ADULT IMMUNIZATION: IT’S YOUR BEST SHOT!

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Faculty/Presenter Disclosure

• Faculty: Vivien Brown

• Relationships with commercial interests:
  • Grants/Research Support: Bayer, Merck
  • Speakers Bureau/Honoraria: Merck, Pfizer, GSK, Amgen, Novartis, NovoNordisk
  • Consulting Fees: Merck, Pfizer
  • Other: I represent the College of Family Physicians on the Board of Immunize Canada, promoting immunization to the public.
  • I am a Board member of the Women’s Brain Health Initiative
  • Vice President Medical Affairs, Medisys Health Group
  • Assistant Professor, Department of Family & Community Medicine, University of Toronto
Disclosure of Commercial Support

• This program has not received specific financial support.
Mitigating Potential Bias

- Any recommendations made regarding products are those of the National Advisory Committee on Immunization (NACI) and/or Immunize Canada
Learning Objectives

1. Understand the need to improve the vaccination coverage rates of the Canadian adult population and decrease barriers to vaccination
2. Review the latest recommendations regarding select adult immunizations
3. Discuss many of the common patient management issues with adult immunization, including vaccine hesitancy
What is our GOAL in Adult Immunization

1. The difference between adult and childhood vaccine
2. The need to clarify the “schedule”
3. Understanding the differences between approval in Canada and recommended
4. Where to look for help?
Immunization – A Global Success Story

- Immunization program is hailed as one of the greatest achievements in medicine
- Improved the lives of every Canadian
- Saved more Canadian lives over the last 50 years, than any other health intervention
- The success of childhood immunization programs have led to record or near-record low levels of vaccine preventable diseases

## Cost per Life Year Saved for Vaccines and Other Public Health Initiatives

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Cost per life year saved</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mandatory Seat Belt law</td>
<td>$69</td>
</tr>
<tr>
<td>Smoking Cessation Counselling</td>
<td>$1,000-10,000</td>
</tr>
<tr>
<td>Bicycle helmet law</td>
<td>$39,000</td>
</tr>
<tr>
<td>Smoke Detectors</td>
<td>$210,000</td>
</tr>
<tr>
<td>Crossing control arm for school buses</td>
<td>$410,000</td>
</tr>
</tbody>
</table>

### Vaccines

<table>
<thead>
<tr>
<th>Vaccines</th>
<th>Cost per life year saved</th>
</tr>
</thead>
<tbody>
<tr>
<td>MMR for children</td>
<td>&lt;0 ($16 saved per $ spent)</td>
</tr>
<tr>
<td>DPT for children</td>
<td>&lt;0 ($6 saved per $ spent)</td>
</tr>
<tr>
<td>Influenza for adults ≥ 65 years</td>
<td>&lt;0 ($45 saved per $ spent)</td>
</tr>
<tr>
<td>Pneumococcal Polysaccharide for adults ≥ 65 years</td>
<td>&lt;0 ($8 saves per $ spent)</td>
</tr>
</tbody>
</table>

Failing to Reach Adult Immunization Targets

• Despite the reduction in many vaccine preventable disease states (VPD) the burden of mortality of many of these disease states remains high
  • 30,000-50,000 North Americans still die each year from VPD (mostly from influenza and invasive pneumococcal disease)

• Adult immunization rates are significantly less than optimal
  • Only 38.2% influenza and 16.7% pneumococcus in Canadian adults 18-64 with chronic medical conditions are immunized
  • Influenza immunization in the US among high-risk patients were 36.8% to 69.7%
  • Rate of immunization of other vaccines were rarely above 50% in high risk patients
  • As risk factors increase so does the probability of immunization


Barriers to Adult Immunization Uptake

- Difficulty of integrating disease prevention strategies in clinical practice
- Provider office structure
- Time pressures on physicians
- Provider attitudes toward immunization
- Cost of adult vaccines
- Patient and society expectations


Ubiquity of (mis)information

• Impact of the media and internet
  • Lack of reference frame
  • Vaccine adverse event reporting system: good or bad depending on understanding “another death vs. one death in 10 million doses”
  • Anti-vaccine web sites increasing
  • Media: often reports adverse vaccine information but not impact on vaccine preventable disease
  • Lack of public education
The Media has a Pervasive Impact on Public Perceptions of Risk

Research has shown that strong beliefs about risk, once formed, change very slowly and are extraordinarily persistent in the face of contrary evidence.

Vincent Convello,
Centre for Risk Communication,
Columbia University
# Human nature – Risk Perception

<table>
<thead>
<tr>
<th>What we fear</th>
<th>What we should fear</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shark attacks (28)</td>
<td>Dog Bites (4.5 million)</td>
</tr>
<tr>
<td>Murder (14,180)</td>
<td>Suicide (33,289)</td>
</tr>
<tr>
<td>Death due to peanut allergy (50)</td>
<td>Death by poisoning (27,531)</td>
</tr>
<tr>
<td>Death by plane crash (321)</td>
<td>Death by car crash (34,017)</td>
</tr>
</tbody>
</table>

Gary Marshal, MD
Louisville, Kentucky
Integrating Adult Immunization into Primary Care

- Adult immunization significantly reduces morbidity and mortality. Vaccines do not eradicate the disease but ↓ disease severity
- Dramatically reduces their risk of vaccine preventable disease
- Barriers can be overcome and this can be integrated into every day family medicine practice
- Be aware of potential issues with different adult immunizations
- Opportunities for immunization occur regularly in daily practice
National Advisory Committee on Immunization (NACI)

- National committee of recognized experts in the fields of pediatrics, infectious diseases, immunology, medical microbiology, internal medicine and Public Health
- Makes recommendations for the use of vaccines currently or newly approved for use in humans in Canada, including the identification of groups at risk for vaccine-preventable disease for whom vaccine programs should be targeted
- Our job as family doctors is to follow the national guidelines and recommendations, despite the varying schedules and coverage in different provinces
Why Do Physicians Recommend Vaccinations?

• In 2008 the Canadian Medical Protective Association (CMPA) concluded:
  “Whether physicians should notify patients…about the use of a new vaccine depends on whether administration of the vaccine in the patient’s circumstances is considered the standard of care by other physicians in the community…. Courts might look to standards expressed in accepted medical publications, the common practice of other physicians, and recommendations adopted by professional bodies or health organizations”

• All healthcare professionals have a shared responsibility to work together to send a consistent message on vaccination
Zoster

- Varicella-Zoster will infect more than 95% of North Americans
- 14-21 day incubation – primary infection causes chickenpox
- Travels to sensory ganglia and remains dormant – lifelong latency
- Reactivation later in life leads to zoster
- Lifetime zoster risk is 25% but if a person lives to > 85 years it is closer to 50%
- Post-herpetic neuralgia is a common complication
  - More than 10% of patients with Zoster
  - 1/3 of patients over the age of 60 years
- Zoster, particularly post-herpetic neuralgia have a significant levels of pain and negatively affect on QOL

Which of the following statements is true?

1. HZ can develop as a result of exposure to chickenpox
2. Chickenpox can develop as a result of exposure to HZ
3. Contact with chickenpox does not help to prevent HZ
HZ Epidemiology

HZ is the clinical manifestation of latent VZV reactivation.

90-95% of the adult population in Canada is seropositive for VZV and this population is aging.

Approximately 20-30% of the adult population will experience HZ; by age 85, 50% of people will have experienced an episode of HZ.

There are approximately 130,000 HZ cases/year in Canada (42% in people ≥60 years of age).

13% of those who have HZ will experience PHN, a neuropathic pain syndrome.

VZV = varicella zoster virus; PHN = postherpetic neuralgia.

Complications, Hospitalizations, and Death from HZ

1,778 hospitalizations/year in Canada
(>60% are adults over 75 years of age)

Average length of hospital stay in elderly
(>75 years old) is >10 days

HZ is estimated to be the underlying cause of
20 deaths annually in Canada

Results in an estimated 108 life-years lost per year

HZ Rash: A Key to Diagnosis

- Unilateral vesicular rash
- Does not usually cross the midline
- Usually follows a single dermatome
- Lesions are rarely below the elbows or knees
PHN: Clinical Features

- PHN patients may experience some or all of the following:
  - Constant pain: aching, burning or throbbing
  - Intermittent pain: stabbing or shooting
  - Allodynia: pain evoked by a mild, normally non-noxious stimulus – heat, cold or tactile
  - Hyperalgesia: severe pain evoked by application of a normally mildly painful stimulus
  - Intense itching

PHN: Clinical Features
Sensory Loss and Allodynia

Click for more information on pathogenesis of HZ acute pain
A Vaccine to Prevent Herpes Zoster and Postherpetic Neuralgia in Older Adults

Zoster Vaccine

- Same preparation used in the varicella vaccine but at a higher dose (14-fold greater)
- Vaccine is effective:
  - 51.3% decrease in incidence
  - 66.5% decrease in post-herpetic neuralgia
- Well-tolerated
  - Injection site adverse effects – erythema, pain, swelling, itching
- Live vaccine
  - Storage is crucial
  - Frozen (-15°C) – Diluent different
  - 30 minutes once reconstituted

Recommended use of the Zoster Vaccine

- Persons ≥ 50 years
- Irrespective of past history of varicella infection
- Past episodes of zoster
- Booster not recommended
- Live vaccine – Avoid in immunocompromised patients
- Can be co-administered with trivalent flu vaccine not PPSV23 (4 weeks)
  - CDC – no longer recommends separation as protection to zoster is the same
- Anti-viral therapy 2 days before vaccine and 14 days after
  - Consider second dose of vaccine 42 days later

NACI Recommendation for Herpes Zoster Vaccination

• Recommended for persons without contraindications 60 years of age and older and may be used in adults aged 50 years and older.
• There is insufficient evidence for or against immunization of individuals with a prior history of HZ disease.
• Should be administered to individuals of the appropriate age who have had prior varicella infection and those in whom varicella history is unknown.
• In general, should not be given to individuals with primary or acquired immune deficiency; consultation with a medical expert is advised.
What do I Need to Know About the Zoster Vaccine in my Adult Patients?

• Zoster leads to significant morbidity in at least 25% of the adult population
• Close to 1/3 of all seniors with zoster will develop post-herpetic neuralgia
• The vaccine reduces both the rate of zoster and the risk of post-herpetic neuralgia
• It is a live vaccine:
  • Not indicated in immunosuppressed
  • Storage and administration instructions should be strictly followed
• Can be given at the same time as influenza vaccine
• Patient’s chicken pox history is not necessary to obtain prior to immunization
HPV Background

- 1,350 new cases and 390 deaths from cervical cancer in 2012
- HPV causes almost every case of cervical cancer
- Highest rates of HPV infections in women < 20 years of age
- Risk of HPV infection continues throughout adulthood
  - 1,610 Columbian women with normal cytological results at baseline
  - 5 year cumulative risk of HPV Infection:
    - 42.5% for women aged 15-19
    - 30.0% for women aged 25-29
    - 21.9% for women aged 30-44

Money D, Provencher D. Journal of Obstetrics and Gynaecology Canada. 2007;29(8 Suppl 3)
Estimated HPV Contribution in Cancer

- Cervix: >99%
- Anus: 84.2%
- Vagina: 69.9%
- Penis: 47.0%
- Vulva: 40.4%
- Oropharynx: 70%
- Oral cavity: 23.5%

Uniqueness of HPV Infection

- Most common sexually transmitted infection
- Does NOT require penetrative intercourse for transmission
- HPV infects epithelial cells but does not induce cell death
- Does not cause viremia and does not induce a significant immune response
  - Natural exposure to the virus may not confer a high enough or sustained antibody response. Previously HPV infection may NOT prevent future infections
- Most patients (80%) will clear HPV over 8-14 months
  - Not clear of the reason some patients have persistence of high risk HPV


Psychosocial Impact of HPV Infection

- Large number of Canadian women receive abnormal Pap results each year
- Almost impossible to determine which women will develop cancerous lesions
- Psychological reaction to these results can be overwhelming
- Can impair relationship with current, past and future partners

Efficacy of HPV Vaccine in Adult Patients

- Gardasil® received indication for up to 45 years
- NACI updated statement on HPV vaccines (Jan 2012)
  - Gardasil® and Cervarix® are recommended for cervical cancer protection in females 9 through 26 years of age and in patients with Pap smear abnormalities and genital warts
  - Gardasil® is recommended for the prevention of vulvar, vaginal, anal cancers and their precursors and anogenital warts in females 9 through 26 years
  - Gardasil® may be administered in women over 26 years
- Efficacy in women 24-45 years (n=3,819) over 90% in all types in Gardasil® vaccine
- There is some cross protection against other HPV types


NACI Recommendation for HPV Vaccination

• HPV2 or HPV4 vaccine is recommended for prevention of cervical cancer in girls and women (9 to 26 years of age, including those who have had previous Papanicolaou [Pap] test abnormalities, cervical cancer or genital warts).

• HPV4 vaccine is recommended for the prevention of vulvar, vaginal, anal cancers and their precursors and anogenital warts in girls and women (9 to 26 years of age).

• HPV2 or HPV4 vaccine may be administered to women 27 years of age and older at ongoing risk of exposure.

• The choice of vaccine for women depends upon the importance of protection against genital warts.

• HPV4 vaccine is recommended for prevention of anogenital cancer and genital warts in boys and men (9 to 26 years of age), including men who have sex with men (MSM) as they are at higher risk of HPV infection and disease.

• HPV4 vaccine may be administered to men 27 years of age and older, at ongoing risk of exposure.
IS IT TOO LATE?

Women Who Have Been Treated for Cervical, Vulvar or Vaginal Disease:

Do They Benefit from HPV Vaccination?
After Treatment for HPV-related Disease
There is High Risk for Developing CIN

<table>
<thead>
<tr>
<th>Description</th>
<th>Cases of CIN (any grade) per 100 person years at risk (placebo arm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Women negative to 14 HPV types and with normal cytology at day 1</td>
<td>2.4*</td>
</tr>
<tr>
<td>Intention-to-treat population (all comers)</td>
<td>4.2*</td>
</tr>
<tr>
<td>Women who underwent cervical definitive therapy</td>
<td>7.5†</td>
</tr>
<tr>
<td>Women who were treated for GW, VIN or VaIN</td>
<td>20.8†</td>
</tr>
</tbody>
</table>
Impact of the Quadrivalent HPV Vaccine on the Incidence of New HPV Disease After Treatment for Cervical Disease

- Any disease: 95% CI (22, 63)
- Any cervical disease CIN1+: 95% CI (19, 68)
- Any CIN2+: 95% CI (20, 86)
- Any GW, VIN or VaIN: 95% CI (4, 71)
- Any 6/11/16/18 related disease: 95% CI (49, 93)

* Irrespective of HPV type

Effect of Vaccination after LEEP on Recurrent CIN 2-3

- **Vaccine**:
  - 2.5% Recurrence Rate

- **No vaccine**:
  - 7.2% Recurrence Rate

NO vaccination after LEEP was an independent risk factor for recurrent CIN2–3  HR = 2.840

Kang et al. Gynecologic Oncology online May 2013
Will These Vaccines Be Effective? Will They Do Their Job?

• The HPV vaccines are a major breakthrough in modern medicine:
  - highly efficacious
  - safe and well tolerated
  - could dramatically reduce the incidence of cancers and anogenital diseases, if effectively delivered to the populations
Rapid Decline in Presentation of GWs Following National Vaccination Program
What Do I Need to Know About HPV Vaccine in Adult Women?

- HPV infection is still prevalent in adult women
- Appointments for contraception and Pap testing are an excellent opportunity to start the discussion on HPV
- Natural infection may not offer immunity from future HPV infections
- HPV infection causes a significant psychosocial reaction in many women
- HPV immunization is encouraged in women aged 26-45 by NACI and has demonstrated significant efficacy in this group
- Vaccine is well tolerated in adult women
- Given newer data on risk of recurrence, advantage to be immunized even after treatment for disease
Isn't it time that boys get protection, too?
Risk Factors for HPV Infection in Males

- Number of sex partners\(^1-3\)
- Infection is often asymptomatic or subclinical, allowing transmission to occur without the knowledge of either partner\(^2\)
- No circumcision\(^1,3-6\)
- **Sex partner with CIN\(^7\)**
- Having a new sex partner\(^8\)
- History of STI\(^5\)
- Having anal intercourse with males\(^2\)
- History of smoking\(^8\)

The Clinical Spectrum of HPV-related Disease in Males

- Genital warts\(^1\)
- Penile intraepithelial neoplasia (PIN) and carcinoma\(^1,2\)
- Anal intraepithelial neoplasia (AIN) and carcinoma\(^1,3\)
- Some oropharyngeal cancers (tongue, tonsillar, throat, and soft palate)\(^1,4\)

HPV Prevalence in Males Enrolled in the HIM Study (n = 1,160)

Anal Cancer

• Canadian incidence among males ≥15 years of age: 1.5 per 100,000 (2006)

• Incidence increased in the US from 1973 to 2000:
  • 160% among men
  • 78% among women

• Among males, anal cancer is associated with:
  • HPV infection, lifetime number of sexual partners, receptive anal intercourse, HIV infection, cigarette smoking

• Males have a lower 5-year survival compared to females (US data): 58% vs 64%
HPV Vaccine for Males - Canada

• **Feb 2011** – Health Canada approval for use of quadrivalent HPV vaccine for use in boys and men aged nine through 26

• **May 2011** - Health Canada approval for quadrivalent HPV vaccine for the prevention of anal cancer in both men and women caused by HPV types 16 and 18 and anal precancerous lesions caused by HPV types 6, 11, 16 and 18

• **NACI** – HPV4 is recommended in males between 9 and 26 years of age for the prevention of anal intraepithelial neoplasia (AIN) grades 1, 2, and 3, anal cancer, and anogenital warts, of penile, perianal and intrepithelial neoplasias. HPV4 is recommended for MSM from age 9

# Recommendations: Males 9-26 years 2012

<table>
<thead>
<tr>
<th>Group</th>
<th>Gardasil®</th>
<th>Cervarix™</th>
<th>Comments</th>
</tr>
</thead>
</table>
| **Males 9-26 years** | ✓ Recommendation Grade A | Not recommended at this time Grade I | • Receipt of Gardasil® between 9 and 13 years of age prior to onset of sexual activity is recommended to maximize efficacy of the vaccine.  
• Males between the ages of 14 and 26 years would benefit from Gardasil® if already sexually active as they may not yet have HPV infection, but very unlikely to have been infected with all four HPV types.  
• Should be made aware of the possibility that they are already infected. |
| ✓ Recommendation Grade B | | • While Gardasil® is not currently indicated for prevention of penile, perineal, or perianal intraepithelial neoplasia, early clinical trial results show good efficacy (85.6%) against 6-month persistent infection, an important predictor for disease development. |
| **Males who have sex with males (MSM) ≥9 years of age** | ✓ Recommendation Grade A | | • Early receipt of Gardasil® would confer maximum benefit, since MSM may become infected with HPV more rapidly due to the high rate of infection in the population. Should be made aware of the possibility that they are already infected. |

### HPV Immunization Programs in Canada

- 2008, all provinces have introduced/announced HPV immunization programs girls

<table>
<thead>
<tr>
<th>Province/Territory</th>
<th>Routine Schedule (0, 2 and 6 months)</th>
<th>Date of Implementation of Routine Program</th>
<th>Catch-up Programs (Date of Implementation)</th>
</tr>
</thead>
<tbody>
<tr>
<td>British Columbia</td>
<td>Girls Grade 6</td>
<td>September 2008</td>
<td>Girls Grade 9 (2008-2011)</td>
</tr>
<tr>
<td>Alberta</td>
<td>Girls Grade 5</td>
<td>September 2008</td>
<td>Girls Grade 9 (2009-2012)</td>
</tr>
<tr>
<td>Saskatchewan</td>
<td>Girls Grade 6</td>
<td>September 2008</td>
<td>Girls Grade 7 (2008-2009)</td>
</tr>
<tr>
<td>Manitoba</td>
<td>Girls Grade 6</td>
<td>September 2008</td>
<td>Girls 9 to 26 years of age with increased risk as determined by a health care provider (2012)</td>
</tr>
<tr>
<td>Ontario</td>
<td>Girls Grade 8</td>
<td>September 2007</td>
<td>Girls Grade 9 to 12&lt;br&gt;Girls that were in grade 8 in the 2007/2008 school year are eligible until June 2013</td>
</tr>
<tr>
<td>Quebec</td>
<td>Girls Grade 4 (doses 1 and 2), in 3rd year of secondary school (dose 3)</td>
<td>September 2008</td>
<td>Girls 9 to 17 years of age&lt;br&gt;Girls 9 to 17 years of age in First Nations communities.&lt;br&gt;3rd year of secondary school (2008-2013)&lt;br&gt;Immunosuppressed girls &amp; women 9-26</td>
</tr>
</tbody>
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## HPV Immunization Programs in Canada

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</tr>
</thead>
<tbody>
<tr>
<td>New Brunswick</td>
<td>Girls Grade 7</td>
<td>September 2008</td>
<td></td>
</tr>
<tr>
<td>Nova Scotia</td>
<td>Girls Grade 7</td>
<td>September 2007</td>
<td>Girls Grade 10 (2009-2010 only)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Girls Grade 8 (2010-2011 only)</td>
</tr>
<tr>
<td>Prince Edward Island</td>
<td>Girls Grade 6</td>
<td>September 2007</td>
<td>Girls Grade 9 (2009-2010 only)</td>
</tr>
<tr>
<td></td>
<td>Boys Grade 6</td>
<td>September 2013</td>
<td></td>
</tr>
<tr>
<td>Newfoundland and Labrador</td>
<td>Girls Grade 6</td>
<td>September 2007</td>
<td>Girls Grade 9 (2008-2010)</td>
</tr>
<tr>
<td>Northwest Territories</td>
<td>Girls Grade 4</td>
<td>September 2009</td>
<td>Girls Grades 11 and 12 (2009-2010)</td>
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<td></td>
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<td></td>
<td>Girls Grades 10 and 11 (2010-2011)</td>
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<td>Girls Grades 9 and 10 (2011-2012)</td>
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<td>Girls Grade 9 (2012-2014)</td>
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<tr>
<td>Yukon</td>
<td>Girls Grade 6</td>
<td>September 2009</td>
<td>Girls Grades 7 and 8</td>
</tr>
<tr>
<td>Nunavut</td>
<td>Girls Grade 6</td>
<td>March 2010</td>
<td></td>
</tr>
</tbody>
</table>


Some other vaccines….

- MMRV age 4-6, separate at earlier age to avoid febrile seizure
- Pertussis: Adult dose
  - Give one adult dose if no dose in adulthood
  - No interval between Td and Tdap
  - Special attention to those exposed to babies
  - Need to assess ongoing boosters
- Preschool booster:
  - 4 to 6 year old booster can be DTaP-IPV or Tdap-IPV
  - Under assessment by NACI
- Pregnancy:
  - Consider use in the second half of pregnancy if in an outbreak
  - NACI assessing use in pregnancy
And what about Varicella?

Immune if any of the following:
• Born before 2004 and have self-reported chicken pox (except health care provider)
• Born in or after 2004 or health care provider, health care provider diagnosed varicella or zoster
• Two doses of documented varicella vaccine
• Laboratory confirmed infection or immunity
Varicella Vaccine Intervals

Between two varicella or MMRV vaccines

- 12 months to 12 years of age, 3 months
  - Could be 6 weeks if rapid protection needed

Between two varicella vaccines

- 13 year of age and over, 6 weeks
Vaccination: What is important to patients?

• 1. Is it SAFE?
• 2. Does it WORK?
• 3. Doctor, what do YOU think?
#1 Barrier

Lack of physician recommendation

Physician recommendation is the most important factor in patient acceptance of vaccination

California Adult Immunization Coalition; Mangtani 2006; Oster 2005; Immerman 2001.
Effect of Healthcare Professional’s Recommendations on Patient Acceptance of Vaccination

*Those who visited a health care professional since October 2005 (n=1,551)
** Those 65+ and those 18-64 with chronic condition other than asthma (n=599)

Missed Opportunities for Immunization

Only 1 out of 4 patients actually received a recommendation for pneumococcal vaccination during a visit with their health care provider.

*Those who visited a health care professional since October 2005 (n=1,551)
** Those 65+ and those 18-64 with chronic condition other than asthma (n=599)

Our Role

We have an exciting opportunity to make a huge impact in our patients’ lives….

We have the tools to do primary prevention, medicine at its best….

And we can remove the barriers to make this happen