to radiation damage from weeks 8 to 15 of gestation.<sup>8</sup> This period is called the “window of cortical sensitivity<sup>9</sup>”. Atomic bomb survivors have shown a reduction in intelligence quotient (IQ) with increasing doses above 100 cGy<sup>10</sup>. Much higher doses up to 1 Gy can result in severe mental retardation. Heterotopic grey matter changes and microcephaly are typical of radiation induced damage<sup>10</sup>. This is the type of damage that could potentially occur after high dose RT to the foetus of a pregnant woman during the first trimester. Diagnostic imaging doses are far lower and would be very unlikely to cause this type of damage.

RT later in pregnancy is associated with an increased risk of childhood cancer<sup>11</sup>. The rate of childhood cancer without radiation exposure is approximately 0.1–0.3% (NCI-SEER 1999). Radiation exposure has been shown to increase the risk of leukemia and other cancers in both adults and children<sup>12</sup>. It is likely that the late stage of fetogenesis (in the last trimester of pregnancy when pregnancy is usually obvious) is the period of highest radiosensitivity with

respect to cancer induction<sup>13</sup>. The fetus is assumed to be as susceptible to the carcinogenic effects of radiation as a young child<sup>14</sup>. The relative risk may be up to 1.4 (40%) increase over normal incidence following a fetal dose of 10 cGy, but the individual risk remains small due to the low incidence of childhood cancer. For 0–15 year olds, this is equivalent to one excess cancer death per 1,700 children exposed to 10 mGy in utero<sup>15</sup>.

RT should be avoided if at all possible during pregnancy, but occasionally this treatment must be given during pregnancy to save a mother's life. When this occurs, the pregnant patient is counselled regarding the risks of RT and has to give consent before therapy can proceed. If RT is given, great care is taken to try to minimize fetal dose and to estimate the level of fetal radiation exposure<sup>16</sup>. It may be possible however, that the patient either does not know she is pregnant or is unaware of the potential adverse effects of radiation exposure to her fetus. Theoretically it is possible for a pregnant cancer patient to be exposed to high doses of ionizing radiation inadvertently during early pregnancy when RT is being planned or given<sup>17</sup>.



### 3 Medical Error

Irradiating a pregnant woman and ignoring the possibility that she might be pregnant is a type of medical error. Medical errors are a major cause of world-wide patient morbidity and mortality.

#### 3.1 Types of Medical Error

In 1999 the American [Institute of Medicine](#) (IOM) released a report on Medical Errors “[To Err is Human: Building a Safer Health care system](#)<sup>18</sup>.” The IOM defined an error as “an act or omission that would have been judged wrong by knowledgeable peers at the time it occurred.” Problems arise from actions taken, but also from actions which are not taken. Therefore an error can be defined as “commission or omission.” An error may occur whether or not there were any actual negative consequences for the patient. The foreseeable complications of a correctly performed procedure are not included in this definition.

Errors can be categorized in different ways. Errors can be defined in terms of the manner in which they arose.

1. System errors or “latent” errors arise from flaws inherent in the practice of medicine.  
The physician is not the root cause of this type of error. The circumstances around him or her increase the risk, but the physician shares the responsibility for the mistake.
2. Individual errors arise because of judgement errors on the part of the physician and may be due to deficiencies in skill, knowledge and attentiveness.

These two types of errors overlap. For example, a physician may fail to notice an abnormal laboratory result which he/she should have known was outside normal limits. However, circumstances at the time (for example a clinic that is overbooked where the physician is

stressed and overwhelmed by a vast quantity of information about different patients) create an environment where an abnormal blood result is far more likely to be overlooked<sup>19</sup>. Schilling et al<sup>20</sup> showed that hospital occupancy, nurse staffing levels, the number of weekend admissions and seasonal influenza were all independently associated with in-hospital mortality. Increased numbers of admissions and lower nurse staffing levels both led to an increased risk of inpatient hospital mortality.

Errors can also be subdivided into those that can be effectively addressed medically and remediated and those that are not amenable to therapy and result in permanent patient damage. James Reason defines an error as the “failure of a planned sequence of mental or physical activities to achieve its intended outcome when these failures cannot be attributed to chance<sup>21</sup>. The inclusion of "intention" is important. According to Reason, the concept of an error is not meaningful without the consideration of intention. An error cannot occur if there was no intended outcome. Errors depend on two kinds of failure, either actions do not go as intended or the intended action is not the correct one. In the first case, the desired outcome may or may not be achieved; in the second case, the desired outcome cannot be achieved<sup>18</sup>.

Reason differentiates between “slips” or “lapses” and “mistakes”. A “slip” or “lapse” is defined as occurring when the action conducted is not what was intended. It is an error of execution. The difference between a slip and a lapse is that a slip is observable and a lapse is not. For example, turning the wrong knob on a piece of equipment would be a slip; not being able to recall something from memory is a lapse.

In a mistake, the action proceeds as planned but fails to achieve its intended outcome because the planned action was wrong in the first place. The situation might have been assessed incorrectly, and/or there could have been a lack of knowledge of the situation. In a mistake, the original intention is inadequate and involves failure of planning<sup>22</sup>.

In medical practice, slips, lapses, and mistakes are all serious and can potentially harm patients. For example, a slip might be involved if the physician chooses an appropriate medication and then writes 10 mg when the intention was to write 1 mg. The original intention is correct (the correct medication was chosen given the patient's condition), but the action did not proceed as planned. On the other hand, a mistake might involve selecting the wrong drug because the physician's diagnosis is wrong. In the case of a patient who was prescribed a teratogenic agent such as radiation therapy in early pregnancy, the possibility of pregnancy was overlooked. However, the radiation therapy was the correct treatment for the underlying cancer. This would be classified as a "slip" though the consequences could be very serious.

In considering how humans contribute to error, it is important to distinguish between active and latent errors<sup>23</sup>. Active errors occur at the level of the frontline operator, and their effects are felt almost immediately. This is sometimes called "the sharp end". Latent errors tend to be removed from the direct control of the operator and include things such as poor design, incorrect installation, faulty maintenance, bad management decisions and poorly structured organizations. These are called "the blunt end". The error of not checking that a patient is pregnant before giving high dose radiation therapy is a latent error.

### 3.2 Collecting Data on Medical Errors

It is difficult to accurately evaluate the true extent of medical error in clinical practice. Accurate systems to collect data are often not in place. Systems may fail because of complex coincidences which are difficult to detect, analyse and predict. Also errors are often discovered once they have occurred. Failures are reviewed in hindsight and this introduces “hindsight bias” which means that factors that were not seen or understood when the error occurred, seem obvious in retrospect. This can lead to simplification of the causes of an accident and the tendency to focus only on a single element as the cause while ignoring multiple contributing factors. Hindsight bias makes it easy to arrive at a simple solution or to blame an individual, but difficult to determine what really went wrong.

Many medical errors go unreported and are not even reviewed in hindsight<sup>24-26</sup>. Policymakers and health care administrators need accurate data on the types, frequencies, and causes of medical errors before systemic reforms can be implemented. To gather the necessary information to implement a systems approach, in the United States, the IOM recommended that each state create a dual reporting system<sup>18</sup>. The IOM encouraged Congress to establish a national system operated by “The National Forum for Health Care Quality Measurement and Reporting” to collect reports from individual states concerning the most serious errors taking place in hospitals and other health care facilities. This led to the establishment of the “National Quality Forum” (NQF) (website at <http://www.qualityforum.org/Home.aspx> )

The NQF is a non-profit organization which aims to improve the quality of health care by measuring and publically reporting performance in health care facilities. Performance is

primarily measured by the incidence of serious reportable events (SREs). The NQF has developed and endorsed a list of SREs (serious, largely preventable and harmful clinical events).

It is assumed that SREs are easily identifiable so that once state departments of health have detected SREs, facilities can be held accountable and protocols can be developed to reduce future errors. The IOM recommended that analyses of the causes of SREs be available to the public. The IOM also recommended that a voluntary reporting mechanism should be developed by the Center for Patient Safety for less serious medical errors. The intention of the IOM was that reports under a voluntary system would receive legal protection from data discovery – unlike the mandatory system. One of the IOM’s aims was to encourage open admission of medical errors to overcome the “culture of blame” that discourages admission of medical errors<sup>27</sup>. The hope was that in these circumstances, accurate data could be collected to identify the causes of errors.

The Centers for Medicare and Medicaid Services require hospitals to report forty-two measures of quality, including some measures of medical errors, in order to receive a full payment update to rates in the following fiscal year<sup>28</sup>. The Agency for Healthcare Research and Quality (AHRQ), part of the Department of Health and Human Services established the Center for Quality Improvement and Patient Safety in 2001 to gather and disseminate information on health care quality measurement and to implement evidence-based preventive practices<sup>27</sup>.

In December 2000, Congress allocated \$50 million to AHRQ for research on methods to reduce medical errors. In July 2005, Congress reinforced its support for error monitoring with the

Patient Safety and Quality Improvement Act, which encouraged voluntary and confidential reporting of adverse events and created a certification process for patient safety organizations to collect and analyze patient safety information. However at present in the United States, no "comprehensive nationwide monitoring system" exists for medical error reporting, and recent attempts to estimate error rates show little change in actual error incidence nationwide<sup>28</sup>. A federal and state patchwork of different reporting systems exists which is unable to gather all of the data regarding SREs.

### **3.3 Frequency of Medical Errors**

On the basis of studies in New York, Colorado and Utah it was estimated that between 44,000 and 98,000 Americans died in hospital settings in 1997 specifically as a result of preventable medical errors<sup>25</sup>. Errors were identified at many points during patient care - at the time of diagnosis, prevention, treatment and follow up. If the rate of serious medical errors had remained constant since the IOM study<sup>28</sup>, these events were responsible for between 49,000 and 109,000 American deaths related to health care<sup>29</sup> in the year of 2006. Many publications continue to document serious medical errors. For example, one study found that orthopaedic hand surgeons had a 20% chance of performing surgery on the wrong side of a patient's body at some point throughout their careers<sup>30</sup>.

The leading Canadian research in the study of medical errors comes from the Canadian Adverse Events Study<sup>31</sup>. A random sampling of patient charts from non-specialized acute care hospitals was reviewed during the year 2000. The overall incidence rate of adverse events was 7.5% or approximately 185,000 adverse events out of 2.5 million admissions in Canada. Over 36% of

these were determined to have been potentially preventable. The most frequent type of adverse event in the study related to surgical procedures, followed by drug or fluid-related events. The Canadian study concluded that almost 16% of adverse events resulted in death and that 5.2% resulted in permanent disability. It was estimated by the Canadian Health Care Information Institute that in 2003, 5.2 million Canadians (approximately 24%) reported that they or a family member had experienced a preventable adverse event and just over 50% reported that this event had a serious effect on their health.

### **3.4 Causes of Medical Errors**

The commonest cause of errors in medical practice is human error<sup>32</sup>. Errors can occur at the level of an individual HCP. The Institute of medicine (IOM) made a strong case that the extent of medical errors was not because there were huge numbers of incompetent HCPs, but that the health care systems in place were inadequate<sup>18</sup>. The report stated that "although some of these cases of preventable adverse events may stem from incompetent or impaired providers, the committee believes that many could likely have been avoided had better systems of care been in place." Health care delivery for any one patient generally involves a variety of complex interlinked systems. Improving safety for patients requires systems modification in order to modify the conditions that contribute to errors<sup>18</sup>. The IOM reviewed the successful systems-based safety improvements in the airline industry and in workplace safety and noted that "Accidents can be prevented through good organizational design and management." James Reason echoes this and argues against "the person approach" which focuses on the errors of individuals blaming them for incompetence, but instead pulling back to take a broader view and concentrating on the conditions in which people work i.e. "the system approach". In this way

systems can be set up to anticipate ways in which errors might occur and build in preventative mechanisms.

Charles Perrow's analysis of the accident at Three Mile Island identified how systems can cause or prevent accidents<sup>33</sup>. James Reason extended the thinking by analyzing multiple accidents to examine the role of systems and the human contribution to accidents<sup>18</sup>. He wrote that "a system is a set of interdependent elements interacting to achieve a common aim. The elements may be both human and non-human (such as equipment and technologies)."

Systems can be very large and far-reaching, or they can be more localized. In health care, a system can be an integrated delivery system, a central multihospital system, or a virtual system comprised of many different partners over a wide geographic area. An operating room or a CT treatment planning unit for radiation therapy is also a type of system which is itself a small part of another system. The CT radiation therapy planning unit is part of a radiation oncology department, which is part of a cancer center, which is part of a larger health care delivery system. The variable size, scope, and membership of systems make them difficult to analyze and understand.

However, errors cannot be entirely attributed to systems based problems. Generally, SREs arise from a mixture of errors by individual HCPs on the background of underlying systems based problems<sup>23</sup>.

Some of the factors that predispose individual HCPs to errors include, the HCP's level of experience, competence and training, the presence of stress and psychological "burn out."<sup>34</sup>



A culture exists where there is significant shame associated with a medical error and HCPs do not want to admit that they made a mistake. Very often errors are not reported because of this leading to an increased risk that the error will be repeated.<sup>35</sup> A professional “code of silence” exists about personal and colleague’s errors – often because of fear of subsequent litigation.

Increasingly physicians do not work independently, but in the settings of hospitals and clinics where their work load is dictated by health care administrators, government policy and available resources. HCPs are often not in a position to control their own work load and find themselves with multiple tasks to complete and insufficient time to consider patient problems accurately (individual HCP trying to cope with a system based problem).

All human beings are prone to cognitive errors<sup>22</sup>. These arise on the basis of “biases” (non-rational strategies) and failed heuristics (mental shortcuts). Biases have been shown to occur in every phase of patient care and an example would be the tendency for HCPs to overestimate the possibility of a diagnosis that is easy to recall. Daniel Kahneman is the author of a book called “Thinking Fast and Slow”<sup>36</sup>. In this he explores why people fail to make rational decisions leading to errors. He identifies two different ways in which the brain thinks. System 1, which is dominant, subconscious, involves swift, intuitive thought and is prone to heuristic thinking and errors. System 2 which is deliberate, conscious thought and is much harder to “turn on”. System 2 thought is very infrequent compared to System 1. The result is that we often feel we have made rational choices, when we have not. Our thinking is prone to biases of which we are unaware.

Factors that are likely to predispose to systems failure include the way that interdisciplinary teams of HCPs are set up to deliver patient care. No procedural guidelines, checklists or

reminders may be in place. As a result, personnel in system may fail to understand their role as part of the team and communication may be poor between different HCPs involved in a patient's care. In health care systems increasingly short of funding, resources may well be inadequate. As previously discussed, there is no comprehensive means of gathering data about mistakes and why they occur. This makes implementation of proactive changes to prevent errors very difficult if not impossible. In North America there is an overarching tort based medico-legal system in place which is punitive. Much has been done to demonstrate that this fails to provide an incentive to be honest about mistakes<sup>37</sup>. Litigation is very time consuming, stressful and threatens a HCP's livelihood. These circumstances do not encourage openness and help to promote a culture of blame.

Although many features of systems and accidents in other industries are also found in health care, there are important differences. In most industries, an accident has an easily recognizable and direct effect on the worker or the company. For example in an aeroplane accident, the pilot is invariably affected by the error as they are actually inside the aeroplane. In health care, the damage happens to a third party - a patient. The HCP or the organization is very rarely directly damaged<sup>18</sup>. In addition the particular HCP who made the error might not be aware of the harm done to the patient unless a "feedback loop" is in place. For example it is possible that the radiation oncologist responsible for the error of prescribing RT in early pregnancy would not be aware of the actual damage done to the fetus. The obstetrician who delivers the baby and the pediatrician who provides subsequent care would be aware of the baby's subsequent health problems.

In medical practice, harm also usually occurs to only one patient at a time; not whole groups of patients. As compared with an industry like air travel, this makes the accident far less obvious.

Human error is one of the greatest contributors to accidents in industry and medicine. In industry, Charles Perrow (a sociological theorist of organizations) estimated that, on average, 60–80% of accidents involved human error<sup>33</sup>. In health care there is evidence to show that the situation is no different. An analysis of anaesthesia mishaps found that human error was involved in 82 percent of preventable incidents and the remainder involved mainly equipment failure<sup>18</sup>. Even when equipment failure occurs, it can be exacerbated by human error.

### **3.5 Medical Errors in Radiation Oncology**

Errors in radiation oncology have been the subject of a series of high profile The [New York Times \(NYT\) articles by Walt Bogdanich](#)<sup>38, 39, 39-41</sup> for the past 1 – 2 years.

The articles are set in the context of ever increasing technological advances in the field of radiation oncology. Administration of RT has become very complex and demands sophisticated equipment and software. An interdisciplinary team of expert HCPs from many fields is necessary to plan and deliver RT safely. This team includes medical physicists, technicians who maintain the complex equipment used to deliver RT (linear accelerators which are complicated and require sophisticated hardware and software to treat patients accurately), radiation therapists (who administer the RT) as well as radiation oncologists.

Errors documented included simple “non-technical errors”, such as the wrong patient receiving RT. The treatment of a pregnant patient with RT inadvertently in early pregnancy would be one of these errors. However, The New York Times (NYT) focussed primarily on errors involving the faulty implementation of advanced technology. Investigators found and documented

multiple episodes of very serious incidents where patients were given massive overdoses of RT and others where RT was not accurately focussed on the cancer, but on normal structures.

Patients suffered severe injury and some died as a consequence. The causes of these errors were found to be increasingly complex operating systems with staff that were not adequately trained to monitor the situation and detect errors. Also in some instances, members of staff were overworked and too busy to catch mistakes. Too much trust had been placed in complex computers systems and there appeared to be little oversight by medical physicists and radiation therapists. Medical physicists play a critical role in ensuring patient safety by checking linear accelerator function, supervising implementation and upgrading of complex software therapy programs and checking patient treatment plans. Though their role is so critical, at least 16 American states and the District of Columbia do not require the licensing or registration of medical physicists.

However, the most ubiquitous problem found was lack of quality control. There were no protocols in use to routinely check treatment accuracy and safety. In one radiation oncology department studied where serious errors had occurred, there was no follow-up program in place. Under these circumstances where there was no feedback regarding any problems with the quality of RT administered and HCPs had no idea if patients were cured of their cancer or if they had significant complications. In addition, there was no peer review, no quality assurance meetings, no outcome studies and no mortality and morbidity conferences. There is no way to address medical errors in this type of culture.

The NYT's investigators found that radiation accidents were chronically under-reported. Regulations varied between different States and laws created to protect patients from harm were weak or unevenly applied. They concluded that new technology in radiation oncology

had “outpaced its oversight” and that hospitals violated safety rules, injured patients and failed to report mistakes. Thirteen states, including California, did not require that errors involving linear accelerators be reported to state health officials. Texas required that they be reported, but had no enforcement authority. New York rarely fined radiation therapy units for substandard care, while Florida frequently did so. There was significant variation between different States regarding the reporting of radiation treatment errors and no requirement that these mistakes be reported to a central database. The American Society for Radiation Oncology called for the establishment of the nation’s first central database for the reporting of errors involving linear accelerators in 2010. So far this has not happened.

In Canada there is presently no central database to document errors made in radiation oncology practice. The Canadian Partnership for quality Radiation Therapy involves collaboration between the Canadian Professional Associations for Radiation Oncologists, Medical Physicists and Radiation Therapists to establish a framework for developing quality control mechanisms. At present however there is no National data collection or reporting system in place. There is also no legal obligation to report errors. The frequency and extent of errors in Canadian radiation oncology practice is unknown. This makes it impossible to study why these errors occur and identify the necessary components of effective preventative program.

### **3.6 Attempts to Prevent Medical Errors and Developing a Culture of Safety (General)**

There are many different approaches to reduce medical error. Over the past 10 years or so there has been increasing emphasis on the development of a “culture of safety” and the

implementation of different systems such as check lists. In North America we have a legal system which was originally designed to discourage errors by the prosecution of HCPs who had made mistakes and to offer restorative justice for patients harmed by those errors. However, as previously described, many now feel that this system, because of its punitive nature does not encourage honesty.

Traditionally the response to medical errors by the court system in both Canada and the United States focuses on medical errors by punishing individual HCPs<sup>42</sup>. Physicians may well be the subject of legal action regarding a medical error and may even be in danger of losing their job. Sometimes individual physicians are clearly negligent, but very often medical errors are the result of systemic failures and cognitive errors<sup>18</sup>. Doctors have been shown to suffer depression, guilt and psychological distress about medical errors they have made<sup>35</sup>. The punitive legal atmosphere in North America does not encourage an honest examination of the facts regarding medical errors, making it difficult to establish if and why a medical error occurred. Litigation is lengthy and very costly in terms of time, finances and mental strength. This only helps to encourage professional codes of silence where physicians are unlikely to report their own or colleague's errors<sup>43</sup>. The law should function to encourage both competent and ethically sound medical practice. There is evidence to show that present North American law does not effectively achieve these goals. An intimidated physician is more likely to deny or cover up a medical error.

The National Patient Safety Foundation defines patient safety as the “avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the processes of health care”<sup>24</sup>. For the IOM report, safety was defined as “freedom from accidental injury”. They have moved away

from the concept that blame should be allotted to a single individual physician. Instead they take the view that “safety” does not reside in a single HCP, device or department, but arises from the interactions of different components of a system. The concept of safe clinical practice is relative and continues to evolve over time. When risks become known, measures to address them should become part of routine safety requirements. Safety is also more than just the absence of errors. A safe health care system should take into account the fact that health care is complex and identify solutions in the broader context and not attach blame to any one individual. There should be a set of processes to identify, evaluate, and minimize hazards. These processes should be in constant evolution and responding to data about medical errors. The goal of reducing the number of medical errors and providing better quality care should be achievable. Ensuring patient safety involves the establishment of operational systems and processes that increase the reliability of patient care.

Operational effective systems<sup>23</sup> include physician-order entry and medication administration systems which have been shown to have a dramatic impact in reducing errors (such as checklists).

To allow for the honest acknowledgment of errors and the implementation of effective operational systems, a culture of safety<sup>23</sup> should be put in place. This involves the creation of a culture by health care organizations oriented toward acknowledging, preventing and intercepting errors that will inevitably occur. There should be an emphasis quality of care review, on teamwork and an ongoing focus on redesigning care systems, particularly in high risk areas such as operating rooms, intensive care units and emergency rooms. Health care facilities should build a culture where mistakes can be readily acknowledged and addressed. Knowledge of

errors can subsequently be used in educational programs to create an environment where process change becomes the norm<sup>44</sup>.

Financial incentives have been used in efforts by United States federal government to promote patient safety. As of October 2008, Medicare no longer paid for ten "reasonably preventable" conditions caused by medical errors, such as bed sores, injuries from falls and some hospital-associated infections<sup>25, 45</sup>. Some problems with this system have been pointed out. In patients who have underlying health problems, the risk of medical complications is increased. There has been debate about which conditions are reasonably preventable. The Canadian Health care system is not financed in this way and it would not be possible to implement these measures across the border.

The [Canadian Patient Safety Institute](http://www.patientsafetyinstitute.ca/English/Pages/default.aspx) was established by Health Canada in 2003. It was designed to work with government, health organizations and healthcare professions to improve patient safety and quality. For example they design products such as the "Canadian Root Cause Analysis Framework" which is a tool for identifying and addressing the root causes of critical incidents in healthcare and provide resources for research. Their website is at:

<http://www.patientsafetyinstitute.ca/English/Pages/default.aspx>

However, there is no mandate in Canadian health care institutions to report to this body and many Canadian HCPs are unaware of its existence.

### **3.7 Check lists**

Check lists are a form of operational effective systems and were recently introduced into surgical practice. Atul Gawande is a surgeon and a writer who has published extensively on this subject.



He is a staff member of Brigham and Women's Hospital, the Dana Farber Cancer Institute and the New Yorker magazine. Details of his career and publications are available at:

<http://gawande.com/about>

He was the instigator of ground breaking research with the World Health Organization (WHO) to reduce morbidity and mortality associated with surgery. "A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population" was published in the New England Journal of Medicine in January of 2009<sup>46</sup>. Surgery is a far more common therapeutic procedure than radiation therapy (prior to starting this project, it was estimated that 234 million operations were performed yearly). Surgical complications are common and often preventable. Dr. Gawande and his team hypothesized that a program to implement a 19-item surgical safety checklist designed to improve team communication and consistency of care would reduce the rate of complications and deaths associated with surgery. Between October 2007 and September 2008, eight hospitals in eight cities (Toronto, Canada; New Delhi, India; Amman, Jordan; Auckland, New Zealand; Manila, Philippines; Ifakara, Tanzania; London, England; and Seattle, WA) representing a variety of economic circumstances and diverse populations of patients, participated in the World Health Organization's "Safe Surgery Saves Lives program". They prospectively collected data on clinical processes and outcomes from 3733 consecutively enrolled patients 16 years of age or older who were undergoing non-cardiac surgery. They subsequently collected data on 3955 consecutively enrolled patients after the introduction of the Surgical Safety Checklist. The primary end point was the rate of complications, including death, during hospitalization within the first 30 days after the operation. Results showed that the rate of death was 1.5% before the checklist was introduced and declined to 0.8% afterward ( $P = 0.003$ ). Inpatient complications occurred in 11.0% of patients at baseline and in 7.0% after introduction of the checklist

( $P < 0.001$ ). The conclusion was that implementation of the checklist was associated with concomitant reductions in the rates of death and complications among patients at least 16 years of age who were undergoing non-cardiac surgery in a diverse group of hospitals.

Atul Gawande has written about the origins of using checklists in his book “The Check list Manifesto<sup>1</sup>”. He describes studying the aeronautical industry and observing pilots running through checklists as they prepared for take-off. It occurred to him that the principle of checklists could easily apply to surgical procedures. Checklists ensure first and foremost that communication improves between the different team members. Prior to the start of any procedure, each member has to introduce themselves and discuss their role as part of that team. A checklist not only ensures that all the necessary equipment for the procedure is present before embarking on surgery, but also improves communication between team members. Different risks are also identified and excluded before the start of surgery.

Checklists help to resist the biases and failed heuristics that lead to medical errors and to facilitate diagnostic reasoning<sup>47</sup>. For example in medical diagnosis, checklists have the potential to decrease reliance on memory, consider a comprehensive differential diagnosis for common symptoms, step back from the immediate problem to examine the reasoning process (metacognition), develop strategies to avoid predictable bias (cognitive forcing functions), recognize altered mood states that arise from fatigue, sleep deprivation, or other conditions and develop strategies to reduce their negative consequences (affective forcing functions)<sup>47</sup>.

### **3.8 Attempts to Prevent Medical Errors and Developing a Culture of Safety (Radiation Oncology)**

#### **3.81 United States of America**

The American Society for Radiation Oncology (ASTRO) started to develop programs to address the issue of errors in radiation oncology after the first New York Times article appeared. Early in 2011 the agenda for the ASTRO Board of Directors' winter meeting was changed to focus on errors in radiation oncology. They proposed the development of a quality assurance plan.

This plan involves the creation of a national database for the reporting of linear accelerator- and CT-based medical errors. Some states (for example Massachusetts) already have error reporting requirements, but not all states do. A national database would capture much needed data about the frequency and types of errors. ASTRO board members felt that it was important that the data base be easy to use, universal, anonymous, and non-punitive. It was acknowledged that the information from this data base must be protected so that lawyers could not use it for law suits. The Federal Aviation Administration (FAA) has an anonymous system for the same reason. The intention would be to capture data about "near-misses" as well as errors to create an early warning system.

An enhanced institutional practice accreditation program is being developed with additional accreditation modules specifically for new advanced technologies in radiation oncology.

Currently ASTRO and the ACR (the American College of Radiology) have a joint voluntary accreditation program. Though the number of institutions requesting accreditation is increasing, the eventual aim would be to make this institutional accreditation program mandatory. The

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Therapy (CARE) bill has been unable to move forward and has been before Congress for the last few years. The bill would require that staff working in radiation therapy and imaging facilities be credentialed and that the facilities themselves be accredited. ASTRO has offered its members' expertise to policy makers and members of Congress to move this legislation forward. ASTRO will also advise the National Institute of Health's Radiological Physics Center to evaluate the safety of treatments.

ASTRO's "Integrating the Healthcare Enterprise-Radiation Oncology connectivity compliance program" will be developed to ensure that medical technologies from different manufacturers can safely transfer information to reduce the chance of medical errors.

ASTRO's plan also included patient education programs to empower patients to ask the right questions about quality checks and what safety programs should be in place.

It was also identified that the FDA review process for manufacturers could be improved and it was suggested that the FDA, users, and manufacturers work together to make the review process more transparent

The AAPM (the American Association of Physics in Medicine), ASTRO, and the ACR formed a radiation therapy task force specifically to discuss patient safety issues. The task force's goal is to help the various groups work cooperatively toward reducing errors in radiation therapy. In addition to supporting credentialing, accreditation, and adverse event reporting, the group is helping develop white papers on best practices for specific technically challenging procedures such as image-guided radiation therapy.

### **3.82 Canada**

The Canadian Association of Radiation Oncology (CARO), the Canadian Organization of Medical Physicists (COMP), the Canadian Association of Medical Radiation Technologists (CAMRT) and the Canadian Partnership against Cancer (CPAC) have joined forces to form the [Canadian Partnership for Quality Radiation Therapy](#) (CPQR). The aim of CPQR is to improve the quality of Canadian radiation therapy services by developing consensus based guidelines and “indicator documents”. They have begun by producing a document which defines the necessary elements for high quality radiation oncology treatment services in a document “[Quality Assurance Guidance for Canadian Radiation Treatment Programs](#).” As far as the reporting of errors in radiation oncology, this document states “The Radiation Treatment Program takes action to prevent critical radiation treatment incidents from recurring. The Radiation Treatment Program reports critical radiation treatment incidents to local, provincial, national and/or international organizations as required, with the aim of preventing similar incidents from occurring elsewhere”. There is no mention of a national data base and no definition of when it be required that data on critical radiation treatment incidents be shared on a national basis.

### **3.83 Europe**

Europe has addressed the problem of errors in radiation oncology therapy with the Ionising Radiation Medical Exposures Regulations 2000 (more commonly known as IRMER). These regulations were introduced in May 2000 to implement the European Directive 97/43/Euratom (The Medical Exposures Directive). The purpose of these regulations was to make the administration of both diagnostic and therapeutic radiation safer.

IRMER documents can be found at:

<http://www.legislation.gov.uk/ukxi/2000/1059/contents/made>

Any cancer treatment center in the United Kingdom must comply with IRMER. Health care institutions are obliged to develop center wide policies which are revised on a regular basis. These policies also have to cover the administration of other teratogenic agents such as chemotherapy and radionucleotides as well as external beam radiation therapy. To comply with European regulations each European institution must establish procedures to meet IRMER regulations with the specific aim of justifying patient exposure to ionizing radiation and reduce risks associated with that exposure. No national data base to collect information on radiation oncology errors exists within Europe.

In the event of a major error an investigation and subsequent report by an inspector appointed by government for The Ionising Radiation (Medical Exposures) Regulations 2000 may be generated and subsequently made available to HCPs and the public. This happened in the highly publicized case of Lisa Norris, a child who was overdosed with radiation therapy in 2006 at the Beatson Oncology Center in Glasgow.

This report is available at: <http://www.scotland.gov.uk/Resource/Doc/153082/0041158.pdf>

A detailed investigation was undertaken to look at how the error arose in the context of the staff involved, their level of training, professional education programs, departmental quality assurance procedures and available resources. It also compared this error to previous errors in UK radiation oncology practice. The report assessed the aetiology of each medical error event and the

circumstantial similarities and differences between the different cases. Recommendations were made in the report to prevent this and other types of errors in radiation therapy clinical practice.

### **3.84 New Zealand**

In 1974 New Zealand adopted a government funded system for compensating people with personal injuries<sup>48</sup>. This was operated by the Accident Compensation Corporation (ACC) and replaced the previous tort based system. This system has therefore been in place for over 30 years. The avoidance of litigation is widely seen as a social gain<sup>49</sup>. In 2005 there were reforms which removed the final fault element from the compensation criteria for medical injuries. The system provides compensation to patients without litigation and the focus is on safety improvement and not on assigning blame and seeking punishment<sup>50</sup>. As the previous analysis from the IOM showed, medical errors are only rarely due to individual HCP incompetence, but often due to the failure of the system in which that HCP works. Mechanisms for professional accountability did accompany this change in medico-legal culture.

These changes in compensation arose as a result of workers compensation reforms. A Royal commission in 1967 concluded that the victims of accidents needed a secure source of financial support. The commission recommended a “no fault” compensation system for personal injury. In the New Zealand system, injured patients receive government funded compensation through the ACC. In exchange they give up the right to sue for damages arising out of any personal injury covered by the accident compensation legislation. It is still possible in this system to bring action for exemplary damages. In 1992 the concepts of medical error and medical mishap were formally introduced into ACC legislation. Medical error was defined as failure to observe a reasonable standard of skill and care. Before 2002 it was not possible to attribute error to any

organization, but only to individuals and it was felt that this had discouraged physicians to be open about medical errors. Medical mishap was defined as a rare and severe adverse consequence of properly given treatment. The mishap concept allowed for recovery of claims that were not due to medical negligence and accounted for the majority of accepted claims.

In 2002 the whole situation was reviewed as there was inconsistency between medical error and the no fault basis of the wider ACC system. As a result of this the terms medical error and medical mishap were replaced by the concept of treatment injury<sup>51</sup>. In this way coverage was broadened to include all personal injuries suffered while receiving treatment from health care professionals. Injuries that are a necessary part or normal consequence of treatment (such as hair loss from chemotherapy) are not covered. There is an independent process for concerns regarding the quality of care and the ACC is required to report any “risk of harm to the public” to the responsible authority. A patient safety team analyses claims data and works with health organizations and researchers to improve patient safety.

The system is far more affordable than the tort based medical malpractice system in North America. Many more patients are likely to be compensated as fault does not need to be found. The levels of compensation to individuals are smaller, but many American awards are excessive. Legal and administrative costs are very much reduced compared with North America<sup>52</sup>. The no fault system does not mean that there is no accountability. A health and disability commissioner promotes patient’s rights and provides accountability where care has been negligent. Complaints are investigated and resolved using patient advocacy and mediation.

New Zealand hospitals have an adverse event rate of 12.9% - which is not lower than other countries and is between the rates of UK and Australia. But it could be that New Zealand is the



only country where adverse events are reported accurately and in other countries adverse events are hidden through fear of litigation – so that the adverse event rate in the UK and Australia could be in fact much higher.

It should be noted that despite the more open “no fault” compensation system in New Zealand, this country does not screen at risk female cancer patients on a routine basis for pregnancy prior to radiation therapy treatment. Nor do they collect information about errors made in the practise of radiation oncology in any systematic fashion. The attempt to eliminate the “culture of blame” and encourage reporting of medical errors has not encouraged HCPs to address this particular problem in any meaningful way.

## 4 Legal Approaches to Medical Error

### 4.1 The Elements of Negligence

Negligence arises in medico-legal cases when the conduct of the health care professional (HCP) falls below the standard established by law for protection of the patient against unreasonable risk of harm.

Negligence law began in the United States during the 1830s and 1840s with recognition of the concept of liability for carelessly caused harm. *Brown v. Kendall* is the first case where negligence was a distinct tort. Chief Judge Shaw's 1850 decision outlined that a person should be subject to liability for carelessly causing harm to another. A dog owner was trying to separate two dogs with a stick and inadvertently struck the claimant in the eye causing serious injury. This was the first case in North America which articulated the need for a causal connection between the defendant's breach of duty and the plaintiff's damage that was natural, probable, proximate, and not too remote. As negligence law developed, it was recognised that there should be essential parts or "elements" which centered on a defendant's failure to exercise due care and the plaintiff's proximately resulting harm.

Four major elements are required for a negligence action:

1. Duty: A health care practitioner (HCP) owes a duty of care to the patient. The duty is defined by the relationship between the HCP and the patient and includes the duty to attend, make the correct diagnosis, confer and refer if necessary to another HCP, coordinate care, ensure informed consent, treat and organize appropriate follow up care.

2. Breach of Duty: The applicable standard of carrying out that duty was breached. The standard of care in Canada is based on what a reasonable practitioner would do in the circumstances.

3. Causation: The injury arose as a result of that breach of duty.

#### 4. Injury

The following cases explore issues of negligence and subsequent legal liability related to the effects of inadvertent administration of teratogenic agents in early pregnancy. There is no Canadian case law regarding the inadvertent administration of radiation therapy (RT) to a pregnant patient. However, RT is a teratogenic agent, which has as much potential to damage an unborn foetus as any of the agents prescribed to plaintiffs in these court cases. In all these cases, teratogenic drugs were prescribed to mothers in early pregnancy and their children were born with significant damage as a result and legal action ensued.

The cases explore the relationship between the HCP and the patient who was treated inadvertently in early pregnancy. They also explore the relationship between the HCP and the unborn fetus.

## **4.2 Relevant Canadian Case Law; Teratogenic Agents in Pregnancy and Discussion of the Concepts of Wrongful Life and Wrongful Birth**

### **4.21 Webster v. Chapman [1997] M.J. No. 646**

This was an appeal by the plaintiff mother (Shirley Webster) and her infant daughter (Kathleen Webster), from judgment dismissing actions for damages caused by negligence. Kathleen Webster was prescribed Coumadin (an anticoagulant drug) for pelvic thrombosis by a specialist. Afterward, she was monitored by one of the defendants, Samuel Heywood (her family physician). Dr. Heywood had warned her against becoming pregnant while taking Coumadin. He also inserted an IUD (intra-uterine device) to prevent pregnancy. She requested that this be removed. Dr. Heywood did this reluctantly, and at the time, the patient insisted that she and her husband would “take care” of birth control. She transferred her care to the other defendant Dr. Chapman because she did not like Dr. Heywood’s attitude. Dr. Chapman continued to prescribe the drug and did not warn her of the dangers of becoming pregnant, but he was aware that she had already been given this advice by Dr. Heywood. When Dr. Chapman learned that Shirley Webster was pregnant, he arranged to meet her on the 22<sup>nd</sup> February (a couple of days after the positive pregnancy test) and made a point of expressing concern about her taking the drug, but told her to continue to take the medication. At this point, he assessed that she was most likely eight-and-a-half weeks pregnant. He arranged for her to see an obstetrician. The obstetrician saw her on a non-urgent basis (the 16<sup>th</sup> March), assessed her as 11.5 weeks pregnant and advised her to immediately stop taking the drug – which she did. The child, Kathleen Webster, was born severely physically and mentally disabled. Mrs. Webster sued both Dr. Heywood and Dr. Chapman for negligence. Expert evidence indicated that a pregnant woman should not be treated

with Coumadin during the first trimester of pregnancy. Experts also agreed that it was impossible to ascertain a specific point at which the harm occurred.

The trial judge concluded that Dr. Heywood exercised the appropriate degree of care and was not negligent. In these circumstances, the element of causation could not be proved. The allegation that if the mother had been warned of the fetal risks, she would have taken better precautions against pregnancy was dealt with. The trial judge found this concept to be highly speculative and unlikely in the circumstances.

The trial judge did however find Dr. Chapman to be negligent in two respects:

1. Failing to consult a specialist on a more timely basis for the purpose of obtaining advice as to continuing his patient on Coumadin once he knew she was pregnant
2. Failing to advise the mother of the risks to the unborn child if she remained on Coumadin

### **Findings in the court of Appeal:**

The appeal agreed with the original judgement and dismissed the appeal case as it affected Dr. Heywood.

As far as Dr. Chapman was concerned, the Appeal judgment started by evaluating whether or not his care had been negligent (which Dr. Chapman disputed). The judge examined the general rule which is that the standard of care required of a physician, is to conduct his or her practice “in accordance with the conduct of a prudent and diligent doctor in the same circumstances”: per Sopinka J. for the majority in *Ter Neuzen v. Korn*, [1995] 3S.C.R. 674 at p. 693<sup>53</sup>. Sopinka J. stated that (at pp. 696-697): “While conformity with common practice will generally exonerate physicians of any complaint of negligence, there are certain situations where the standard

practice itself may be found to be negligent. However, this will only be where the standard practice is “fraught with obvious risks” such that anyone is capable of finding it negligent, without the necessity of judging matters requiring diagnostic or clinical expertise”.

Therefore, it would be possible for a judge to find medical negligence not only in the absence of expert evidence, but also to do so in the face of evidence by experts approving that particular conduct. This situation occurred in a previous Canadian case (*Reibl v. Hughes*, *supra*, at p. 894<sup>54</sup>) where experts told a judge that a risk was not material and therefore in their opinion, did not need to be disclosed. The judge did not agree with this opinion and established that medical negligence could also be found when an act or omission of the defending doctor is “fraught with obvious risks” to a lay person. Justice Sopinka ruled that the usual reliance placed on the opinions of medical experts was not an invariable requirement. Depending on the circumstances of the case and the nature of the act or omission relied on as negligence, it was ruled that sometimes a judge could find negligence without proof of a general standard and despite expert evidence exonerating the defending doctor. The Case against Dr. Chapman was felt to be one where it was obvious that he should have consulted a specialist in a more timely fashion and should have warned the mother about the dangers of continuing to take Coumadin in early pregnancy. Causation then had to be demonstrated. It had to be shown that the negligence of Dr. Chapman resulted in the fetal injuries. The original judge inferred that by the time Dr. Chapman learned of the pregnancy, it was already too late to avoid serious damage and that the injuries the baby had been born with were already sustained. Experts speaking for both the plaintiffs and the defendants both agreed about the teratogenic effects of Coumadin in early pregnancy, but they could not agree about the exact time in the first trimester that this damage actually occurred. The Appeal judge ruled that to link Dr. Chapman’s negligence with the

damage to the central nervous system of the infant plaintiff, it was sufficient for the plaintiffs to have proved on a balance of probabilities that the mother's ingestion of Coumadin between 22<sup>nd</sup> February 1984, when Dr. Chapman renewed her prescription for the drug, and 16<sup>th</sup> March 1984, when the specialist advised her to stop taking the drug, materially contributed to the damage. The judge found that the negligent administration of Coumadin during part of that period must have been a materially contributing factor. The appeal was allowed and the previous judgement set aside dismissing the action. It was directed that judgment be entered for the plaintiffs against Dr. Chapman on the issue of liability.

This case ruled on issues around medical negligence and causation. To meet professional standards, the physician was required to discuss risks associated with the ingestion of a drug with teratogenic potential and alert the patient to the possibility of fetal damage during the first trimester. This is relevant to the prescription of any teratogenic (but therapeutic) agent and especially to RT which has been documented to have serious effects upon foetal development. Dr. Chapman was found negligent in that he did not inform the patient about the serious risks when he first found she was pregnant, but advised her to continue to take the teratogenic agent. Also he did not seek expert advice or consultation in a timely manner.

This case is especially relevant when considering the standard practice of radiation oncologists in British Columbia. The results of our survey study (in Part IV) showed that it was not routine for the majority of radiation oncologists to discuss the risk of exposure of the fetus to RT in early pregnancy with potentially fertile female patients on a routine basis. It could be argued that this is in fact ``the standard of care`` for radiation oncologists and therefore, there would not be any

professional expectation for a radiation oncologist to do otherwise. However, this case explores in detail the nature of medical negligence and that negligence can be found when an act or omission of the defending doctor is “fraught with obvious risks such that anyone is capable of finding it negligent, without the necessity of judging matters requiring diagnostic or clinical expertise” (from the judgment of Sopinka J)<sup>55</sup>. It could be argued that anyone looking at the situation would assess the risk as obvious, even though this risk is not routinely mentioned by radiation oncologists. RT is an agent that has the potential to cause significant damage to an unborn child and anyone (not an expert, but a reasonable, average person) could regard the practice of not discussing these risks “negligent” prior to prescribing this therapy.

In this case there is no liability assigned to the patient herself. It was acknowledged that the plaintiff was counselled by the first physician (Dr. Heywood) involved in her care not to become pregnant under any circumstances while taking Coumadin. He also put an IUD in place, which was removed at her insistence and he communicated that he did not think that this was a good idea. The case against Dr. Heywood was dismissed, but then a second doctor failed to warn her adequately about the dangers of ingestion of the same drug – though she had been given an initial warning and acknowledged this. This second doctor was found liable (though, he was found liable for the delay in seeking a specialist opinion and in continuing to prescribe the Coumadin). Currently there is an increasing emphasis on patient autonomy. Did the patient herself have a duty of care to the unborn child to take the first doctor’s advice seriously?



The conclusion from these cases must be that in the eyes of the law, the only responsible party recognized thus far is the prescribing physician. Therefore, liability in Canada for a radiation oncologist who fails to warn about the dangers of radiation in early pregnancy would be very likely to rest on his or her shoulders alone.

#### 4.22 Lacroix (Guardian of) v. Dominique

Lacroix (Litigation guardian of) v. Dominique, [2001] M.J. No.

311 MBCA 2001/06/29 Manitoba Judgments

This is a case from the court of Appeal of Manitoba and was an appeal from the dismissal of the plaintiffs' malpractice suit. The adult plaintiffs wished to have a family, but were concerned that this might be unsafe as the female plaintiff was taking anticonvulsant medication (Phenytoin). There was controversy about what professional advice had been given to the couple. The defendant denied that he had not warned them about the dangers of pregnancy while taking this drug. The original trial judge accepted the plaintiff's version and found that the defendant had failed to warn the plaintiffs of the risks associated with Phenytoin ingestion during early pregnancy. He also found that the mother would not likely have become pregnant with either child if she had received a full explanation of the risks from the defendant. The female plaintiff became pregnant within two years of her consultation with the defendant and gave birth to a healthy child. She then became pregnant again six months after the birth of her first child. The minor plaintiff, Donna, was then born with significant congenital abnormalities which were attributed to the ingestion of Phenytoin during early pregnancy. The action was commenced on 1<sup>st</sup> May 1991, more than six years after Donna's birth. No prior application for leave to commence the action out of time, pursuant to s. 14 of *The Limitation of Actions Act*, R.S.M. 1987, c. L150, was made. The defendant originally did not plead in his defence the expiry of the relevant limitation period. It was only in 1997 that the defendant sought leave to amend his defence by alleging that the action was barred by virtue of *The Limitation of Actions Act* and s. 61 of *The Medical Act*, R.S.M. 1987, c. M90. The application was opposed, but leave was granted. The trial judge held that, but for the limitation defence, the adult plaintiffs would have

had a claim for “wrongful birth.” He held that the action statute barred and dismissed their claim only on that basis.

**Findings of court of Appeal:** Justice Twaddle explored the concepts of wrongful life and wrongful birth. He ruled that cases involving a claim by a child born with congenital abnormalities could be categorized as two types. The first were cases in which the abnormalities were caused by the wrongful act or omission of another. A cited example of this was *Cherry (Guardian ad litem of) v. Borsman* (1990), 75 D.L.R. (4th) 668 (B.C.S.C.), *aff'd* (1992), 12 C.C.L.T. (2d) 137 (B.C.C.A.). In this case the fetus was damaged by attempted therapeutic abortion. The attempted abortion was in the first trimester and Dr. Borsman believed that the abortion had been successful. However, it was not and the infant plaintiff was born with permanent and severe deficits. The trial judge held that the injuries to the child were caused by a breach of the duty of care owed to the unborn child at the time of the attempted therapeutic abortion. Damages were awarded to child after birth for injuries. Justice Twaddle also categorized *Webster v. Chapman*, [1998] 4 W.W.R. 335 (Man. C.A.) as this type of case. The primary finding of negligence was the doctor's failure to consult a specialist on an urgent basis to obtain advice about continuing Coumadin and not advising the plaintiff to discontinue this medication.

The second type of case was where if it were not for the wrongful act or omission, the child would not have been born at all. In this instance the parent's claim is for “wrongful birth”. The HCP fails to warn the mother of the risk of giving birth to an abnormal child as a result of a factor (such as infection in early pregnancy or hereditary disease) over which the HCP has no control. Justice Twaddle referred to an English case: *McKay and Another v. Essex Area Health*

Authority and Another, [1982] 2 All E.R. 771 (C.A.) where a doctor failed to diagnose rubella in early pregnancy and the baby was born with severe congenital anomalies. In this case, the doctor's negligence did not cause the injuries to the child. However, the doctor's negligence deprived the mother of the option of having an abortion. The term "wrongful birth" was used in the sense that the parents could have chosen to avoid the birth but for the negligent advice or lack of it. Parents need to establish that, if they had been properly advised, they would have avoided the pregnancy or arranged an abortion. Their loss is the cost of caring for the damaged child who, but for the negligence, would not have been born. The child's claim was characterized as being for "wrongful life." The child's life was damaged and the child would not have been born but for the negligent advice or lack of it. Justice Twaddle agreed with the judgement in McKay and Another v. Essex Area Health Authority and Another, [1982] 2 All E.R. 771 (C.A.) and ruled that it was impossible to assess the value of this loss and existence could not be compared to non-existence. An action for wrongful life has not been recognized in Canada. How can a court determine what damages a child has suffered from being born compared to not existing?

The appeal was dismissed. There was leave to continue the action only if the plaintiffs neither knew nor ought to have known that the claim was statute barred when the action was commenced. The latter requirement was not met, as the statement of claim alleged a complete cause of action which arose more than six years before the claim was filed. Dominique's failure to plead the limitation defence from the beginning was likely an oversight rather than a demonstration of an unequivocal intention to abandon the defence constituting a waiver. The child's claim for wrongful life was rejected on the basis of the impossibility of comparing existence with non-existence. Finally, the appeal was dismissed because of the expiry of the

relevant limitation period, not because of the validity of the claim. It would seem therefore that finally this case was dismissed on technical grounds.

#### **4.23 Paxton v. Ramji 2008 ONCA 697**

This case was heard at the Ontario Court of Appeal in 2008. On appeal from the judgment of Justice Margaret Eberhard of the Superior Court of Justice dated 24<sup>th</sup> March 2006 and reported at 2006 CanLII 9312 (ON S.C.). In this case, maternal ingestion of Accutane led to foetal teratogenic changes and Jaime Paxton (the infant plaintiff) was born with serious congenital abnormalities. Legal action was taken against the physician who prescribed the Accutane, Dr. Shaffiq Ramji.

From the court proceedings: “The acne drug, Accutane, is a teratogenic drug that carries the risk of causing fetal malformation. The respondent, Dr. Shaffiq Ramji, prescribed Accutane to Dawn Paxton, the mother of the appellant child, Jaime Paxton, on the understanding that the mother would not become pregnant while taking the drug. The doctor’s understanding was based on the fact that the appellant’s father had had a vasectomy 4 ½ years earlier that had been successful up to that time. Unfortunately, the vasectomy failed just when the Accutane was prescribed and the appellant was conceived. She was born with considerable damage caused by the Accutane and the infant plaintiff sued the respondent for negligence in prescribing the Accutane to her mother. Dr. Ramji had taken a certification course regarding the prescription of Accutane (PPP) to potentially fertile patients and the dangers of prescribing this drug in early pregnancy. He warned the patient not to become pregnant while taking the drug Accutane and determined that over 4 years ago, her husband had undergone a vasectomy and no subsequent pregnancy had occurred since that time. Her husband had a vasectomy and was her only sexual partner. He therefore categorized the plaintiff as not being of “child bearing potential.” The vasectomy failed at the time that she was given the Accutane, a second pregnancy test was done too early to

be positive and by the time the pregnancy was discovered, significant foetal damage had been done. Jaime Paxton was born with very severe disabilities.

The original trial judge considered the question whether Jaime's claim should be characterized as one for "wrongful life". It was reiterated that a claim for wrongful life was defined as a claim brought by a child against a doctor or other health-care provider for allowing a child to be born with birth defects where, but for the wrongful act or omission of the doctor, the child would not have been born at all. Liability in such cases is framed "but for the negligence I would not have been born" (words of trial court judge). For Jaime's claim to be characterized as one for wrongful life, it would be because, had Dr. Ramji adhered to the PPP in counselling Dawn Paxton to use two forms of birth control while on Accutane, Jaime may not have been born. The judge found that a claim framed that way would be one for "wrongful life" and this (as discussed previously) is not legally recognizable in Canada. In the trial judge's view, the claim should not have been thought of as one for wrongful life (i.e., not one where the claim against Dr. Ramji was because Jaime should not have been born), but should instead have been thought of in terms of duty of care for the unborn child and negligence. If Dr. Ramji had abided by his duty not to prescribe Accutane to Dawn Paxton, if she was a woman of childbearing potential, then Jaime could have been conceived, but with no exposure to Accutane. The claim against Dr. Ramji was therefore not a claim for wrongful life, but for malpractice directly leading to Jaime's disabilities. The duty of care owed by Dr. Ramji to the unborn child and to the patient was explored and there was deliberation regarding his liability. In the original trial it was assumed that Dr. Ramji did have a duty of care to the unborn infant. The judge approached the liability issue by asking whether Dr. Ramji was entitled to be satisfied that Dawn Paxton was not a woman of childbearing potential. In Ontario the original trial judge found that, a doctor will meet the

standard of care, if the doctor is satisfied that a woman is not of childbearing potential and the PPP is followed, because she is abstinent, has had a hysterectomy, is menopausal, is surgically sterilized, or if her only partner has had a 4 ½ year vasectomy. Paul Paxton, Dawn Paxton's only sexual partner, had had a successful vasectomy some 4 ½ years earlier and therefore the trial judge found that Dawn Paxton could not be characterized as a woman of childbearing potential and Accutane was therefore no longer contraindicated. Therefore it was concluded that Dr. Ramji met the standard of care and did not breach his duty of care to the potential child of his patient by prescribing the Accutane. Accordingly, the trial judge dismissed the claim against him.

#### **Findings in the court of Appeal:**

The following issues were raised on the appeal:

- Did Dr. Ramji owe a duty of care to the future child of Dawn Paxton?
- If a duty of care was owed, did the trial judge err in finding that Dr. Ramji met the standard of care when he relied on Paul Paxton's 4 ½ year vasectomy?
- If a duty of care was owed, did the trial judge err by finding that Dr. Ramji met the standard of care when he prescribed Accutane to Dawn Paxton without performing a risk/benefit analysis, given that Dawn Paxton was not prepared to have an abortion if she became pregnant while on Accutane?
- Did the trial judge err by not awarding punitive damages against Dr. Ramji for altering his clinical notes?



The appeal was dismissed on the basis that the respondent owed no duty of care to the appellant. The “Anns test” was applied and on appeal it was found that the trial judge erred in finding that the respondent owed a duty of care to a potential child when prescribing Accutane to Dawn Paxton. The grounds for claim of damages on the grounds of “wrongful life” were explored and it was found that this was not an appropriate basis for claim. On appeal, the basis of the claim was seen to be best addressed by examining whether a duty of care was owed by the mother’s physician to the unborn child and was therefore, negligent in prescribing Accutane during early pregnancy. Accutane was well known to be an agent likely to harm a potential future child. However, policy considerations, including conflicting duties owed by the doctor to the future child and his or her female patient, and the indirectness of the relationship, were felt to mitigate against a finding of the necessary proximity to establish this duty of care between the unborn foetus and the mother’s doctor.

This judgement explored issues regarding physician liability for harm suffered before birth by the unborn foetus as a consequence of the actions of the mother’s physician. Also the concept of “wrongful birth” was discussed. The judge focused on the duty of care of a doctor towards a future child to give the child’s mother (or his/her parents) the opportunity to avoid the child’s conception or to abort the foetus. The definition of “wrongful life” was discussed and reference was made to *Lacroix (Guardian of) v. Dominique*. The Judge reiterated that in Canada “wrongful life” is not recognized and ruled that the claim should not be characterized as one for wrongful life. There was disagreement with the ruling in *Lacroix (Guardian of) v. Dominique*. Instead the judge explored the concept of duty of care. Did Dr. Ramji have a duty of care to the unborn infant? Should Dr. Rhamji be held liable in negligence for harm done to Dawn Paxton? The duty of care owed by the defendant to the plaintiff was explored in detail by using the “Anns

test.” The Anns test was used to assess the nature of the relationship between Dr. Ramji and Dawn Paxton and whether he owed her a duty of care. Sufficient “proximity” or closeness must be judicially recognized for a duty of care to exist. It is not possible to find a physician’s actions below the standard of care unless a duty of care exists in the first place. The judge ruled that the proposed duty of care was a new one and not one previously recognized in a Canadian court. The “Anns test” is used to determine whether an alleged wrongdoer owes a duty of care to the plaintiff. This test includes three components which are considered in a two-stage process:

First phase:

1. Reasonable foreseeability of harm:
2. Proximity

Second phase:

3. Policy factors

The Supreme Court described the two-stage process for determining the existence of a duty of care in *Syl Apps* at para. 24<sup>56</sup>, as follows: “To determine whether there is a *prima facie* duty of care, we examine the factors of reasonable foreseeability and proximity. If this examination leads to the *prima facie* conclusion that there should be a duty of care imposed on this particular relationship, it remains to determine whether there are nonetheless additional policy reasons for not imposing the duty.” If a *prima facie* duty of care is found, then at the second stage of the Anns test, the court assesses whether there are residual policy considerations that militate against finding a new duty of care”. Abella J. described the second stage “If a *prima facie* duty of care is found to exist based on reasonable foreseeability and proximity, it is still necessary for a court to

submit this preliminary conclusion to an examination about whether there are any residual policy reasons which make the imposition of a duty of care unwise”. The Anns test was applied to establish whether or not Dr. Ramji was liable in negligence to Jaime Paxton because he owed her a duty of care. In Canada, it was previously ruled that a mother does not owe a duty of care to her fetus: *Dobson (Litigation Guardian of) v. Dobson*, [1999] 2 S.C.R. 753. A mother and her fetus are not viewed as separate legal entities. This was explained by the Supreme Court of Canada in *Winnipeg Child and Family Services*, where McLachlin J. stated at pp. 944-45: Before birth the mother and the unborn child are one in the sense that “[t]he ‘life’ of the foetus is intimately connected with, and cannot be regarded in isolation from, the life of the pregnant woman” It is only after birth that the fetus assumes a separate personality and therefore the law has always treated the mother and unborn child as one.

This case explored in detail the duty of care that a physician owes to the unborn child in addition to the established duty of care to the mother (his patient). The conclusion by Justice Feldman was that no duty of care is recognized between the unborn child and the physician treating the mother as this relationship fails the Anns test.

It might be argued that as the judge ruled “the mother and child are as one” then the damage done by the ingestion of a teratogenic drug to the unborn infant, is also done to the mother because they are “as one”. Possibly the judge used this line of reasoning to prevent legal liability for broader policy reasons.

### **4.3 Duty of Care:**

#### **4.31 Where Does the Duty of Care Rest in the Health Care Professional Team?**

The relationship between patient and physician can be characterized by “fiduciary duty”. The early basis for physician liability was contractual. The offer was the patient's request for treatment and acceptance was the doctor's care. Most actions against doctors have been based on negligence for the past century or so and from this arose from the idea of duty as an integral part of the doctor patient relationship. This duty of care exists independently of any contract between the doctor and patient.

Over the past 10 to 20 years there has been increasing emphasis on the fiduciary nature of the doctor-patient relationship. This means that doctors have an obligation to their patients to act in the utmost good faith and loyalty and must never allow their personal interests to conflict with their professional duty. A fiduciary duty is the highest of duties one could owe to another. One party should only act in the best interests of another. Fiduciary duty arises in a situation where there is an imbalance of power or knowledge – such as between a patient and physician. A breach of a fiduciary duty would be in itself an injury and in court there would be no need to demonstrate causation of any other injury.

The fiduciary nature of the doctor-patient relationship is well articulated in Canadian case law. However, case law has not yet examined duty of care from the prospective of other members of the health care team in any detail. The delivery of radiation therapy, like many other treatment modalities involves a team of other HCPs. This team includes medical physicists who are responsible for maintaining complex equipment (e.g. a linear accelerator) and ensuring that it is functioning safely. Medical physicists are also very much involved in treatment planning and

ensuring that radiation is “targeted” to treat the tumor and spare surrounding normal tissues. Radiation therapists are the HCPs who actually administer the radiation treatments and are also very much involved in treatment planning. There are interesting questions to explore in the practice of radiation oncology about the nature of duty of care owed to the patient by the different team members and where any legal liability would rest<sup>57</sup>. Though RT is prescribed by the radiation oncologist, it is generally given on multiple occasions over many weeks in the absence of the radiation oncologist. The radiation oncologist would be principally responsible as the HCP who actually prescribes the RT, but what about the radiation therapists who administer the RT? Do they have an obligation for example to ask patients prior to treatment if they think they might be pregnant? In addition, what about the institution in which the HCPs work? Does that institution have an obligation to ensure that measures are in place (such as the display of prominent warning signs) to warn patients about the risks of radiation exposure to the unborn child?

The case law previously discussed explores legal liability, but only in terms of the physician prescribing the teratogenic agent. The examination is restricted entirely to thinking about legal duty in terms of the mother’s physician and that physician’s duty of care to the mother and unborn infant. There is no question of liability as far as other HCPs involved in the care of the mother are concerned. Pharmacists dispense medications and often give detailed information to patients regarding drug dosage, side effects and interactions. Were the pharmacists in any of the preceding legal cases under any legal obligation to give information about potential medication side effects when they were dispensing those drugs? This question never arose. By extension to a theoretical case in which radiation therapy was administered inadvertently to a woman in early pregnancy, it would seem very unlikely that there would be any legal liability for the radiation

therapist who actually administered the RT without checking the pregnancy status of the patient. It would seem from the three legal cases reviewed that liability would rest only with the physician prescribing the radiation therapy.

#### **4.4 Disclosure of Medical Error to the Patient and Ethical Duty**

An English study<sup>58</sup> surveyed 227 patients and relatives who were taking legal action against their physicians. Over 70% of respondents were seriously affected by the incidents that gave rise to litigation with significant long term health problems that affected many aspects of their lives. The decision to take legal action was determined by the desire to obtain compensation for the original injury, concerns with the standard of medical care they had received and the desire to ensure that this would never happen to someone else. They also wanted an explanation as to how their injury had arisen and believed that HCPs and the organisation should be accountable for their actions. Many of these plaintiffs complained about HCP insensitivity and poor communication after the incident. Where explanations were given, less than 15% were considered satisfactory. In another study<sup>59</sup> more than 70% of patients filing malpractice claims were dissatisfied with the level of information given to them by their doctor. Of these patients, 13% of sample complained that their doctor would not listen, 32% that the doctor would not talk openly and 48% felt that their doctor was deliberately misleading them (48%). Patients wanted to be informed if a medical error has occurred, want details about the nature of that error and what measures are be put in place to prevent that error from happening again<sup>60</sup>.

The American College of Physicians Ethics Manual contains the statement “Situations occasionally occur when a patient suffers significant medical complications that may have resulted from a physician’s mistake or judgement. In these situations the physician is ethically

required to inform the patient of all the facts necessary to ensure understanding of what has occurred”. The Canadian Medical Association’s code of Ethics was updated in 2004 to state that “Physicians should take all reasonable steps to prevent harm to patients; should harm occur, disclose it to the patient.” Prior to this there was no explicit reference to medical errors.

The foundation of medical ethics is to “do no harm” also called non-maleficence. This concept is not restricted to deliberate harm and equally applies to harm from medical errors. Once a medical error has occurred, there is an ethical duty for the physician to disclose that error to their patient.

An article in the CMAJ stated that "Failing to disclose errors to patients undermines public trust in medicine because it potentially involves deception and suggests preservation of narrow professional interests over the well-being of patients"<sup>61</sup>. Physicians are in a position of power and the non-disclosure of a medical error would be an abuse of that power. A physician always has a “fiduciary duty” to act in the best interests of his or her patients and to put that duty first, above all others. Honesty in these circumstances is mandatory.

Asides from the concept of fiduciary duty, there are other ethical reasons for telling the truth about medical errors to patients. Patients ought to be given information about medical errors out of respect for them as autonomous persons. Also the principle of ethical justice means that they should be able to seek recompense if they have been harmed by an error and they can only do this if they know of the error in the first place. Consequentialism mandates following the path which leads to the best outcome – the best outcome results from trying to rectify and address an error which can only happen if the error is acknowledged. Deontology demands that physicians follow the path of duty and what ought to be done. This duty is rooted in the fiduciary relationship between the HCP and the patient which demands that a medical error is openly acknowledged and addressed.

Despite these strong ethical considerations, physicians do not always admit medical errors to patients. In one study 76% of physicians interviewed stated that at one time or another they had not disclosed a serious medical error to a patient who had suffered harm as a consequence<sup>62</sup>. In another study physicians were more likely to disclose errors, but still 22% of respondents would not disclose a medical error leading to a patient's death<sup>63</sup>. The more serious the nature of the medical error, then the less likely the physician was to disclose the error. Ethically the duty to disclose a medical error should increase with the seriousness of the medical error. However, the major reason for the reluctance of physicians to be honest about medical errors is the fear of litigation.

Also the amount of information given to patients regarding the exact nature and extent of the medical error varies – there is no recognized standard for disclosure of medical errors<sup>64</sup>.

#### **4.5 Legal Duty**

The legal position regarding disclosure to patients of any medical error is very clear in Canada. In common law it is the legal duty of the physician to disclose a medical error made in the course of treatment to the patient, “if it is something which a reasonable person in the patient's position would want to know”. The Canadian case that set the precedent for informing patients of medical error was *Stamos v. Davies*<sup>65</sup>, in which a surgeon punctured his patient's spleen in the course of performing a lung biopsy. He was held to have had a legal duty to inform the patient about what had happened. Likewise in a British Columbia case, [\*Shobridge v. Thomas\*](#)<sup>66</sup>, a surgeon mistakenly left abdominal packing inside the plaintiff's abdomen. This caused serious infection and the packing was found after repeat laparotomy. It was ruled that the surgeon's



conduct of attempting to conceal his error (he did not tell the patient about the finding the packing at repeat operation for two months) showed bad faith and unprofessional conduct deserving of punishment.

In *Stamos v. Davies* it was ruled that the doctrine of informed consent mandated the disclosure of medical errors. If patients have a legal right to know what may go wrong with an anticipated procedure before they consent to have that procedure, then they also have the right to know what problems arise during the procedure. Though informed consent principles remain the foundation of the ethical duty to disclose medical error, the courts have also now added fiduciary principles and have held that the legal duty to disclose is a fiduciary obligation of physicians. As yet, no court in Canada has extended the legal duty to disclose to nurses or hospitals. In *Shobridge v. Thomas*, it was held that the nurses had no legal duty to report the error and that duty rested solely with Dr. Thomas. The operating room nurses had actually not counted the packing correctly during the first surgical procedure and were responsible for the accuracy of the surgical sponge count. It was therefore odd to assume that they had no duty to disclose the error. The court only paid attention to the physician–patient relationship and held that Dr. Thomas was entirely responsible for the error. This was largely because he acted in bad faith and attempted to conceal the error for over two months before he told the patient what had happened. However, the court's conclusion was that the nurses (who were aware of Dr. Thomas' error), did not have any legal duty to tell the patient. The court ruled that this role belonged to the surgeon alone. In the eyes of Canadian law at present, nurses and other HCPs do not have a fiduciary duty towards patients in the manner that physicians do. Health care is rarely if ever, delivered by a physician in isolation and a team of HCPs (nurses, pharmacists and technicians) are generally involved. It would seem strange to think that these HCPs did not have a fiduciary duty to the patient.

Legal Liabilities of Doctors and Hospitals in Canada<sup>67</sup> p. 367, lists the most common duties owed by a hospital to patients. The hospital has a duty to select competent staff and to monitor their continued competence, to provide proper instruction and supervision, to provide proper facilities and equipment and to establish systems necessary for the safe operation of the hospital. Legal action has been taken against hospitals in Canada for failure to provide bed rails (the patients fell out of bed and were injured). However liability was not found.

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## **5 Research Project: Assessing the Risk of Inadvertent Radiation Exposure of Pregnant Patients during Radiation Therapy Planning and Treatment in British Columbia:**

### **5.1 Objectives:**

The primary aim was to obtain data regarding instances where patients were actually treated or almost treated inadvertently with radiation therapy in early pregnancy. This study was also intended to increase Canadian health care professional (HCP) awareness of this risk in clinical radiation oncology practice and to set a precedent for multi-disciplinary collaboration to improve patient safety. The administration of radiation therapy involves a team of multiple HCPs (radiation oncologists who prescribe radiation therapy), radiation therapists (who administer the treatment and supervise patient care during therapy and medical physicists (who are responsible for radiation therapy planning, software and hardware maintenance radiation safety)). The survey was designed to ask all the different members of this team if they had ever observed this adverse event almost or actually occur. It was also to ascertain if these different HCPs thought that there was a significant patient safety issue and to ask them how the situation could be improved.

This adverse event may only occur a few times every year, but the outcome for the fetus and mother would likely be devastating. This study was designed to change patterns of practice and improve patient safety.

The hypothesis was that there was a previously undocumented risk that pregnant patients could be given unintentional RT in Canadian Radiation Oncology Centers which could be addressed by policy and practice changes.

The objectives were to:

1. Raise awareness amongst HCPs of this risk in Canadian Radiation Oncology practice.
2. Explore perceptions of this problem amongst HCPs working in Canadian Radiation Oncology Centers.
3. Explore views regarding responsibility and legal liability and where this would rest in a hypothetical case of accidental RT therapy of a pregnant patient.
4. Establish if any such episodes of near accidental RT or actual accidental RT to pregnant patients have ever occurred.
5. Gain some knowledge of events leading up to accidental RT of pregnant patients by requesting anonymous details.
6. Ask all groups of HCPs in the field their opinion about what methods might be effective to reduce the risk of this adverse event.
7. Encourage collaboration between the members of the radiation oncology treatment team which is comprised of different groups of HCPs (radiation oncologists, radiation therapists and medical physicists) to improve patient safety.

8. Develop templates for a preventative program (eg. Procedure checklists, patient and HCP educational materials) with the guidance of the Canadian Association of Radiation Oncologists (CARO) Safety Committee.

## **5.2 Design**

A survey was sent to all HCPs working in radiation oncology departments at the BC Cancer Agency (BCCA). This included all treatment facilities in British Columbia (BC). This survey was entirely anonymous to overcome potential reluctance on the part of HCPs to discuss medical errors. The survey asked if any HCPs working in BCCA centers had been aware of any instance where a pregnant patient had almost been treated or actually treated by accident. We asked how this had been discovered and sought to define risk factors. We also asked HCPs what measures they thought could be used to reduce or eliminate this risk. For example we asked for opinions regarding the effectiveness of options such as the development of national guidelines to standardize approaches. We also explored attitudes about where responsibility would rest for an adverse event of this nature and about perceived liability. The study was designed to provide data relevant to determine the need for and potential content of a “checklist” for use in the clinic prior to RT in the treatment of any female patient who might potentially be pregnant.

The survey was generated using Survey Monkey to send to HCPs working in British Columbia radiation oncology departments. Respondents included radiation oncologists, radiation oncology residents, radiation therapists and medical physicists working in British Columbia.

The draft of this survey was at : (<http://www.surveymonkey.com/s/BT29XYZ>) (though this has now been altered for a subsequent National study).

An email was sent to all these HCPs containing the link to the Survey Monkey questionnaire, explaining the study rationale and emphasizing that participation is voluntary. The results of the survey were accessible only to co-investigators listed in this study.

Survey Monkey has mechanisms in place to ensure that the results of any survey remain confidential and are not lost. Results are stored on their server in the United States. There is no way to trace the identity of any respondents as the information gathered did not contain any personal identifying information. There was no subject identification as part of the survey, and so no risk existed of a breach of confidentiality or harm to survey respondents.

Due to the sensitive nature of this survey the respondent's name and cancer centre were entirely anonymous and this information was not captured. Therefore an honour system was employed to request that these professionals to only complete the survey once. It may be that using this methodology the same episode would be reported by different individuals more than once. However, some anonymous basic details were sought to help differentiate cases. This limitation was discussed in the manuscript submitted for publication.

## **5.3 Results**

### **5.31 Respondent Characteristics**

The survey was sent to 342 HCPs (228 Radiation Therapists [187 females, 41 males], 59 Radiation Oncologists, 43 Medical Physicists, 12 Radiation Oncology Residents) – all HCPs working in BCCA Radiation Oncology departments. A total of 119 responses were collected. The majority (64.7%) of respondents identified themselves as Radiation Therapists. The rest of

respondents were as follows: Radiation Oncologist (22.7%), Medical Physicist (7.6%), Radiation Oncology resident (3.4%), and unknown (1.7%). 72.3% were female, largely because of the large proportion of RTTs that are female. The mean duration of experience was 13.9 years (range 1-25). Most respondents worked in a radiation therapy department with 5 to 10 linear accelerators (60.5%).

### 5.32 Informing Patients of Risk

The respondents were asked if, as part of the radiation therapist's education session with potentially fertile female patients, it was mandatory to discuss the risk of radiation therapy during pregnancy. The majority (62.2%) felt it was not part of the discussion, while 24.4% were unsure if it was routinely discussed. As shown in Table 1, those that identified themselves as Radiation Oncologists “almost always” or “always” remembered to discuss the risk of radiation therapy in pregnancy at the time of consult or treatment planning less than half the time.

**Table 5.1: How often do you remember to discuss the risk of RT in early pregnancy with patients at the time of initial consultation or radiation therapy planning?**

<b>Oncologist</b>	<b>Percent</b>	<b>Oncologist</b>	<b>Percent</b>
<b>Discuss at</b>	<b>(n=27)</b>	<b>Discuss at</b>	<b>(n=27)</b>
<b>Consult</b>		<b>Planning</b>	
Never	7.4%	Never	7.4%
Almost Never	11.1%	Occasionally	29.6%

<b>Oncologist Discuss at Consult</b>	<b>Percent (n=27)</b>	<b>Oncologist Discuss at Planning</b>	<b>Percent (n=27)</b>
Occasionally	33.3%	Almost Always	11.1%
Almost Always	37.0%	Always	11.1%
Always	11.1%	No Information	40.7%

Respondents' comments indicated that most physicians do not ask about pregnancy since the majority of patients they see do not have the potential to become pregnant (e.g. elderly).

However, as indicated by a particular comment, it is also possible that "it is sometimes difficult to remember as often trying to treat the cancer becomes the most important objective and other objectives are forgotten".

### **5.33 Warning Signs in Radiation Therapy Departments**

The majority of respondents (52.9%) did not know whether warning signs (alerting patients to the risk of radiation therapy in early pregnancy) were posted in their radiation therapy department, while 27.7% believed there were warning signs, and 18.5% were unsure of the correct answer. In fact there were very small "A4" paper size notices in 5 – 10% of changing rooms in the Vancouver clinic. In addition, 31.1% of respondents did not think there were handouts available, and 61.3% were unsure if such existed. In fact, no patient handouts about



this subject were available. Often respondents commented that if signs were present, they were very small and not easily noticeable by both staff and patients.

### 5.34 Respondent Experiences with Potential Patient Exposure

**Table 5.2: The frequency of respondent experience with RT given or almost given to pregnant patients.**

<b>Frequency of Experience</b>	<b>Inadvertent RT almost given Percent (n=119)</b>	<b>Inadvertent RT given Percent (n=119)</b>
Never	83.2%	84.0%
Once	6.7%	9.2%
Twice	5.0%	0.8%
Three Times	0%	0.8%
Not Provided	5.0%	5.0%

**Table 5.3: A selection of responses from the comment section of the corresponding questions.**

<b>Comments regarding witnessing a pregnant patient <u>almost</u> treated with Radiation Therapy.</b>
“The patient was... about to have a planning scan and then suddenly she mentioned that her period was late for 6 weeks and she wondered if she might be pregnant... The pregnancy test was positive. She did have a therapeutic abortion and went on to have abdominal radiotherapy...”
“(Young) woman with DCIS of the breast, was coming in for radiotherapy planning...As we walked in to the CT scanner, she mentioned she had not had a period for two months and thought she might be pregnant. This was confirmed on blood test, and then ultrasound. In the end she kept the pregnancy and did not have RT. “
“It wasn't in Canada - the woman thought that she might be pregnant and told me on the day she was meant to start RT. I sent her to nurses for a pregnancy test prior to treatment - she was not pregnant so treatment went on. She met with her RO after to remind her not to become pregnant while having cancer treatment.”
<b>Comments regarding witnessing a pregnant patient treated with Radiation Therapy.</b>
“She discovered that she was pregnant after she had RT. A retrospective measurement of potential dose received by the fetus was performed by the radiation safety officer. “
“The patient was (very young) with metastatic lung cancer. It was a terribly sad situation

and I never thought about the possibility that she could be pregnant. She had palliative radiotherapy to her lumbar spine during the first trimester. She had a therapeutic abortion when the situation was discovered...”
“Radio iodine given to patient who did not realize that she was pregnant at the time.”
“Although the risks of pregnancy during treatment were explained (and documented in her chart) she had unprotected sex and only discovered that she was pregnant after RT (to the neck) had been completed. “
“The patient was a very young... woman and it was discussed with her that further pregnancies would not be recommended but she, or her family, were adamant that a pregnancy/delivery occur... irrespective of her medical diagnosis and treatment. The pregnancy was revealed after 1-3 fractions of RT by the patient because she wanted to make sure there would be no risk to the fetus. All further cancer treatment was "postponed". She never returned for follow-up or further care.”
“While I was a resident our facility had one case of pregnancy discovered during radiation. Patient careless with contraception when her period stopped and was irregular during chemo - she assumed incorrectly she was infertile during chemo. Also received some chemo while pregnant too as well as the radiation...”
“She had brain metastasis and her husband was unaware - had not been keeping track of her cycle while she was in this state. No testing was done - unaware she was still sexually active while incoherent. Patient passed away before pregnancy came to term.”

### **5.35 Potential Future Interventions**

Although 47.9% of respondents did not think that mandatory pregnant tests were routine at their centre, 70.6% thought instituting mandatory pregnancy tests would be appropriate. The comments this particular question drew were extremely variable from “this is probably best, and if they refuse, they should sign a waiver” to “I would consider this extreme”.

Many respondents (48.7%) felt using a checklist-based format would help to ensure potentially pregnant women were well informed of the risks. The majority (73.8%) of respondents thought a set of National Canadian Guidelines would be useful to prevent accidental radiation treatment of pregnant patients.

**Table 5.4: Presentation of how effective respondents felt several potential interventions to prevent inadvertent radiation exposure to pregnant patients would be.**

	<b>Signs</b>	<b>Radiation Therapist to Discuss</b>	<b>Radiation Oncologist to Discuss</b>	<b>Handouts</b>	<b>Mandatory Pregnancy Tests</b>
1  (not effective)	3.4% (4)	5.0% (6)	2.5% (3)	6.7% (8)	6.7% (8)
2	13.4% (16)	3.4% (4)	0.8% (1)	12.6% (15)	5.0% (6)
3	24.4% (29)	8.4% (10)	4.2% (5)	29.4% (35)	13.4% (16)
4	30.3% (36)	27.7% (33)	17.6% (21)	23.5% (28)	15.1% (18)
5  (very effective)	22.7% (27)	49.6% (59)	68.1% (81)	20.2% (24)	51.3% (61)
No  Information	5.9% (7)	5.9% (7)	6.7% (8)	7.6% (9)	8.4% (10)
Mean (SD)	3.59 (1.11)	4.21 (1.10)	4.59 (0.85)	3.41 (1.18)	4.08 (1.26)

## **5.4 Discussion**

This research showed that though inadvertent radiation therapy in early pregnancy is very rare in BC radiation oncology facilities, it does occur. Almost 25% of respondents had encountered this error in clinical practice and 7 different clinical scenarios were described in detail where a patient had been given inadvertent radiation therapy in pregnancy. Thousands of women have been treated for cancer at the BC Cancer Agency over the past 10 – 20 years or so and this adverse event is very rare, but the potential serious nature of the outcome (significant fetal damage) would make this medical error very undesirable. We showed that there was no consistent process in place to prevent this error from occurring. The survey demonstrated that the perceived risk was considered to be unacceptably high by the great majority of respondents. When analyzing responses from the entire group, 62.2% felt discussing the risk of RT exposure in pregnancy was primarily the role of the radiation oncologist – though radiation therapy as with many clinical procedures involves a multidisciplinary team. A significant proportion of radiation oncologists admitted that they did not always remember to discuss the risk of radiation therapy in early pregnancy with patients. Our study demonstrated the need to instigate a preventative program to reduce the risk of this error occurring.

## **5.5 Dissemination**

A manuscript describing this research was submitted to the Journal of Practical Radiation

An abstract was submitted and accepted for presentation at the American Society of Radiation Oncology meeting in 2011. Also the resident who worked with the team on this project was invited to give an oral presentation at the annual Canadian Radiation Oncology Meeting in 2011.

After the results of this BC survey were analysed, a survey was sent out to all HCPs working in Canadian Radiation Oncology facilities. This involved contacting the administrators of the Canadian Association of Radiation Oncologists (CARO), the Canadian Association of Medical Radiation Technologists (members employed as radiation therapists) and the Canadian Organization of Medical Physicists.

## **6 Practical Application of Research Results: The Current BCCA Program**

### **6.1 Current Practice**

As a result of this study, policy changed at the BC Cancer Agency in all the Provincial cancer treatment centers (appendix A).

A “pregnancy determination process” was developed by a multidisciplinary team. This team included physicians, nursing staff, medical physicists and radiation therapists. The process (appendix B) has evolved with time and consists of different components. Mandated screening occurs at different points during the patient’s assessment and treatment planning, together with communication about this risk, educational materials and improved signage.

1. During the new patient appointment, the clinical nurse will ask a female patient (between the age of 11 and 56 years old) if there is any chance that she might be pregnant and discuss the risks. The physician will then review the information with the nurse and patient and sign the screening form. At this time the patient will also be given a patient information booklet about radiation therapy which includes a section about the risks of radiation therapy in early pregnancy.
2. The second check takes place immediately prior to radiation therapy CT planning when the radiation therapist will ask the patient again about the possibility of pregnancy. The radiation therapist will also discuss the risks of radiation therapy in early pregnancy as part of an educational session about radiation therapy.
3. The last check takes place just prior to the first radiation therapy treatment when the radiation therapist will check again just prior to the start of radiation therapy that the patient is not pregnant.



Prominent signage (in English, Punjabi and Mandarin/Cantonese) has been designed to be displayed in the radiation therapy department changing and waiting rooms.

The screening form to ensure that HCPs (clinical nurses, oncologists and radiation therapists) all discussed the risk of radiation therapy in early pregnancy was designed (appendix C) and approved for use in March 2011. This form was originally a “stand alone” form, but for the past month or so, has become an integral part of the radiation therapy requisition form – so that it has to be completed as part of the order to plan and book radiation therapy for a particular patient.

Pregnancy tests are administered if there is any risk that the patient might be pregnant. At the Vancouver clinic a blood pregnancy test is drawn and at the Fraser Valley Cancer Clinic, a urine pregnancy test is performed (this is according to the recommendations of the different laboratories in the two centers).

The program was first implemented on the 24<sup>th</sup> October 2012. Many staff were unaware of this program initially and ongoing educational sessions were organized to ensure that the different groups of HCPs were aware of the change in policy.

One BCCA center delayed implementation of the process and in December of 2011 a critical incident occurred where a female patient was given high dose radiation therapy for a tumor involving the upper thigh inadvertently during the first trimester of pregnancy. This resulted in a moderately high dose of radiation therapy to the fetus. When this was discovered, the error was acknowledged and the incident was discussed in detail with the patient. The patient’s pregnancy was terminated. This incident led to the development of poster style signage and an effort to ensure that information about this topic was prominently included in patient radiation therapy

information leaflet. The pregnancy determination process has now been fully implemented in all of the BC Provincial Radiation Oncology Departments (appendix B).

## **6.2 Future Directions**

This integrated program with multiple components introduced into all the BCCA Provincial clinics should reduce the risk of inadvertent radiation therapy in pregnant patients. To check the efficacy of this program, a survey would have to be conducted a in perhaps 3 or 5 years' time to ask HCPs working in radiation oncology departments if the situation has changed.

We hope that publications and presentations of our work will lead to a National change in policy and that this problem will be addressed on a routine basis in every radiation oncology center in Canada. It may be possible to extend this project to include Australia and New Zealand, as this risk is not specifically addressed in radiation oncology practice in these countries. It may also be possible to also recruit centers from the United States of America. However, in the US policies differ significantly depending on the institution and the State and it is likely to be more difficult to assess the extent of this problem

## 7 Conclusion

Medical errors in clinical practice are a major problem. It is now more than ten years since a national panel of health care experts released and published the IOM report on medical errors in the American health care system, “To Err is Human: Building a Safer Health System”<sup>18</sup>. They estimated at that time, that as many as 98,000 people died in hospitals each year as a result of preventable mistakes. The major conclusion of the report was that medical errors were primarily a result of “faulty systems, processes and conditions that lead people to make mistakes or fail to prevent them”. The report also outlined many different strategies which if put in place, would help to prevent medical errors.

As a result of the IOM report, more rigorous hospital accreditation standards and procedures were instituted. Public reporting and transparency has improved, though is by no means fully comprehensive. Many hospitals have developed programs to improve safety e.g. surgical checklists are now routinely used in many health care facilities. For over a decade, systems failure has been seen as the major problem to address in health care.

However, a more critical view of the IOM report has started to emerge. A 2009 article<sup>68</sup> in the New York Times documented the views of a physician who is a leader in health safety and challenges these assumptions. Dr. Robert M. Wachter, a professor of medicine at the University of California, San Francisco has published articles which are critical of some basic tenants of the safety movement<sup>69</sup>. He believes that physicians must to acknowledge their individual responsibility for medical errors before patient safety can improve. He is quoted as saying: “A blame-free culture carries its own safety risks. As we enter the second decade of the safety movement, while the science regarding improving systems must continue to mature, the urgency of the task also demands that we stop averting our eyes

from the need to balance ‘no blame’ and accountability.” He calls for physicians to acknowledge the mistakes they make and to be accountable. He does believe that patient safety has improved considerably since the IOM report was published, but that more can be done.

He uses as an example the medical error of surgeons operating on the wrong side<sup>70</sup>. This can happen because the surgeon either is not diligent or refuses to perform a safety check mandated by the hospital. When surgeons do not take the trouble of performing a simple safety precaution such as marking the side where the surgery should take place, then they should be held personally responsible for that medical error. Dr. Wachter believes it is too easy for physicians to become complacent and blame the “system”. He argues for punishment (for instance temporary loss of operating room privileges) if a physician fails to comply with routine safety checks.

I understand Dr. Wachter’s concern and have witnessed situations where incompetent physicians were personally responsible for patient injury and death. Many years ago as a junior doctor in the United Kingdom, I worked in a hospital where one of the surgeons was alcoholic and had very poor judgement. Patients rarely survived if he took them to the operating room for complex surgery. Once I asked my senior registrar (someone I respected enormously and who was himself a meticulous and excellent physician), why this situation was allowed to continue. My registrar was astonished that I should even ask such a question. His rebuke was unforgettable “You should never criticize a senior colleague – every one of us can make mistakes!” Yet, it was so obvious that the surgeon in question was a danger to the patients he operated on. How many physicians make such serious errors? Where do you draw the line? It was the surgeon who was the problem. The only thing wrong with the system was the lack of any mechanism for stopping him.

On the other hand I have seen good physicians make mistakes in circumstances that contributed very significantly to their errors. One of my peers in medical school was working extraordinarily long shifts (as many of us did then). After a weekend of continuous “on call” when he was very sleep deprived, he gave a patient an overdose of intravenous potassium. The patient died and my friend committed suicide shortly after. My friend was conscientious and kind. I have no doubt that his exhaustion and overwhelming workload were significant factors in those events.

Medical errors are rarely generated by poor physician judgment alone or by circumstances alone. The magnitude and type of the error together with the circumstances in which that error arose are all important. What is important is that medical errors are honestly acknowledged, the different reasons for the error are examined and then measures are put in place to try to prevent the mistake from happening again.

Acknowledging that you, as a doctor, made a medical error is essential if the cause of that error is going to be understood and the error not repeated – but this is not an easy thing to do. There are few incentives in North America to make accepting responsibility the preferred option for a physician. Every doctor that I know dreads the thought of a law suit and would do almost anything to avoid one. The circumstances around the error are not taken into account in Canadian law. Mistakes are not looked at in the context of broader clinical practice and systematic problems, but as isolated episodes. The system is also punitive. Law suits drag on for years and take their emotional and mental toll. The process of discovery of the facts is adversarial. Cross examination is very stressful and causes significant mental anguish. I worked with a colleague who always seemed emotionally robust and the only time I ever saw her cry was after cross examination for discovery in a legal case. This fear of litigation discourages physicians from being open and motivates

them to hide mistakes. Also because the consequences of truth telling are so dire, an atmosphere exists which punishes “whistle blowers” – those who make errors and unethical behaviour public. Whistle blowers in medicine have been subject to harassment and reprisal<sup>71-73</sup>.

The question remains as to how to achieve a balance, so that negligence which falls below the expected standard is punished, but HCPs are encouraged to be honest about mistakes.

The error of inadvertently treating a patient with radiation therapy in early pregnancy is a simple error, but like many medical errors is caused by flawed thinking (focusing on the treatment of a patient’s cancer and not examining other facets of a patient’s health). The tendency to make this error is likely exacerbated by workload and inability to take the time to “step back” and think through all the possible repercussions of radiation therapy in a young woman. The research project I began identified this as a problem in clinical radiation oncology practice and led to the establishment of a prevention program. This meant that a single physician did not have to try to remember on a case by case basis to check patient’s pregnancy status. The new process involves patient education and warning signs as well as multiple checks (or points of communication) where patients and HCPs are reminded that this is a risk. Now the HCP team (including the physician) work in a system which takes account of the fact that sometimes people might forget. All the members of the HCP team were involved in developing this program to improve patient safety.

In Canada, the development of this program was voluntary and there are still Canadian Oncology centers where programs like this are not in place. Europe has a system where a legal framework (the Ionising Radiation Medical Exposures Regulations introduced in May 2000 to implement the European Directive 97/43/Euratom) mandates that all institutions must demonstrate that they have developed policies to prevent the inadvertent exposure of

pregnant patients to radiation therapy (and to chemotherapy). In this way institutions have no choice but to put in place a system to prevent this particular medical error. This would seem to be the most effective way to ensure that programs like this are put in place.

The only way that information could be gained about the incidence of this particular error in the past, was to ask questions using an anonymous survey. To collect accurate data about medical errors in general, HCPs should be able to submit anonymous reports of adverse events. Data bases should exist where this information is available and reviewed by all treatment centers. However, the information gathered should be anonymous and protected from retrieval for use in litigation. This would help to encourage reporting of adverse events in radiation oncology departments. The Canadian Partnership for quality Radiation Therapy holds key to the future. Policy statements about improving the quality of radiation therapy are a beginning, but they need to be followed by the development of a national data base to track medical errors made in Canadian radiation oncology practice.

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## Appendices

### Appendix A: Pregnancy Determination Policy

#### PROVINCIAL RADIATION THERAPY PROGRAM

#### • POLICY

<b>Title:</b> <b>CHECKING PREGNANCY STATUS OF FEMALES PATIENTS</b>	
<b>Effective:</b> October 1, 2011	<b>Approved By:</b> <b>Provincial RT Program Leadership</b>

#### POLICY

The pregnancy status of female patients of reproductive age (11-56 years) shall be reviewed and documented prior to the delivery of any radiation for planning or treatment purposes.

Screening for pregnancy shall be completed by a Health Care Professional using a process of history taking and, if required, appropriate pregnancy testing.

Signs shall be posted in the radiation therapy planning and treatment areas alerting patients to the dangers of radiation exposure during pregnancy. Signage shall contain directions of who to contact should they suspect that they are pregnant.

Each centre will have a current procedure in place to ensure this policy is adhered to.



## Appendix B: Pregnancy Determination Process

### British Columbia Cancer Agency □ DEPARTMENT DIRECTIVE

Title: PREGNANCY DETERMINATION PROCESS		Number:
Department: Radiation Therapy		Policy Reference No:
Effective Date: October 24 2011	Approved By: RT Leadership	

#### Rationale:

Purpose of this directive is to ensure female patients between the ages of 11 – 56 years are screened for pregnancy prior to the start of radiation treatment.

The Pregnancy Determination Pre Printed Order (PPO) will follow the patient.

#### Process Flow:

Screening will occur at:

- new patient appointment
- prior to radiation therapy ct simulation and
- prior to 1<sup>st</sup> radiation therapy treatment.

If a patient is not screened at new patient appointment, screening must occur prior to the delivery of any radiation.

When the patient is in an exam room:

- the LPN/RN will confirm pregnancy status and communicate to the physician.
- the physician will then review the information with the patient and sign bottom section of pregnancy determination PPO.

The physicians' signature authorizes subsequent pregnancy lab testing for the patient and the health unit coordinators will receive this as a Dr's order. If a pregnancy test is ordered it will be done as a STAT order. The regular serum chemistry requisition is to be used and the test required is the HCG (quantitative)/Pregnancy Screen test. Ensure the date, patients' information, Dr ordering, call local \_\_\_\_\_ with results, diagnosis and STAT are on chemistry requisition (Form M152D).

The CAIS entry for this will be booked under the resource TESTS and PREG used for activity code. Please put RMO, pt sent to lab per DR\_\_\_\_ in notes. The PPO will then be placed in the ct tray for the CT clerk to pick up.

#### At CT Simulation:

The therapist will confirm pregnancy status. If a pregnancy lab test is required, the Patient Review clerk will process the orders.

The lab requisition should indicate STAT and call with result to local\_\_\_\_\_. (RT Therapist local).

In either instance if a blood test is required the physician will be informed.

At the first treatment the RT Therapist will perform assessment.

If a pregnancy blood test is required Patient Review will be notified to process orders.

The patient will be sent to the blue waiting area. The LPN or Patient Review clerk will give blood test requisition (STAT call Local\_\_\_\_) (therapist local) to patient and direct them to the lab. When patient is finished at lab they must return to CT or treatment unit to wait for results.

At any stage of assessment if the blood test result is positive for pregnancy the physician will be informed immediately.

When the patient has completed Radiation Therapy the pregnancy determination pre printed order form will then be filed in the patient chart by HIS.

## Appendix C: Pregnancy Determination Form (which is part of the radiation therapy requisition)

### PRE-PRINTED ORDERS: PREGNANCY DETERMINATION

*For FEMALE patients of reproductive age (post-menarche to menopause - i.e. age 11–56 years).*

\* Pregnancy serum beta-HCG testing is required if the patient responds "Yes" to any of these questions, is uncertain of the date of her last menstrual period (LMP), or thinks that there is a possibility that she might be pregnant.

☐ Pregnancy not medically possible. Do **NOT** continue with any further screening of patient.

<p align="center"><b>AT THE TIME OF INITIAL CONSULTATION</b></p> <p>1. To the best of <u>her</u> knowledge, could she be pregnant? <small>(patient must be directly asked and respond)</small>  <input type="checkbox"/> Yes*    <input type="checkbox"/> No    <input type="checkbox"/> Possibly/Not Sure*</p> <p>2. If answer to question #1 is "Yes" what was the first day of her LMP?  Date: _____ <small>(dd/mm/yyyy)</small>  <input type="checkbox"/> Unsure <small>(If less than 10 days from first day of LMP then pregnancy is unlikely)</small></p> <p>3. Patient sent for pregnancy test?  <input type="checkbox"/> Yes    <input type="checkbox"/> No    _____ <small>(initials)</small></p>	<p align="center"><b>RESULT OF PREGNANCY TEST</b></p> <p><input type="checkbox"/> Positive for Pregnancy _____  <small>(initial &amp; date)</small></p> <p><input type="checkbox"/> Doctor Informed _____  <small>(initial &amp; date)</small></p> <p><input type="checkbox"/> Negative for Pregnancy _____  <small>(initial &amp; date)</small></p>
<p><b>Nurse or Physician's</b>  Signature: _____ <small>(mandatory)</small>    <b>Date:</b> _____ <small>(dd/mm/yyyy)</small></p>	
<p align="center"><b>IMMEDIATELY PRIOR TO RADIATION THERAPY CT SIMULATION</b></p> <p>1. Check for prior pregnancy test results, if applicable.</p> <p>2. To the best of <u>her</u> knowledge, could the patient have become pregnant since she was last asked?  <input type="checkbox"/> Yes    <input type="checkbox"/> No    <input type="checkbox"/> Possibly/Not Sure</p> <p>3. Patient sent for pregnancy test?  <input type="checkbox"/> Yes    <input type="checkbox"/> No    _____ <small>(initials)</small></p>	<p align="center"><b>RESULT OF PREGNANCY TEST</b></p> <p><input type="checkbox"/> Positive for Pregnancy _____  <small>(initial &amp; date)</small></p> <p><input type="checkbox"/> Doctor Informed _____  <small>(initial &amp; date)</small></p> <p><input type="checkbox"/> Negative for Pregnancy _____  <small>(initial &amp; date)</small></p>
<p><b>Radiation Therapist's</b>  Signature: _____ <small>(mandatory)</small>    <b>Date:</b> _____ <small>(dd/mm/yyyy)</small></p>	
<p align="center"><b>IMMEDIATELY PRIOR TO 1<sup>ST</sup> RADIATION THERAPY TREATMENT</b></p> <p>1. Check for prior pregnancy test results, if applicable.</p> <p>2. To the best of <u>her</u> knowledge, could the patient have become pregnant since she was last asked?  <input type="checkbox"/> Yes    <input type="checkbox"/> No    <input type="checkbox"/> Possibly/Not Sure</p> <p>3. Patient sent for pregnancy test?  <input type="checkbox"/> Yes    <input type="checkbox"/> No    _____ <small>(initials)</small></p>	<p align="center"><b>RESULT OF PREGNANCY TEST</b></p> <p><input type="checkbox"/> Positive for Pregnancy _____  <small>(initial &amp; date)</small></p> <p><input type="checkbox"/> Doctor Informed _____  <small>(initial &amp; date)</small></p> <p><input type="checkbox"/> Negative for Pregnancy _____  <small>(initial &amp; date)</small></p>
<p><b>Radiation Therapist's</b>  Signature: _____ <small>(mandatory)</small>    <b>Date:</b> _____ <small>(dd/mm/yyyy)</small></p>	
<p><i>Physician's signature authorizes the test(s) above to be obtained.</i></p> <p>Signature: _____ <small>(mandatory)</small>    Date: _____ <small>(dd/mm/yyyy)</small></p>	