Newsletter
Federation of Medical Women of Canada
Fédération des femmes médecins du Canada
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Calgary here we come!

We are bringing the FMWC Leadership and Advocacy workshops to you June 22-23, 2008.

By Executive Coordinator, Andrée Poirier

That's right we are heading to Calgary June 22-23, 2008 for the Annual General Meeting and Leadership and Advocacy workshops. We will be holding interesting workshops in the afternoon of June 22, followed by the Annual Board meeting in the evening. The business meeting will be held on the Monday, June 23, 2008 in the first hour of the day and this will be followed by our Leadership and Advocacy workshops.

Our AGM this year will move forward our agenda of helping members with their Advocacy Toolkit. Communication is the theme. Workshops will include Media Training, Letters to the Editor and Conflict Resolution (Hint - watch for some big names as speakers). We may even finish with a meeting of the Editorial Board of the Calgary Herald. You don't want to miss this!

The event will be held at the Fairmont Palliser, 133 9th Avenue SW in Downtown Calgary. We are planning to send out the registration information to everyone soon. We hope our meeting in Calgary will be as successful as the one in Ottawa.

Remember to invite your colleagues (physicians, nurses, physician-assistants & other medical health providers) to attend and to block off June 22-23, 2008 for exciting workshops, great networking opportunities and lots of memorable moments.

FMWC Mission Statement

The Federation of Medical Women of Canada (FMWC) is committed to the development of women physicians and to the promotion of the well-being of all women.

La Fédération des femmes médecins du Canada est vouée à l'épnaouissement des femmes médecins ainsi qu'à la promotion du bien-être des femmes en général.

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FMWC Newsletter

Editor: Dr. Nahid Azad

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President's message

January 2008

By Janet Dollin, MD, MDCM

On being A Federation of Medical Women of Canada member: more good days than bad

We are most lucky in this life when we have a passion and are able to make a living at it. That's why, as women physicians, we are so blessed. Canadian women physicians are up to some amazing and passionate work. Our day-to-day work, for most of us, is to take care of our patients. As women physicians, we have a privileged and trusted position and can feel great fulfillment from this. That is on the good days. And it is on the occasion of the New Year that I feel gratitude for all that I have and I ponder where I might make meaningful change in the next year to have more of those good days. We each have bad days too.

Our patients are more than individual Canadians; they are also the health care delivery system, and the public. Our patients are a majority of Canadian women. We know the issues because we 'live' them. We are keenly aware of the fact that women's health is far more than reproductive health, that access to health care services has bigger implications for women than the usual hips, knees and hearts. We are the front line providers of, as well as being the designers of public preventive health services. We feel the impact of health care provider shortages in a different way. We feel the pulls to enjoy mothering and caregiving for family members in a different way.

I have learned from my work with the FMWC, that women physicians want to do all of these things with grace and with equity. We want to provide seamless services to our patients and we want to do it with equitable processes and outcomes. We want to see preventive services distributed equitably and access to care that takes account of the social determinants of health. We want our colleagues to have equitable advancement, funding and pay. We want to do this beside our male colleagues, not above or below them. And so we do this work, day to day, with as much grace and equity as is possible in a less than perfect system. At FMWC we talk about it together, and that allows us to notice themes in the personal issues we each hit our heads up against in our day to day work on any bad day.

For me at this stage of my career, I am grateful to have many more good days than bad with my relationships with individual patients. Lately though, most bad days usually have to do with healthcare system access issues, or they might have to do with doctor shortages. Bad days frequently come at me in themes- weeks where I see intimate partner violence destroying health with no mental health services to be found, weeks where poverty and poor access are dominant, weeks where the media undoes any good we thought we might be achieving for women's health and I need to spend hours at fighting myths of vaccine angst, weeks where wait lists have destroyed access to non-prioritized services, weeks where I need to repeatedly refuse a single other new patient into my practice…each of these (and many other) demoralizing issues eating away at my job fulfillment. I have had other stages in my career where balancing parenting was a bigger challenge, and I expect caregiving issues might be in my future. I am quite struck by how the 'personal is political'.

FMWC is a place to talk about it together. These issues I list are not mine or yours alone. If we realize together that the personal is political, we can then get our collective voice heard. FMWC is working to improve our ability to do exactly this. In the next year, watch for website upgrades, training programs at our AGM on communication skills, online advocacy training, online discussion groups. In particular, watch for and respond to the Needs Assessment which will be coming early this year. We are doing this to allow you to express the issues that give you pause in your work, the ones we can only work at collectively, chip away at together. These issues will be what FMWC want your involvement in, at a branch, regional or national level. Your experiences and lessons learned can be important lessons to others. We most definitely will need the passion of Canadian women physicians to contribute to this in order to succeed. You, as individual women physicians have to agree that there is value in speaking together. We can speak together to create more good days than bad.

Dr. Kathleen Gartke Accepts challenging position of President-elect

By Kathleen Gartke

Kathleen is an orthopaedic surgeon at the Ottawa Hospital. She has been in practice for 23 years and focuses on problems of the Foot & Ankle. For the past 5 years, Kathleen has been president of the Ottawa Branch of the FMWC.

It is both exciting and challenging to accept the position of President Elect of the FMWC. I will be following in some amazingly deep footsteps and only hope that I can contribute in some small way to strengthening an organization that has focused on women physicians and issues relevant to women's health for 83 years.

I first joined the FMWC over 30 years ago as a medical student where I began to appreciate the fellowship offered by such an organization. So much has been accomplished over the intervening years to strengthen the position of women in medicine and yet there is still much to be done. It is important that the FMWC continues to evolve and reorganize as our needs change so that we can remain relevant to our membership.

In this era of electronic communications, it is easier to reach out to our members, but their needs are increasingly sophisticated. We must remain streamlined and agile in our organization, to allow us to respond to these needs and must have a clear succession strategy to "pass on the torch" to the next generation. If I can add anything to this process during my tenure, it will be an honour.

When is knowledge "ripe" for translation?

By Editor, Dr. N. Azad

The transfer of research knowledge into practice is often a slow and haphazard process. It is estimated that 30%-45% of patients are not receiving care according to scientific evidence ("lost in Translation") and that 20%-25% of the care provided is not needed or is potentially harmful. There are also problems with the premature adoption of some treatments before they have been shown to be beneficial. When this occurs, patients are exposed to potentially ineffective and even harmful outcomes. So what should we do?

Knowledge Translation (KT) is a new buzz word employed to describe the exchange, synthesis, and ethically-sound application of research findings. The KT process is inclusive, involving all stakeholders including researchers, professionals, patient, administrators, policy makers, and industry. KT is based on mature knowledge; i.e. how good is the evidence and the appraisal of the evidence. But, how good is good enough? Awareness of potential biases is important for both researchers and policy-makers in public health; both for researchers when designing and conducting studies and for policy-makers when reading study reports and making decisions.

There is an assumption that research is bias free. However, 109 types of bias have been reported in epidemiological studies. Sources of bias could start with the literature review, continue with the study design or execution, the data collection or the analysis and interpretation of results, and, finally, with the publication. Investigators and editors are tempted to publish results, no matter how preliminary or shaky and the majority of negative result studies never get published.

The big question for KT is: Do we need impeccable knowledge? Is this realistic? What framework should guide our judgment in moving knowledge into action with a minimal deployment gap?

So with all this background complexity, a currently relevant question on HPV vaccination is: How can FMWC be either an independent voice or a partner with a credible knowledge broker for HPV vaccination? To perform either role, FMWC must understand the research, digest all relevant knowledge, advocate the balance of intervention risk and benefit, and understand the public health implications. FMWC must also be sensitive to health system level key barriers to the immunization program, assisting with informed decision options for girls and parents when there is ambiguity, liaising between provider and consumer; and with mass media campaigning to raise awareness at the individual level.

In this issue of the FMWC newsletter an insert is provided on the topic of HPV vaccination from different organizations and opinion leaders. As always, we welcome readers to please send us your thoughts and contributions on issues.

Reflections on Every Woman, Every Man: Ottawa Collaborative Breakfast on Violence

By Leighann Burns, Executive Director of Harmony House (women's shelter) and guest writer for FMWC.

When the December 6th collaborative event began to take shape and it became apparent that I would have an opportunity to speak to how the anti-violence sector and the medical sector might better collaborate, I began to reflect on what I might have to say. In the past ten years or so and really throughout my entire career of anti-violence work my preoccupation has been largely centered on legal systems and how they continually fail abused women and their children. In truth, I hadn't thought much in recent times about the medical system and women's interactions with it. That is probably because abused women's interactions with legal systems seem more urgent. Decisions made about custody and access, whether the woman or her abuser is charged, and outcomes of criminal charges all have very significant and sometimes devastating consequences. There seems a sense of urgency about this area and a sense that things could be done much better if a proper feminist lens were applied.

Over the month or so that I pondered what I would say to medical practitioners, I reflected on what I believe are still the most important intersections between our worlds. It is widely acknowledged that isolation is a critical component of abusive relationships. Abused women do not get many opportunities to reach out for information or assistance. We know that even though shelters are the resources called upon most often by women coping with male violence, the women who use shelters are the minority of all abused women. Most abused women never reach out to any resource or system for assistance. As a result, it is imperative to equip other resources and systems that are likely to have contact with abused women to be able to respond appropriately when they do. Critical to this is the ability to identify abused women, and, having done so, being able to respond appropriately.

It has been my experience that abused women are willing to disclose the abuse they are experiencing in their lives. Indeed, women I have worked with have told me about times when they described to their doctors what was clearly abusive and controlling behavior by their partners, only to be met with "encouraging words" such as "focus on the positive" or "try to relax" along with a prescription for anti-depressants. Often abused women will present with symptoms of the abuse that should trigger further questioning by their physicians. The woman herself may not identify the abuse as such but may describe being overwhelmed, exhausted, unsupported, isolated, belittled, and depressed. When asked about her relationship with her partner it may become clear that there is more going on. Recently I spoke with a woman who on two separate occasions begged her physician not to send her home after short hospital stays. Those were clear entry points.

I would encourage all physicians to routinely ask their women patients about their relationships. In order to do so you must ensure her partner is nowhere within earshot and you must reassure her that you will not disclose to her partner anything that she has told you. Critical to success here is the time and the ability to listen without judgment. Each woman has her own process for figuring out what she needs and wants. She is the expert on her situation and she may require multiple visits with her physician, multiple visits to community resources, and a long process for determining what she wants to do. For those who wish to support her, it can be difficult to not move immediately to action to resolve the situation. Patience is the hallmark of good support.

Through this collaboration I learned that a challenge for medical practitioners is to have the time necessary to devote to an abused woman who needs to talk. We have all heard about the duress under which most medical professionals operate. There are so many people who don't have doctors and those who do, see doctors that have overwhelming numbers of patients squeezed into every day. How, then, do we reconcile the notions of having enough time to talk and to listen when you don't have enough time in a day to do the basics? I believe this is an area in which our two sectors could collaborate and we could seek governmental support for the OHIP code required to allocate time to respond appropriately to a woman in an abusive situation.

Then there is the question of how to respond to a woman who has disclosed violence and is feeling overwhelmed and depressed about her situation. Before you pick up a prescription pad, stop, and ask yourself is this REALLY necessary? Or is it simply treating the symptom rather than the underlying problem? Women in abusive situations need to keep their wits about them. Medicating the symptoms can actually interfere with her ability to read her situation accurately and respond accordingly. Far more effective, in my view, is the willingness to listen for her skills and her resourcefulness and to foster them. Believe me; women coping with abusive partners are extremely creative and resourceful. Their partners may have stripped their abilities to see anything worthy about themselves, but those skills are there and need to be fostered until they can regain clarity about their circumstances.

Doctors can also be crucial links to community resources. I have come across quite a few women over the years who did not want to access shelters due to misconceptions about what they would find there. They believed that shelters for abused women would be dangerous places where people with severe addictions and mental health issues would present dangers to their children. In fact, most shelters for abused women try hard to approximate a home-like setting.

Some women do not want to stay in shelters as they do not want to disrupt their children's lives, particularly with a change of schools. Many community centers and community health centers now have violence against women programs and there are transitional support workers throughout the city who can provide supportive services to women wherever they are located. This is important information doctors can share with the women they see.

Finally, my central message to doctors on December 6th and throughout the year

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Every Woman, Every Man: A Collaborative Breakfast on Violence Against Women

A celebration of a polyphony of voices and a call to continue to work together

by Dr Nili Kaplan-Myrth

December 6th is the anniversary of the Montreal Massacre and the National Day of Remembrance and Action on Violence Against Women.

To commemorate December 6th last year, the Ottawa branch of the FMWC held a panel discussion on violence against women at the Royal Ottawa Hospital. Although the speakers were wonderful, our audience was made up of a very small group of physicians and one or two medical students. Just prior to that, Dr Nahid Azad and I attended a town hall meeting, *What Women Want from the Government of Canada*, hosted by the Canadian Federation of University Women. A large auditorium of the main branch of the Ottawa Public Library was overflowing with community organization representatives, lawyers, union organizers, child care workers, various other professionals, academics and activists, but Dr Azad and I were possibly the only two medical people in attendance. During the question period at the public forum I stood up and asked how, given the importance of cross-disciplinary work, we might join together as one voice. I wrote a piece for the FMWC newsletter last winter, "One Voice, Infinite Possibility**,"** suggesting that we need to find our political/leadership voices and we need to use those voices to work collaboratively toward improving the status of women in Canada.

This summer, as I was planning events for FMWC students (I'm the U of Ottawa senior student representative), I started to think about how we might bring physicians and medical students together with the Ottawa community. By chance, I received an email from the Centre for Women's Global Leadership encouraging organizations to participate in the "16 Days of Activism Against Gender Violence." The 16 Days campaign (http://www.cwgl.rutgers.edu/16days/home.html) is a strategy to eliminate all forms of violence against women by:

- raising awareness about gender-based violence as a human rights issue at the local, national, regional and international levels
- strengthening local work around violence against women
- establishing a clear link between local and international work to end violence against women
- providing a forum in which organizers can develop and share new and effective strategies
- demonstrating the solidarity of women around the world organizing against violence against women
- creating tools to pressure governments to implement promises made to eliminate violence against women

Participants and organizers of the event.

I brought information about the 16 Days campaign to the FMWC Ottawa branch and I also brought information about the campaign to a discussion group that I facilitate, Feminist Women of Ottawa Reading Diverse Subjects (F-WORDS). After much discussion, we initiated "Every Woman, Every Man: A Collaborative Breakfast on Violence Against Women."

Four women and I organized the event: Dr Janet Dollin (F-WORDS member and FMWC President), Dr Mamta Gautam (FMWC Ottawa President), Ms Leighann Burns (F-WORDS member and Director of Harmony House, a local women's shelter) and Ms Lynne Oreck-Wener (F-WORDS member and Past-Chair of the Shalom Bayit Committee, Jewish Family Services Ottawa). Dr Dollin, Dr Gautam and I rallied the medical community while Ms Burns and Ms Oreck-Wener set to work recruiting representatives of community organizations to speak at the breakfast.

Given the limited scope of FMWC student budgets, I needed external funding for the breakfast. We also wanted to strengthen links between organizations (in keeping with the 16 Days strategy). We therefore wrote to the Women's Outreach Committee at the Ontario Medical Association to ask for their support for this event. The OMA's endorsement of the breakfast was matched by support from the Canadian Medical Association, the Association of Faculties of Medicine of Canada, the Society of Obstetricians and Gynecologists of Canada, Jewish Family Services Ottawa, Family Services à la Famille Ottawa, the Office of Equity, Diversity and Gender in the University of Ottawa's Faculty of Medicine, and Ottawa Public Health.

The invitations then went out to our colleagues in community-based organizations, social services, the health professions, educational institutions and municipal, provincial and federal government. In our invitation we wrote:

Every woman and every man in Ottawa knows at least one girl or woman affected by violence.

In Ontario, 7% of women – more than 200,000 women – reported incidents of physical or sexual violence, perpetrated by

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An Inspirational Week

By President, Dr. Janet Dollin

This Thanksgiving I spent a grateful weekend reflecting on one incredible week in the life of this Family Physician, feeling honoured to be FMWC representative for a number of wonderful events. Let me share some of these experiences with you.

On Sunday September 30th, 2007, I was present as one of the 15,000 pink people in a sea of pink at the "Run for the Cure". We formed a snakelike mass as we traveled along the Parkway in Ottawa- some running, some walking and many being wheeled. The Federation of Medical Women of Canada team was out and we were but one of thousands of teams present that day, wearing the names of loved ones on our pinnies. There was a particularly inspirational moment when I caught a glimpse of the vista from a bit of a hill, and down in front of me, framed by the oranges and reds of the autumn trees, I could see the huge mass that we were, and feel like a small part of the bigger power and courage so obvious that day, in the battle against breast cancer.

On Monday I was inspired, as always, by the individual stories that my patients bring and the power and courage I see within them as they navigate their personal illnesses.

Dr Janet Dollin, Lily Cao (junior student rep-Ottawa U), Nili Kaplan-Myrth (senior student rep-Ottawa U), and Dr Jennifer Yau. There were thirteen people on the Ottawa team and we raised $1,612 (for a total of $2,697 Ottawa and Calgary combined).

On Tuesday October 2nd, 2007, I was a part of a bigger power collective as a participant at the 10th annual induction ceremony for the Canadian Medical Hall of Fame. As a representative of the FMWC, I was proud to visit the Hall itself, located in London, ON, and see the inspirational men and women who are our heroes. These are the people who made momentous medical discoveries and who really have changed the world with their discoveries or their actions. I felt inspired to be present at the induction ceremonies, and to see Dr Elizabeth Bagshaw, a founding member of FMWC, be inducted into the Hall of Fame for her great achievements in the field of women's health, in particular for the bold leadership she showed in making (what was then illegal) contraception accessible to Canadian women. I encourage everyone to please go to www.cdnmedhall.org/nominate/ and print out a nomination form. Consider who your medical heroes have been and nominate a worthy woman for the Canadian Medical Hall of Fame. Canadian medical women deserve their place in that hallowed Hall.

On Wednesday, after a few more inspirational patient stories, I joined with other FMWC and non FMWC Women from Ottawa to attend the Margaret Atwood play, The Penelopiad. There I saw what it means to effectively use a "gender lens". This is a technique we are trying hard to apply to medicine, medical research and medical education. Once again, we need to remember to honor the arts as a source of learning and inspiration for medicine.

On Thursday October 4th, 2007, evening I was invited to attend a dinner for a fledgling FMWC chapter in Montreal. There, I was inspired by the young Quebecoise women who know that the future of Medicine is theirs. Quebec has led the country in its acceptance of women students, and these women face a very different reality than Women in Medicine have the past. I hope that I in turn was able to inspire them with the photos I brought from MWIA's 27th International Congress which I had attended this summer in Ghana.

On Friday October 5th, 2007, I was most inspired to be invited to the "white coat ceremony" for my daughter's medical school class. There, the "Donning of the Healer's Habit" ceremony has become an opportunity to reflect on our vows to our profession and to our patients. Most striking was the sea of fresh, smart and caring faces that filled the room with the recitation of their shared vows, seen in the context of a week that included the Medical Hall of Fame. Which of those young men and women were one day going to be on those walls?

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HPV Supplement

Federation of Medical Women of Canada
Fédération des femmes médecins du Canada

What's up with that?

Janet Dollin, MDCM, CCFP, FCFP.
President, Federation of Medical Women of Canada.

As president of the Federation of Medical Women of Canada, as a family physician providing daily advice to girls and women, and as a mother who is aware of the risks of HPV, I was disappointed to learn that the public HPV vaccination program has not had a stellar uptake in Ontario. There are a number of factors to blame for this. As physicians, perhaps we can have an influence on this. Unbalanced presentation in the media is not doing women's health a favor whatsoever. Patient resistance to vaccination in general and the angst and religious fervor of "refusniks" is something this family physician is very familiar with, spending hours in the office trying to find a way to change mythical belief systems. Human Papilloma Virus (HPV) is the cause of real disease, with potentially serious consequences. There exist safe and effective vaccines to prevent it. Yes, there remain unanswered questions, but a wonderful opportunity can be lost or delayed if we hesitate on prevention now. Vaccine technology has its limitations, but we have to recognize and honour its important place in changing the face of infectious disease globally and for Canada. This vaccine is no different from all of the others that have revolutionized medicine. We are honoured to be able to provide this protection to our patients. Why do we need to convince so many patients of that?

There is mounting evidence to support the safety and effectiveness of this vaccine. In December 2007 Canadian Family Physician published a critical appraisal of the FUTURE II study that was published in NEJM. (2007;356(19):1915-27). This concluded by saying there is good evidence for vaccination of girls and women who are susceptible to HPV types 16 and 18 for the prevention of high grade lesions and cancer. They reinforce the reasons why the best results will only happen if we vaccinate before the onset of sexual activity. They also restate that even in the face of vaccination, cervical screening will continue to be necessary. In MacLean's in August 2007 we read a sensational article about one dissenting author group from the Canadian Medical Association Journal's August 28th, 2007 issue. All 5 other HPV articles in the same CMAJ issue speak to the vaccine's effectiveness and safety. Where was Maclean's interview of any of these other authors? Where was her interview of Dr David Butler-Jones, Canada's chief public health officer? Where was her reporting of the summary of reputable groups of intelligent and well meaning researchers and doctors such as the well researched and carefully worded statement made by National Advisory Committee on Immunization (NACI) or the Canadian Pediatric Society (CPS) or the Society of Obstetricians and Gynecologists of Canada (SOGC) or Cancer Care Ontario or the Canadian Cancer Society? Why are none of these well respected opinions included? These reports all say that we should proceed while continuing to ask important questions. And let's be honest, there are some unanswered questions. These, however, do not take away from the reality that we are witness to a breakthrough in women's health and in cancer prevention in general. At the Federation of Medical Women of Canada we want to be sure that unanswered questions are heard and not lost in the hype of false media sensationalism and divisions into "pro" and "con" groups.

Both sides are clearly saying that effective cervical cancer screening programs for all of Canada, which take into account subgroups with different risk across the country, need further development. Both sides argue that we must be clear about vaccine program objectives and must gather the evidence we need to decide to vaccinate boys, men, girls and women if we hope for serious reduction in HPV disease morbidity and mortality, since there is no doubt from either camp that this is a preventable sexually transmitted infection. Suggesting that vaccination will cause a disregard of safe sex behaviors is underestimating and insulting women. Sadly, this vaccine resistance movement appears to support the argument that 400 deaths in Canada are not really "enough" to consider this a priority disease. Such arguments have created an opportunity to fuel the fires of difference and the myths of vaccine angst.

For me, I feel privileged to be present at this time in history when our government has made a financial commitment to the health of women, and I can save my patients from the pain, devastation and death from HPV illness. I urge the Canadian public to trust physicians and their policy making advisory groups and go ahead with HPV vaccination now, as has been recommended in 2007. I am confident our ability to fight HPV disease will evolve as we know more and as we see the research unfold, but that does not change the need to vaccinate now. We will advance more effectively if we all talk together and do not form camps or feed unfounded fears.

Editor's note: Dr. Dollin has not received any funds for writing this article and therefore there is no conflict of declaration.

SOGC Conference Highlights

Evolving Human Papillomavirus (HPV) Vaccine Landscape

A Report from the 63rd Annual Clinical Meeting of
The Society of Obstetricians and Gynaecologists of Canada

Up to 80% of women will acquire a human papillomavirus (HPV) infection in their lifetime (Baseman & Koutsky, *J Clin Virol* 2005;S16-24., Ho et al, *NEJM* 1998;338:423-228., Brown et al 2005;191:182-192). Of these, 75% are cancer-causing (oncogenic) HPV types (Bosch et al, *J Clin Path* 2002;55:244-265, Koutsky, *AMJ* 1997;102(5A):3-8). Current knowledge on HPV indicates that natural immunity does not reliably protect against future infections as only about 50% of those infected with HPV seroconvert and, of those who do seroconvert, antibody titers tend to be slow to develop. Thus, re-infection can occur with the same or different HPV types. This re-occurrence illustrates the immune evasiveness of the HPV and the sub-optimal response to a natural HPV infection. HPV infections are also more likely to persist as women age and as the immune response declines.

Infection with HPV, a double-stranded DNA virus, is easily transmitted, usually soon after sexual debut (McIntosh, *JHPIEGO*, 2000, www.reproline.jhu.edu/english/3cc/3refman/cxca_hpv1.htm., Baseman & Koutsky, *J Clin Virol* 2005;32S:S16-S24) and the risk of infection continues over a woman's lifespan. Therefore, all sexually active women remain at risk of oncogenic HPV infection throughout their lifetime and require protection. Dr Dirk Campens, MD, MBCPM, Director of the Worldwide Medical Affairs HPV Vaccines, GlaxoSimithKline Biologicals states that the goal is to develop a vaccine which targets prevention of cervical cancer in females from 10 years of age onwards. Globally, approximately 500,000 new cases of cervical cancer are diagnosed annually with approximately 270,000 deaths per year; disproportionably the highest numbers are in developing countries. In Canada, approximately 1450 women are diagnosed with cervical cancer annually and 420 die (Canadian Cancer Society/ National Cancer Institute of Canada: Canadian Cancer Statistics 2006). Cervical cancer ranks as the second most common cancer after breast cancer amongst women aged 20-44 (CancerCare Ontario: Cancer in Young Adults in Canada, Toronto, 2006).

Vaccines are immunostimulatory, but nonpathogenic, protein antigens used to confer immunity against the disease caused by infectious agents. Dr. Carolynn E. Pietrangeli, Senior Research Scientist, CTI, Clinical Trial and Consulting Services, Cincinnati, Ohio suggests that building an effective vaccine against HPV involves (a) understanding the natural infection process and the protective immune response against the virus, (b) identifying the viral antigens and immunization schedule that neutralizes HPV and triggers strong rapid memory response thereby providing long-term immune protection and (c) demonstrating that the vaccine prevents disease or modifies the risk of developing surrogate markers of disease (e.g. Cervical Intraepithelial Neoplasias 2+).

In humans, 15 HPV types have been associated with the development of cervical cancer. Of these cancer-causing HPV types, types 16, 18, 45 and 31 account for up to 80% of cervical cancer worldwide. Other types, including HPV 6 and HPV 11, cause genital warts and are considered to be low risk viral types.

The bivalent cervical cancer candidate vaccine contains Virus-Like Particles (VLP)s containing L1 derived from the oncogenic types HPV 16 and 18. To appreciate the clinical significance of HPV vaccines, it is crucial to understand why the HPV is different from other viruses (e.g. Hepatitis B). Dr. Pietrangeli explains that natural infection with HPV is immune evasive as (a) HPV is not a blood borne infection and (b) the site of the infection, the cervix, is inaccessible to the immune system since it infects the basal layer of the cervical epithelium, an area that is relatively devoid of antigen-processing and presenting dendritic cells. This allows HPV to avoid a primary step in immune recognition and processing resulting in viral antigens not being efficiently transported to the lymph node, producing a suboptimal adaptive immune response. Finally, the virus does not cause cytolysis (death of the infected cells). This process generates a low level of viral antigenic "noise" and inhibits the inflammation that would stimulate the antiviral immune response and viral clearance. The potential result of immune evasion is persistent infection, a risk factor for the development of cervical cancer (Stanley, *Vaccine* 2006;24Suppl1:S16-22).

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This past fall, the National Office distributed a very brief survey to the members to assess the level of knowledge our members had regarding this new HPV vaccine. We received 89 responses. The following shows the results to the questions:

The result of Survey Monkey for 89 respondents:

1. Are you confident in your current position on HPV vaccination?

   60% said yes
   23% said somewhat
   17% said no

2. Do you have a good understanding of the scientific information supporting HPV vaccinations for girls age 9 - 29 years old?

   50% said yes
   40% said somewhat
   10% said no

3. Do you believe that you have heard a balanced view on HPV vaccination?

   52% said yes
   30% said somewhat
   18% said no

4. How strongly do the positions of opinion leaders influence your opinion?

   8% said not at all
   31% said minimally
   44% said moderately
   17% said considerably

(Continued from page 2)

HPV actively evades adaptive immunity and suppresses the production of neutralizing antibodies. Therefore, an ideal cervical cancer vaccine must generate a strong and sustained immune response to overcome the HPV immune evasiveness, establish a protective neutralizing antibody response at the site of infection and provide long-term protection against new infection that can be acquired over a woman's lifetime. The challenges posed by these unique characteristics of the HPV require an innovative approach to vaccine development.

An innovative facet in vaccine development has focused on the development of adjuvant systems with a dual role of carrier (typically aluminum) and an immunostimulant to increase the intensity, quality and duration of the effective adaptive immune response. As HPV Types 16 and 18 are responsible for approximately 70% of invasive cervical cancers worldwide, GSK's cervical cancer candidate vaccine has been formulated with the HPV-16 and HPV-18 L1 VLP antigens + a novel Adjuvant System 4 (AS04) which combines an Aluminum Hydroxide ($Al(OH)_3$) adjuvant (carrier) + monophosphoryl Lipid-A (MPL: immunostimulant). The ultimate goals of this vaccine are to enhance the immune response against HPV, overcome HPV immune evasion and provide strong and sustained protection against cervical cancer.

A recent finding from GSK's clinical trials has been the observation that serum antibody levels against HPV 16 and 18, generated as a result of vaccination, correlate with levels of antibodies in the cervix, thus providing strong evidence that antibodies in the serum transude from the blood into the cervical epithelium. Since the AS04 adjuvant system provides higher levels of antibodies compared to the vaccine that has been adjuvanted with alum alone, these results suggest that this vaccine delivers higher levels of antibodies at the cervical epithelium where HPV infection occurs. Long-term immunological protection may be further facilitated through the ability of AS04 to generate higher number of Memory B cells, which may serve to better protect against future infection.

Dr. Campens articulates the development vision, vaccine design and the initial and long term efficacy and safety results and immunogenicity results of ongoing Phase II and Phase III clinical trials in females 10-55 years of age (Harper et al., *Lancet* 2004;364:1757-65, Harper et al. *Lancet* 2006;367:1247-55). In the initial efficacy and extended follow-up to 5.5 years study (n= 776 women), combined results indicated substantial protection against HPV 16 /18 persistent infections (6 month and 12 month persistence) and CIN (1+ and 2+) outcomes (Figure 2). High HPV 16 and 18 antibody levels and seropositivity (≥ 98%) were sustained for 5.5 years at levels approximately 11 times higher than the natural infection antibody level.

Additional protection was also suggested beyond HPV 16 and 18 in terms of cytological abnormalities and CIN1+ and CIN2+ outcomes. Substantial cross protection against incident infection with the third and fourth most common types found in cervical cancer (i.e. HPV Types 45 and 31) was also shown (Figure 3) over a period up to 5.5 years.

In the extended follow-up study, the safety profile (Gall, ACCR, Los Angeles, April, 2007), including Adverse Events (women with one adverse event and the number of adverse events), New Onset of Chronic Disease (including but not exclusive to autoimmune diseases, endocrine, musculoskeletal, connective tissue, metabolism and nutrition, respiratory and thoracic disorders), and Serious Adverse Events (Women with at least one Serious Adverse Event, and the number of adverse events reported) was comparable between the vaccine group (n=373) and the control group (n=370).

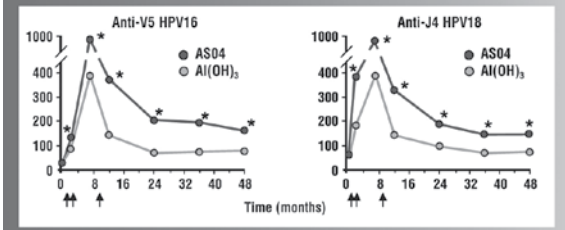
Phase III efficacy studies are currently underway in a broad population. The purpose of these trials is to increase the robustness of the Phase II observations in terms of high vaccine efficacy, high immunogenicity, cross protection and safety in a population of 18,644 women that spans 4 continents and includes women previously exposed to oncogenic HPV. The study population includes women 15-25 years old, including women with current or prior oncogenic HPV infection, who at entry had normal low grade cytology and high grade cytology, and who had at least 1 vaccine dose. Eligible women were randomized 1/1 to a double blind controlled trial where the total vaccinated cohort for efficacy consisted of 18,525 women randomized to HPV Vaccine (n=9,258) or Hepatitis A Vaccine (n=9,267) with mean follow-up of 15 months. Results of this most recent study will be available in the near future.

Finally, Dr. Campens presented data on the immunogenicity results in women 10 to 55 years of age. The rationale for vaccinating girls 10-14 years included their low

(Continued on page 4)

Figure 1. Rationale for Selection of AS04 Adjuvant

Induction of neutralizing antibodies



Statistically significant differences during the 4 yr FU period

Vaccine adjuvanted with AS04 induces a stronger and more sustained antibody response vs. vaccine adjuvanted with Alum

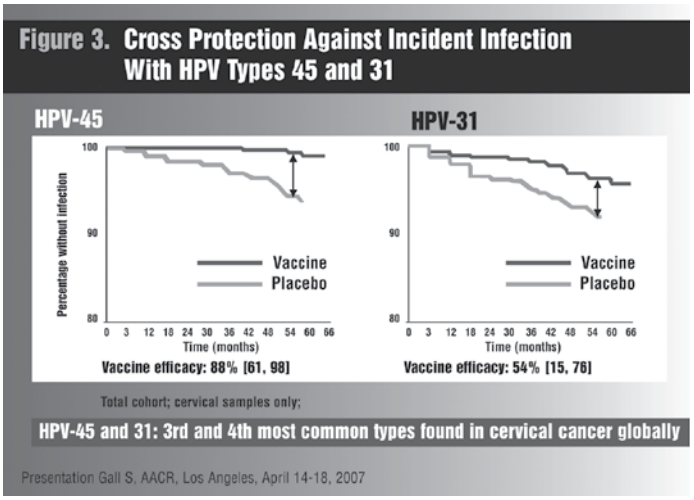
Giannini S, et al. Vaccine. 2006

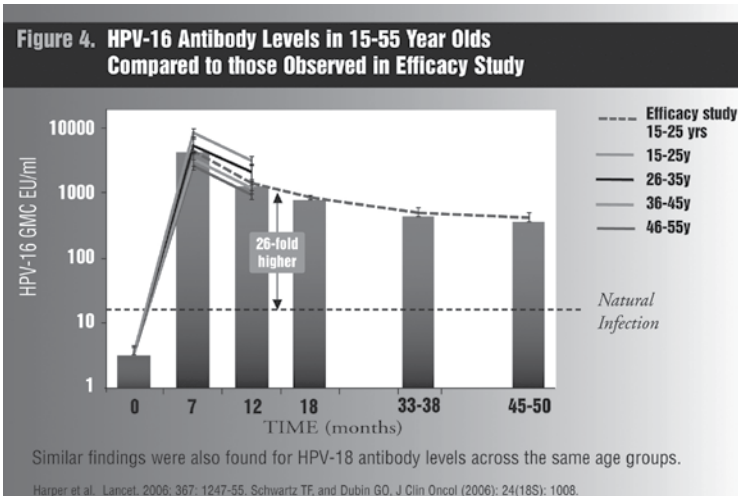
Figure 2. Up to 5.5 years Substantial Protection against HPV-16/18 infections and CIN outcomes

Endpoints*	Vaccine	Control	Vaccine Efficacy	
	n	n	%	95% CI
6 Month Persistence	0	29	100	88-100
12 Month Persistence	0	14	100	72-100
CIN1+	0	11	100	62-100
CIN2+	0	7	100	33-100

*Combined analysis initial efficacy study and extended follow-up
ATP analysis for virologic endpoints; ITT analysis for cytologic and CIN endpoints

Presentation Gall S, AACR, Los Angeles, April 14-18, 2007





(Continued from page 3)

levels of current infection, but high risk of future infection as well as the expected good immune response. The principles of immunobridging between age groups were upheld as higher antibody levels were found in the 10-14 year old age groups for both the HPV-16 and 18 Types when compared to 15-25 year olds. An immunobridging study was also performed in women 26-55 years whose antibody responses were compared to a group of 15-25 year old women for whom efficacy results had already been established. Given that immune responses tend to decline with age, questions on the adequacy of the antibody response were paramount. In this study, 100% of the women aged 26-55 seroconverted at month 7 following vaccination and the levels of serum antibodies (measured in Geometric Mean Titers or GMTs) against HPV 16 and 18 were in the same range of magnitude of those observed in the 15-25 year old women, even if there was a decline in levels of antibodies with age as seen with other vaccines. Results of HPV-16 antibody levels in 15-55 year olds suggest antibody levels at 12 months (Figure 4) that are in the same range as those observed in the efficacy study in women 15-25 years of age followed-up over a period of 5.5 years. Similar findings were also found for HPV-18 antibody levels across the same age groups.

In summary, the GSK cervical cancer candidate vaccine based on HPV 16 and HPV 18 L1 VLP formulated with the AS04 adjuvant (Alum + MPL) to enhance immune responses, demonstrates high efficacy in females 15-25 years of age, appears to induce a strong and sustained immune response and is well tolerated in females 10-55 years of age. The 5.5 year follow-up data may also be predictive of what is to be expected from an efficacy point of view in the future.

The distribution of this report is supported through an unrestricted educational grant from GlaxoSmithKline Inc.

November 23, 2007

Point of View on HPV Vaccine

Vivien Brown MDCM, CCFP, FCFP

As a primary care provider, we are always in the position of putting out the various brush fires of illness, trying to avoid the forest fires. We rarely have the luxury of taking away the matches. And then there is the unique experience of immunization. Here we have the ability to stop the process before it even begins. We have the tools to do primary prevention, not merely secondary management. And we are complacent. For the most part, we do not see the diseases we prevent. We so casually immunize the public for polio, tetanus and others. These were the killer diseases not so very long ago. And despite the fact that immunization has saved more lives in Canada than any other preventative health care initiative in the last fifty years, we are blasé and less than excited. Statistically we do a relatively poor job in immunization as many adults have not received the basic immunization. Despite government funding our population in under immunized. We do know clearly however, that when physicians recommend vaccine, when we educate the patients that we care for, then they are much more likely to choose vaccination and protect themselves against vaccine preventable illness.

With the launch of HPV vaccine, we again are in a unique position. We have a fantastic tool in our hands to alter the paradigm of cervical cancer. And we have clear and appropriate guidelines from NACI, giving us the strategy to help make those medical decisions. It is reassuring to realize that NACI has been there since 1968 to help set those standards of care. And NACI is not big pharma, not the government of the day, not the various laboratories or hospitals or other group with any bias, but rather the objective, autonomous, scientific body that helps me to practice according to Canadian standards. We as family physicians throughout Canada have the opportunity to change the focus of women's health in this arena from a treatment modality to a prevention modality. And we will.

Editor's note: Dr. Brown has not received any funding for writing this article.

June 25, 2007

HPV, Vaccines, and Gender: Policy Considerations

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This paper reflects data available to us as of June 2007. Studies about HPV vaccines -- their efficacy, safety, place in women's health care -- and research on the implications of initiating vaccination programs continue to evolve. We will be adding new references and links to some of this work as best we can in the future.

A summary of this paper is to appear in the 28 August 2007 Canadian Medical Association Journal; a pre-released version can be found online now at: http://www.cmaj.ca/cgi/content/full/177/5/484.

Read the full paper: HPV, Vaccines, and Gender: Policy Considerations (PDF 238k/19p)

Executive Summary

Cancer prevention remains a high priority for women and men in Canada, and critical steps for cancer prevention are identifying and eliminating the causes of such diseases. The federal government's recently-announced $300 million investment toward a program for vaccinating girls and women with the currently available human papillomavirus (HPV) vaccine, *Gardasil* (manufactured by Merck Frosst) framed by some as a way to prevent cervical cancer in Canada, has generally been welcomed by a wide range of commentators. The policy commitment to improve the health of women and girls is laudable and emerging research about the effectiveness of immunization in reducing HPV prevalence is promising.

However, although HPV infection is necessary for the development of cervical cancer, and while evidence suggests that *Gardasil* may prevent primary infection with HPV types 16 and 18 (currently thought to be a necessary cause of about 70 per cent of cervical cancer cases), we propose that these facts be assessed within a broad context, which at this moment contains many unknowns, before immunization policies are developed and implemented.

A careful review of the literature, including that which was submitted by the manufacturer with its application for approval of *Gardasil*, reveals a sufficient number of unanswered questions to lead us to conclude that a universal immunization program aimed at girls and women in Canada is, at this time, premature and could possibly have unintended negative consequences for individuals and for society as a whole. We suggest that rather than giving widespread administration of this vaccine a "green light," a more appropriate policy at this time would be a "yellow light" of caution. We recommend that the funding announced by the federal government be used to support the research needed to answer the many questions outlined below; to fund a public education campaign to quell the unfounded anxiety that has been instilled by marketers of the vaccine that HPV represents a "new" or "imminent" threat; and to ensure equal access to Pap testing, including timely follow-up and application of improvements in testing. Only when there is a solid evidence base and an appropriately-provisioned cervical screening program accessible to all can we determine the most appropriate holistic strategy - and the place of vaccination in it - to address cervical cancer and the transmission of HPV between and among Canadian girls, boys, women, and men. We have been given an exciting opportunity to establish effective guidelines and to create a model of how to approach future vaccines. We must take full advantage of it.

In this paper, we summarize some of the major questions and concerns that need to be addressed before there is a full-scale roll-out of an HPV vaccination program. These closely reflect issues raised in the analytical framework created by Erickson et al.[i] in the context of the development of the National Immunization Strategy (NIS), and support efforts to ensure a comprehensive and systematic evaluation of all relevant factors before decisions regarding the importance of a new immunization program are made. As well, they echo some of the research questions identified as important in the Final Report from the Canadian Human Papillomavirus Vaccine Research Priorities Workshop held in Quebec City in 2005.[ii]We hope raising these questions now will contribute to the deliberations necessary to ensure a responsible and transparent evidence-based decision-making process.

Our major points, summarized here, are discussed in detail in the text that follows. They are also summarized in a Commentary appearing in the 28 August 2007 issue of the *Canadian Medical Association Journal (CMAJ)*, online as of 1 August 2007.

1. There is no epidemic of cervical cancer in Canada . According to Canadian Cancer Statistics 2006,[iii] approximately 400 women were anticipated to die of this disease in 2006.
2. Invasive cervical cancer typically follows a slowly progressive course that can be halted at one of various stages. Consequently, deaths associated with cervical cancer, relatively rare in Canada, but always unfortunate and not distributed evenly among women, must be considered as a failure in the adequate support of both the primary care and reproductive health services that would guarantee healthy living conditions for all women as well as ensure all women get appropriate Pap testing and follow-up.
3. Most HPV infections are cleared spontaneously. Recent research using available molecular detection technologies suggests that clearance occurs within one year for about 70 per cent of those infected, and within two years for 90 per cent. Thus, HPV infection and cervical cancer must not be conflated: most women who are infected with even a "high-risk" strain of HPV will not develop cervical cancer.[iv]
4. The nature of an immunization program is necessarily dependent upon the definition of clear and tangible goals. To date, such goals have not been made explicit with regard to a Canadian initiative. Is the aim of the vaccination program the eradication of high-risk HPV types from the population? Or is the aim to reduce the number of cervical cancer deaths? These different goals require different strategies.

(Continued on page 7)

GARDASIL®

[Quadrivalent Human Papillomavirus (Types 6,11,16,18) Recombinant Vaccine]

Prescribing Summary

Patient Selection Criteria

THERAPEUTIC CLASSIFICATION

Active Immunizing Agent (Suspension for injection)

INDICATIONS AND CLINICAL USE

GARDASIL® is a vaccine indicated in girls and women 9-26 years of age for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16, and 18 and the following diseases associated with these HPV types:

- Cervical cancer
- Vulvar and vaginal cancers
- Genital warts (condyloma acuminata)
- Cervical adenocarcinoma *in situ* (AIS)
- Cervical intraepithelial neoplasia (CIN) grade 2 and grade 3
- Vulvar intraepithelial neoplasia (VIN) grade 2 and grade 3
- Vaginal intraepithelial neoplasia (VaIN) grade 2 and grade 3
- Cervical intraepithelial neoplasia (CIN) grade 1

Pediatrics (<9 years of age) / Geriatrics (>65 years of age)

The safety and efficacy of GARDASIL® have not been evaluated in children younger than 9 years and in adults above the age of 26 years.

CONTRAINDICATIONS

- Patients who are hypersensitive to the active substances or to any of the excipients of the vaccine. For a complete listing, see the DOSAGE FORMS, COMPOSITION AND PACKAGING in the Supplemental Product Information.
- Individuals who develop symptoms indicative of hypersensitivity after receiving a dose of GARDASIL® should not receive further doses of GARDASIL®.

SPECIAL POPULATIONS

For use in special populations, see WARNINGS AND PRECAUTIONS, Special Populations.

Safety Information

WARNINGS AND PRECAUTIONS

General

As for any vaccine, vaccination with GARDASIL® may not result in protection in all vaccine recipients.

This vaccine is not intended to be used for treatment of active genital warts; cervical, vulvar, or vaginal cancers; CIN, VIN, or VaIN.

This vaccine will not protect against diseases that are not caused by HPV.

GARDASIL® has not been shown to protect against diseases due to non-vaccine HPV types.

As with all injectable vaccines, appropriate medical treatment should always be readily available in case of rare anaphylactic reactions following the administration of the vaccine.

The decision to administer or delay vaccination because of a current or recent febrile illness depends largely on the severity of the symptoms and their etiology. Low-grade fever itself and mild upper respiratory infection are not generally contraindications to vaccination.

Individuals with impaired immune responsiveness, whether due to the use of immunosuppressive therapy, a genetic defect, Human Immunodeficiency Virus (HIV) infection, or other causes, may have reduced antibody response to active immunization (see DRUG INTERACTIONS in the Supplemental Product Information). No specific data are available from the use of GARDASIL® in these individuals.

This vaccine should be given with caution to individuals with thrombocytopenia or any coagulation disorder only if the benefit clearly outweighs the risk of bleeding following an intramuscular administration in these individuals.

Routine monitoring and Pap test should continue to be performed as indicated, regardless of GARDASIL® administration.

Special Populations

The safety, immunogenicity, and efficacy of GARDASIL® have not been evaluated in HIV-infected individuals.

Pregnant Women: There are no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, pregnancy should be avoided during the vaccination regimen for GARDASIL®. For more details see WARNINGS AND PRECAUTIONS, Special Populations in the product monograph.

Merck Frosst Canada Ltd. maintains a Pregnancy Registry to monitor fetal outcomes of pregnant women exposed to GARDASIL® vaccine. Patients and health-care providers are encouraged to report any exposure to GARDASIL® vaccine during pregnancy by calling 1-800-567-2594.

Nursing Women: It is not known whether vaccine antigens or antibodies induced by the vaccine are excreted in human milk.

GARDASIL® may be administered to lactating women. For more details see WARNINGS AND PRECAUTIONS, Special Populations in the product monograph.

ADVERSE REACTIONS

(see Supplemental Product Information for full listing)

Adverse Drug Reaction Overview

In clinical trials, GARDASIL® was generally well tolerated when compared to placebo (aluminum or non-aluminum containing).

Clinical Trial Adverse Drug Reactions

The most commonly reported vaccine-related injection-site adverse experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 5 days post-vaccination,in females 9 through 26 years of age in clinical trials with GARDASIL® (n=5088), aluminum-containing placebo (n=3470) and saline placebo (n=320), respectively, were pain (83.9%, 75.4%, 48.6%), swelling (25.4%, 15.8%, 7.3%), erythema (24.6%, 18.4%, 12.1%) and pruritus (3.1%, 2.8%, 0.6%). The most commonly reported vaccine-related systemic adverse experiences (reported at a greater frequency than that observed among placebo recipients) 1 to 15 days post-vaccination, in females in clinical trials with GARDASIL® (n=5088) and for aluminum and non-aluminum containing placebo (n=3790), respectively, were fever (10.3%, 8.6%), nausea (4.2%, 4.1%), dizziness (2.8%, 2.6%) and diarrhea (1.2%, 1.5%).

For more details on adverse events reported during clinical trials, see ADVERSE REACTIONS in the Supplemental Product Information.

To report a suspected adverse reaction,
please contact Merck Frosst Canada Ltd. by:
Toll-free telephone: 1-800-567-2594
Toll-free fax: 1-877-428-8675
By regular mail: Merck Frosst Canada Ltd., P.O. Box 1005, Pointe-Claire – Dorval, QC H9R 4P8

Administration

DOSAGE AND ADMINISTRATION

Recommended Dose and Dosage Adjustment

GARDASIL® should be administered intramuscularly as 3 separate 0.5 mL-doses according to the following schedule:

- First dose: at elected date
- Second dose: 2 months after the first dose
- Third dose: 6 months after the first dose

Individuals are encouraged to adhere to the 0, 2, and 6 months vaccination schedule. If a deviation from the recommended schedule occurs, it is recommended that the second dose be administered at least 1 month after the first dose, and the third dose be administered at least 3 months after the second dose. All 3 doses should be given within a 1 year period.

Administration

GARDASIL® should be administered intramuscularly in the deltoid region of the upper arm or in the higher anterolateral area of the thigh.

GARDASIL® must not be injected intravascularly. Subcutaneous and intradermal administration have not been studied, and therefore are not recommended.

The prefilled syringe is for single use only and should not be used for more than one individual. For single-use vials, a separate sterile syringe and needle must be used for each individual.

The vaccine should be used as supplied; no dilution or reconstitution is necessary. The full recommended dose of the vaccine should be used.

Shake well before use. Thorough agitation immediately before administration is necessary to maintain suspension of the vaccine. After thorough agitation, GARDASIL® is a white, cloudy liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration. Discard the product if particulates are present or if it appears discolored.

Single-dose Vial Use: Withdraw the 0.5 mL dose of vaccine from the single-dose vial using a sterile needle and syringe free of preservatives, antiseptics, and detergents. Once the single-dose vial has been penetrated, the withdrawn vaccine should be used promptly, and the vial must be discarded.

Prefilled Syringe Use: Inject the entire contents of the syringe.

For instructions for using the prefilled single-dose syringes preassembled with needle guard (safety) device, see DOSING AND ADMINISTRATION, Administration in the product monograph.

STORAGE AND STABILITY

Store refrigerated at 2°C to 8°C. Do not freeze. Protect from light. GARDASIL® should be administered as soon as possible after being removed from refrigeration. When out of refrigeration at room temperature at or below 25°C, administration may be delayed for up to 3 days.

Study References

1. Canada Communicable Disease Report (CCDR). National Advisory Committee on Immunization. Statement on Human Papillomavirus Vaccine, February 15, 2007. Available at: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/07pdf/acs33-02.pdf

Supplemental Product Information

DESCRIPTION

GARDASIL® [Quadrivalent Human Papillomavirus (Types 6, 11, 16, 18) Recombinant Vaccine] is a recombinant, quadrivalent vaccine that protects against Human Papillomavirus (HPV). It is a sterile liquid suspension prepared from the highly purified virus-like particles (VLPs) of the recombinant major capsid (L1) protein of HPV Types 6, 11, 16, and 18. The L1 proteins are produced by separate fermentations in recombinant *Saccharomyces cerevisiae* CANADE 3C-5 (Strain 1895) and self-assembled into VLPs.

ADVERSE REACTIONS

Clinical Trial Adverse Drug Reactions

In 5 clinical trials (4 placebo-controlled), subjects were administered GARDASIL® or placebo on the day of enrollment, and approximately 2 and 6 months thereafter. GARDASIL® demonstrated a favorable safety profile when compared with placebo (aluminum or non-aluminum containing). Few subjects (0.2%) discontinued due to adverse experiences. In all except one of the clinical trials, safety was evaluated using vaccination report card (VRC)-aided surveillance for 14 days after each injection of GARDASIL® or placebo. The subjects who were monitored using VRC-aided surveillance included 6160 subjects (5088 females 9 through 26 years of age and 1072 males 9 through 16 years of age at enrollment) who received GARDASIL® and 4064 subjects who received placebo.

The vaccine-related adverse experiences that were observed among recipients of GARDASIL® at a frequency of at least 1.0% and also at a greater frequency than that observed among placebo recipients, in the male and/or female population, are shown in Table 1 and Table 2 of the product monograph.

Overall, 94.4% of subjects who received GARDASIL® judged their injection-site adverse experience to be mild or moderate in intensity.

In addition, bronchospasm was reported very rarely as a serious adverse experience.

Serious Adverse Experiences

A total of 102 subjects out of 21,464 total subjects (9- to 26-year-old girls and women and 9- to 15-year-old boys) who received both GARDASIL® and placebo reported a serious adverse experience on Day 1-15 following any vaccination visit during the clinical trials for GARDASIL®. The most frequently reported serious adverse experiences for GARDASIL® compared to placebo and regardless of causality were:

- Headache (0.03% GARDASIL® vs. 0.02% placebo),
- Gastroenteritis (0.03% GARDASIL® vs. 0.01% placebo),
- Appendicitis (0.02% GARDASIL® vs. 0.01% placebo),
- Pelvic inflammatory disease (0.02% GARDASIL® vs. 0.01% placebo).

One case of bronchospasm and 2 cases of asthma were reported as serious adverse experiences that occurred during Day 1-15 of any vaccination visit.

Deaths
Across the clinical studies, 17 deaths were reported in 21,464 male and female subjects. The events reported were consistent with events expected in healthy adolescent and adult populations. The most common cause of death was motor vehicle accident (4 subjects who received GARDASIL® and 3 placebo subjects), followed by overdose/suicide (1 subject who received GARDASIL® and 2 subjects who received placebo), and pulmonary embolus/deep vein thrombosis (1 subject who received GARDASIL® and 1 placebo subject). In addition, there were 2 cases of sepsis, 1 case of pancreatic cancer, and 1 case of arrhythmia in the group that received GARDASIL®, and 1 case of asphyxia in the placebo group.

All-cause Common Systemic Adverse Experiences
All-cause systemic adverse experiences for female and male subjects that were observed at a frequency of greater than or equal to 1% where the incidence in the vaccine group was greater than or equal to the incidence in the placebo group are shown in ADVERSE REACTIONS, Table 3 of the product monograph.

Systemic Autoimmune Disorders
In the clinical studies, subjects were evaluated for new medical conditions that occurred over the course of up to 4 years of follow up. The number of subjects who received both GARDASIL® and placebo and developed a new medical condition potentially indicative of a systemic immune disorder is shown in ADVERSE REACTIONS, Table 4 of the product monograph.

Post-Market Adverse Drug Reactions
The following adverse experiences have been spontaneously reported during post-approval use of GARDASIL®. Because these experiences were reported voluntarily from a population of uncertain size, it is not possible to reliably estimate their frequency or to establish a causal relationship to vaccine exposure.

Nervous system disorders: dizziness, syncope.

Gastrointestinal disorders: nausea, vomiting.

Immune system disorders: Hypersensitivity reactions including anaphylactic/anaphylactoid reactions, bronchospasm, and urticaria.

DRUG INTERACTIONS

Drug-Drug Interactions
Use with Other Vaccines: Results from clinical studies indicate that GARDASIL® may be administered concomitantly (at a separate injection site) with hepatitis B vaccine (recombinant).

The safety of GARDASIL®, when administered concomitantly with hepatitis B vaccine (recombinant), was evaluated in a placebo-controlled study. The frequency of adverse experiences observed with concomitant administration was similar to the frequency when GARDASIL® was administered alone.

Use with Common Medications: In clinical studies, 11.9%, 9.5%, 6.9%, and 4.3% of individuals used analgesics, anti-inflammatory drugs, antibiotics, and vitamin preparations, respectively. The efficacy, immunogenicity, and safety of the vaccine were not impacted by the use of these medications.

Use with Hormonal Contraceptives: In clinical studies, 57.5% of women (aged 16 to 26 years) who received GARDASIL® used hormonal contraceptives. Use of hormonal contraceptives did not appear to affect the immune responses to GARDASIL®.

Use with Steroids: In clinical studies, 1.7% (n=158), 0.6% (n=56), and 1.0% (n=89) of individuals used inhaled, topical, and parenteral immunosuppressants, respectively, administered close to the time of administration of a dose of GARDASIL®. These medicines did not appear to affect the immune responses to GARDASIL®. Very few subjects in the clinical studies were taking steroids, and the amount of immunosuppression is presumed to have been low.

Use with Systemic Immunosuppressive Medications: There are no data on the concomitant use of potent immunosuppressants with GARDASIL®. Individuals receiving therapy with immunosuppressive agents (systemic doses of corticosteroids, antimetabolites, alkylating agents, cytotoxic agents) may not respond optimally to active immunization (See WARNINGS AND PRECAUTIONS, General).

Drug-Food Interactions: Interactions with food have not been established.

Drug-Herb Interactions: Interactions with herbal products have not been established.

Drug-Laboratory Interactions: Interactions with laboratory tests have not been established. There was no evidence from the clinical studies database of impact of GARDASIL® administration on the performance characteristics of the Pap test and some commercially available HPV tests.

OVERDOSAGE

There have been occasional reports of administration of higher than recommended doses of GARDASIL®.

In general, the adverse event profile reported with overdose was comparable to recommended single doses of GARDASIL®.

DOSAGE FORMS, COMPOSITION AND PACKAGING

Vials: GARDASIL® is supplied as a carton ofone 0.5 mL single-dose vial

Syringes: GARDASIL® is supplied as a carton of one 0.5 mL single-dose prefilled Luer Lock syringe, preassembled with an UltraSafe Passive®† delivery system. One needle is provided separately in the package.

COMPOSITION

Active Ingredients: GARDASIL® is a sterile preparation for intramuscular administration. Each 0.5 mL dose contains approximately 20 µg of HPV 6L1 protein, 40 µg of HPV 11 L1 protein, 40 µg of HPV 16 L1 protein, and 20 µg of HPV 18 L1 protein.

Inactive Ingredients: Each 0.5 mL dose of the vaccine contains approximately 225 µg of aluminum (as amorphous aluminum hydroxyphosphate sulphate adjuvant), 9.56 mg of sodium chloride, 0.78 mg of L-histidine, 50 µg of polysorbate 80, 35 µg of sodium borate, and water for injection. The product does not contain a preservative or antibiotics.

PACKAGING

Vials and prefiled syringes components are latex free.

†UltraSafe Passive® delivery system is a Trademark of Safety Syringes, Inc.

(1094-a,6,07)

84140464, 84140464a

PRODUCT MONOGRAPH AVAILABLE AT
www.merckfrosst.com
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PAAB

(Continued from page 5)

5. Information about the efficacy of Gardasil appears promising, but remains uncertain. Recent reports seem to suggest that Gardasil 's efficacy may be significant only for grade 2 cervical intraepithelial neoplasia (potentially removable pre-cancerous lesions 40 per cent of which regress spontaneously and which may not even be recommended for treatment), while the data are "insufficient to support a conclusion of efficacy for grade 3 cervical intraepithelial neoplasia or adenocarcinoma in situ."[v]

   Related to this are other unknowns about the vaccine's effectiveness in the "real world" including the possible need for booster shots, concerns about altering the natural history of viral infection, and the impact of vaccination programs on safer sex practices and Pap screening rates, all of which highlight the essential need for careful health services research for the development of appropriate vaccination policies.

6. Relatively few young girls (about 1200 aged 9 - 15 years) were enrolled in the clinical trials of Gardasil. Of these, a mere 100 were nine years of age, with the youngest being followed for only 18 months.[vi] Yet, based on the assumption that they will not yet have been exposed to HPV viruses, girls in this age group represent the priority "target" population for mass vaccination. Clearly, this is a very weak information base on which to construct a policy of mass vaccinations for all girls aged 9 to 13, as per the National Advisory Committee on Immunization's (NACI) recommendations.[vii]

7. Rigorous collection and analysis of reports on adverse effects are needed for risk-benefit assessments that would allow for truly informed consent by individuals offered the vaccine. A list of adverse events is being compiled in the USA Food and Drug Administration (FDA) Vaccine Adverse Event Reporting System (VAERS)[viii] database, but because these reports are both incomplete and hard to interpret, there remains a need for careful and unbiased analyses of harm.

8. Media and marketing claims about the impact of HPV prevalence are very misleading and the naming of *Gardasil* as the "cervical cancer vaccine," implying the vaccine eliminates all cervical cancer, is incorrect. The marketing of *Gardasil* , which began in the United States even before it had been approved by the FDA, has made it difficult for there to be reflective discussions between parents and children, health care providers and their clients, as well as among the public and policy makers, about the nature and meaning of HPV and of vaccination.

9. There is a great need for cost/effectiveness analyses of proposed vaccination programs, since the "added value" of the vaccine is far from clear: girls and women, even if vaccinated, will still need to practice safe(r) sex and have access to existing reproductive and primary care programs - not only for Pap testing, but for other aspects of reproductive care as well. Such analyses are usually done prior to the initiation of a mass vaccination program to ensure that the most efficient and appropriate approaches are taken.

Notes:

i Erickson LJ, De Wals P, and Farand L. An analytical framework for immunization programs in Canada. *Vaccine*. 2005; 23: 2468-2474.

ii Public Health Agency of Canada. Canadian Human Papillomavirus Vaccine Research Priorities Workshop: Final Report. November 17th -18th, 2005; Quebec City. CCDR 2006;32S1:66. http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/06vol32/32s1/index.html.

iii Canadian Cancer Society and National Cancer Institute of Canada. Canadian Cancer Statistics 2006. Toronto, Canada, 2006.

iv Public Health Agency of Canada. What everyone should know about Human Papillomavirus (HPV): Questions and Answers. http://www.phac-aspc.gc.ca/std-mts/hpv-vph/hpv-vph-qaqr_e.html (Accessed February 20, 2007).

v Sawaya G, and Smith-McCune K. HPV Vaccination- More Answers, More Questions. *The New England Journal of Medicine*. 2007; 356: 1991-1993.

vi Rabin, R. "A new vaccine for girls: but should it be compulsory?" *New York Times*, July 18th, 2007.

vii National Advisory Committee on Immunization (NACI), Statement on human papillomavirus vaccine. *Canada Communicable Disease Report*. Februrary 2007; 33, ACS-2 15.

viii U.S. Food and Drug Administration. Vaccine Adverse Event Report System (VAERS) http://www.fda.gov/cber/vaers/vaers.htm. Accessed 24 May 2007.

Posted: August 1, 2007

July 18, 2006

GOC Position Statement Regarding Prophylactic HPV Vaccines

Cervical cancer continues to be a significant health problem for women in Canada and worldwide. In 2005, 1350 women in Canada were diagnosed with cervix cancer and 400 women died from the disease. For each new case of cervical cancer, there are about 50-100 women diagnosed with suspicious or pre-cancerous changes of the cervix that require management and treatment. The incidence and mortality from cervix cancer in Canada have declined since the mid-sixties until about 10 years ago mostly due to the availability of Pap test screening. This is a great accomplishment. Over the last decade, however, there has been no further reduction in incidence of this largely preventable disease that disproportionately affects women between the ages of 30 and 45 making it the second most common cancer in this age group. These women are affected by a devastating disease at a time when they are playing critical roles in society and serving as the nurturing parent for their children. Women of low socioeconomic status, high parity, immigrant women, and women of First Nations ancestry are also disproportionately affected, largely due to inadequate screening or higher risk among these groups.

It has been evident for decades that cervix cancer is caused by a sexually transmitted agent and that agent is now known to be the Human Papillomavirus (HPV). HPV infection is the most common of all sexually-transmitted infections. There are over 100 types of the virus and nearly 40 of them can infect the genital tract. Though most genital types are not related to cervical cancer, HPV types 16 & 18 are responsible for 70-80% of all cervical cancers. Among genital types considered of low or no oncogenic risk, HPV types 6 and 11 are responsible for more than 90% of benign genital warts, which do not incur risk of progression to cancer. Oncogenic HPVs initially induce a sequence of pre-cancerous changes which can be detected by Pap tests. Once detected, the pre-cancerous changes can virtually always be treated thus preventing the development of cancer of the cervix. Cervical cancer occurs when women fail to get screened or when Pap tests fail to detect pre-cancerous cells.

A vaccine to prevent HPV infection and cervix cancer has recently been approved for use in the U.S. and a second vaccine is in the approval process; approval of both in Canada is expected very soon. Phase II and phase III randomized clinical trials have shown that the vaccine is safe and effective, providing sustained protection from infection with HPV 16 and 18 as well as reducing the risk of developing pre-cancerous changes in the cervix. The first vaccines to come to the market are nearly 100% efficacious, one against HPV types 6, 11, 16, and 18 and another against types 16 & 18. This is a most exciting development in cancer prevention. For maximal effectiveness, the vaccine should be administered to young girls aged 9-12 prior to beginning sexual activity and as such, prior to there being any likelihood of infection with the cancer-causing HPV types. There may be a role for use of the vaccine in women after initiation of sexual activity but in that context, its efficacy in preventing infection and thus cervix cancer is restricted to the HPV types present in the vaccine to which the woman has not yet been exposed. Use of these vaccines for therapy of established HPV related conditions is not indicated. Other vaccines are being investigated for this purpose.

Preventing cervical cancer via large-scale vaccination against its causative agent is the ideal cancer control approach, particularly when combined with widespread and effective public and provider education strategies. Although it will take decades before all women can be protected from HPV infection, widespread vaccination would allow us to re-think the way cervical cancer screening (Pap tests) will be carried out. Rational algorithms incorporating Pap tests, HPV testing and the lower likelihoods of disease after vaccination will need to be developed and some of this work is underway in Canada. Only when uptake of the vaccine can be assessed and its efficacy in the general population demonstrated can the implications for changes in Pap test screening be determined. In the interim, cervical cancer screening must continue as per existing provincial and professional guidelines.

The Society of Gynecologic Oncologists of Canada (GOC), the national body of health professionals dedicated to prevention, treatment and study of gynecologic malignancies, has taken a lead role in the education of physicians and promotion of public awareness of all gynecologic cancers. Our membership has extensive expertise in all aspects of cervical cancer and its prevention. The GOC Task Force on Cervical Cancer Prevention and Control in particular and the membership in general will work to optimize application of this and other opportunities for improvement in our management of cervical cancer, its focus being on prevention.

The GOC supports the use of the HPV vaccine to prevent cervical cancer. Exactly how the vaccine will be implemented, in Canada and elsewhere, is currently undergoing intense review by a wide range of stakeholders. GOC is actively involved in these processes and exploring opportunities for research and innovation that will further define the safest and best use(s) of the vaccine and the necessary future modifications to current screening practices. Through a variety of initiatives, GOC will ensure that its membership, primary care providers and the public are kept abreast of evolving information regarding HPV vaccines, their availability and their applications. The GOC will also bring to the table our members' gynecologic cancer expertise to work with partners in related specialties such as primary care, pediatrics, vaccinology, infectious disease and public health as well as with industry and government, to develop knowledge and best practices as our experience with the vaccines evolves so that this novel approach to cancer prevention can be used to have its greatest impact on the health of all women in Canada.

The Society of Gynecologic Oncologists of Canada (GOC) is delighted that this in-

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September 10, 2007

GOC Responds To Public Concerns Regarding HPV Vaccine And Cervical Cancer Prevention

In Ontario, as of September 2007, the HPV vaccine will be freely offered through the school system, for the next three years, to girls entering into grade eight. Distribution of the HPV vaccine will be through a voluntary immunization program that will leave parents and their children with the decision of whether to vaccinate or not. The recent media blitz surrounding the HPV vaccine, although welcomed for the attention given to the often-neglected issue of cervical cancer, has been profoundly negative. In fact, the rhetoric by its very tone has the potential to derail a major advance in public health and cervical cancer prevention. It is imperative that a fair and balanced view of the HPV vaccine be presented so that parents and children can make informed decisions.

The burden of cervical cancer, and its precursors, has often been misrepresented as affecting only 1,400 women yearly, from which 400 will die. Some critics have suggested that there is no epidemic of cervical cancer in Canada that requires a move to HPV vaccination at this time. They contend that the problem is effectively dealt with by routine cervical screening with the Pap test, and this strategy is sufficient to keep the disease at bay. They would argue that the HPV vaccine should not be introduced, as proposed, until more research regarding dosing schedules and long term effects are fully understood – essentially maintaining the status quo for the time being. However, one must look a little deeper at the true burden of the disease to realize that the current prevention strategies are limited in the light of new technologies.

Prevention of cervical cancer comes at a very high price, in both human and financial terms. The current approach, a secondary prevention strategy (i.e. identifying a disease, or its precursors, and treating it while it is still curable) is based on Pap test screening. When a Pap test is abnormal, as is the case for approximately 400,000 Canadian women each year, cervical abnormalities are identified and results must be followed-up. This requires further Pap testing, additional visits to the doctor, and in many cases treatment to eradicate the cellular abnormalities. While treatment is typically localized to the cervix, and is successful at eradicating pre-cancerous abnormalities, it is not without problems. For some, treatment has resulted in infertility, for others pain, infection or bleeding - sometimes an urgent middle of the night visit to the local hospital emergency is required. Treatment for pre-cancerous abnormalities of the cervix results in anxiety, inconvenience, and intrusion, all of which may have a significant overall negative psychological impact.

While this secondary prevention strategy has been successful in reducing cervical cancer incidence since the early 60's, there has been minimal or no reduction of cervical cancer in the last 15 years. Up to 25% of Canadian women are seldom or never screened and these include women from the most vulnerable populations – this is an issue of equity and access.

Our current approach of testing over and over in the hope of picking up early abnormalities is based on a redundancy paradigm that was fuelled originally by a lack of understanding of the cause of cervical cancer. It works only at great cost, estimated at approximately 300 million dollars per year, and the need for an infrastructure within the health system to screen virtually every woman. In Canada, we have not been able to mount the political will to take this process to the next step where it will become more effective.

Over the past 30 years, three major Canadian reports have recommended organized cervical screening information systems at the provincial/territorial and/or national levels. Such a system would keep track of individual Pap test results, the need for repeat tests or updated tests, and would ensure that each eligible woman and their doctor would be sent reminders about when to have a Pap test. The need to move from a spontaneous system, where a patient gets a Pap test only if they turn up to receive one, to that of an organized electronic system, was advocated in each of the three national reports. Despite the overwhelming amount of evidence of the benefits of organized screening approaches, and repeated advocacy efforts, cervical cancer prevention using a secondary approach has been stalled for many years. Yes, overall rates have been reduced over time with the Pap test, but unless change occurs, cervical cancer rates will go no lower.

It is now known that the cause of cervical cancer is an oncogenic cancer-causing HPV viral infection that is transmitted sexually. For the first time it is possible to employ a primary prevention strategy through the HPV vaccine. The HPV vaccine acts to stimulate the immune system to prevent the infection responsible for cervical cancers, and related pre-cancerous lesions, before they can develop. Thus, there is the need to implement this new strategy, based upon a biological paradigm, whereby the majority of the disease is prevented before it can occur. Not only does primary prevention have the potential to increase the standard screening interval from once

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novation in cancer prevention has been developed and is likely to be available in Canada soon. We are committed to providing professional leadership and guidance concerning proper deployment of HPV vaccines and surveillance of their efficacy to ensure that they are safely and effectively applied to benefit women in Canada.

For more information, please refer to the GOC website at www.g-o-c.org.

On behalf of the Executive Council of The Society of Gynecologic Oncologists of Canada,
Barry P. Rosen, MD, FRCS(C)
President
The Society of Gynecologic Oncologists of Canada

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every two to three years, to perhaps once every five years, but more importantly, the vaccine has the potential to greatly reduce the number of abnormal Pap tests, with the associated follow-up and treatment implications. There can be no argument, even from the opponents of HPV vaccination, that the tenets of primary prevention are vastly superior to that of secondary prevention.

The implications of this biological paradigm argue strongly not only for vaccination programs to reduce the burden of the disease, but also for a fundamental shift in monitoring and testing for specific viruses. Secondary prevention strategies will still be needed under this new paradigm; however it is hoped that this will occur through linkages with existing cervical cancer screening programs and networks, and over time their focus will be revised.

The efficacy data around the HPV vaccine are sound and compelling. A systematic review of randomized trials (reported in the August 2007 issue of the CMAJ) clearly shows almost 100% protection from HPV infection and related disease caused by four major HPV subtypes (6,11,16,18). These subtypes account for 70% of all cervical cancers and 90% of all genital warts. The vaccine has been shown to be effective over five years of follow-up.

The argument that cervical cancer was not an endpoint in these studies, and as such cannot justify the implementation for cervical cancer prevention, is not valid. Endpoints in the trials were carefully chosen with the input from regulatory agencies including the U.S. Federal Drug Administration (FDA). These endpoints were surrogates for cancer (i.e. high grade precancerous lesions and infections with high grade risk types) simply because the long duration of the natural history of cervical cancer (decades) would make the endpoints of cervical cancer unmanageable and unethical in these studies.

The argument that investigation on about 1,200 girls aged 9 to 15 years of age cannot justify the use of the vaccine in the recommended 9-13 age cohort does not tell the whole story. All of the trials to date report data on outcomes of disease or infection for thousands of women between the ages of 15 and 26 years of age. With FDA approval, the younger age group was chosen only for immunogenicity data (i.e. to look to see whether this group would make antibodies against the HPV subtypes to a level equal to or greater than the 15 to 26 year age group) and not on efficacy (which addresses protection against infection). This is not only understandable but is practical as well. It would be unethical to submit younger girls to biopsies and examinations, especially when this age group generally does not have exposure to HPV infection. In the immunogenicity studies, the antibody responses were much higher than in the older age group. These data predict well for persistence of protection over time, and also provides the rationale for inoculation at an earlier age. Also, the vaccine was most effective when given prior to exposure to HPV infection.

In addition to the efficacy data established in the randomized trials, large ongoing phase IV trials (some groups being followed for life) are being conducted. These groups are five or more years ahead of any population implementation that we would choose to do now in Canada. The data from these groups will be shared worldwide to further inform issues regarding HPV vaccine implementation.

The issue of whether a booster will be necessary is important, and while there is presently growing evidence of long-term immunity, that data will need to be monitored prospectively. The situation is not unlike the precedent of the hepatitis B vaccine that is now routinely administered in schools, and one that uses the same vaccine technology with similar long-term protective effects. In addition, there are also ongoing reports from the various trials of immune memory responses in which women that are challenged with the HPV antibodies after 5 years are showing that they are able to mount a response.

The randomized trials, which were very tightly monitored for safety events, showed that there were more minor adverse events such as pain, redness, or swelling at the injection site associated with the vaccine. However, there were no differences in the number of serious adverse events or in deaths between those who received the HPV vaccine and those who received an inert placebo injection. These compelling data show that severe adverse events, even death, can occur in a study population, or in the real world, even when there are no reasons for such reactions (such as a placebo injection). The HPV vaccine has also been subjected to ongoing rigorous review by regulatory bodies around the world including Health Canada and the U.S. FDA. There is consensus by experts about the safety of the vaccine. With over seven million doses of the vaccine distributed in the USA alone, rates of serious adverse events have been less than expected, at approximately five percent of the 2,531 adverse events reported to date (U.S. VAERS database). This is lower than the average 10%-15% event rate seen with other similar vaccines. To date there has been a lack of causality related to the vaccine for the serious adverse events that have occurred. Based on this data, the American Advisory Committee on Immunization Practices has recently confirmed their support for the safety of the vaccine.

There are other issues that must also be addressed. One is that the HPV types not covered by the vaccine may take the place of the viruses that we are protecting against. This is considered by most experts to be a theoretical concern only, but to be safe, ongoing surveillance will be necessary.

It has also been speculated that girls may be more sexually promiscuous because they have had a vaccine to prevent against some types of HPV. This is wild speculation at best; it may very well be that greater awareness of sexually transmitted infections may have the exact reverse effect.

Other concerns focus on how to ensure equitable access to the vaccine, especially in under-serviced areas or on the impact to the screening system. Will women forget to get screened, or will the lack of a cervical screening registry become more of an issue? How do we tell who has been vaccinated and who has not? How do we make sure that girls and women will get the actual three doses and not just one dose? Are two doses as good as three doses? What about the cost? Is it cost effective? Is it the best way to spend our health care dollars to protect the health of women against this disease? Do we have

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the educational tools required to provide women, girls and parents with enough information to make an informed decision in a voluntary vaccination process? All these questions can be addressed through the ongoing integrated monitoring of vaccine implementation programs.

Therefore, what is the impact of waiting 10 to 20 years to see the results of cervical cancer rates drop before implementing the vaccine? What is the impact of a generation of adolescents not protected against the virus while we have the technology available to us? That needs to be figured into the equation. These questions all fall into the realm of implementation science, the next part of the story. Critics are correct; the data of how to do this right and for the best cost-effectiveness are not complete. This issue has received tremendous focus by experts across Canada leading to many documents outlining the strategies required for appropriate data gathering and infrastructure required to answer some of these questions.

As far as the cost-benefits are concerned, several modeling studies have quantified the possible impact of vaccination. Most of these studies show cost-effectiveness in favour of vaccine implementation versus other traditional strategies. The recent August 2007 CMAJ article by Brisson et al. reports that the number needed to vaccinate to prevent a cancer death with the HPV vaccine is actually superior to similar numbers than for the influenza, the meningococcal and the varicella vaccines.

A rush for needles into arms however is not the simple answer. Implementation must be done in concert with enhancing existing cervical screening programs, including the ideal of a cervical cancer-screening information system, advocated for over 30 years, and a parallel integrated strategy for the systematic monitoring of vaccine uptake and immunization outcomes. An information system would not only monitor adverse events and ongoing efficacy issues, but also provide information on implementation datasets needed to advance our knowledge (long term efficacy, optimum dosing, the need for boosters, impact on the health system, etc). To date the rhetoric has focused on other issues but in reality a key missing piece to the puzzle is to advocate for an organized implementation infrastructure. This part of the process will need to have the highest profile as the biological approach to this disease eradication unfolds. Will we have to wait another 30 years for the infrastructure pieces to fall into place to complete this puzzle? This is the drum-beat that should be used by all stakeholders, from across the many different perspectives, to advance the state of the art in this very important women's health issue.

The controversy in the lay and medical press belie the multitude of perspectives on this issue – socially charged as it crosses sexual issues, religious issues, women/girl's issues, health-related politics, federal and provincial politics, big pharmacy, and not least money. While it is easy to see how viewing these incomplete datasets around implementation as a lightning rod for opposing perspectives, one must not lose sight of the big picture. The burden of disease, the stalled nature of cervical cancer prevention, and the impact of primary prevention have created not a perfect storm, but a perfect opportunity to galvanize the various stakeholders. What is now needed is to put our shoulders behind the eradication of cervical cancer not as a possibility but as a reality. With the HPV vaccine, the ongoing monitoring, follow-up, and integration with existing cervical cancer prevention practices will provide a lasting framework for success in the reduction of the burden of cervical cancer.

THE SOCIETY OF GYNECOLOGIC ONCOLOGISTS OF CANADA

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Links to other position statements on HPV vaccination from various agencies or medical associations.

Due to delay in the approval process to permit us to reproduce these statements we are providing you with the web link and invite you to go on these websites and read these agencies/medical organizations position statements.

National Advisory Committee on Immunization (NACI)

http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/07vol33/acs-02/index_e.html

Canadian Society of Paediatrics

http://www.cps.ca/english/statements/ID/ID07-01.pdf

Cancer Care Ontario

http://www.cancercare.on.ca/documents/CCO-HPVVaccinePosition-2007Oct5.pdf

The one and only quadrivalent vaccine that helps protect against infection from Human Papillomavirus types 6, 11, 16, and 18 and the diseases they cause:

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Now is the time to vaccinate girls and young women 9 to 26 years of age[1,*]

GARDASIL™ is a vaccine indicated in girls and women 9-26 years of age for the prevention of infection caused by the Human Papillomavirus (HPV) types 6, 11, 16, and 18 and the following diseases associated with these HPV types: cervical, vulvar, and vaginal cancers, genital warts, cervical adenocarcinoma *in situ* (AIS), cervical intraepithelial neoplasia (CIN) grades 1, 2 and 3, and vulvar and vaginal intraepithelial neoplasia (VIN/VaIN) grades 2 and 3.

The most commonly reported vaccine-related injection-site adverse experiences in clinical trials with GARDASIL™ in females (n=5,088), aluminum-containing placebo (n=3,470) and saline placebo (n=320), respectively, were pain (83.9%, 75.4%, 48.6%), swelling (25.4%, 15.8%, 7.3%), erythema (24.6%, 18.4%, 12.1%) and pruritus (3.1%, 2.8%, 0.6%). The most commonly reported vaccine-related systemic adverse experience in females was fever: 10.3% for GARDASIL™ (n=5,088) vs 8.6% for aluminum and non-aluminum containing placebo (n=3,790).

This vaccine is not intended to be used for treatment of active genital warts; cervical, vulvar, or vaginal cancers; CIN, VIN, or VaIN.

This vaccine will not protect against diseases that are not caused by HPV.

Pregnancy should be avoided during the vaccination regimen for GARDASIL™.

As for any vaccine, vaccination with GARDASIL™ may not result in protection in all vaccine recipients.

* NACI recommends GARDASIL™ for females 9 to 13 years of age, as this is generally before the onset of sexual intercourse **and** females 14 to 26 years of age even if they are already sexually active, have had previous Pap abnormalities, cervical cancer, genital warts or HPV infection.

Reference: 1. Canada Communicable Disease Report (CCDR). National Advisory Committee on Immunization. Statement on Human Papillomavirus Vaccine, February 15, 2007. Available at: http://www.phac-aspc.gc.ca/publicat/ccdr-rmtc/07pdf/acs33-02.pdf

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Join the FMWC team and take the CPAR challenge April 7, 2008!

For the second year, FMWC have registered as a team to the CPAR challenge. To register or to sponsor your team leader Dr. Janet Dollin go to the www.fmwc.ca website to link or simply enter this link on your internet explorer and join the team!

https://secure.e2rm.com/registrant/StartUp.aspx?EID=15383&Lang=en-CA

We are registered as the Federation of Medical Women of Canada. Let's beat last year total of $2375.00. Let's try and reach the $3000 mark this year.

Should you have any problems registering, contact the National Office at fmwc-main@fmwc.ca or call 1-877-771-3777.

Reflections….
(Continued from page 4)

is: please join us in seeing violence against women not as an inevitable and chronic health problem to be managed, but rather as a human rights violation that could be eradicated in our lifetime. Like polio and small pox before it, with determination and allocation of resources violence against women could be ended.

I believe that a true collaboration between doctors and others in the health sector and shelters and the violence against women sector could make a real difference to women coping with male violence. I want to thank the members of the organizing committee and in particular Dr. Nili Kaplan-Myrth for her leadership and vision in bringing this collaboration into reality and I look forward to a continued partnership as we go forward.

For resources developed to train medical personnel in emergency room settings please visit: www.dveducation.ca

Annual General Meeting in Calgary – June 22 & 23, 2008 – Reserve your hotel room now!

We are really excited about our upcoming meeting and hope to have many speakers and subjects finalized soon so we can send you the preliminary program and registration form.

What you can do however is make sure you book your room at the Fairmont Palliser as soon as possible. We received the information for our block of rooms and you may reserve as of now by calling **1-800-441-1414** and make sure to mention that you wish to reserve under the block **RESID: JJL041**. The cost of the room is set at $209.00 per night. The cut-off date for this block of rooms is **May 22, 2008**, so be sure not to be disappointed and reserve now!

Please note: For those of you who are staying in Calgary to attend the SOGC meeting, please note that you must make separate room reservations under their block group code: SOGCC before May 16, 2008.

A Word from the Secretary General

Dr. Shelley Ross, Secretary General

It has now been four months since our congress in Ghana and it has been a busy time for the members of MWIA. Later in the Update, you will hear word of various meetings where MWIA has been represented.

The projects are up and running, but there is still opportunity to join projects or committees. Please email me if you have a particular area where you would like to serve MWIA.

2008 holds the opportunity to meet colleagues at various regional meetings. In addition, please mark your calendar now for the 28th MWIA International Congress in Munster, Germany, which will be held July 27-31, 2010.

Please remember that although the vice presidents send news of their regions to the Updates, any member is welcome to send me information that they would like included. The Commission on the Status of Women will be held in New York from February 25 to March 7, 2008.

Similarly, if you wish to attend the World Health Assembly of WHO in Geneva, which is being held May 18-28, 2008, please let me know.

The contact information for the new Secretariat is:

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North America, Canada, United States of America

Dr. Shirley Hovan, Vice President North America, Canada

Please mark your calendars for the North American Regional Meeting to be held on board ship in the fall of 2009. Rather than repeating the trip to Alaska from Vancouver, this time we will see the eastern part of Canada and the USA, leaving from the province of Quebec and sailing to the North Eastern Seaboard of the USA. The schedules of the ships for 2009 are not yet available, but watch the website for further updates. The theme will be **Taking Care of the Caregiver,** namely women in medicine.

Canada

For this coming year, Dr. Ruth Wilson from Kingston, Ontario, and a long time FMWC member is the President of the College of Family Physicians of Canada and Dr. Shamam Jetha from Vancouver is the President of the British Columbia Branch of the College of Family Physicians.

The Canadian Medical Association Journal of July 27, 1963, had an article about the Presidential Insignia of the Federation of Medical Women of Canada. The article states that the Arnheim Medal was a gift from the medical women of Holland to the Federation of Medical Women of Canada. It marked their recognition of the part played by Canadians in the liberation of Holland, particularly in the Battle of Arnheim, and also expressed appreciation for Canadian hospitality during the war years to the Queen and the Royal Family of the Netherlands. The Arnheim Medial was presented to Dr. Margaret Owens at the International Congress of Medical Women, held in Amsterdam in 1947. Since that time, it has been used at the Presidential Insignia of the Federation and is presented annually.

United States of America

The American Medical Women's Association's Annual Meeting will be held March 7-8, 2008, at the Doubletree Inn in Anaheim, CA. This meeting will be held in conjunction with the Women's Healthcare Forum and promises to be one of the largest AMWA meetings in recent years.

AMWA has had the opportunity to talk with the Presidential candidates regarding their ideas about health care.

The American Medical Women's Association is rolling out a new division dedicated to pre-medical women, called the Association of Future Female Physicians (AFFP). The pre-medical division has been created to help educate, support and empower women interested in a career in medicine. The goal of AFFP is to promote service projects that benefit the community, while instilling leadership and awareness; foster valuable alliances with current female medical students and practicing female physicians; encourage and advocate for aspiring female undergraduate students; offer opportunities to gain insight about women's issues that help aid and commit them to improving women's health; and, offer forums that provide the knowledge, insight, and perspective that will further aid women through their progression in medicine. For more information, visit www.futurefemalephysicians.com.

The Foundation for the History of Women in Medicine is housed at Drexel University College of Medicine in Philadelphia. For information, contact fhwim@burkhargroup.com. The website is www.fhwim.org.

Every Woman, Every Man.…

(Continued from page 5)

a spouse, over a five year period. We know that less than 10% of assaults are reported to police and our statistics significantly underestimate the prevalence of violence against women. Despite Canada signing the United Nation's 1993 *Declaration on the Elimination of Violence Against Women,* we also know that our rates of violence against women have not changed (*Measuring Violence Against Women*, Statistics Canada 2006*)*. What will it take to end violence against women?

On the morning of Dec 6, representatives of the Federation of Medical Women of Canada, Harmony House, Immigrant Women Services Ottawa, Lanark County Interval House, Elizabeth Fry Society, Jewish Family Services, Catholic Family Services, The Men's Project, the Muslim Association and Oshki Kizis Healing Lodge are meeting at the University of Ottawa's Faculty of Medicine.

The goal of the breakfast is to speak about our work on violence against women, to build Ottawa-area networks and affirm our commitment to *ending violence together*.

To our delight, by 7:30am on December 6th the main atrium of the University of Ottawa's Faculty of Medicine was overflowing with more than 100 guests. The FMWC, each of the nine community organizations listed above, and two young women who recently launched a web site about rape (http://www.stoprape.ca) spoke about what their organizations do in the area of violence against women. Each speaker also outlined their key issues – rates of violence, barriers to accessing services, legislative challenges – providing an excellent introduction to issues of violence from the perspective of Jewish communities, Catholic communities, Aboriginal communities, rural communities, men's groups, women's groups… There were also stations set up with posters and pamphlets for people seeking more information.

We were honoured by the presence of Members of Parliament Paul Dewar and Dr Carolyn Bennett, Ottawa City Councilors, representatives of Ottawa Public Health, Trustees of the Ottawa Carleton District School Board, representatives of First Nations, Inuit and Métis organizations, many other community-based organizations, our academic and professional colleagues in the Social and Health Sciences, Law, Social Work and Crime Prevention, as well as representatives of the FMWC, CMA, OMA, AFMC, SOGC, Health Canada, the University of Ottawa's Faculty of Medicine, local physicians and medical students.

Dr. Mamta Gautam with her sons Neal and Shawn and Dr. Kaplan-Myrth's son Noah.

After the breakfast, community members approached us to say that it was the first time that they had been invited to a medical event or that it was the first time that they had been invited to a violence against women event. Several people commented that it was wonderful to see so many men at a violence against women event. People also enjoyed that guests brought their infants and children to the breakfast. One of the school board trustees said she would like to organize a similar event for educators. Representatives of medical organizations said that they would like to send out the invitation to everyone on their mailing lists if we do the event again next year.

The event was covered by the local media. The Ottawa Citizen quoted the Honourable Dr Carolyn Bennett, our final panelist, who commented that doctors have "This unbelievable privilege, having people tell them their secrets. The worst thing for a physician to do is to patch them up and send them straight back into the situation that made them sick in the first place." Unfortunately, physicians send women back into situations of violence far too frequently. It may be because we weren't trained to ask our patients about violence (past or present), or we were afraid to ask, or we didn't take the time to ask, or we asked and we knew about the violence but we didn't know what to do about it.

What will it take to end violence against women? We do not have an answer to that question. But our collaborative breakfast was a success because we had physicians and community organizations and politicians talking to each other about violence against women, talking about individual, population and legislative concerns. It was an exciting polyphony of voices. Perhaps our December 6th breakfast will lead to collaborative action. Our organizing committee plans to meet to discuss our next steps.

I ended my piece last year with a list of on-line women's advocacy groups. It is not possible to list all the local, regional, national and international organizations that deal with issues of violence against women. It is up to you, in your FMWC branches, to explore and build links with medical and community organizations. We are strongest as leaders in our communities when we ***work together*** with our communities.

An Inspirational Week.…

(Continued from page 6)

Back row: Dr. Susan Woolhouse, Dr. Dustin Costescu, Dr. Barb Lent, Dr. Janet Dollin, Ms. Iva Vukin
Front row L to R.: Dr. Deb Penava, Dr. Jo-Anne Silcox, Dr. Sheila Dunn, Dr. Mary McKim and Ms. Farah Naaz Manji.

Saturday was our day to eat turkey and be grateful for family, and that was exactly how we spent it, with a fun crowd, love and laughter. Sunday was another inspirational, albeit sad day as I witnessed my mother go through a monument unveiling ceremony for her dear sister. I have watched her go through the loss of 4 of her siblings, within a very short time frame this year, and this was the 4th unveiling in 2 months. At my aunt's graveside I could see her monument placed beside that of her husband, the man who was my inspiration to go into Medicine. My mother tells me that it is a normal part of being 85 yrs old, to watch your friends and family die. The inspiration is in witnessing her strength through this. The inspiration is also in understanding how we are all a part of the same continuum of birth and death. Lives lived well are inspirational.

So you see, this was an incredibly inspiring week. I was proud to be there as FMWC President, but equally proud to be there as a woman, as a woman physician, as a mother and as a daughter.

UPCOMING MEETINGS

MWIA AND INTERNATIONAL ORGANIZATIONS - CONGRESSES AND MEETINGS

2008

March 7-9, 2008 – Anaheim
Convention Center / Doubletree Hotel
Anaheim, California
American Medical Women's Association Annual Meeting in conjunction with the Women's Healthcare Forum. Use priority code WHFA803 and contact https://www.expotracshows.com/whf/2008/anaheim/ for the $75 registration fee

March 10-14, 2008
Society of Obstetricians & Gynaecologists of Canada, International CME.
La Antigua, Guatemala,
www.sogc.org.

May 18-28, 2008 – Geneva, Switzerland
World Health Assembly of WHO
For further information contact www.who.int. Contact the MWIA Secretariat if you wish to attend.

June 22-23, 2008
Federation of Medical Women of Canada Annual General Meeting and Leadership & Advocacy Workshops
Fairmont Palliser, Calgary, Alberta.
More information to follow on www.fmwc.ca soon.

June 25-29, 2008
Society of Obstetricians and Gynaecologists of Canada Annual Clinical Meeting
Calgary, Alberta, www.sogc.org.

July 9-13, 2008 - Puerto Rico
MWIA Latin American Regional Meeting
Holiday Inn Isla Verde in Puerto Rico
For further information contact mirepint@yahoo.com.mx

September 3-6, 2008 - Malmö, Sweden
MWIA Northern European Regional Congress
Theme: "Bridge the Gender Gap."
Contact robert@malmokongressbyra.se

September 12-14, 2008 – Stockholm, Sweden
3rd International Congress of Gender Medicine
Contact gim-office@charite.de

October 17-19, 2008 - Melbourne, Australia
MWIA Western Pacific Regional Meeting
For further information, visit the website http://wwwafmw.org.au

October, 2008 – Seoul, Korea
World Medical Association
For further information contact www.wma.org

November 27-29, 2008
Family Medicine Forum 2008
Sheraton Centre Hotel, www.cfcp.ca

Congratulations!

Brienne McLane from the University of Calgary and one of our medical student members, was awarded one of the 16 CFPC Medical Student Scholarships during the annual Family Medicine Forum held in Winnipeg from October 8-13, 2007. Great work Brienne!

Obituaries

Dr. Lois Hazen of Lower West Pubnico, Nova Scotia – one of our Senior/Life member 2007.

Dr. Margaret West of Halifax, Nova Scotia- one of our Senior/Life member passed away August 30, 2006.

Membership Renewal and Recruitment

Your membership fees support many FMWC activities including a home office and executive coordinator position, direct financial support for branch activities, Medical Women's International Association (MWIA) membership, FMWC newsletter and maintenance and upgrades on the www.fmwc.ca website (which we hope to soon make bilingual).

We need to not only keep all our present members but to grow those numbers. We challenge each of you to at least pass the FMWC information on to one fellow physician or allied health care professional. Remember, you can also gift a year's membership to a medical student. Membership forms available from www.fmwc.ca

As a thank you to anyone identified as sponsoring a new FMWC member before Dec. 31, 2008, we will mail you one copy of the book Honour Due: The Story of Dr. Leonora Howard King, by Margaret Negodaeff-Tomsik (value of $24.95).

If you wish to have extra application forms on hand, do not hesitate to contact the National Office by email fmwcmain@fmwc.ca or by phone at 1-877-771-3777 toll free or in the Ottawa area at 613-569-5881 or simply go online at www.fmwc.ca and click on How to Join and you should be able to click on membership dues application to download and copy the membership form.

FMWC Membership Application Form

First Name: _____ Last Name: _____

Address: _____

City: _____ Province: _____ Country: _____ Postal Code: _____

Tel (Office): _____ Tel (Home): _____ Fax: _____

E-mail Address: _____

❍ Yes, you may share my coordinates (name, address, email, phone number, fax number) with other FMWC members as required for completion of FMWC business.

Membership Categories:

❍ Full Membership:	$135.00	❍ Associate:	$50.00	❍ Resident:	$50.00
❍ Retired:	$50.00	❍ 1st/2nd Year in Practice:	$75.00	❍ Medical Student:	$25.00
❍ Out-of-country:	$50.00				

How did you hear about the FMWC? _____

A member suggested I join (member's name): _____

Would you be willing to be interviewed by the media on behalf of the FMWC? ❍ Yes ❍ No

Would you be interested in receiving media training? ❍ Yes ❍ No

Membership Dues *(A tax deductible receipt will be sent)* $ _____

Maude Abbott Scholarship Fund Donation *(A tax deductible charitable donation receipt will be sent)* $ _____

Maude Abbott Research Fund Donation *(A tax deductible charitable donation receipt will be sent)* $ _____

TOTAL $ _____

Method of Payment: ❍ Cheque (Payable to "FMWC") ❍ Visa ❍ Master Card

Card Number: _____ Expiry date: _____/ _____

SIGNATURE: _____

Fax to FMWC 1-877-772-5777 or (613) 569-4432 or mail to 780 Echo Drive, Ottawa, ON, K1S 5R7.

**Membership is renewed on an annual basis (each January).*

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2 vacancies

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To reach one of the Board members, simply email fmwcmain@fmwc.ca or call the National Office and your message will be forwarded to them (1-877-771-3777 –toll free or 613-569-5881 in Ottawa)