The Latest Facts about the Diaphragm Pacing Stimulation (DPS) System

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Most of us who use ventilators are aware that the late Christopher Reeve had some kind of experimental diaphragmatic stimulator implanted in 2003 to help decrease his dependence on his ventilator. Many folks may think this technology is only available for the rich and famous. Not true!

It is true, though, that Reeve was one of Dr. Raymond P. Onders's first success stories. Having completed 38 of these procedures to date – 27 in people with spinal cord injury (SCI), 11 in people with ALS – Dr. Onders is now performing one or two every month with a 96% success rate in people with SCI (an intact phrenic nerve is key), enabling them to breathe with an adequate tidal volume without a ventilator. He has performed the procedure both soon after an injury and up to 25 years post-injury.

For about two decades, Onders and his colleagues, Anthony DiMarco, MD, and J. Thomas Mortimer, PhD, pondered the issue of some kind of implanted device to improve the quality of life for ventilator users. Today, as the Director of Minimally Invasive Surgery at University Hospitals of Cleveland in Ohio and Associate Professor of Surgery at Case Western Reserve University, Dr. Onders is making this dream a reality.

The device is called the NeuRx Diaphragm Pacing Stimulation (DPS) System. Its goal is to free a person's dependence on a ventilator over time by stimulating the diaphragm with intermittent electric impulses. They cause the diaphragm, the primary muscle for breathing in, to contract, thus enabling air to enter the lungs as in normal respiration. The impulse sensation has been described as similar to a flick of the finger.

In a two-hour outpatient procedure, electrodes are placed directly on the diaphragm near the phrenic nerves using a laparoscope. The wires from the electrodes are attached to an external battery pack about the size of a remote control and set at a determined rate, usually 10 to 14 discharges per minute. Because the procedure is still considered investigational by the FDA, potential candidates* and dedicated caregivers must follow precise post-operative instructions and return for all scheduled follow-up appointments.

Full FDA approval is expected in about one year for people with SCI to receive the DPS System. Its protocol has been designated "category B" by the FDA, making it eligible for Medicare billing.

*The clinical trial is currently recruiting patients at the University Hospitals of Cleveland and the Shepherd Center in Atlanta. A third site is planned for the West coast. Detailed information is online at www.clinicaltrials.gov/ct/show.

Contact Mary Jo Elmo, NP, University Hospitals of Cleveland, 216-844-8594, maryjo.elmo@uhhs.com or Michelle E. Nemeth, PT, The Shepherd Center, 404-350-7688, Michelle_Nemeth@shepherd.org.
All the people who have had the procedure so far were covered by Medicare, Medicaid or private insurance with the usual copay. For non-US citizens paying cash, the bill includes device cost, surgery, anesthesia, professional fees and x-rays for a total cost of approximately $20,000. Transportation costs are the patient's responsibility.

I had an opportunity to ask Dr. Onders and Nurse Practitioner Elmo questions about this important work.

**Q:** How do you measure success?

**A:** In our ongoing studies, 27 SCI patients using mechanical ventilation via tracheostomy were implanted with the DPS System. All procedures were performed on an outpatient basis with no intra-operative complications. One patient had a false positive preoperative phrenic nerve conduction study, and therefore was never able to pace. The remaining 26 patients (96%) achieved greater than their predicted tidal volume during stimulation; 24 patients underwent weaning from the ventilator at home by capping the trach while the DPS System stimulated their diaphragm. Fifteen patients now use the device fulltime, and eight use it 12-24 hours a day resulting in more than 40 years of cumulative active implantation time. The home-based weaning protocol allows patients to maintain caregiver support, work and significantly lower expenses.

**Q:** How does this work for people with ALS?

**A:** The objective of our study in people with ALS was to use diaphragm pacing technology to maintain respiratory muscle function. If successful, at least two significant benefits may occur. Life threatening respiratory muscle dysfunction may be significantly delayed. And, diaphragm pacing may be effective in ventilatory support of patients with ALS, either decreasing or obviating the need for assisted mechanical ventilation.

We have now implanted 11 ALS patients with the DPS System. These patients had a forced vital capacity (FVC) of at least 50% at the initial screening and had not yet required invasive mechanical ventilation. The first four patients have used the system for more than one year. The results to date have confirmed that there is a sound scientific rationale for electrical stimulation of the diaphragm in ALS, especially in this group of patients whose FVC at implantation was 53% or lower.

In our first four patients who have surpassed the one-year mark, we have shown a 65% decrease in the rate of respiratory decline. The pre-implant rate of decline was 4.1% per month, while the post-implant rate after conditioning with DPS was 1.4% per month. This corresponds to more
than an additional 20 months of survival without a ventilator.

**Q:** What is the goal of DPS?
**A:** Our goal with people with SCI is to replace the ventilator. The longest-term patient was implanted March 6, 2000 and has been using the DPS System as his sole means of respiratory support for more than six years. With the ALS population, we are evaluating whether electrical stimulation of the diaphragm will slow the rate of progression and delay the need for a ventilator.

**Q:** Is the DPS System less expensive than a ventilator?
**A:** Economically, when balanced against the long-term costs of ventilator equipment, supplies and care, the DPS System is far less costly. After the cost of the procedure itself, there are minor costs for battery and external cable replacements. Our data show that savings for one patient who uses the DPS System fulltime are $13,000 per month for Ohio Medicaid.

**Q:** Are there other benefits to using DPS?
**A:** Physically, individuals with the DPS System are able to smell, eat and talk more "normally." They also report less need for suctioning and fewer hospitalizations.

During hurricanes and other natural disasters, the widespread loss of electricity can cause significant and life-threatening problems for anyone who uses a ventilator more than a few hours per day. Ventilator batteries last from only one to eight hours before requiring electricity for recharging. The DPS System uses a standard disposable 12V external battery that lasts 500 hours, and patients are supplied with a stock of batteries. The DPS System improves the quality of life during these events by decreasing anxiety, easing evacuation if necessary, and simplifying temporary housing until power is restored.

**Q:** Who are other potential candidates for DPS?
**A:** We expect to branch into the muscular dystrophies, post-polio and hypoventilation syndromes, such as CCHS, within a year.

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**Laszlo Nagy** (laszlon@adelphia.net) became a C3 quadriplegic as a result of a motorcycle accident in June 2002. Nagy says, "I was implanted with the DPS System exactly one year later. Seven weeks after the surgery, I was ventilator free for 24 hours a day, seven days a week. Since then, I have never needed to use a ventilator, and I have been infection free. I have also developed the ability to breathe on my own for up to several hours, turning off the DPS System. I use this as my 'backup,' although I keep an Ambu bag on my wheelchair."

Nagy retained his tracheostomy for suctioning, usually only once a day. He says, "I am able to live in my own home. On August 12, I got married. The DPS System allows me to travel and to leave my home virtually worry free. It has made my life much easier."

**Tom Davis** (tmdavisfl@cox.net), a C1/C2 quadriplegic, had the DPS System procedure in May 2004. One month later he was completely "freed from the ventilator" and remains so. Davis says, "The DPS System has revolutionized my lifestyle. I no longer have to lug around that heavy ventilator on the back of my chair. Instead, I have a small box that is tucked in the waistband of my pants. Without the ventilator, the length of my wheelchair has been shortened by nearly two feet and has given me much more maneuverability in tight spaces.

"When they turned the pacer on for the first time, I could smell everything in the room. This of course has made food taste much better, which has caused me to gain a little weight. The procedure has cut in half the amount of times I need suctioning.

"Also, I no longer have those long pauses between breaths from the ventilator. When people talk to me on the phone, they have no idea that I use an assisted breathing device. I love it!"

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**References**


Office of Public Affairs. Christopher Reeve Receives New Implantable Breathing Device Developed by Faculty. School of Medicine, Case Western Reserve University.

What Is Telehealth?

The American Telemedicine Association defines telemedicine or telehealth as the use of medical information exchanged from one place to another via electronic communications to improve patients' health status. Physicians can use interactive video along with the collection and transfer of medical data to assist in treating their patients. It can be as basic as seeking medical advice over the telephone or as complex as using satellite technology to broadcast a consultation to multiple locations, using videoconferencing and medical imaging.

Telehealth services include:

- **Specialist referral services** involving a specialist who assists a general practitioner in making a diagnosis;
- **Patient consultations** using audio, video and medical data between a patient and a primary care or specialty physician in making a diagnosis and treatment plan; and
- **Remote patient monitoring** using devices to remotely collect and send data to a monitoring station for interpretation. “Home telehealth” applications might include a specific vital sign, such as blood glucose or heart ECG. These services can be used to supplement the use of visiting nurses.

Remote patient monitoring is the type of telehealth service most likely to benefit home ventilation users. Historically, remote patient monitoring was driven by inadequate health services to persons living in inaccessible locations. Now, both providers and patients stand to gain from the development of telehealth. For providers, it promotes timely, high quality care and cost savings. For patients, telehealth provides accurate, timely and key information without the need to visit the hospital or healthcare provider.

Key factors affecting the widespread adoption of telehealth:

- **Limited scope of reimbursement**
The limited nature of reimbursement for telehealth continues to impede its widespread use. Recently, Medicare and Medicaid expanded its coverage adding to the reimbursement allotted for people located in Rural Health Professional Shortage Areas (HPSAs). Only a few third party private payors provide telehealth coverage in selected states.

- **Legal questions about geographic boundaries**
Given that the Internet knows no boundaries, issues pertaining to the practice of telehealth between patients and providers across states have raised legal questions. At present, about 26 states have laws that regulate out-of-state telehealth practitioners. The vast majority of states require full licensure for an out-of-state physician who is providing telehealth services to patients residing in that state.

- **Safety and standards for telehealth applications**
As the use of telehealth expands, there is a stronger need for clinical protocols and guidelines that set standards for treatment and ensure patient safety. The key bodies in the USA involved in establishing widely adopted standards and guidelines include the Food and Drug Administration (FDA), the Federal Trade Commission (FTC), as well as the Center for Devices and Radiological Health (CDRH). The Joint Commission for the Accreditation of Healthcare Organizations (JCAHO) has its own standards on credentialing and telemedicine services.

- **Privacy, security and confidentiality of patient data**
With a growing number of health-related inquiries on the web and a wealth of personal information being stored online, there are serious issues pertaining to the security of and access to patient data. The Health Insurance Portability and Accountability Act (HIPAA) mandates the adoption of standards pertaining to national electronic health transactions.

**Online resources:** To learn more about telemedicine and telehealth and related topics, such as reimbursement policies in your state and standards for telehealth programs, visit American Telemedicine Association at www.americantelemed.org.

Another valuable online resource for telehealth information is the Telemedicine Information Exchange (www.teledmed.org), which contains news about telehealth, listings of new and ongoing programs, and telehealth funding opportunities.
In April 2006, IVUN members with computer access were invited to participate in focus groups about telehealth for home ventilation users. The purpose was to discuss the use of telehealth to improve home mechanical ventilation care in the USA and to gather the opinions and observations from both home ventilation users and service providers.

The focus group was initiated by PHD Medical, a diagnostic software development company based in Montreal, Quebec, Canada. PHD Medical has participated in the development of a telehealth solution for ventilator-assisted patients in Canada.

The sessions were conducted remotely using the online collaboration tool WebEx™ and conference calls. Participants attended two 1-hour sessions, held on consecutive weeks in April 2006. The first session described and demonstrated the proposed telehealth model for home ventilation in Quebec, Canada, and distributed a questionnaire. The second session reviewed the responses, which was followed by a discussion of challenges faced by home mechanical ventilation users and providers in utilizing telehealth.

**Focus group participants**
The provider focus group consisted of five participants with experience in respiratory therapy, nursing, ventilator manufacturing, clinic administration, and rehabilitation. The user focus group consisted of ten participants who use bi-level devices, volume ventilation or an iron lung. Participants had been using home ventilation 4.5 to 52 years.

**The results from the provider group**
Have you ever used telehealth technology in a clinical setting? Most participants were new to telehealth, but one participant used it regularly to monitor patients in a remote hospital. Some had project and planning experience in telephone triage. It was noted that most respiratory therapists (RTs) would have some basic telehealth experience due to frequent use of the phone for ventilator troubleshooting.

**Do you think telehealth can improve the quality of care for home ventilator users?** All agreed that it would provide faster, more frequent and more comprehensive treatments, would be particularly useful in remote or rural areas, and would help reduce fear and isolation for ventilator users.

**Do you think that telehealth can help providers to reduce costs?** Mostly agreed, with key comments being:
- Providers might anticipate savings by reducing travel cost and time.
- If the equipment isn't expensive and providers are paid for the telehealth consultations, it could reduce the provider's overall cost.
- Cost savings would depend on type of provider and type of service offered. For example, telehealth could be of greater value to an HMO that provides multiple services, such as RT and MD consultations, and medical equipment. However, a provider who only provides services relating to ventilator operation is
less likely to save costs by using a similar telehealth system.

- There could be potential savings due to reduced emergency room visits.

Is telehealth a long-term service, or is it more beneficial for certain times, under certain conditions? The group thought that there was potential under both. Home ventilation users have different levels of needs, but all agreed that there is a clear benefit for all users during the early stages of the return to the home. The length of time that a telehealth system would be most beneficial would depend on each patient's condition and requirements.

What are the top three challenges for telehealth for home ventilation users? All the challenges listed fell into the following three categories:

1. **Financial**: A primary concern was determining who will pay for telehealth products/services.
   - Would a provider be paid for delivering telehealth services, or would it be strictly a means for reducing the cost of providing remote care?
   - Would the telehealth equipment be affordable?
   - Would the costs associated with delivering the service be reasonable?
   - How will liability issues be defined for remote consultations using telehealth?

2. **Practical**: Another concern was the equipment.
   - Would the technology be user-friendly for home ventilation users?
   - Would the equipment be convenient and available to providers?

The group expressed concern about the personnel needed to install and to train in use of the telehealth equipment and the need to hire technical personnel to manage the equipment for the providers.

3. **Conceptual**: A major challenge will be the acceptance of telehealth by the various stakeholders.

Physician support is needed, and medical professionals will have to believe in the benefits before committing to the technology.

Consumer acceptance is required, and users will not only have to understand the benefits and become comfortable with the technology, but be able to purchase the equipment or pay for the service, possibly with the assistance of private insurance or other payers.

Payers such as private insurance or Medicare/Medicaid will have to be convinced that telehealth technology does indeed improve health outcomes while reducing the overall cost of care.

It was the general opinion of the provider group that the financial and practical issues would have to be addressed and resolved in order for telehealth technology to reach widespread acceptance in the home care/home ventilation community.

**The results from the users group**

The user focus group was also given a questionnaire that included five questions, whose responses were discussed.

1. How many times a year do you typically see the following medical professionals?
   - General practitioner: 1–3 times/year
   - Respiratory specialist: 0–6 times/year
   - Respiratory therapist: 0–weekly/year
   - Homecare nurse: 0–8 times/year

Based on the responses from long-time ventilation users compared to relatively new ventilation users, the
comments on medical visits seem to confirm the provider group’s comment that medical visits are more frequent during early use of home ventilation and tend to decrease over time.

2. Do you think that telehealth could help improve your quality of care? Quality of life would be improved by avoiding hospitalizations, saving on travel costs and expediting treatment, and improving the monitoring and followup on ventilation equipment.

The system would be particularly helpful for users in remote areas with limited clinical support and resources.

3. Do you think telehealth is beneficial in the long term, or at certain times, and under certain conditions? The user group felt that telehealth would be most beneficial to home ventilation users in these three ways:

   ■ During the first six months of the return to the home.
   ■ During critical times, such as during respiratory infections, or when experiencing mechanical problems with the ventilator.
   ■ To help in the long term with reminders and equipment maintenance verification.

4. What are the top three challenges you would face if you were given the opportunity to receive telehealth services? The main challenges noted by the user group were mostly in the area of practical use:

   ■ Setting up and finding space for the equipment.
   ■ Training on the equipment, for both the user and personal care assistant/caregiver.
   ■ Being able to operate the equipment with limited dexterity or relying on caregiver’s ability to set up and operate the equipment.

Aside from practical challenges, all users felt that the cost of the equipment and the service from the provider, and the terms of the service contracts would be major factors that would affect their ability to try a telehealth service.

5. Do you think that you benefited from participating in this focus group? The users all agreed that participating in the focus group was a worthwhile experience, and that while learning about new technology seems interesting, they benefited most from hearing about and sharing experiences with other home ventilation users.

Conclusions

Many of the participants in both user and provider groups expressed their satisfaction with being given the opportunity to share their knowledge and experiences with their peers. Although most agreed that telehealth technology presented some interesting potential benefits for the home ventilation community, there were still challenges and questions that would have to be addressed.

About PHD Medical

PHD Medical, www.phdmedical.com, is a Canadian company based in Montreal, Quebec, that designs and develops software and hardware applications for the medical community in the areas of home health diagnostics and telehealth. PHD Medical applies its strengths in software design and technology integration to develop solutions to improve the delivery and management of remote patient care and home diagnostic testing.
Request for Increased Funding for Veterans Using Home Ventilators

Sandra Stuban, RN, BSN, EdM, MSN, MHSA, Lieutenant Colonel, Retired, US Army, initiated a request to establish a third level of Aid and Attendance (A&A) from the Veterans Administration.

The A&A, established by Congress, is an important financial benefit that allows severely disabled veterans to privately hire aides or attendants to assist with activities of daily living. Two levels of the A&A currently exist. The need for another level of care has recently emerged and is not adequately supported by the current allowance – support for ventilator-assisted veterans at home, such as Stuban who lives in Virginia.

The current highest level of A&A is $2,455 per month, which is inadequate for a home ventilator user requiring a higher level of 24-hour skilled caregiving.

Stuban's research determined that using $24 an hour as an industry standard for a LPN, it would cost a ventilator-assisted veteran $17,280 per month to live at home for 30 days, without family support and coverage. The cost of 30 days in a Virginia-based rehabilitation and health care center is double that.

The population of ventilator-assisted veterans who live at home is unknown. However, certain assumptions can be made by looking at support of home ventilator users by a few of the more than 100 Veterans Administration Medical Centers (VAMC). Washington, DC and Tampa each support four living at home; Richmond two.

This small number may increase if a certain number of institutionalized veterans opt to move back to their homes should more financial support become available.

Stuban's request for a higher level of A&A at $17,280 per month, specifically for ventilator-assisted veterans living at home, is supported by the American Legion.

In a letter to each member of Congress, Steve Robertson, Director, National Legislative Commission, wrote, “The American Legion fully supports Ms. Stuban’s efforts to have A&A payments increased for ventilator-dependent veterans. Furthermore, the American Legion respectfully requests that you ... consider a legislative remedy to address this inequity.”

For more details and to learn how you can support this effort also endorsed by IVUN, contact Sandra Stuban at stubann@aol.com or visit www.post-polio.org/ivun.
For Parents and Kids

Barriers to Respiratory Care
Presentations from Parent Project Muscular Dystrophy's 2006 Annual Conference, held in Cincinnati, Ohio, July 13-16, are now available online. Jonathan Finder, MD, discussed breathing in DMD in “Barriers to Respiratory Care for Patients with DMD or ... Creative Use of Outrage in Advancing Healthcare in DMD.” Go to www.parentprojectmd.org/site/DocServer/finder-breathing_2006.pdf?docID=1213. Dr. Finder is Associate Professor of Pediatrics, University of Pittsburgh School of Medicine, Pennsylvania.

http://idea.ed.gov Launched
The Office of Special Education and Rehabilitative Services (OSERS) and the Office of Special Education Programs (OSEP), at the US Department of Education announced the release of the final Part B regulations implementing the 2004 reauthorization of Individuals with Disabilities Education Act (IDEA). OSERS created this site to provide a “one-stop shop” for resources related to IDEA and its implementing regulations. The site provides searchable versions of the statute and regulations, as well as access to cross-referenced content from other laws, such as the No Child Left Behind Act and the Family Educational Rights and Privacy Act.

Bullying Prevention Site: www.pacerkidsagainstbullying.org
Pacer Center, Minneapolis, Minnesota, has a new website that teaches second through sixth graders what bullying is, how to respond to it, and how to prevent it. Geared for all children, the site includes children with disabilities who can be particularly vulnerable to bullying.

Equipment/New Interfaces

Mojo™ SleepMask™, a new full face mask from The SleepNet Corporation, features a pliable ring and flexible shell for instant customization. A comfortable fit is achieved through a contour shell that easily bends inward and outward. A gel forehead pad stabilizes the mask, and easy-release magnetic clips keep the straps in place. Contact your local home health dealer or SleepNet, www.sleep-net.com.

Hybrid™, new from Hudson RCI, is designed to be a universal interface, used either as nasal pillows or an oral interface, or a combination of the two. Pressure points on the forehead and bridge of the nose are eliminated. Glasses can be worn by the user because tubing does not go up and over the head. Good for mouth breathers, a built-in chin flap supports the chin. Contact your local home health dealer or Hudson RCI Customer Service at 866-246-6990, or visit www.hudsonrci.com.
In Memoriam

JOHN (JACK) L. QUIGLEY, JR., died August 25, 2006 in Mount Pleasant, South Carolina. Long-time members of IVUN will remember Jack as a contributor to the Rehabilitation Gazette, where he contributed his experiences of living with a spinal cord injury and using nighttime ventilation. Quigley was a personal friend of Gini Laurie, the founder of the organization, and eloquently honored her at the Fifth International Polio & Independent Living Conference in June 1989, just one month before her death. He served on the Board of Directors of the Gazette International Networking Institute for several years and was its President from 1988-1990.

Ventilator Users’ Medical Emergency (VUME) Project Update

“Here’s what we’ve done since our last update:

- Prepared and distributed a questionnaire to health professionals (pulmonologists, physiatrists, respiratory therapists) who are IVUN members and to select health professionals in other associations, such as those in emergency medicine and critical care.
- Interviewed leaders in non-profit associations for persons with neuromuscular conditions such as ALS, spinal cord injury and muscular dystrophy.
- Recruited Robert Casko, PhD, in Iowa City, Iowa, to interview health professionals and to assist with analysis of the data received.

“Our next step is to write the ‘guidelines’ for ventilator users, their attendants and for the health professionals who may treat them during an emergency situation.”

Norma Braun, MD, FACP, FCCP, Retires

IVUN salutes Norma Braun, MD, who retired in July as Senior Attending Physician, Pulmonary and Critical Care Division, St. Luke’s-Roosevelt Hospital in New York City. Dr. Braun writes, “Although I am retiring from private practice, I am trying to set up a neuropneumology clinic at St. Luke’s where I will volunteer to see patients with ventilatory problems due to neuromuscular diseases. This will include all my present ventilator patients.”

Dr. Braun started her internship on the Bellevue Chest Service where in 1963 she first saw the use of noninvasive ventilation: iron lungs for patients with COPD. This spurred her research and led her to the study of respiratory muscle function. Dr. Braun published the first study of the relationship between respiratory muscle strength and the ability to sustain eucapnia (the condition in which the CO₂ tension of the blood is normal).

Dr. Braun has taught at all levels as a clinical professor of medicine at Columbia University; served on medical boards; published more than 50 papers, abstracts, book chapters and e-internet articles; and most importantly, been a strong and ceaseless advocate for her patients.
Join IVUN! Support International Ventilator Users Network’s educational, research, advocacy and networking mission.

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Membership Application

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Country
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Payment Options

- Enclosed is my check made payable to Post-Polio Health International. (US dollars only)
- OR, charge my: VISA MasterCard Discover

Card # ____________________________
Name on card ____________________________ Exp. date ____________________________
Signature ____________________________

Send to:

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HEALTH
INTERNATIONAL
4207 Lindell Blvd., #110
Saint Louis, MO 63108-2915 USA
314-534-5070 fax

VL 20/3
Get Ready for Another Flu Season

According to the Centers for Disease Control and Prevention (CDC), all people ages 50 and older should receive the influenza vaccine during October and November.

The vaccine is recommended to several groups of high-risk individuals including "people with any condition that makes it hard to breathe or swallow such as brain injury or disease, spinal cord injuries, seizure disorders, and other nerve or muscle disorders."

New to the high-risk category are children ages 6 months to 59 months, increasing the upper age limit from last season's 23 months of age.

Reminder: The inhaled vaccine is approved only for healthy people between 5-49 years, excluding pregnant women.

Looking for a flu shot? Go to www.flucliniclocator.org, coordinated by the American Lung Association. All you do is put in your zip code. Or call the CDC at 800-232-4636.