



Top: Ultramarathon cyclist and grateful patient Graham Hallward trains on Arizona's Mount Lemmon last February. After suffering a spine injury in 2000, Hallward says he became a couch potato and gained about 10 pounds. He is so grateful to the surgeons who gave him his good health back that he has donated hundreds of hours of his time and helped fundraise \$2 million for the Holland Orthopaedic and Arthritic Centre of Sunnybrook Health Sciences Centre. Bottom: John and Anna Povegliano have raised \$2 million for Toronto's Hospital for Sick Children in honour of their son, Daniel, who died in 1996 at the age of four.

# A condition that doesn't need a cure: Grateful patient syndrome

Health facilities reap rewards of giving good care when patients return the favour by donating their time and money, a million times over

by Alison DeLory

TORONTO | After his wife had hip replacement surgery and he had spinal surgery at the Orthopedic and Arthritic Institute of Toronto, Graham Hallward said he came down with a new kind of affliction: grateful patient syndrome. Fortunately, this syndrome was easier to bear than his previous back pain and he was able to address it by giving money and later, his time, to the institute.

The year was 2000 and the institute had not yet merged into the Holland Orthopaedic and Arthritic Centre of Sunnybrook Health Sciences Centre. "You actually got to know the doctors, some of the nurses. It was well-run, very effective, had a good reputation, probably the best for hip and knee replacements in Canada," said Hallward. "You make a donation because you're grateful and one thing leads to another and before you know it you're volunteering."

Hallward laughed when asked about the term "grateful patient syndrome" which appeared in a *New York Times* article this past August. "I thought I made it up!"

The terminology may be new, but the concept—of patients so thankful for the medical care they or a family member have received that they want to give back—is not. What continues to be tricky, however, is determining who may be willing to donate and how to capitalize on their goodwill.

The Hallwards were invited to sponsor the Night of Stars, a variety show fundraiser that has raised almost \$2 million for the Holland Centre since the show's debut in 1995. Graham Hallward was co-chair in 2004 and 2007, and estimates donating hundreds of hours of his time to planning Night of Stars. Though he's otherwise busy running an endowed charitable foundation and training for long-distance bike marathons, Hallward, 51, said it was time well spent.

"It's actually fun. You get involved in events or on boards and you meet some very passionate people, and they believe in supporting and growing the organization as well," he said.

### Asking patients

Patients often want to donate money or volunteer

### How volunteer time is spent

Volunteer rate and percentage of total volunteer hours, by selected organization type, age 15+, Canada, 2004



Source: Statistics Canada, Canada Survey of Giving, Volunteering and Participating, 2004

their time and may just need some gentle prompting. Yet it is awkward for doctors to ask patients, explained Sharon Sholzberg-Gray, president of the Canadian Healthcare Association. "A doctor is supposed to be there only to take care of their patients' health-care needs. Trying to ask a patient for a donation is really difficult."

The request should probably come from a foundation, she said, or from doctors who are very diplomatic and careful—patients mustn't feel coerced. However, if patients initiate the conversation by saying they would like to give back, doctors should offer them ways to do so, said Sholzberg-Gray.

According to Lisa Hartford of Imagine Canada—an umbrella organization that raises the profile of and provides support to the non-profit and charitable sector—there are two main motivators behind giving. One is that people wish to help a cause they believe in. The other is that they have a personal connection **see Reluctant | page 40**



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# 'Reluctant heroes' appreciated

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to a cause. She wasn't familiar with the term "grateful patient syndrome" but said it is logical that people who have (or have a family member who has) overcome an illness, would want to show their appreciation.

Sholzberg-Gray said even when patients are dying, they are often still grateful for the excellent care they're receiving. They sometimes leave money in their wills for hospitals or medical research, and their obituaries may thank their caregivers and encourage donations to a research cause or care institution—even when the outcome wasn't perfect.

## 'Reluctant heroes'

The outcome was definitely less than perfect for the Povegliano family of Toronto. Four-year-old Daniel Povegliano died at

the Toronto Hospital for Sick Children in 1996, while being treated for systemic mastocytosis. Despite suffering almost constant pain, Daniel loved life and smiled and laughed often, inspiring his parents to create the Smiles of Innocence Memorial Charity in his honour. Friends and family set a goal of raising \$10,000 through galas, auctions, golf and bowling tournaments, and Christmas toy drives. This month, on the 10th anniversary of Smiles of Innocence, more than \$2 million will have been raised.

"It is because of the Hospital for Sick Children that Daniel's years with us were full of love and strength. Because of that, I am forever grateful," said Daniel's father, John Povegliano. The funds have helped purchase equipment and establish an international fellowship pro-

gram in dermatological research.

SickKids Foundation spokesperson Carol Duncan said these donations are particularly important because they help raise awareness and funds for orphan diseases, which receive little or no research money. Rather than "grateful patients," she said the foundation refers to people like the Povegliano's as "reluctant heroes" and added that without philanthropy, the SickKids Research Institute wouldn't exist.

SickKids Foundation is the largest hospital foundation in Canada, with total fundraising of \$81.5 million for the year ending March 31, 2007. It provides base funding for the research institute, including \$44 million in 2006/07. The institute conducts more research than any other hospital in Canada. Yet at other hospitals "there

## Philanthropy now

The most common ways in which charitable donations are made:

1. In response to a request through the mail
2. When asked by someone doing door-to-door canvassing
3. When asked by someone canvassing for a charitable organization at a shopping mall or on the street.

Overall, Canadians gave the most money by making donations through their church, via the mail, by attending charity events and by giving on their own. Those who plan their donations in advance were much more likely than others to make larger donations.

Source: Canadian survey of giving, volunteering and participating, Statistics Canada, 2004

is untapped potential," Hartford said. "Hospitals have a large presence in a community. They have a captive audience." Yet many have small foundations.

Sholzberg-Gray said some have greater challenges than others. For example, raising money for mental health care institutions can be tricky, because of the stigma associated with mental illness and because these patients often don't have much money.

"Certain parts of the health system are also easier to sup-

port; sexier, so to speak," said Sholzberg-Gray, like children's care, cancer and heart disease.

Data collected by Statistics Canada, in a report commissioned by Imagine Canada called the "Canadian survey of giving, volunteering and participating," shows donations to hospitals, health organizations and medical research totalled less than 22% of all donations in 2004. Religious organizations, by comparison, received 45% of all donated dollars.

In May 2006, however, the government of Canada eliminated capital gains tax on gifts of publicly traded securities to public foundations. Now when people donate publicly traded stock and securities to support health institutions they receive a tax receipt for the full appreciated value of the donation and no longer have to pay capital gains tax. Although the numbers aren't in, Sholzberg-Gray said the federal tax law change has resulted in many millions of dollars in extra donations.

## Time well spent

Beyond financial contributions, an important element of grateful patient syndrome is encouraging volunteerism. The Imagine Canada/Statistics Canada survey found that Canadians donated a total of two billion volunteer hours in 2004. Four per cent of these hours went to health organizations, 3% went to hospitals and 11% went to education and research (which includes medical research). Sports and recreation organizations had the greatest participation (see chart page 39).

"In the health-care system there is certainly a history of patients, or relatives of patients, donating and volunteering. This could be as a government volunteer, on a board or a regional health authority, or as a fundraising volunteer, or a greeter in a facility. Whether people are doing enough of this is unclear," said Sholzberg-Gray. She said the health system needs volunteerism but the infrastructure isn't always there. Volunteers need screening, training and support: "Volunteerism is a more complex sector than people realize." She said it may require greater government support.

Despite the time commitment, Hallward said he will continue to be involved with the Night of Stars.

"I still believe it's a great facility worth nurturing. There will be an even greater demand for musculoskeletal care as the population ages."



**Therapeutic classification:** Solution for Injection  
Active Immunizing Agent for the Prevention of Meningococcal Disease

### DESCRIPTION

MENACTRA™ (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine) is a sterile, intramuscularly administered vaccine that contains *Neisseria meningitidis* serogroups A, C, Y and W-135 capsular polysaccharide antigens individually conjugated to diphtheria toxoid protein. The polysaccharides are covalently linked to diphtheria toxoid and purified by serial ultrafiltration. The four meningococcal components, present as individual serogroup-specific glycoconjugates, compose the final formulated vaccine. No preservative or adjuvant is added during manufacture. MENACTRA™ is a sterile, clear to slightly turbid liquid.

### INDICATIONS AND CLINICAL USE

MENACTRA™ (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine) is indicated for active immunization of individuals 2 to 55 years of age for prevention of invasive meningococcal disease caused by *N. meningitidis* serogroups A, C, Y and W-135.

MENACTRA™ is not indicated for the prevention of invasive meningococcal disease caused by serogroup B.

### CONTRAINDICATIONS

Postponement of vaccination should be considered in case of febrile or acute illness to avoid superimposing adverse effects from the vaccine on the underlying illness or mistakenly identifying a manifestation of the underlying illness as a complication of vaccine use.

Known systemic hypersensitivity to any component of MENACTRA™ (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine), or its container, or a life-threatening reaction after previous administration of a vaccine containing similar components.

Known history of Guillain-Barré Syndrome (GBS) is a contraindication to vaccine administration. (See WARNINGS AND PRECAUTIONS.)

### WARNINGS AND PRECAUTIONS

**General** Guillain-Barré Syndrome (GBS) has been very rarely reported in temporal relationship following administration of MENACTRA™ (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine). (See ADVERSE REACTIONS, Post-Marketing Reports.) Persons previously diagnosed with GBS should not receive MENACTRA™.

As with all products, Epinephrine Hydrochloride Solution (1:1,000) and other appropriate agents should be available for immediate use in case of anaphylactic or acute hypersensitivity reaction occurs. Healthcare providers should be familiar with current recommendations for the initial management of anaphylaxis in non-hospital settings, including proper airway management.

The possibility of allergic reactions in persons sensitive to components of the vaccine should be evaluated.

For instructions on recognition and treatment of anaphylactic reactions, see the current edition of the *Canadian Immunization Guide* or visit the Health Canada website.

As vial stoppers contain dry natural rubber latex, caution should be exercised when the vaccine is administered to subjects with known hypersensitivity to latex. The syringe presentation of this vaccine contains no latex.

MENACTRA™ can only protect against *N. meningitidis* A, C, Y and W-135 serogroups and will not protect against any other microorganisms.

MENACTRA™ vaccination is not indicated for immunization against diphtheria. (See CONCOMITANT VACCINE ADMINISTRATION.)

MENACTRA™ should not be administered into the buttocks due to the varying amount of fatty tissue in the region since this method of administration may induce a weaker immune response.

Do not administer by intravascular injection; ensure that the needle does not penetrate a blood vessel.

Before administration, take all appropriate precautions to prevent adverse reactions. This includes a review of the patient's history concerning possible hypersensitivity to the vaccine or similar vaccine, previous immunization history, the presence of any contraindications to immunization and current health status.

Before administration of MENACTRA™, healthcare providers should inform the patient, parent or guardian of the benefits and risks of immunization, inquire about the recent health status of the patient and comply with any local requirements regarding information to be provided to the patient before immunization.

As with any vaccine, immunization with MENACTRA™ may not protect 100% of susceptible individuals.

Aseptic technique must be used. Use a separate sterile needle and syringe, or a sterile disposable unit, for each individual dose to prevent disease transmission.

**Hematologic** MENACTRA™ has not been evaluated in persons with thrombocytopenia or bleeding disorders. As with any other vaccine administered intramuscularly, the vaccine risk versus benefit for persons at risk of hemorrhage following intramuscular injection must be evaluated.

NACI has published recommendations for the immunization of people with hemophilia and other bleeding disorders.

**Immune** No data are available on the use of MENACTRA™ in immunodeficient subjects. If the vaccine is used in persons undergoing immunosuppressive therapy, the expected immune response may not be obtained. If possible, consideration should be given to delaying vaccination until after the completion of any immunosuppressive treatment.

Individuals with functional or anatomical asplenia may produce an immune response to MENACTRA™; however, the degree of protection that would be afforded is unknown.

**Perioperative Considerations** If possible, this and other indicated vaccines should be given 10 to 14 days before splenectomy.

### Special Populations

#### PREGNANT WOMEN: PRECLINICAL TOXICITY STUDIES AND HUMAN EXPERIENCE:

Animal reproduction studies have not demonstrated a risk with respect to effects on pregnancy and embryo-fetal development, parturition and postnatal development. However, since there are no data on the use of this vaccine in pregnant women, MENACTRA™ should be given to a pregnant woman only if clearly needed and only following an assessment of the risks and benefits.

**NURSING WOMEN:** It is not known whether the active substances included in the vaccine are excreted in human milk, but antibodies to the polysaccharides have been found transferred to the suckling offspring of mice.

Animal studies conducted in mice have not shown any harmful effect on offspring postnatal development caused by maternal antibodies induced by the vaccine. However, the effect on breast-fed infants of the administration of MENACTRA™ to their mothers has not been studied. The risks and benefits of vaccination should be assessed before making the decision to immunize a nursing woman.

**GERIATRICS:** Clinical data are available in persons up to the age of 55 years.

**Duration of Protection** A group of 2- to 3-year-old children ( $n=92$ ) were followed for up to 3 years after a single dose of MENACTRA™. These participants had 1.7- to 5.2-fold higher bactericidal antibody levels than an age-matched vaccine naive control group. Conjugation of the capsular polysaccharide antigens to the diphtheria protein converts a T-cell independent response to one that is T-cell dependent. However, the duration of protection against invasive meningococcal disease remains unknown.

### ADVERSE REACTIONS

Clinical trials are conducted under very specific conditions. Therefore, the adverse drug reaction rates observed in the clinical trials may not reflect the rates observed in practice and should not be compared to the rates in the clinical trials of another drug. Adverse drug reaction information from clinical trials is useful for identifying drug-related adverse events and for approximating rates.

**Children 2 to 10 Years Old** Safety was evaluated within the first 7 days, 28 days and 6 months after vaccination. MENACTRA™ (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine) was well tolerated among children. The majority of the solicited local and systemic reactions reported within 7 days after vaccination were mild, with a mean duration of no more than 3 days for the local reactions and less than 4 days for the systemic reactions. The most commonly reported solicited adverse reaction was pain at the injection site (40–48% of the participants). (See Table 1.)

Study A was a primary immunogenicity study that also was designed to evaluate the rates of fever post-vaccination. The results show no statistical difference between the treatment groups. Overall, the rates of local and systemic reactions were similar. In this study, the rates of severe local and systemic reactions were generally more frequent in MENACTRA™ recipients, although the study was not statistically powered to detect significant differences for these reactions between the two study groups.

Study B was a primary safety study designed to evaluate the rates of severe systemic reactions post-vaccination. The results show no statistical difference between the treatment groups. Rates of local reactions were more frequent in MENACTRA™ recipients while the rates of systemic reactions were similar.

**Table 1: Percentage of MENACTRA™ and Menomune®-A/C/Y/W-135 Recipients Reporting at Least One Solicited Local and/or Systemic Reaction Within 7 Days, by Reaction Type in Children 2 to 10 Years Old, by Study**

Event	Study A MENACTRA™ (n=692)		Study A Menomune®- A/C/Y/W-135 (n=692)		Study B MENACTRA™ (n=1704)		Study B Menomune®- A/C/Y/W-135 (n=1515)	
	Any*	Severe†	Any	Severe	Any	Severe	Any	Severe
<b>Local Reactions</b>								
Pain	48.1	0.7	46.9	0.3	39.7	0.2	30.4	0.0
Redness	29.5	4.3	30.4	0.4	17.9	2.8	9.4	0.0
Induration	22.1	1.0	15.6	0.1	16.1	0.9	5.2	0.0
Swelling	20.5	1.2	14.6	0.3	14.3	1.3	4.9	0.0
<b>Systemic Reactions</b>								
Irritability‡	35.2	2.7	30.1	0.6	11.0	0.2	12.1	0.4
Drowsiness§	26.0	1.6	24.1	1.1	10.4	0.2	10.9	0.3
Anorexia¶	22.7	1.7	20.3	0.4	8.3	0.3	9.2	0.7
Diarrhea**	15.9	1.6	15.7	0.4	12.1	0.2	13.0	0.3
Fever††	11.4	0.9	12.0	0.6	5.9	0.2	6.0	0.3
Vomiting‡‡	5.9	0.7	7.0	1.1	3.5	0.2	3.1	0.4
Hives§§	1.2	—	0.4	—	—	—	—	—
Arthralgia	—	—	—	—	7.3	0.1	7.6	0.0
Rash¶¶	—	—	—	—	4.1	—	3.5	—
Seizures**†††	—	—	—	—	0.0	—	0.0	—

\*Any denotes the proportion of participants reporting any reaction, regardless of the severity.

† Severe local reaction denotes swelling, redness or induration  $\geq 2.0$  inches in diameter or pain resulting in unwillingness to move the affected arm.

‡ Severe: requiring bed rest. § Severe: skipped  $\geq 3$  meals.

¶ Severe:  $\geq 5$  episodes. \*\* Severe:  $\geq 39.5^\circ\text{C}$ .

†† Severe:  $\geq 5$  episodes. ‡‡ Severe:  $\geq 3$  episodes.

§§ These solicited adverse events were reported as present or absent only.

In a clinical trial conducted in the U.K. in children 2 to 4 years old, previously immunized with a monovalent meningococcal conjugate vaccine, MENACTRA™ was shown to be well tolerated and had a safety profile comparable to another polysaccharide protein conjugated vaccine (Hib (PRP/T)) used as a control.

**Participants 11 to 55 Years Old** MENACTRA™ was well tolerated among adolescents and adults. The most commonly reported solicited adverse reactions in adolescents and adults (see Table 2) were local pain, headache and fatigue. Except for redness in adults, local reactions were more frequently reported after MENACTRA™ than after Menomune®-A/C/Y/W-135. The majority of local and systemic reactions following MENACTRA™ or Menomune®-A/C/Y/W-135 were reported as mild to intense. No important differences in rates of malaise, diarrhea, anorexia, vomiting or rash were observed between the vaccine groups.

**Table 2: Percentage of MENACTRA™ and Menomune®-A/C/Y/W-135 Subjects from Comparative Trials Reporting at Least One Solicited Local and/or Systemic Reaction Within 7 Days, by Reaction Type in Adolescents (11 to 17) and Adults (18 to 55)**

Event	MENACTRA™ Adolescents (n=2702)*		Menomune®- A/C/Y/W-135 Adolescents (n=1411)*		MENACTRA™ Adults (n=2824)†		Menomune®- A/C/Y/W-135 Adults (n=1613)†	
	Any*	Severe†	Any	Severe	Any	Severe	Any	Severe
<b>Local Reactions</b>								
Pain	64.0	0.2	29.4	0.0	52.2	0.1	33.9	0.0
Induration	18.0	0.5	6.4	0.0	16.6	0.6	8.2	0.0
Redness	11.5	0.4	6.0	0.0	13.5	0.8	12.9	0.0
Swelling	12.6	0.6	4.5	0.0	11.7	0.7	6.1	0.0
<b>Systemic Reactions</b>								
Headache**	37.1	1.1	32.5	0.9	40.7	0.8	39.5	1.0
Fatigue**	29.9	1.1	24.6	0.4	34.0	0.7	30.2	0.7
Malaise**	21.9	1.1	16.8	0.4	22.9	0.8	21.0	1.1
Arthralgia**	17.4	0.4	10.2	0.1	19.5	0.4	15.0	0.2
Diarrhea**	11.8	0.3	11.4	0.1	16.6	0.4	14.4	0.4
Anorexia**	11.0	0.4	9.1	0.4	11.6	0.3	9.3	0.4
Chills**	7.0	0.2	3.5	0.1	8.4	0.3	5.0	0.1
Fever***	4.8	0.0	2.8	0.1	1.2	0.0	0.5	0.0
Vomiting**	2.0	0.3	1.6	0.3	2.0	0.1	1.4	0.3
Rash***	1.6	—	1.5	—	1.4	—	1.2	—
Seizures***	0.0	—	0.0	—	0.0	—	0.0	—

\* Includes all subjects who provided data from comparative trials 4 and 5.

† Includes all subjects who provided data from comparative trials 1 and 2.

‡ Any denotes the proportion of participants reporting any reaction regardless of the severity.

§ Severe local reaction denotes swelling, redness or induration  $\geq 2.0$  inches in diameter or

pain resulting in unwillingness to move the affected arm.

\*\* Severe: requiring bed rest. †† Severe:  $\geq 5$  episodes.

‡‡ Severe: skipped  $\geq 3$  meals. §§ Severe:  $\geq 3$  episodes. \*\*\* Severe:  $\geq 39.5^\circ\text{C}$ .

††† These solicited adverse events were reported as present or absent only.

**Post-Marketing Reports** Based on spontaneous reporting, the following additional adverse events have been reported during the commercial use of MENACTRA™. These events have been very rarely reported. However, because these events were reported voluntarily from a population of uncertain size, it is not possible to reliably calculate their frequencies.

**Nervous system disorders:** • transverse myelitis • Guillain-Barré Syndrome (GBS): Very rare cases of GBS have been spontaneously reported, since the vaccine was marketed in the U.S.A. The cases have been reported in 17- to 18-year-old individuals, and the onset of GBS was 11–31 days after administration of MENACTRA™. The cause of GBS in these vaccine recipients has not been identified. The evidence is not sufficient to conclude that MENACTRA™ caused GBS in these patients.

**Hematologic disorders:** • thrombocytopenia

**Skin and subcutaneous tissue disorders:** • urticaria

Physicians, nurses and pharmacists should report any adverse occurrences temporally associated with the administration of the product in accordance with local requirements to the Global Pharmacovigilance Department, Sanofi Pasteur Limited, 1755 Steeles Avenue West, Toronto, Ontario, M2R 3T4, Canada. 1-888-621-1146 (phone) or 416-667-2435 (fax).

### CONCOMITANT VACCINE ADMINISTRATION

The concomitant use of MENACTRA™ (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine) with tetanus and reduced-dose diphtheria vaccine (Td) was evaluated in 11- to 17-year-old adolescents ( $n=507$ ). The concomitant administration of the two vaccines to adolescents revealed no apparent increase in reported adverse events or specific safety concern related to the diphtheria toxoid carrier protein content, although the anti-diphtheria response was much higher after concomitant administration of Td with MENACTRA™ compared to the administration of Td followed by MENACTRA™ 28 days later. The proportion of participants with a 4-fold rise or more in SBA-BR titre was also higher in subjects who received MENACTRA™ and Td concomitantly than those who were given Td first and MENACTRA™ 28 days later. There are currently no data available on the concomitant administration of MENACTRA™ with other diphtheria-containing vaccines such as DtaP or Tdap or on intervals considered safe for the administration of diphtheria-containing vaccines before or after MENACTRA™.

The concomitant administration of MENACTRA™ and TYPHIM Vi® (Salmonella typhi Vi Capsular Polysaccharide Vaccine) was evaluated in 945 adults, 18 to 55 years old. The immune response to the two vaccines was comparable when MENACTRA™ and TYPHIM Vi® were given concurrently or separately, 28 days apart.

MENACTRA™ must not be mixed with any vaccine in the same syringe. Separate injection sites should be used in case of concomitant administration.

### DOSAGE AND ADMINISTRATION

MENACTRA™ (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine) should be administered as a single intramuscular injection of one dose (0.5 mL), preferably in the deltoid region.

The use of MENACTRA™ is for a single-dose vaccination. The need for, or timing of, the administration of a booster has not yet been determined.

Inspect for extraneous particulate matter and/or discoloration before use. (See DESCRIPTION.) If these conditions exist, the product should not be administered.

For information on vaccine administration, see the current edition of the Canadian Immunization Guide or visit the Health Canada website.

When administering a dose from a stoppered vial, do not remove either the stopper or the metal seal holding it in place. Aseptic technique must be used. (See WARNINGS AND PRECAUTIONS.)

Avoid injecting the vaccine intradermally or subcutaneously since clinical studies have not been done to establish safety and efficacy of the vaccine using these routes of administration. Needles should not be recapped and should be disposed of properly.

Give the patient a permanent personal immunization record. In addition, it is essential that the physician or nurse record the immunization history in the permanent medical record of each patient. This permanent office record should contain the name of the vaccine, date given, dose, manufacturer and lot number.

### ACTION AND CLINICAL PHARMACOLOGY

**Pharmacodynamics** Serum levels of complement-mediated bactericidal antibody to *Neisseria meningitidis*, acquired through natural exposure or induced by vaccination, are generally accepted to correlate with protective immunity to meningococcal disease and therefore are used as surrogate markers for vaccine efficacy. However, except for serogroup C, no correlation has yet been established between SBA-BR titres and protection against meningococcal invasive disease.

MENACTRA™ (Meningococcal (Groups A, C, Y and W-135) Polysaccharide Diphtheria Toxoid Conjugate Vaccine) was shown to be immunogenic in children  $>2$  years old, adolescents and adults against *Neisseria meningitidis* serogroups A, C, Y and W-135. A group of 2- to 3-year-old children ( $n=92$ ) were followed for 2 to 3 years after a single dose of MENACTRA™. These participants had 1.7- to 5.2-fold higher bactericidal antibody levels than an age matched vaccine naive control group.