

The newsletter of the Immunization Technical Assistance Team (ITAT), a partnership of leaders from various organizations who are dedicated to improving and maintaining maximum immunization rates utilizing practice-based interventions

## The Colorado Immunization Program at the Colorado Department of Public Health and Environment

### by Jamie Damico, RN, MSN, CNS

he Colorado Immunization Program at the Colorado Department of Public Health and Environment (CDPHE) has a new Program Manager, Joni Reynolds, RN, MSN, CNS. We'd like to take this opportunity to introduce her and to let you know about the other staff at the State's Immunization Program.

Although appointed as 'acting' Program Manager for the Colorado Immunization program for several months, that title became permanent for Joni on October 1, 2006. Joni is a familiar face for Public Health in Colorado as she has worn many hats before this current position. She has had many years experience as a public health nurse, epidemiologist, consultant/educator and supervisor of staff and programs both for local public health agencies and the state health department. She is also on the faculty of the University of Phoenix teaching nursing students in all aspects of nursing curriculum. Joni's responsibilities in this new position include providing program guidance and direction for CDPHE's immunization activities and oversight for the implementation and evaluation of objectives and activities for CDC grants and Colorado state funding.

Rosemary Spence is the nurse consultant who oversees all aspects of the Vaccine for Children (VFC) and the Vaccine Management Unit activities. She supervises seven staff members on that team and offers presentations, consultation services and AFIX/VFC site visits.

Nurse consultants, Karen Willeke (Northeast Region), Debra

Zambrano (Southeast Region) and Cinda Ewing (Northwest Region) provide consultation and education for health care providers in the VFC programs. They also field calls and provide immunization resources for the physician's offices, clinics and health departments in their designated areas. Lori Quick, the VFC nurse consultant in the Southwest Region, in addition to the above roles, works with the Colorado Clinical Guidelines Collaborative to update and distribute the ACIP/AAP/AAFP approved pediatric immunization schedule. She also represents the CDPHE at the Southwest Children's Immunization Coalition quarterly meetings.

Other Staff members in the VFC program include Rudy Balquin, Gretchen Motley and Robert Bruce. Rudy has extensive involvement in all aspects of vaccine monitoring, benchmarking and population data analysis and vaccine needs assessment for VFC. He is also involved in site visits and develops protocols for proper storage and handling of vaccines for local health departments, hospitals and private providers participating in management of the VFC vaccine as well as training management for new VFC participants. They also provide valuable support and assistance to internal immunizations staff.

Roberta Smith is the nurse appointed as 'acting' Unit Supervisor for the program's 'Schools and Community' immunization section. She supervises four staff members and overseas those programs specific to immunizations as they relate to schools and communities in Colorado. Roberta is also the

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coordinator of the adult immunization area and addresses the State's influenza and pneumococcal issues.

Other staff members in 'Schools and Community' include Lillian Spreng, Teri Lindsey, Margaret Huffman and Jamie Damico. Lillian oversees the distribution of printed immunization resource materials and is responsible for updating the program's webpage. She also assists with the Yellow Fever certification process and has been instrumental in revising and updating the Immunization Correspondence Course for Childcare Providers. Teri is the contract monitor for the Immunization Program's contracts and coordinates and facilitates the Immunization Technical Assistance Team (ITAT) and the Sharpshooter newsletter. She also handles the VAERS (vaccine adverse events reports) as well as immunization outreach requests.

Margaret Huffman is the nurse consultant involved with both CDPHE's Emergency Preparedness Division and the Colorado Immunization Program acting as a liaison related to immunization issues surrounding pandemic influenza coordination and planning. She's also instrumental in providing technical advice and information from an immunization/vaccine-preventable disease point of view to emergency planners within CDPHE, local public health agencies, school districts, mental health agencies, etc. Nurse consultant, Jamie Damico, is responsible for addressing immunization issues and providing immunization education to Colorado schools (including colleges and universities) and childcare providers and staff. She also provides assistance to local health departments and health care providers clarifying issues as they relate to school immunization requirements and the Colorado Board of Health Rules pertaining to school immunizations.

The 'Data Group' consists of Lane Wake and Marianne Koshak who focus on assessment measures and projects related to immunization data collection. They provide support and data analysis for immunization assessment projects for local public health agencies. Additionally, they handle information requests to display data in a format that provides clear and meaningful interpretation.

Beth Hoffman is the financial manager for the immunization program and assists with the grant budget, the tracking of expenses and the creation of reports for the program manager. She also oversees the immunization expenditures and makes sure they meet all State and Federal policies and guidelines.

To contact anyone at the Colorado Immunization Program, call the main number at 303-692-2650. To review the program's immunization webpage, please go to:

http://www.cdphe.state.co.us/dc/immunization 🛇

## Human Papillomavirus (HPV) vaccine: A step towards cervical cancer elimination.

### by Roberta Smith, BSN, MSPH

n June 8, 2006 the Food and Drug Administration (FDA) licensed the first vaccine developed to prevent cervical cancer and other disease in females caused by certain types of genital human papillomavirus (HPV). The quadrivalent vaccine, Gardasil®, manufactured by Merck, protects against four HPV types (6,11,16,18) which are responsible for 70 percent of cervical cancers and 90 percent of genital warts. Soon another HPV vaccine from the manufacturer GlaxoSmithKline will be on the market. The Advisory Committee on Immunization Practices (ACIP) voted in June 2006 to recommend this vaccine for females aged 9–26 years.

More than 20 million men and women in the United States are currently infected with HPV and there are 6.2 million new infections each year. About 15 percent of men and women between the ages of 15 and 49 are currently infected with HPV. By age 50, at least 80 percent of women will have acquired HPV infection at some time in their life. Persistent infection with high-risk types of HPV is associated with almost all cervical cancers. In 2006, the American Cancer Society estimates that 9,710 women in the United States will develop cervical cancer and 3,700 will die of the disease.

The HPV vaccine has been tested in over 11,000 females (9–26 years of age). These studies have showed that the HPV vaccine was safe and caused no serious side effects. In the clinical trials females who were HPV naïve at time of vaccination demonstrated nearly 100 percent efficacy in preventing vulvar and vaginal precancers and genital warts caused by the targeted HPV types. Although the vaccine holds great promise towards the elimination of cervical cancer, the vaccine should not take the place of regular cervical cancer screening. The vaccine only protects against some HPV infections and not other sexually transmitted infections. Therefore it is important that females receiving the vaccine continue to practice protective sexual behaviors (e.g., abstinence, monogamy, limiting the number of sex partners, and using condoms), which may have a protective effect on HPV acquisition, reduce the risk of HPV associated

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diseases, and mitigate the adverse consequences of infection with HPV.

Ideally, the vaccine should be administered before the onset of sexual activity. However, females who are sexually active also may benefit from vaccination. Females who have not been infected with any vaccine HPV type would receive the full benefit of vaccination. Females who already have been infected with one or more HPV type would still get protection from the vaccine types they have not acquired. Few women are infected with all four HPV types in the vaccine. The vaccine is routinely recommended for girls 11–12 years of age. It is given as a 3-dose injection series over 6 months. The vaccine is also recommended for girls and women 13–26 years of age who did not receive the vaccine when they were younger. HPV vaccine may be given at the same time as other vaccines. Currently the duration of protection is unclear. Current studies (with five-year follow up) indicate that the vaccine is effective for at least five years. There is no evidence of waning immunity during that time period. This information will be updated as additional data regarding duration of immunity becomes available.

The introduction of the HPV vaccine is exciting because it is the first truly anti-cancer vaccine. With new cervical cancer screening tools and the vaccine, public health is ready to arm itself to fight this cancer.

For more information:

www.cdc.gov/std/HPV

### www.cancer.org

www.fda.gov/bbs/topics/NEWS/2006/NEW01385.html O

## New Vaccine for Shingles recommended by ACIP

### by Roberta Smith, BSN, MSPH

n October 25, 2006, the Advisory Committee on Immunization Practices (ACIP) recommended that people age 60 and older receive a new vaccine to prevent herpes zoster, or shingles, a condition that often leads to debilitating chronic pain. Zostavax, manufactured by Merck, is the only US-licensed vaccine that reduces the risk of reactivation of the varicella zoster virus (VZV).

The initial studies for Zostavax enrolled approximately 38,000 people within the United States who were 60 years of age or older. Half of the participants received Zostavax and half received placebo. Study participants were followed on average for about three years to see if they developed shingles and if they did, how long the pain lasted. At the conclusion of the studies, researchers found that overall (in persons age 60 years and older) the vaccine reduced the occurrence of herpes zoster (shingles) by 50 percent. The vaccine effect was highest at 64 percent in people between the ages of 60–69, but its effectiveness declined with increasing age; to 41 percent for the 70–79 age group and 18 percent for those 80 years of age and older.

While the ability for the vaccine to prevent shingles declined with age, the risk of chronic pain among those older vaccinated persons who still developed shingles was lowered. The most common reported side effects in vaccine recipients were mild, such as reactions at the injection site and headache.

Shingles is caused by the VZV, the same virus that causes chickenpox. Only someone who has had a case of chickenpox, or gotten the chickenpox vaccine, can get shingles. After initial infection, the virus becomes dormant within the nerves following exposure or a case of chickenpox. It can reactivate later in life to cause shingles. About 25 percent of people develop zoster during their lifetime, and there are about one million cases of shingles per year. Shingles is much less contagious than chickenpox, and one cannot catch shingles from another person with shingles. However, a person who has never had chickenpox (or the varicella vaccine) could get chickenpox from someone with shingles.

The vaccine is a live attenuated vaccine that is stored frozen and should be reconstituted immediately upon removal from the freezer. The diluent should be stored separately at room temperature or in the refrigerator. Zostavax is administered subcutaneously and is administered as a single dose (see prescribing information).

Zostavax is contraindicated for the following groups:

- Anyone who has ever had a life-threatening allergic reaction to gelatin, the antibiotic neomycin, or any other component of shingles vaccine.
- Anyone who has a disease or condition that causes a weakened immune system (such as an immune deficiency, including leukemia, lymphoma, HIV/ AIDS) or are taking high doses of steroids by injection or mouth.
- Anyone who has active TB (tuberculosis) that is not being treated.

Please refer to prescribing information and Advisory Committee on Immunization Practices (ACIP) recommendations for complete list of contraindications.

Many people have been concerned with the reimbursement for Zostavax. Zostavax reimbursement differs from some other vaccines commonly used for Medicare beneficiaries. The pneumococcal and influenza vaccines are covered under

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Medicare Part B for all beneficiaries. The hepatitis B vaccine is covered under Part B for patients at high or intermediate risk of contracting hepatitis B. According to the Medicare Modernization Act, new vaccines, and those not covered under Medicare Part B, are reimbursed under the outpatient drug benefit, Medicare Part D. Therefore, Zostavax is covered under Medicare Part D, the prescription drug plan through Medicare. Since physician's offices are considered to be out-of network providers for Part D, when administered in a physician's office, Zostavax is covered under the out-ofnetwork access rules.

Currently, there is no ready mechanism for physicians to bill Part D plans for Part D-covered vaccine costs. At this time, if a patient receives Zostavax in a physician's office, the patient must pay the physician for the Part D-covered vaccine cost and submit a paper claim for reimbursement to their insurance company or Part D plan. Medicare is still working out different strategies for billing for Zostavax. In-network reimbursement strategies proposed by the Centers for Medicare and Medicaid Services (CMS) include patients receiving the vaccine in a pharmacy where billing would be handled online or physicians contracting with specialty pharmacies to handle billing and shipment of the vaccine to physician's offices. While Part D plans are expected to cover Zostavax, none of the out-of-network reimbursement strategies proposed by CMS are currently available.

In Colorado, some local county health agencies and select Safeway pharmacies currently have the Zostavax vaccine. Final ACIP recommendations will be published in the Morbidity and Mortality Weekly Reports (<u>www.cdc.gov/mmwr</u>).

There is an interim vaccine information statement that can be downloaded at:

www.cdc.gov/nip/publications/VIS/shingles

More information on CMS coverage can be found at:

www.cms.hhs.gov/PrescriptionDrugCovContra/ Downloads/BvsDCoverage\_07.27.05.pdf �

## 2005 Colorado National Immunization Survey Results

### by Lane Wake, MS

he 2005 National Immunization Survey (NIS) found that 83.4 percent (± 4.4 percent) of children 19–35 months of age were up to date for the 4:3:1:3:3 series and 78.6 percent (± 5.1 percent) were up to date for the 4:3:1:3:3:1 series. An oversample in Denver, Adams, Arapahoe and Douglas counties in 2005 allowed calculation of immunization rates for this 4 county geographic area. The rates in the 4 county area were 83.8 percent (± 6.6 percent) for the 4:3:1:3:3 series and 78.8 percent (+ 7.5 percent) for the 4:3:1:3:3:1 series among 19–35 month olds. CDC announced that the 4:3:1:3:3:1 series will be used as the standard from now on, whereas, the 4:3:1:3:3 series had been used in the past (see table below).

Immunization Series in Children 19–35 Months	Colorado	Denver, Adams, Arapahoe & Douglas Counties
4:3:1:3:3 Series		
4 DTaP, 3 Polio, 1 MMR, 3 Hib, and 3 Hepatitis B Rate Immunization rate range with 95 percent confidence intervals	83.4 ± 4.4 (79.0 - 87.8)	83.8 + 6.6 (77.2 – 90.4)
4:3:1:3:3:1 Series		
4 DTaP, 3 Polio, 1 MMR, 3 Hib, 3 Hepatitis B and 1 Varicella Immunization rate range with 95 percent confidence intervals	78.6 + 5.1 (73.5 – 83.7)	78.8 + 7.5 (71.3 – 86.3)

Estimates for the series and specific vaccines were similar in the Denver, Adams, Arapahoe, and Douglas county area as compared to the rest of Colorado. For the state, there were statistically significant increases for Hepatitis B and Pneumococcal vaccines from 2004 to 2005.

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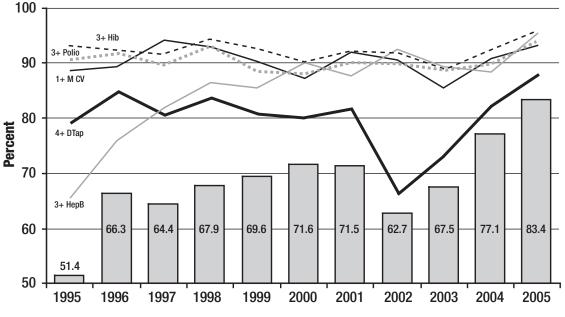
Following the release of NIS data the first question asked is "What is our ranking?" Although it is often presented in this way, ranking the point estimates by state is problematic. The confidence intervals reported with the point estimates represent the range of values where the true rate lies 95 percent of the time. Confidence intervals are used for data that are a sample of the population. For example, the point estimate for Colorado in 2005 for children 19–35 months of age for the 4:3:1:3:3 series is 83.4 percent with a 95 percent confidence interval of  $\pm$  4.4 based on a sample of 394 children. This means that the true coverage rate fell between 79.0 and 87.8. The larger the sample the smaller the confidence intervals will be. The national rate for children 19–35 months of age for 4:3:1:3:3 in 2005 was 80.8 percent with a 95 percent

confidence interval of  $\pm$  1.0 based on a sample of approximately 30,000 children.

Point estimates are used to rank states regarding immunization status. State rankings assume that point estimates are different, however, the rankings do not take into account the confidence intervals that overlap. In 2005, Colorado was ranked 16th among all states. Within the 95 percent confidence intervals Colorado was statistically the same as the 3rd to the 33rd ranked state.

The very good news of course, is that Colorado has moved up substantially from being ranked 50th in the nation in 2002 and 2003. The chart below shows the 4:3:1:3:3 rates for Colorado across all years with the single antigen rates across the top.

### 4:3:1:3:3\* and Single Antigen Estimate Vaccination Coverage among Colorado Children 19–35 Months of Age, by Year, National Immunization Survey (NIS)



Since 2000, with the exception of the 4th DTaP, the single antigen rates of children 19–35 months of age have hovered around 90 percent. In 2002, a DTaP vaccine shortage with the subsequent recommendation to suspend the 4th and 5th dose resulted in a drop in the 4:3:1:3:3 series.

Several factors most likely contributed to increasing 4:3:1:3:3 rate including

- Vaccine availability
- Following Colorado's 50th ranking, increased funds to CDPHE and local health agencies for immunization services
- Increased awareness of immunizations following the significant amount of press coverage regarding Colorado's 50th ranking

\*4:3:1:3:3 Series—4 DTaP, 3 Polio, 1 MMR, 3 Hib, and 3 HepB

The NIS data are just one piece of the puzzle and, unfortunately, offer no local data because of sample size limitations. 2005 is the only year that data will be available for the Denver, Adams, Arapahoe and Douglas county area. Future NIS data will be for the entire state. Other sources of data include surrogate measures, such as children living in poverty or new mothers with risk factors known to be associated with not having their children immunized; local and/or CIIS registry data where available and; private provider specific immunization rates determined using the CoCASA software. It's important to review all the data available in a particular area with health providers knowledgeable about that area. In this way the data can be put into context with what local providers know and be used to indicate where immunization services may best be targeted.

## Sharp Shooter Marksman Corner Highlighting Outstanding Work

### by Anne L. Hammer, RN Denver Health Immunization Program

Denver Health & Hospital Authority Community Health Services was recently honored as a Joint Commission on Accreditation of Healthcare Organizations (JCAHO) national Codman Award Winner for improvement of pediatric immunization rates. Named for the physician regarded in health care as the "father of outcomes measurement," the Ernest Amory Codman Award showcases the effective use of performance measurement by health care organizations to improve the quality and safety of health care.

Denver Health's initiative stemmed from an assessment that showed low immunization rates at its primary care sites were putting the community at risk for diseases that can easily be prevented. Beginning in 1993, the organization sought to change this trend by developing an initiative that included multiple strategies known to improve pediatric immunization rates. The key methods to improve vaccine rates were to accurately track patients, to regularly assess immunization levels, and to improve the on-time delivery of vaccines in primary care clinics. The initiative spanned 1995–2005 and as a result, immunization rates improved by 46 percent for two-year old patients and by 26 percent for one-year old patients, with documented immunization rate of 84 percent for 4-3-1-3-3 series and 92 percent coverage for 3-2-2-2 series.

Leaders from throughout the Denver Health & Hospital Authority agency including Community Health, Public Health, Inpatient Newborn Nursery and Information Services divisions were involved in the planning of the initiative and commitment of resources. Site-specific physician and nursing leaders and their immunization teams implemented the initiative at their clinic sites. Immunization teams included clinical and clerical staff and the designated nursing immunization "champion" (local resource for staff members regarding immunizations and the recommended schedule, immunization registry superuser, and responsible for maintaining the clinic's vaccine inventory). The initiative was implemented at all Denver Community Health Services primary care clinics (9 Family Health Centers), with additional Denver Health immunization registry participation from the Public Health Immunization Clinic,

Inpatient Newborn Nursery, network of 12 School-Based Health Centers, on-campus Pediatric Urgent Care Center and Immunization Outreach Clinic projects at 15 sites.

Site-based process improvement activities included:

- Quarterly CASA immunization assessments for 3-2-2-2 series completion by 1-year of age and 4-3-1-3-3 series completion by 2-years of age. Site-specific immunization rates are tracked and disseminated by trendline, by quarterly clinic Report Card, and via CASA diagnostic reports.
- Semiannual immunization team meetings, facilitated by partnership with the Colorado Community Health Network (CCHN) state primary care association.
- **Reminder/Recall** activities including lists for clinic staff and postcards for mailing to parents of children age birth–11 months at least one month behind on vaccine(s) and children age 12–23 months at least two months behind on vaccine(s).
- Development and sharing of immunization "best practices" including: standing orders for immunizations generated by computerized registry based on child's age and vaccine history, use of registry at every pediatric visit including acute visits and recheck visits, education about vaccination screening and true contraindications, assignment of a local immunization champion, and referral from Public Health and Outreach activities for assignment of a primary care clinic as medical home.
- Celebrating successes and team incentives. Denver Community Health Family Health Centers participate in the CCHN Annual "Excellence in Quality Clinical Reception." Denver Health & Hospital Authority holds an annual "Day of Celebration" where teams are encouraged to present posters that highlight their accomplishments in areas of process improvement.

For more information about this great project, please contact Anne Hammer at Denver Community Health Services at 303-436-7924 (<u>anne.hammer@dhha.org</u>) or Mette Riis at Denver Public Health Department at 303-436-3724 (<u>mette.riis@dhha.org</u>). ◆

## ASK the EXPERTS

The column in The ITAT Sharp Shooter newsletter that allows you to get your questions answered by the professionals. We hope it's content will be both informative and helpful.



### When are Vaccine Information Statements (VISs) released for new vaccines?

A Vaccine Information Statement (VIS) is released as soon as possible after ACIP votes on recommendations for use of the vaccine. Please note that unique VISs do not exist for certain combination vaccines (e.g., Comvax, Pediarix)—so health professionals in instances like these should provide a VIS for each vaccine component. CDC only publishes VISs in English; all translations have been developed by others. To access all currently available VISs in more than 30 languages and some alternative formats (audio/video), go to www.immunize.org/vis.

### Answered by Immunize.org

### We see immigrant children who have no immunization records. Should we be concerned about "over immunization"?

A The only vaccines for which extra doses are a concern are those that contain diphtheria and tetanus toxoids. Excessive doses of DTP, DTaP, DT, Tdap, or Td probably increase the risk of a local adverse reaction. As a general rule, ACIP recommends that persons who do not have valid documentation of vaccinations be revaccinated. Serologic testing can be considered in some situations. This issue is discussed at length in the 2002 ACIP General Recommendations on Immunization. Go to <u>www.cdc.gov/mmwr/PDF/</u> <u>rr/rr5102.pdf</u> (p. 20).

## Do persons who received chemotherapy need their vaccines repeated?

A Vaccines received before starting chemotherapy do not need to be repeated after chemotherapy is completed. Chemotherapy does not negate vaccine-induced immunity. However, revaccination is recommended for persons who are recipients of a hematopoietic stem cell transplant (HSCT), such as a bone marrow transplant, because immunity present before the transplant is lost; it may not be replaced by donor cells. (5/05)

### Answered by Immunize.org

## Is it true that pertussis in children is increasing? Are more infants dying from the disease?

A Since the 1980s, the number of reported pertussis cases has increased. These increases have been noted in both infants younger than age 1 year, particularly among infants younger than age 6 months, adolescents age 11–18 years, and adults. An increase in the number of reported deaths from pertussis among very young infants has paralleled the increase in the number of reported cases. Reasons for the increases in pertussis are not completely clear; improvements in diagnosis and reporting of pertussis in adolescents and adults appear to be important factors contributing to the overall increase.

#### Answered by Immunize.org

### What are the recommendations for use of HPV vaccine?

In June 2006, the Advisory Committee on Immunization Practices (ACIP) voted to recommend that HPV vaccine be routinely given to girls ages 11-12 years, although it can be given to girls as young as 9 years. ACIP also voted to recommend that girls and women ages 13 through 26 years receive the vaccine. Ideally vaccine should be administered before onset of sexual activity, but sexually active females should still be vaccinated.Gardasil is licensed as a 3-dose series, with dose #2 given 2 mos after dose #1, and dose #3 given 4 mos after dose #2. The minimum interval between doses #1 and #2 is 4 weeks, and between doses #2 and #3 is 12 weeks. The vaccine should be given IM in the deltoid. For more information on the use of HPV vaccine, see the provisional ACIP recommendations from CDC at www.cdc.gov/nip/recs/provisional\_recs/hpv.pdf or consult the package insert at www.fda.gov/cber/label/ hpvmer060806LB.pdf. ACIP recommendations do not become official until they are published in the MMWR, which is expected to occur in early 2007.

#### Answered by Immunize.org

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# Feature Articles

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  ASK the EXPERTS

This Spring edition of *The ITAT Sharp Shooter* also includes important phone numbers and websites listed throughout.



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This newsletter should be directed to all staff involved in immunizations, including: \_\_\_\_\_clerical and billing staff; \_\_\_\_\_RNs; \_\_\_\_PAs; \_\_\_\_PAs; \_\_\_\_PAs; \_\_\_\_DOs; \_\_\_\_Clinical Director or Clinical Manager



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