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Treatment for Methamphetamine Abuse and Dependence: The Matrix Model

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Background

The Matrix Model is an evidence-based psychosocial treatment used to treat stimulant dependence. Although the primary goal for the originators of the Matrix Model was to develop an effective outpatient treatment for cocaine, they later successfully extended the treatment to methamphetamine. As the methamphetamine epidemic spread eastward across the US, the Matrix Model gained popularity,[1-3] and in 1999 the Center for Substance Abuse Treatment sponsored a large scale randomized clinical trial of the Matrix Model.[4]

Methamphetamine Abuse in Indian Country

Lori De Ravello, MPH, CDC Assignee to the National STD Program, volunteered to coordinate two special issues of *The IHS Provider* dedicated to the problem of methamphetamine abuse in Indian Country. The first issue, a series of articles *defining the problem,* appeared in the December 2006 issue. The second issue devoted to *working together on solutions*, was published in January 2007. Due to the enthusiastic response of the many authors who volunteered for this project, we have several additional articles that appear now in this issue. We wish to recognize Ms. De Ravello's initiative and hard work that made this project possible. We also express our appreciation to the many authors who worked so hard to prepare these many articles.

Matrix Model in Indian Country

While the use of methamphetamine increased across the nation, it skyrocketed in the AI/AN population. In August 2006, the Desert Sun newspaper reported,

> *"In the past few years, meth has replaced alcohol as the No. 1 substance abuse problem in Indian country,*

In this Issue...

tribal leaders say. The consequences have been even more devastating. American Indians are more likely than other racial groups to use meth, according to a 2004 survey by the Substance Abuse and Mental Health Services Administration"

"It's the biggest problem facing tribal police now, said Chris Chaney, Bureau of Indian Affairs' director of law enforcement."[5]

Although Matrix staff were consulting with various Indian governments and doing some training, the materials had not been adapted for AI/AN. The adaptation of the Matrix Model client handouts for AI/AN began as part of a CSAT/SAMSHA-funded project in 2003. The project was initiated by the Friendship House in San Francisco, who enlisted the help of the Matrix Institute to adapt the materials.

These materials formed the basis for the eventual evolution of the Matrix Model publication, *Culturally Designed Client Handouts for American Indians and Alaskan Natives*.[6] The Native American symbols, quotations, folklore, ceremonial references, etc. were garnered from a number of different indigenous nations and generalized in a fashion such that each tribe could superimpose their own cultural and anthropological identifiers and qualifiers on the handout. The collaborators involved in this adaptation encourage each tribe to utilize their elders or healers or whomever is appropriate to fill in or flesh out the appropriate tribal morals, ethos, and cultural practices as indicated in each handout.

The Matrix Model's culturally appropriate handouts for Native Americans were officially introduced at the Indian Health Services/SAMSHA National Behavioral Health Conference in San Diego, Calif. in June 2006. As AI/AN people begin using the Matrix Model, they may find the experience of Glenn Cummings, who works with the Gila River Indian Community, helpful. This group was working with the materials prior to the cultural adaptation.

The Gila River Indian Community's Experience

The Gila River Indian Community (GRIC) was established in 1939 as a federally recognized tribe and is located in the desert of south central Arizona. The GRIC Department of Human Services (DHS) provides outpatient substance abuse services for the community of about 18,000 enrolled members in three locations, with approximately 275 active clients. About 85% of the individuals seeking services from DHS are court ordered.

Until 2002, the outpatient model utilized by DHS was individual counseling sessions combined with a few educational and cultural groups each week. Attendance was often sporadic, and the number of clients successfully completing treatment was low. In an attempt to improve outcomes, DHS decided to implement an intensive outpatient program (IOP) to see if attendance, completion rates, and overall effectiveness would improve. The structure of the IOP was three days per week for three hours each day, for eight weeks. The content was of GRIC's own design and included psycho-educational groups, process groups, and cultural groups in our curriculum.

In early 2005, Glenn Cummings was asked by the Director of DHS to determine if the program was providing the best service available. He discovered they were having difficulty keeping clients in the program and that while some of the groups were well attended, others were not. GRIC began to have conversations with both the Matrix Institute and Hazelden about the program. Although GRIC had some initial concerns regarding the Matrix Model (since it was tailored to mainstream culture with a strong focus on methamphetamine abuse), several Native American programs trained in the model provided positive feedback. GRIC believed it was very important to use the model the way it was designed and not to dissect it.

"It was sometimes challenging convincing our 15 member clinical team that we needed a new program, and there was some resistance to changing to this new model. The administrative team kept 'selling' the idea to the counseling staff and there were many discussions about how this would make for a better program. Administration kept planning for the implementation of the Matrix Model and arranged for the entire staff to be trained by a trainer from Matrix."

DHS began using the Matrix Model in its first location September 2005, and by October 2005 was providing it in all locations. Some of the counseling staff had to adjust to this new model because their role was now one of cheerleader, teacher, coach, and counselor. When asked, the counselors report the biggest challenge they faced when starting Matrix was learning the new format. Counselors agree that they appreciate the structure of the program and having the therapist manual to follow, because there is less preparation time. Counselors who are community members feel the content of the model is universal, so cultural appropriateness is not an issue. They believe that the culture comes out in the delivery of the model, not the subject matter.

"The issues we had seem small now but at the time were challenging." Our biggest problems were the following:

1) Producing and storing the client notebooks.
2) Buying DVDs for all our locations.
3) Learning to track client progress in a program almost twice as long as our previous IOP.
4) Arranging for counselors to see only their clients in groups.
5) Urine testing each client every week. (Instead we do random UAs)
6) Finding enough 12-step meetings for clients and getting them there. Here we have substituted weekly cultural groups in each location. In these groups, talking circles are held, language is introduced and taught, history is shared, and stories are told; although this is helping the clients, some of the basic tenets of the 12-step philosophy still need to be incorporated into our program.

In order to provide the best service possible and to maintain fidelity to the model, GRIC sent two staff to the Matrix Institute for "Key Supervision" training. GRIC audiotapes groups facilitated by each counselor and supervisors sit in on groups to determine strengths and training needs.

"The program is alive and changes from time to time. We keep close watch on it so we can continue to have positive outcomes for the people we serve. Representatives from our program have been invited to speak with other Native American service providers who are interested in the Matrix Model to share with them how it has been used in Gila River. We share our experience, the pros and cons, but the most important information we share is how our clients experience their treatment with us.

The majority of clients report that they enjoy the Matrix Model IOP because they learn something new and valuable each time they come to group. While we haven't conducted formal outcome measures, we believe our effectiveness has improved enormously because our attendance has more than tripled in the year we have been using the Matrix Model, and our completion rate has more than doubled."

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Taking Control of Methamphetamine in Our Communities: An Opportunity of Necessity

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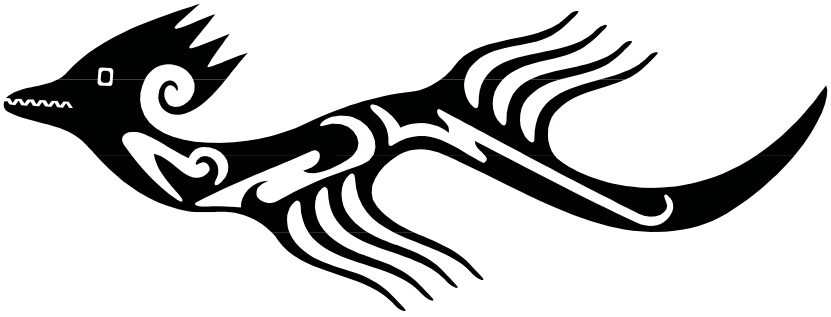
The Substance Abuse and Mental Health Services Administration (SAMHSA) recognizes that the production and consumption of methamphetamine takes a severe toll on all Americans. However, the affect on American Indians and Alaska Natives (AI/AN) is particularly severe. Thus, it is essential that we continue our partnership with AI/AN communities in an effort to contain and neutralize the impact that methamphetamine use has in Indian Country.

In our effort to address methamphetamine use in Indian Country, SAMHSA partners with Indian Health Service (IHS) as well as other Agencies and Departments within the Federal government. We are an active member of the Office of National Drug Control Policy's Executive Tribal Law Enforcement Workgroup, which includes representatives from the IHS, Department of Justice, Department of Interior, Environmental Protection Agency, Federal Bureau of Investigation, Tribal Law Enforcement, and the Drug Enforcement Agency. The goal of this workgroup is to address methamphetamine use and production in Indian Country and to help educate AI/AN communities about methamphetamine. We also partner with the National Institute on Drug Abuse in an effort to foster appropriate treatment strategies, and with the Centers for Disease Control and Prevention to address the infectious disease aspects of methamphetamine use and abuse.

Methamphetamine use and abuse has created an opportunity of necessity. Small laboratories are on the decline in many areas, but they still remain a problem. In addition to laboratories, law enforcement agents recognize the need to address the problem of across-the-border smuggling and drug dealing.

While there are no magic solutions to the problem of methamphetamine use and abuse, there is the realization that the health of the AI/AN communities rests on the wisdom of those communities to work together within and outside of Indian Country with people of good will committed to the well-being of these communities. With this partnership, progress can be made and will be made.



Promising Practices for Treating Methamphetamine Use Disorders

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Evidence-based practice (EBP) strategies are often considered the gold standard for providing psychiatric treatment services. EBPs are interventions that have been rigorously tested, have yielded consistent, replicable results, and have proven safe and beneficial for the majority of people who have been treated with them.[1] Unfortunately, no treatments for methamphetamine use disorders have yet satisfied these criteria. This is true not only for American Indians/Alaska Natives (AI/AN) but for *all* methamphetamine abusing populations. The lack of treatment services for AI/AN methamphetamine abuse and dependence is a top concern for tribal communities, their leaders, and the Indian health/tribal/urban health care system.

This article will briefly outline chemical dependency treatment practices and strategies for which there is evidence of usefulness in the AI/AN population and those for which effectiveness in the general population shows reason to predict successful translation in Indian Country. We will focus the majority of the article on Contingency Management (CM), which we believe is one of the treatment practices that have a high likelihood of feasibility and effectiveness in AI/AN communities.

Pharmacotherapy

There is an ongoing search that is both vigorous and rigorous, largely led by the National Institute of Drug Abuse's Medication Development Program, to identify effective pharmacotherapies for treating methamphetamine use disorders.[2] While progress is being made in identifying and eliminating potential candidate medications,[3-6] no medication or combination of medications has yet been approved for the treatment of methamphetamine use disorders.

Immunotherapy

An interesting approach to treating or preventing substance use disorders is to vaccinate individuals against the effects of the drugs.[7] While this technique has been discussed for decades,[8] it has not been approved for use in humans yet. Safety concerns, which are being addressed with new technology, and ethical concerns about who would decide who would receive the vaccination, have proven to be significant roadblocks to the dissemination of this treatment strategy.

Psychosocial/Behavioral Treatment Strategies

The current National Institute of Drug Abuse (NIDA) publication "Drugs, Brains, and Behavior: the Science of Addiction," states that because addiction can affect so many aspects of a person's life, treatment must address the needs of the whole person. These needs may include medical, psychological, social, vocational, and legal. NIDA names Cognitive Behavioral Therapy (CBT), Motivational Incentives, Motivational Interviewing, and Group Therapy as elements of comprehensive treatment programs.[9]

CBTs are based on principles largely derived from learning theory to help consumers reduce or stop drug and alcohol use by altering the way they think and feel about drugs and their use. Variants of this strategy have been employed in the treatment of methamphetamine addiction.[10,11]

Motivational Incentives and Motivational Enhancement Therapy (MET) are CBTs that can readily be used in community-based substance abuse clinics in an attempt to alter a consumer's motivation for treatment attendance, engagement, or abstinence.[12,13] These techniques are already being successfully used in Indian Country to address other health concerns (e.g., diabetes).[14,15] The nationwide Project Match trial, conducted in the 1990s, compared 12-step facilitation therapy, cognitive-behavioral therapy, and MET. A retrospective study of the outcomes of AI/AN showed they had significantly better outcomes with MET.[16]

Motivational Incentives are described below in the section on Contingency Management. The Community Reinforcement Approach (CRA) uses these techniques within a family and community context.[17] Finally, Relapse Prevention is a strategy that helps consumers identify, avoid, and/or diffuse situations that increase the probability of their drug use; it is a commonly employed procedure in many treatment plans.[18]

The Matrix Model and much treatment as usual for methamphetamine addiction currently incorporate aspects of these treatment strategies. The Matrix Model is currently the psychosocial approach with the most support in treating methamphetamine use disorders.[19]

In practice, many of the above mentioned techniques are delivered in a combined fashion. Day-to-day practice, in which clinicians encounter consumers with different addictions, triggers, life-situations, levels of psychiatric comorbidity, and health status, dictates that a well-trained clinician be able to draw on a store of procedures to help treatment-seeking individuals on their recovery journey.

Contingency Management

CM is a behavior change technique that has been adopted for the treatment of substance use disorders, especially cocaine addiction.[20] Recent research suggests that it will be useful in treating methamphetamine use disorders.[21-23] CM is based on the finding that drugs of abuse (including methamphetamine) are powerful positive reinforcers. Addicts choose to seek and obtain these drug-based reinforcers to the exclusion of other vital behaviors (e.g., providing for children and family members, maintaining their own health, employment, etc.). CM arranges a situation in which an addict must choose between drug-based reinforcement and another type of salient reinforcement (e.g., a voucher with a monetary value delivered contingent upon verified abstinence). For example, a person in treatment for a methamphetamine use disorder who attended a scheduled clinic visit and provided a urine sample that showed no recent methamphetamine use would receive a voucher with a specified monetary value. This voucher could then be exchanged for a good or service that would help in supporting a drug-free lifestyle. Ideally, the voucher would be exchanged for something that would help the addict come into contact with readily available reinforcers in their environment. This could include things like spending quality time with their children, parents, or spouse (e.g., skiing, fishing, attending a movie, ice skating, etc.). The intent would be that the reinforcing aspects of the interaction would serve to compete with drug use.

Other types of CM have been explored, including those that deliver prizes for abstinence instead of vouchers,[24,25] take home doses of methadone,[26] employment opportunities,[27] housing,[28] and access to one's disability income.[29] Two recent meta analyses have concluded that CM is among the most effective drug abuse treatment strategies.[30,31] It is beyond the scope of this article to detail the procedures of CM interventions. An excellent resource for that purpose is Petry.[32] It is important to note that CM can be readily combined with other treatment approaches. Finally, while the forgoing focuses on positive reinforcement for abstinence, other types of CM (e.g., drug court models) often focus on punishment for failure to abstain.[33]

Experience with CM in the Treatment of Methamphetamine Use Disorders among AI/AN

Most AI/AN with addictions do not get to treatment centers very easily, and some may even die from their addictions. Those of us in the addiction fields try and learn the new methods to reach the difficult and resistant population. We implement the best avaiable therapies and programs, but we still experience a high rate of chemical abuse, resistance to change, and difficulty attracting and engaging clients in treatment. If we cannot attract clients into a program, treatment will not work. CM helps to attract and retain clients.

One way that CM has worked most dramatically within our communities is through the implementation of a tribal youth drug court system. With the help of the tribal court, we are able to utilize the leverage of the court to engage the client's participation, but our observation is that it has been the incentives and sanctions (e.g., CM) that have sustained engagement over time.

Our experience is that when CM is used within a treatment milieu, greater change occurs. What our counselors are discovering is that CM gets the client engaged. Even the most resistant clients want incentives, especially when they have little or no means of income. As we attract and retain clients, then we begin the real work of healing.

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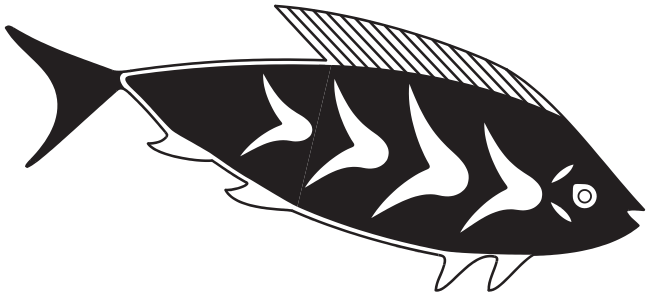

A Special Care Clinic for Substance Abuse During Pregnancy

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> "Pregnancy is a powerful motivator…when you find people receptive to treatment . . . If you are able to get away from it during your pregnancy, that can carry over to a time when you're not pregnant."
> —*Randy Stevens, MD, addiction researcher*

At the Phoenix Indian Medical Center (PIMC), we have found these words to be true. In 2003, the nurse-midwifery service and the behavioral health department at PIMC started a clinic for women with high risk psychosocial conditions, including substance abuse, homelessness, domestic violence, mental illness, adult fetal alcohol spectrum disorders, and other special conditions.

During its three years of operation, over 350 women have been served. Seventy percent of these women have had substance abuse conditions, most frequently marijuana and methamphetamine abuse. Although alcohol use in pregnancy can be more difficult to detect, some studies suggest that when other illicit drugs are used, concurrent alcohol use can be assumed. Thus, the earlier a woman can be identified, the better for her, her unborn child, and the health care system that she uses.

The key components of our program are:

- An obstetric provider
- A behavioral health provider
- A clinical setting for both providers
- Gifts and incentives

The obstetric provider (in our case usually a nurse-midwife) initially sees the patient. If a woman has been referred to this clinic because of substance abuse, this is discussed with her in a non-confronting way and she is invited to attend our "Special Care Clinic." She is made aware of the positive nature of this program, supporting her choice to learn to abstain from drugs. If she agrees, she signs a contract, agreeing to urine drug screens at each visit and counseling appointments. She receives a gift for herself and the baby at each visit, such as skin and hair care products, and baby clothing and care items. Routine prenatal care is provided, with special attention to screening for sexually transmitted diseases, including chlamydia, gonorrhea, syphilis, HIV, hepatitis B and C, and Pap testing.

Next she sees a behavioral health provider. This is done in the same clinic, with the prenatal provider introducing the patient to the behavioral health provider, and the work of counseling begins. This is truly the heart of this program. Our counselors are all Native American women who are dedicated to this program and the women it serves. They assess each woman and her circumstances, and assist her with the treatment and recovery process. Referrals to appropriate programs are made. For most women, prenatal and counseling services provided in the clinic are their primary source of support for their recovery program.

It is very important that the behavioral health services are readily accessible. In the past, women had to go across the PIMC campus to another building, sign in, and wait until a social worker was available. Often, patients did not go at all, fearing having to explain to clerical staff what they were there for. Being pregnant and admitting to substance abuse is a shameful thing for women, and the importance of providing discreet services and protecting the woman's privacy cannot be overstated.

Contingency Management

Contingency management programs are based on a simple behavioral principle that if a behavior is reinforced it is more likely to occur. It is well documented in the literature that incentives for abstinence from drugs are the preferential treatment modality for stimulant users. The Center for Substance Abuse Treatment (CSAT) has a very useful publication, "Treatment for Stimulant Use Disorders," which was used in the development of our program. It provides extremely useful guidelines, emphasizing the use of incentives or rewards to encourage abstinence from stimulant drugs. This publication can be obtained free of charge from the National Clearinghouse for Alcohol and Drug Information (*http://ncadi.samhsa.gov*).

In our program, whenever three negative drug screens are obtained, the woman is given a $15 gift card for a retail outlet, such as Wal-Mart, Target, or a food store. These are given in addition to her two gifts at each visit, one for herself and one for her baby. The emphasis on the baby helps to reinforce her bonding with it, and helps again to support her abstinence from drugs. All gifts and incentives are donated by a faith-

based organization, "Mother's Lifeline," which works to improve the lives of low-income women and children.

For heavy methamphetamine users, a residential program may be the treatment of choice. These women are identified physically by their skin pallor and sore, rotted teeth, persistent weight loss, and psychosocially by their resistance to treatment, many missed appointments, and denial of substance abuse or need for treatment.

For heroin-addicted women, we have combined outside, often court-mandated methadone programs with our special care clinic protocol to get positive results. Women on methadone then deliver, and the newborn is kept for 6 to 8 weeks to be gradually weaned from methadone.

Co-Occurring Mental Health and Addictive Disorders

The Methamphetamine Treatment Project (1999-2001), described in the *American Journal of Addictions*, looked at over 1,000 methamphetamine users and found high levels of coexistent psychiatric diseases, especially depression, anxiety, schizophrenia, anger, assaultive behavior, and past suicide attempts. It is important for health care givers to be aware that patients often use stimulant drugs to treat their psychiatric disease, and may need treatment for an underlying mental health disorder also. In our "Special Care Clinic," we frequently refer to mental health providers when psychiatric disease is suspected.

Drop in Deliveries With Positive Urine Drug Screens

Women who drop in without prenatal care and deliver may be positive for methamphetamines or other substances. These women can be very difficult to successfully treat for their addictions, since they often have no interaction with health care providers except for delivery. It is most important that they are seen by a behavioral health worker, encouraged to participate in treatment, and that all proper child protection referrals are made, as mandated by the state of residence. They should be encouraged to participate in a family planning method before they leave the hospital, and given future appointments to see their counselor. A case manager could be assigned to such patients to ensure that appointments are kept and to be used as a point of contact should desire for rehabilitation services occur. In our program, a nurse-midwife follows these patients and encourages contraception and recovery services.

A second "Special Care Clinic" in a small satellite facility has been operational for almost a year. They, too, have had many successful participants. We believe that this program works well in a large clinic or in a small one.

Summary

We began by forming a multidisciplinary team, doing a literature search, and developing guidelines using known treatment protocols. Our program was marketed to all departments of the hospital via e-mail, staff meetings, conferences, and posters. The behavioral health team taught us to use non-punitive, non-judgmental approaches to caring for pregnant, substance abusing women. We also learned to encourage the natural maternal instincts not to harm their unborn baby, by simple things like naming their babies, collecting clothing and blankets for them, by talking to their babies, and singing to them. We celebrate their successes with them whenever we can. As a team, we continue to meet regularly and discuss and improve our processes.

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The Chief Clinical Consultant's Newsletter (Volume 5, No. 4, April 2007) is available on the Internet at http://www.ihs.gov/MedicalPrograms/MCH/M/OBGYN01.cfm. *We wanted to make our readers aware of this resource, and encourage those who are interested to use it on a regular basis. You may also subscribe to a listserv to receive reminders about this service. If you have any questions, please contact Dr. Neil Murphy, Chief Clinical Consultant in Obstetrics and Gynecology, at* nmurphy@scf.cc**.**

OB/GYN Chief Clinical Consultant's Corner Digest

Abstract of the Month
Quadrivalent Human Papillomavirus Vaccine: Final ACIP Recommendations

Genital human papillomavirus (HPV) is the most common sexually transmitted infection in the United States, causing an estimated 6.2 million new infections every year. Persistent genital HPV infection can cause cervical cancer in women. In June 2006, the quadrivalent HPV vaccine types 6, 11, 16, and 18, under the trade name Gardasil™ (manufactured by Merck and Co.), was licensed for use among females aged 9 - 26 years for prevention of HPV type-related cervical cancer, cervical cancer precursors, vaginal and vulvar cancer precursors, and anogenital warts. This report presents recommendations by the Advisory Committee on Immunization Practices (ACIP) on the use of the HPV vaccine.

Recommendations for Routine Use and Catch-Up

Routine Vaccination of Females Aged 11 - 12 Years. ACIP recommends routine vaccination of females aged 11 - 12 years with three doses of quadrivalent HPV vaccine. The vaccination series can be started as young as age nine years.

Catch-Up Vaccination of Females Aged 13 - 26 Years. Vaccination also is recommended for females aged 13 - 26 years who have not been previously vaccinated or who have not completed the full series. Ideally, vaccine should be administered before potential exposure to HPV through sexual contact; however, females who might have already been exposed to HPV should be vaccinated. Sexually active females who have not been infected with any of the HPV vaccine types would receive full benefit from vaccination. Vaccination would provide less benefit to females if they have already been infected with one or more of the four vaccine HPV types. However, it is not possible for a clinician to assess the extent to which sexually active persons would benefit from vaccination, and the risk for HPV infection might continue as long as persons are sexually active. Pap testing and screening for HPV DNA or HPV antibody are not needed before vaccination at any age.

Dosage and Administration. The vaccine should be shaken well before administration. The dose of quadrivalent HPV vaccine is 0.5 mL, administered intramuscularly (IM), preferably in the deltoid muscle.

Recommended Schedule. Quadrivalent HPV vaccine is administered in a three-dose schedule. The second and third doses should be administered 2 and 6 months after the first dose.

Minimum Dosing Intervals and Management of Persons Who Were Incorrectly Vaccinated. The minimum interval between the first and second doses of vaccine is four weeks. The minimum recommended interval between the second and third doses of vaccine is 12 weeks. Inadequate doses of quadrivalent HPV vaccine or vaccine doses received after a shorter-than-recommended dosing interval should be readministered.

Interrupted Vaccine Schedules. If the quadrivalent HPV vaccine schedule is interrupted, the vaccine series does not need to be restarted. If the series is interrupted after the first dose, the second dose should be administered as soon as possible, and the second and third doses should be separated by an interval of at least 12 weeks. If only the third dose is delayed, it should be administered as soon as possible.

Simultaneous Administration with Other Vaccines. Although no data exist on administration of quadrivalent HPV vaccine with vaccines other than hepatitis B vaccine, quadrivalent HPV vaccine is not a live vaccine and has no components that adversely impact safety or efficacy of other vaccinations. Quadrivalent HPV vaccine can be administered at the same visit as other age appropriate vaccines, such as the Tdap and quadrivalent meningococcal conjugate (MCV4) vaccines. Administering all indicated vaccines together at a single visit increases the likelihood that adolescents and young adults will receive each of the vaccines on schedule. Each vaccine should be administered using a separate syringe at a different anatomic site.

Cervical Cancer Screening Among Vaccinated Females. Cervical cancer screening recommendations have not changed for females who receive HPV vaccine. HPV types in the vaccine are responsible for approximately 70% of cervical cancers; females who are vaccinated could subsequently be infected with a carcinogenic HPV type for which the quadrivalent vaccine does not provide protection. Furthermore, those who were sexually active before vaccination could have been infected with a vaccine type HPV before vaccination. Health-care providers administering quadrivalent HPV vaccine should educate women about the importance of cervical cancer screening.

Groups for Which Vaccine is Not Licensed. Quadrivalent HPV vaccine is not licensed for use among females aged < 9 years or those aged > 26 years. Studies are ongoing among females aged > 26 years. No studies are under way among children aged < 9 years.

Vaccination of Males. Quadrivalent HPV vaccine is not licensed for use among males. Although data on immunogenicity and safety are available for males aged 9 - 15 years, no data exist on efficacy in males at any age. Efficacy studies in males are under way.

Special Situations Among Females Aged 9 - 26 Years

Equivocal or Abnormal Pap Test or Known HPV Infection. Females who have an equivocal or abnormal Pap test could be infected with any of approximately 40 high-risk or low-risk genital HPV types. Such females are unlikely to be infected with all four HPV vaccine types, and they might not be infected with any HPV vaccine type. Vaccination would provide protection against infection with HPV vaccine types not already acquired. With increasing severity of Pap test findings, the likelihood of infection with HPV 16 or 18 increases and the benefit of vaccination would decrease. Women should be advised that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or cervical lesions.

Females who have a positive HC2 High-Risk test conducted in conjunction with a Pap test could have infection with any of 13 high-risk types. This assay does not identify specific HPV types, and testing for specific HPV types is not conducted routinely in clinical practice. Women with a positive HC2 High-Risk test might not have been infected with any of the four HPV vaccine types. Vaccination would provide protection against infection with HPV vaccine types not already acquired. However, women should be advised that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or cervical lesions.

Genital Warts. A history of genital warts or clinically evident genital warts indicates infection with HPV, most often type 6 or 11. However, these females might not have infection with both HPV 6 and 11 or infection with HPV 16 or 18. Vaccination would provide protection against infection with HPV vaccine types not already acquired. However, females should be advised that results from clinical trials do not indicate the vaccine will have any therapeutic effect on existing HPV infection or genital warts.

Lactating Women. Lactating women can receive HPV vaccine.

Immunocompromised Persons. Because quadrivalent HPV vaccine is a noninfectious vaccine, it can be administered to females who are immunosuppressed as a result of disease or medications. However, the immune response and vaccine efficacy might be less than that in persons who are immunocompetent.

Vaccination During Pregnancy. Quadrivalent HPV vaccine is not recommended for use in pregnancy. The vaccine has not been causally associated with adverse outcomes of pregnancy or adverse events in the developing fetus. However, data on vaccination during pregnancy are limited. Until additional information is available, initiation of the vaccine series should be delayed until after completion of the pregnancy. If a woman is found to be pregnant after initiating the vaccination series, the remainder of the three-dose regimen should be delayed until after completion of the pregnancy. If a vaccine dose has been administered during pregnancy, no intervention is needed. A vaccine in pregnancy registry has been established; patients and health care providers should report any exposure to quadrivalent HPV vaccine during pregnancy (telephone: 800-986-8999).

Precautions and Contraindications

Acute Illnesses. Quadrivalent HPV vaccine can be administered to persons with minor acute illnesses (e.g., diarrhea or mild upper respiratory tract infections with or without fever). Vaccination of persons with moderate or severe acute illnesses should be deferred until after the patient improves.

Hypersensitivity or Allergy to Vaccine Components. Quadrivalent HPV vaccine is contraindicated for persons with a history of immediate hypersensitivity to yeast or to any vaccine component. Data from passive surveillance in Vaccine Adverse Event Reporting System (VAERS) indicate that recombinent yeast derived vaccines pose a minimal risk for anaphylaxic reactions in persons with a history of allergic reactions to *Saccharomyces cerevisiae* (baker's yeast).

Preventing Syncope After Vaccination. Syncope (i.e., vasovagal or vasodepressor reaction) can occur after vaccination, most commonly among adolescents and young adults. Among reports to VAERS for any vaccine that were coded as syncope during 1990 - 2004, a total of 35% of these episodes were reported among persons aged 10 - 18 years. Through January 2007, the second most common report to VAERS following receipt of HPV vaccine was syncope. Vaccine providers should consider observing patients for 15 minutes after they receive HPV vaccine.

MMWR. March 12, 2007/56(Early Release);1-24.

Editorial comment

Amy Groom, Steve Holve, and Ros Singleton

Strategy for a Successful HPV Vaccine Rollout in Indian Country

The Advisory Committee on Immunization Practices (ACIP) recommends that the human papillomavirus (HPV) vaccine be routinely administered to females 11 - 12 years of age, with catch up vaccination for women 13 - 26 years. This vaccine is available at no charge through the Vaccines for Children program for all VFC-eligible women 9 - 18 years, per the VFC resolution.

The quadrivalent HPV vaccine is remarkably effective. In

studies, the vaccine was 100% effective in preventing carcinoma in situ (CIN) 2/3 from 16/18 which are associated with 70% of cervical cancer, but this success comes at a cost. In the private sector, the vaccine costs $120 per dose or $360/person for a complete series of three vaccinations. IHS and tribal sites that are eligible and order through the VA Pharmaceutical Prime Vendor (PPV) can get the vaccine at $84.17/dose.

While the quadrivalent HPV vaccine was placed on the CDC federal contract in October 2005, and is currently available through VFC in most states, some states have been delayed in the roll out of the vaccine or have had to restrict access to the vaccine to certain age groups due to limitations in VFC and state funds. Eventually coverage with HPV vaccine for all VFC eligible female patients 9 - 18 years of age should be available.

IHS recommends implementation of the full ACIP recommendation, targeting females 11 - 12 year olds with routine vaccination, and catch up vaccination for 13 - 18 or 13 - 26 year olds where possible. In states where HPV vaccine is not yet available for 11 - 18 year olds due to limits in supply and/or funding, IHS recommends the following:

1. Target girls 11 - 12 years old and 17 - 18 years old with HPV vaccine starting this summer and fall. This will capture older girls who will lose their VFC eligibility if we don't try to immunize them this year.
2. Ensure that each state has reliable numbers of the IHS female user population 9 - 18 years of age. This may assist states in lobbying the CDC for additional funds for HPV vaccine which should ultimately allow for full implementation of the ACIP recommendation for VFC-eligible patients seen by IHS and tribal facilities.
3. If a state is unable or unwilling to provide vaccine to at least the 11 - 12 year olds and 17 - 18 year olds, than consideration should be given for the agency to approach the CDC about increasing funding to ensure that AI/AN girls receive the HPV vaccine to which they are entitled by statute.

In order to vaccinate women 19 - 26 years old, the following strategies may help to offset the cost:

Medicaid. If Medicaid covers HPV vaccine for this age group in your state, contact your billing department to see how to bill for this vaccine. If you have a single fee for Medicaid visits, you may be able to schedule vaccinations with a billable provider (e.g., physician, nurse practitioner, physician assistant, or midwife; not a nurse only visit) which may allow clinics to recover the cost of this immunization. The Alaska Native Medical Center (ANMC) in Anchorage has come up with a method to bill Medicaid by writing a prescription for HPV vaccine so that it can be billed separate from the clinic visit.

Merck Vaccine Patient Assistance Program (PAP). The Merck PAP allows patients over age 19 years who meet certain income and insurance coverage criteria to obtain HPV vaccine for free. Sites purchase some vaccine up front, and for patients who are approved by the Merck program, the vaccine is replaced by Merck to the dispensing pharmacy on a quarterly basis. The applicant must apply from a facility that is not "wholly owned and operated by the government." Hence, all tribal and urban facilities would qualify, plus those IHS facilities that receive additional funding, other than federal funding, e.g., grants, contracts, private funding, etc. If you are in doubt whether your facility qualifies, please contact (800) 293-3881 toll free 8:00 am to 8:00 pm EST Monday - Friday. If your facility does not qualify, then the patient could apply from a different facility, e.g., private, or semi-governmental clinic. The application process is straightforward. Sites usually hear within the hour if the application is approved, although it can take up to four hours.

From Your Colleagues
Stephen W. Heath, Albuquerque
When Things Go Wrong: Responding to Adverse Events

A Consensus Statement of the Harvard Hospitals, Burlington, Massachusetts, Massachusetts Coalition for the Prevention of Medical Errors. This consensus paper of the Harvard-affiliated hospitals proposes full disclosure when adverse events or medical errors occur, including an apology to the patient. The paper represents the collaborative effort of a group of clinicians, risk managers, and patients participating from several Harvard teaching hospitals and the Risk Management Foundation.

OB/GYN CCC Editorial comment
Another reason to attend the Native Women's Health and MCH Conference

As the program is rather extensive, if you didn't have enough reasons already, Stephen Heath will present on the nuances of systematic error and its effect on Risk Management in Indian health. The Conference will be in Albuquerque, New Mexico, August 15 - 17, 2007. The theme of the meeting is "Improve the System: Improve the Outcome," so it will explore how we can all work together to raise the AI/AN health status to the highest possible level. The meeting is only held every three years, so you and a team from your facility should try your best to attend.

Breastfeeding
Suzan Murphy, PIMC
Inquiring families want to know: what about breastfeeding and . . .

Is it okay if the mom smokes or chews tobacco and breastfeeds? According to American Academy of Pediatrics, the benefit of breastfeeding outweighs the potential risk of tobacco metabolites in the mother's milk. The greater concern is that the baby not be exposed to second hand smoke.

Can a mom still breastfeed if she has pierced nipples? La Leche League reports that body piercing, including nipple

piercing has been a common practice throughout history. There have not been problems reported that are specifically associated with breastfeeding and pierced nipples. General recommendations include keeping the area clean and removing nipple jewelry before allowing the baby to breastfeed. Also, nipple piercing while breastfeeding is probably not feasible due to the three month or longer healing time required.

Can moms drink alcohol and breastfeed? Yes and maybe. Numerous professional sources including Thomas W. Hale, RPh, PhD, University of Texas (author of Medication and Mother's Milk), American College of Nurse-Midwives, and American Academy of Pediatrics agree that moderate and occasional consumption of alcohol is usually compatible with breastfeeding. Important considerations are:

- The baby's age. A newborn has an immature liver and will take longer to metabolize any of the alcohol that gets into the mom's milk.
- Moms body size. A larger mother can metabolize alcohol more quickly than a smaller mom.
- Amount of alcohol consumed. Most sources report that waiting two hours for every drink (12 oz beer, 5 oz wine, 1 standard drink, including 1 shot of spirits such as vodka, whiskey, rum, tequila, etc) or until the mother feels neurologically normal, is a reasonable waiting period.
- A helpful calculator for how long alcohol takes to be metabolized can be found online

Please note that moms do not need to pump to get rid of the alcohol. A mom's milk is a dynamic fluid, the milk and alcohol are not trapped. A mom's liver will metabolize the alcohol in the breastmilk like the alcohol in her blood stream.

What about caffeine? American College of Nurse-Midwives provides a well documented and succinct recommendation. Though dietary caffeine appears in breast milk, nursing mothers can safely consume small amounts of caffeine without passing on a significant amount to the baby. Higher caffeine amounts could potentially cause problems such as poor sleeping, nervousness, irritability, and poor feeding, so limiting your caffeine intake makes sense.

Caffeine tends to build up in babies' systems because their bodies cannot get rid of it very easily. Try using decaffeinated coffee and tea, and avoid colas and other carbonated drinks that have added caffeine. The American Academy of Pediatrics recommends that nursing women limit consumption to the caffeine equivalent of 1 to 3 cups of coffee per day.

If you have other asked/unasked questions (and answers) about breastfeeding, please send them to *suzan.murphy@ihs.gov* for the future articles.

Elder Care News

Guidelines for Palliative Care Services in the Indian Health: Now Online

The newly released Guidelines for Palliative Care Services in the Indian Health System provide guidance and common language around what constitutes a program of palliative care for our IHS, tribal, and urban Indian health programs, as well as a tool for implementation of services. The Guidelines were adapted from the work of the National Consensus Project for Quality Palliative Care (NCP) whose purpose is "to promote the implementation of Clinical Practice Guidelines that ensure care of consistent and high quality, and that guide the development and structure of new and existing palliative care services."

An interdisciplinary Indian health workgroup adapted the NCP guidelines to the Indian health setting, aiming for guidelines that were feasible within our system and still provided a high level of quality. This workgroup had the help of a large number of national experts in palliative care who reviewed the guidelines and provided valuable suggestions in their development. For questions or assistance in the development of palliative care services, contact Mary Jo Crissler, Tim Domer, or Bruce Finke (*Bruce.Finke@ihs.gov*).

Medical Mystery Tour

Prolonged second stage with an epidural

Let's review last month's case briefly. A primigravid at 41 3/7 weeks with a history of polycystic ovarian syndrome, a 41 lb. weight gain, a known female infant, and one abnormal result on a 3-hour glucose tolerance test had a prolonged second stage with epidural anesthesia. Exam had revealed an estimated fetal weight of "9 + lbs." Her temperature rose to 100.6 F and she was started on intravenous gentamicin and ampicillin. Stage I was desultory after misoprostol cervical ripening and required pitocin augmentation.

As Stage II neared four hours, the risks and benefits of vacuum assistance were discussed with the patient and it was agreed to proceed. The vacuum extractor was placed during three contractions. Subsequently, the fetal presenting part descended to +3/5 with the scalp visible without pushing. The fetal heart tones were reassuring throughout. The patient is noticeably beginning to tire and subjectively seems to be pushing less effectively.

What would you have done at that point?

- Allow the patient to push for 30 minutes more and re-evaluate
- Notify the OR team and discuss cesarean delivery
- Wait for the epidural to completely wear off
- Apply the vacuum for a second trial
- Add clindamycin
- Other

Let's take a 'time out' here. A valid argument could be made for virtually all the above choices. Assuming a reassuring fetal tracing, there is no magic to a certain numerical length of Stage II, especially if the patient did not have a strong sensation throughout and was allowed to 'labor down' with an epidural. If you choose that course be sure your documentation reflects that the patient was not actively pushing during that period. On the other hand, the delivery

provider should be aware that the patient has developed several risk factors that make a successful vaginal delivery fraught with potential difficulty.

The one exception would the choice to reapply the vacuum for a second trial. Before we explore that option though, perhaps we may want to re-explore the use of the vacuum the first time. This patient had several risk factors that predispose patients to a possible shoulder dystocia.

Risk factors for shoulder dystocia include the following:

- Fetal macrosomia
- Glucose intolerance
- Operative vaginal delivery
- History of shoulder dystocia
- Labor abnormalities
- Postterm pregnancy
- Male fetal gender
- Obesity and high weight gain
- Advanced maternal age
- Shoulder-pelvis disproportion

Shoulder dystocia is best defined as the need for additional obstetric maneuvers to effect delivery of the fetal shoulders at the time of vaginal delivery. It occurs in 0.2 to 3 percent of all births and represents an obstetric emergency. Shoulder dystocias can be anticipated only rarely, as many occur in the absence of identifiable risk factors. Therefore, all obstetric care providers must be prepared to recognize a shoulder dystocia immediately and proceed through an orderly sequence of steps to effect delivery in a timely manner and minimize risk to the mother and fetus. It should be noted, however, that permanent birth injury, and even fetal death, can result in cases of shoulder dystocia that are appropriately identified and managed. This patient has the majority of the above risk factors. Let us explore a two of the more salient aspects.

One abnormal glucose tolerance test result is often overlooked, but is associated with macrosomia. Women with one abnormal value on the oral GTT demonstrate fasting insulin concentrations and insulin resistance comparable to that of women with GDM, and they are more likely to deliver a macrosomic infant than women without GDM or women with GDM that is treated. The management of these patients is controversial. Some have recommended that they be treated the same as women who meet standard criteria for GDM; others have not considered further intervention or recommended repeating the oral GTT in four weeks. Studies have shown that treatment of women with one abnormal GTT value decreases the risk of a macrosomic infant and is cost-effective.

Operative vaginal delivery is a risk factor for shoulder dystocia. It is not known whether shoulder dystocia is a result of instrument-aided descent of the fetus or is the underlying reason the fetus has not descended naturally. In a classic study, the combination of macrosomia (defined as birth weight greater than 4000 g), prolonged second stage, and midpelvic operative delivery was associated with a 21 percent incidence of shoulder dystocia. By comparison, when only prolonged second stage and midpelvic operative delivery were present, the risk fell to 4.57 percent and was 0.16 percent in the absence of these risk factors. One review concluded that instrumental delivery was the intrapartum risk factor most associated with permanent brachial plexus injury.

While operative vaginal delivery is just one of many risk factors, it represents a 'sin of commission.' In many cases one never knows exactly what will/will not occur without prior intervention in a rare event like shoulder dystocia. On the other hand, if one has performed an operative vaginal delivery, then, right or wrong, all the subsequent events are viewed within the purview of that action. Hence, it becomes a post hoc assumption that the fetus was 'pulled' into the shoulder dystocia.

In this case, the vacuum extractor was re-applied for three more applications of traction which brought the presenting part to crowning shortly followed by the 'turtle sign.' Gentle traction, McRoberts, and nuchal cord release x 2 were performed without success. A procto-episotomy was performed without success, followed by the Woods screw maneuver without success. Attention was then paid to the posterior arm and delivery was accomplished after a total of 2 minutes on the perineum. The parturient was taken to the OR for a 4th degree laceration repair. The patient notes continued fecal incontinence at this writing.

The infant had good cord pH(s), but Apgars of 2/5. The infant was admitted to the special care nursery for one day after resuscitation in the labor suite due to hypotension and ventilation requirements. The infant weighted slightly more than 9 pounds and had a fractured clavicle. The infant was discharged in stable condition after one subsequent day in the step down unit. There were no neurologic deficits and the child has done well in well child care.

In retrospect, though shoulder dsytocia is a rare event and this one was managed quite well, I think there is an element of it being 'lucky rather than good.' Perhaps this represents a 'near miss,' if you will. In either case, I submit that if you have what is very likely a macrosomic infant with a prolonged labor, that you not perform operative vaginal delivery.

In addition, I strongly suggest that when you do attend a macrosomic delivery, that you encourage the fetus to 'deliver through.' In other words, once the fetus is in the final expulsive effort, that you continue the downward momentum until the anterior shoulder is visible, e.g., do not stop the downward progress to suction the oropharynx. In regard to operative vaginal delivery in this setting, it is perhaps best to remember the Latin phrase, *primum non nocere,* "first, do no harm."

Midwives Corner, Lisa Allee, CNM, Chinle

Being present: The spirituality of presence in midwifery care

Pembroke and Pembroke have written an article that is a "must read" for all of us who attend women in pregnancy, labor, and birth, and, actually, it is highly relevant in the

provision of any kind of health care. It is essential reading for the student who needs to learn the art and not just the technical science of what we do, and it will remind experienced providers of the human contact we must strive to achieve even on the busiest day. I highly recommend that you read the entire article (if you cannot get the full text through PubMed, please contact me and I will e-mail it to you) but here are a few highlights.

"Presence involves an offering of self (Scoppo, 2003). In being present to the other, one generously makes available one's personal resources. To be present as a midwife is to be open, available and receptive to the needs and preferences of the woman (Berg et al., 1996; Lundberg, 2004)."

"A caring presence involves creating an environment of trust and security." The authors present a discussion of spirituality, which is a clear reminder that our work is not about us and our egos — it is about being with the other.

"The spiritual person identifies making meaning out of one's existence on earth as a central human task. The journey into meaning usually involves self-transcendence. To be spiritual is to break through the confining and limiting grip of egoism. Egotistic persons are locked up inside themselves; they have little or no capacity to reach out to others and to the world around them. Overcoming selfish tendencies in order to help others is central in an authentic spirituality."

Next they present two concepts that make presence possible — responsibility and availability. The discussion of responsibility is based on Buber's work: "He is talking about 'responsiveness,' about the ability to respond to the other person and her needs and aspirations. For Buber, responsibility is a deep capacity to respond to the claims others make on us. It requires an acute awareness of the other through which she becomes present in her wholeness and uniqueness."

"In order to be genuinely responsive to a woman, it is necessary to include oneself in her inner world. That is, one must discover precisely what it is that she needs and values. Women ask to be sensitively listened to. Further, they ask that the midwife approach them with a respect for their uniqueness."

The authors discuss availability in terms of receptivity and being open and "porous" or permeable to the communication from others. They also discuss hospitality as pivotal and present a fascinating picture of midwife as host: "Hospitality plays a vitally important role in engaging on a personal, friendly level with women. We need to ask, however, whether or not it is appropriate to refer to a midwife as a host. Many would rather have it that the midwife is the invited guest (Leap, 2000; Kenedy, 2003). The primary actor in the birthing experience is the woman. She invites others to be with her as she gives birth. There is still a place, we contend, for the appellation 'host' in relation to the midwife's role. It is clearly wrong to refer to him or her as host of the birthing process. To speak of him or her as host in the context of the relationship he or she shares with the woman is, however, not only appropriate but also illuminating. It is illuminating because it reminds us that the midwife is called upon to mentally establish an open space that will be filled by the woman's needs and preferences. To be available to the woman involves listening to her and following her lead through the process of childbirth (Lundgren, 2004). Midwives need a certain 'incohesion' in order to be truly receptive. If they fill their internal spaces with their own commitments and preferences, there is no place for the woman to make contact."

Pembroke NF, Pembroke JJ. The spirituality of presence in midwifery care. *Midwifery*. 2007 Feb.

Navajo News Jean Howe, Chinle

New ACOG recommendations challenging for rural IHS sites — a plea for sharing strategies to meet national standards in the face of limited resources

One new challenge facing Navajo Area prenatal providers, and probably many others providing care to pregnant women at rural sites throughout IHS, is what to do about all the new options for prenatal genetic screening. ACOG recently issued a Practice Bulletin, Screening for Fetal Chromosomal Abnormalities, which reviews the tests currently available and acknowledges how confusing this area has become. You know you're in a difficult situation when ACOG includes a section entitled, "With so many Down syndrome screening tests available, how do I decide which tests to offer?"

Before one wades through the array of available tests, it seems important to acknowledge a couple of new guiding principles that we are being asked to incorporate into our practice:

1. It's not just about age any more. Although the risk of Down syndrome and other chromosome abnormalities increase with age for individual women, most Down syndrome babies are born to young women. It has become the standard of care to offer prenatal screening for chromosome abnormalities to all women as part of routine prenatal care.
2. It's not just about second trimester screening anymore. There are now well-established methods of first trimester screening. We need to figure out how to make these testing options available to our patients.

Other principles haven't changed at all. Our job as providers is to share information about screening options and offer non-directive counseling. It is still the woman's choice to decide what (if any) tests she would like to have done and her right to decline testing altogether. Some women seek information to consider termination of pregnancy, others to make special preparations before the birth of a baby with additional needs. Also, because of the distance to tertiary care facilities, some infants may benefit from prenatal diagnosis that allows planned deliveries in urban centers with additional resources.

There are several markers that can be used to calculate a

risk for Down syndrome. One relatively new test is the nuchal translucency measurement (NT), a measure of the thickness of the fluid collection at the back of the fetal neck in the first trimester. To be used for calculating Down syndrome risk, NT measurements must be performed by certified sonographers with special training and ongoing monitoring. Optimal NT measurements are obtained at 12 - 13 weeks although the test may be performed from 10 4/7 to 13 6/7 weeks. Not all patients sent for NT testing will be able to have images successfully obtained. Serum first trimester measurements include PAPP-A (pregnancy-associated plasma protein A) and total or free ? hCG. Second trimester serum markers include MSAFP (maternal serum alpha-fetoprotein), hCG, and unconjugated estriol, which are used in calculation of a "triple screen"; with the addition of inhibin A this becomes a "quad screen." The main focus of this testing has become the identification of Down syndrome, although some of these markers are also used in the identification of other conditions, including trisomy 18 and open neural tube defects.

The ACOG Practice Bulletin provides much detail about the different screening tests, their detection rates, and their false positive rates. One relevant comparison for any facility still doing second trimester triple screen testing is the improved detection of Down syndrome with the change to Quad screening (from < 70% to over 80%). ACOG answers the question about how to choose with several considerations, including the following: "...If nuchal translucency measurement is not available or cannot be obtained in an individual patient, a reasonable approach is to offer serum integrated screening [with a detection rate of 85 - 88%] to patients who present early and second-trimester screening to those who present later."

This still leaves a great deal of work to be done. A review of the tests available through our contracted laboratory provider fails to identify any test options that combine first and second trimester serum testing but do not also rely on NT measurements. And as NT measurements are only available at tertiary care facilities several hours away, this just isn't a realistic option for wholesale screening for our rural facility, especially given the narrow window of dates when testing can be done. So, for our site, and some other sites in Navajo, we've transitioned to Quad screening but haven't resolved the first trimester dilemma. If you work at a rural site and have successfully addressed this problem, we'd like to hear from you. Also, if anyone has found or created a culturally sensitive patient education brochure about prenatal genetic screening, please share!

OB/GYN CCC
Editorial comment
Let's begin a dialogue

I want to thank Jean Howe for bringing up this issue, as it is a major concern nationwide. Various suggestions have included that we adapt a serum screening strategy whereby we only refer the women who have abnormal results. Each Area would need to negotiate with their lab, or find a new lab, e.g., is the lab able to integrate the NTD results? The PAPP-A and free bHCG can be done at 10 - 13 wks if the patient comes early enough. If so, then perform the quad screen at 15 - 20 and integrate the results, or refer if there is an abnormal 1st trimester result. Patients who come later can get a quad screen, and refer those with abnormal results if they so wish.
Let us know how your Area has solved this emerging problem.

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Oklahoma Perspective Greggory Woitte – Hastings Indian Medical Center
Cesarean Delivery on Maternal Request

It was in June of last year when I last wrote about the NIH Consensus conference on Cesarean Delivery on Maternal Request (CDMR). Over the past year there have been several articles written on the subject, the most recent of which is published in the *New England Journal of Medicine* by Ecker and Frigoletto (referenced below).

Here at Hasting's Indian Medical Center, we are beginning to explore this issue through journal clubs and dialogue. We have had more patients recently requesting cesarean delivery over the past year. A review of the NIH Consensus conference points out that most of the evidence is weak or non-existent to support planned vaginal or cesarean delivery. Moderate quality evidence is available for only three outcome variables (postpartum hemorrhage, maternal length of stay, and neonatal respiratory morbidity). .

ACOG sent out a news release on May 9, 2006 after the NIH consensus conference. In it they point out that more research is needed and that CDMR is not recommended for women planning on having several children due to the risks of placenta previa and placenta accreta increasing with each cesarean delivery. In addition, Dr. Zinberg, Deputy Executive Vice President of ACOG states "ACOG continues to review all of the issues surrounding maternal-request cesarean, but at this time our position is that cesareans should be performed for medical reasons."

A number of the articles written have pointed out ACOG's position that a cesarean delivery on maternal request can be ethically justified at times. In ACOG's "Surgery and Patient Choice: The Ethics of Decision Making," ACOG states that "In the absence of significant data on the risks and benefits of cesarean delivery, the burden of proof should fall on those who are advocates for a change in policy in support of elective cesarean delivery (i.e., the replacement of a natural process with a major surgical procedure."

As many of the articles and editorials written over the past

year have pointed out, caution should be used when a patient requests a cesarean delivery. Moving slowly in the absence of good evidence is a prudent option. While support for a women's choice is without question of paramount importance, performing cesarean deliveries on maternal request may ultimately lead to a violation of the Hippocratic Oath to do no harm.

OB/GYN CCC
Editorial comment:
Looking for sanity in the ever increasing cesarean delivery rate

Ecker and Frigoletto state the key question centers on both the number needed to treat to avoid one adverse neonatal outcome and the level of risk that is currently considered acceptable. As practicing obstetricians, we find that the risk that women are now willing to assume in exchange for a measure of potential benefit, especially for the neonate, has changed: for many, the level of risk of an adverse outcome that was tolerated in the past to avoid cesarean delivery is no longer acceptable, and the threshold number needed to treat has thus been reset.

In the face of the resulting continued increase in cesarean deliveries, our obligation as providers is to educate patients about the trade-offs entailed in choosing a particular course or intervention and to ensure that their choices are congruent with their own philosophy, plans, and tolerance of risk. In areas in which there is still uncertainty, we must organize clinical trials that will produce the data we require for counseling patients. For the moment, however, few of the relevant factors seem likely to change, and the cesarean rate can be predicted to continue its climb.

The March 2006 National Institutes of Health (NIH) State-of-the-Science Conference report concluded that there was a need for research that explicitly compared outcomes of planned cesarean delivery with outcomes of planned vaginal delivery. Declercq et al examine six years of data from a population-based linked data system to create a refined measure identifying women with planned cesareans and planned vaginal births and comparing maternal outcomes and costs associated with these two options. They conclude 1) Planned cesarean increases complications and re-hospitalizations and 2) planned cesarean increases cost.

Declercq, et al document a small, but consistent growth in planned primary cesareans, but higher costs, longer hospital stays, and substantially greater risks of maternal re-hospitalization associated with these deliveries. The authors found that

- The rate of re-admission to a hospital (per 1,000) within 1 month of delivery for planned vaginal births was significantly lower than that for planned primary cesarean births (7.5 vs. 19.2). Adjusting for age, race or ethnicity, and parity, a woman who had a planned primary cesarean birth was 2.3 times as likely as a woman who had a planned vaginal birth to be re-admitted in the first month after the birth.
- The leading reason for re-admission associated with planned primary cesarean births in the first 30 days after birth was surgical wound complications. Postpartum infections were a major cause of re-admission for both groups, with the rate of re-admission for infection after planned primary cesarean births almost twice as high as that of infection after planned vaginal births.
- The average initial maternal (excluding infant) hospital costs in 2003 dollars for a planned primary cesarean birth were 76% higher than the average initial costs for a planned vaginal birth ($4,372 vs. $2,487).
- Women who had a planned primary cesarean birth averaged 4.3 days in their initial stay and 4.4 days in cases of re-admission, compared with 2.4 and 3.9 days, respectively, for those with a planned vaginal birth.
- Costs associated with a planned primary cesarean birth, compared with costs associated with a planned vaginal birth, were higher for both delivery (65%) and postpartum re-admission (11%).

Kennare R, et al just reported that after the first cesarean, the risks increase in the next pregnancy. Specifically, cesarean delivery is associated with increased risks for adverse obstetric and perinatal outcomes in the subsequent birth. However, some risks may be due to confounding factors related to the indication for the first cesarean.

Dr. Woitte reminds us to do no harm. Declercq et al and Kennare R, et al findings suggest that planned primary cesareans are not without immediate health consequences for mothers and financial implications for society. Clinicians should be aware of the increased risk for maternal re-hospitalization after cesarean deliveries to low-risk mothers when counseling women about their choices.

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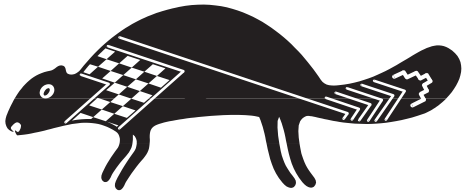

This is a page for sharing "what works" as seen in the published literature, as well as what is being done at sites that care for American Indian/Alaskan Native children. If you have any suggestions, comments, or questions, please contact Steve Holve, MD, Chief Clinical Consultant in Pediatrics at sholve@tcimc.ihs.gov.

IHS Child Health Notes

Quote of the month

"I find that a great part of the information I have was acquired by looking up something and finding something else along the way."

Franklin P. Adams

Articles of Interest

Infant deaths associated with Cough and Cold Medications – 2005. *MMWR*. 2007;56:1-4 *http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5601a1.htm*.

Cough and cold medications that contain decongestants, antihistamines, and cough suppressants are often used to relieve symptoms of upper respiratory infection in children < 2 years of age. During the 2004 - 2005 winter season, 1,519 children were treated in US emergency departments for adverse events relating to cough medications. In response, the CDC and the National Association of Medical Examiners investigated deaths in US infants < 12 months old associated with the use of cough medications. Three such infants were identified, in all of whom high levels of pseudoephedrine were found. None of the deaths were felt to be intentional, and none of the infants had underlying cardiac anomalies.

Editorial Comment

In children < 2 years of age, systematic reviews of controlled trials of over the counter cough medications have concluded that such medications are no more effective than placebo in reducing acute cough. The American Academy of Pediatrics issued a policy statement in 1996 advising that parents be informed of the lack of anti-tussive effect and the potential for adverse events of cough medication use in young children. In 2006 the American College of Chest Physicians released clinical practice guidelines suggesting that health care providers refrain from using cough suppressants and over-the-counter medications for young children because of associated morbidity and mortality.

Pseudoephedrine has been removed from many cough medications since 2006 because of the federal Combat Methamphetamine Epidemic Act. This may reduce the risk of adverse events, as pseudoephedrine was implicated in all three deaths reviewed from 2005.

In summary, cough medications should be avoided in children < 2 years of age. If used at all, caregivers need to be aware of the correct dosage and risk for adverse effects with these medications.

Infectious Disease Updates

Rosalyn Singleton, MD, MPH

Prevention of Childhood Pneumococcal Invasive Disease with Pneumococcal Conjugate Vaccine: Contrasting Experiences in Alaska Natives and Navajo/Apaches

With routine use of 7-valent pneumococcal conjugate vaccine (Prevnar®, PCV7), we have monitored invasive pneumococcal disease (IPD) in Alaska and Navajo/Apache children to look for the impact on prevention of disease from the seven serotypes in the vaccine (vaccine serotype disease) and for possible emergence of disease caused by serotypes not contained in PCV7, so-called replacement disease with non-vaccine serotypes. Before PCV7 introduction, vaccine serotypes accounted for 68% and 74% of IPD in Navajo and Alaska Native children <2 years old, respectively; thus we expected that overall IPD rates could only go down by this amount at most.

Since PCV7 was first used nine years ago among Navajo and Apache, and six years ago among Alaska Natives, vaccine serotype IPD has virtually disappeared among those less than 2 years of age. However there are significant differences in these populations with respect to non-vaccine type IPD. Among Navajo and Apache children, there has been no overall increase in the rate of non-vaccine serotype IPD through 2005. Some non-vaccine serotypes have become slightly more common and some have become less common, with no change overall. Alaska's experience with non-vaccine serotype disease was similar during the first three years after PCV7 introduction; however, in the past three years (i.e., 2004 - 2006), IPD of non-vaccine serotypes has emerged among the Alaska Native children less than 2 years of age and is now more common than it was prior to the introduction of PCV7. Since 2004, the IPD rate caused by nonvaccine serotypes (especially 19A) has increased 140% compared with the prevaccine period, while there has been a 96% decrease in PCV7 serotype disease. Compared with the pre-vaccine era, the rate of IPD from all pneumococcal serotypes among Navajo children < 5 years of age has gone down by 56% in 2001 - 2005, while the reduction in overall IPD in 2004 - 2006 for Alaska Native children < 2 years of age is 39%.

Whether replacement disease will start to erode the impact of PCV in populations other than Alaska is unclear. The good news is that expanded-valence vaccines (13-valent and 10-valent) are in clinical trials and should be licensed in the US by 2010. These vaccines include the most common serotypes (especially 19A) which are causing IPD. Although replacement disease is limiting the effect of PCV7 in Alaska, we should remember that hundreds of cases of IPD have been prevented. The pneumococcal experience has similarities to the Hib vaccine story. While the first Hib vaccine was licensed in 1985, it wasn't until 1990 that the current effective Hib vaccines were licensed, which have led to a 96% decline in Hib disease.

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Recent literature on American Indian/Alaskan Native Health

Doug Esposito, MD

Acosta D, Olsen P. Meeting the needs of regional minority groups: the University of Washington's programs to increase the American Indian and Alaskan Native physician workforce. *Acad Med*. 2006;81(10):863-70. *http://www.ncbi.nlm.nih.gov /entrez/query.fcgi?db=pubmed&cmd=Retrieve&dopt=AbstractPlus&list_uids=16985341&query_hl=1&itool=pubmed_DocSum*.

The authors describe a multifaceted program at the University of Washington School of Medicine (UWSOM) designed to increase the number of minority physicians in the US. This report specifically focuses on a description of the program and its successes with regard to Native Americans.

Currently, minority populations comprise slightly more than one quarter of the US population. By 2010, minorities are projected to represent 32% and by 2050, nearly 50% of the total population. However, only 12% of the students enrolled in allopathic medical programs in the US are minority and only 0.9% are AI/AN. This is important when considering the issue of health disparities since minority physicians are more likely than white physicians to work with underserved and under-represented minority populations, to practice in poor communities, and to accept patients covered by Medicaid. Additionally, minority patients report greater satisfaction when their physicians are of the same ethnic or racial background.

In an effort to rectify this problem, several institutions have developed pipeline programs. These programs are designed to boost the number of practicing minority physicians through increased recruitment into the profession. In addition to pipeline programs, the UWSOM has developed other programs that focus on enhanced retention of students through to graduation and on career development of minority faculty members. The authors describe the specific programs as they function at the UWSOM, their structure, their successes, and the issues going forward.

UWSOM serves a five state region, including Washington, Wyoming, Alaska, Montana, and Idaho (WWAMI). Approximately 24% of the AI/AN population in the US inhabits this region, representing 41 of the more than 550 federally recognized tribes. As such, the UWSOM considers itself to be well positioned to address AI/AN physician under-representation, both regionally and nationally.

In 1992, the Native American Center of Excellence (NACOE) was established. Together with the UWSOM, they have created several innovative and effective pipeline programs. Funded by HRSA, UDOC is a program that exposes high school juniors and seniors to college life and the health professions, and encourages applications from under-represented minority students. Since 1994, 99 AI/AN students have completed the UDOC program. In the Summer Medical and Dental Education Program (SMDEP), disadvantaged college students are enrolled in a six-week course designed to enhance their competitiveness in gaining entrance to dental or medical school. This program, funded through the Robert Wood Johnson Foundation, has enrolled 358 AI/AN students since 1989. During the period, 54% of these students applied to medical school and 61% were accepted.

The Prematriculation Program focuses on medical student retention through to graduation by helping successfully transition students into the rigors of medical school. Funded by HRSA, students are enrolled into an intensive six-week summer course that condenses the first quarter histology course into just five weeks. Also offered are courses in study skills, test taking, and stress and time management. Since 1986, 42 Native American students have been enrolled, 100% of whom passed the histology course, thereby reducing their course load during the first regular quarter of medical school. Several other programs, including a mentorship program and a program allowing students to expand their first or second years of medical school, have been developed that have had a positive impact on retention of AI/AN students and their rate of successful completion of their medical education.

The Indian Health Pathway (IHP) is an innovative curriculum that seeks to provide students with knowledge and experience that better prepare them to address the health care needs of AI/AN communities. Formal courses and preceptorships relevant to Indian health occur throughout the four-year medical education for students enrolled in the IHP. All UWSOM students are required to conduct a research project in order to graduate. However, IHP students must conduct a scholarly project investigating an issue in Indian

health. Since its inception in 1992, 39 Indian health research projects have been supported by the NACOE.

Finally, the UWSOM and the NACOE have created the NACOE Faculty Development Fellowship in an effort to address the tremendous under-representation of AI/AN faculty in medical education. In 1992, there were 114,087 total faculty members in US allopathic medical schools. Of these, 71.9% were white, 12.6% were Asian, and only 7.2% were Hispanic, black, AI/AN, or Native Hawaiian/other Pacific Islander. Only 117 (or 0.1%) of this total were AI/AN. Since the fellowship was created in 1993, five AI/AN faculty members have completed the program. Four of the five are currently medical school faculty members.

Here are a few other interesting statistics reported by the authors:

- One hundred and two of the 477 (21%) AI/AN students who participated in the UWSOM pipeline programs (UDOC and SMDEP) between 1989 and 2005 entered medical school.
- The UWSOM has graduated 50 AI/AN medical students between 1993 and 2005.
- Thirty-nine percent of the UWSOM medical school graduates chose primary care specialties, a statistic which is in accordance with the national statistic that minority students are 2 - 3 times more likely to choose primary care specialties than whites.
- Among 35 UWSOM AI/AN graduates in practice as of 2005, 20 work in the IHS, one works with a tribal program, one is in private practice, ten practice in urban community health centers, and three are in academic medicine.

Editorial Comment

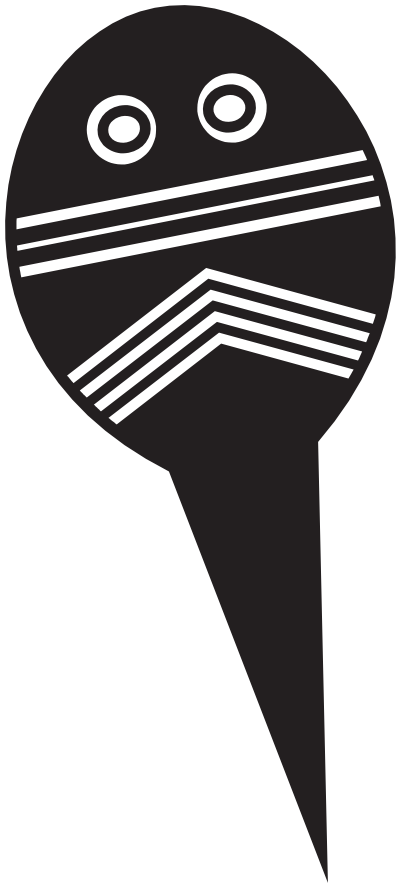
A diverse physician workforce is critical to the overall effectiveness and quality of the US health care system. The positive impact of having Native American medical providers working in Native communities is critically import and is borne out in the literature. Enhanced patient satisfaction, improved quality of care, and heightened cultural appropriateness of care occurs as the number of AI/AN physicians and other health care professionals practicing in Native communities rises. Unfortunately, the very survival of programs designed to expand the Native American health care workforce such as those described in the above report is in jeopardy. Significant funding issues loom on the horizon as health care costs continue to rise and competition for ever scarcer health care dollars intensifies. Typically, as financial pressures come to bear, programs that specifically benefit minority groups tend to experience the first and deepest cuts. It will be difficult to protect these valuable and necessary educational supports that are so critical to the fight for better health for our Native children and their families. Their loss will be tragic, indeed.

Announcements from the AAP Indian Health Special Interest Group

Sunnah Kim, MS

Locums Tenens and Job Opportunities

If you have a short or long term opportunity in an IHS, tribal or urban facility that you'd like for us to publicize (i.e., AAP website or complimentary ad on Ped Jobs, the official AAP on-line job board), please forward the information to *indianhealth@aap.org* or complete the on-line locum tenens form at *http://www.aap.org/nach/locumtenens.htm*.

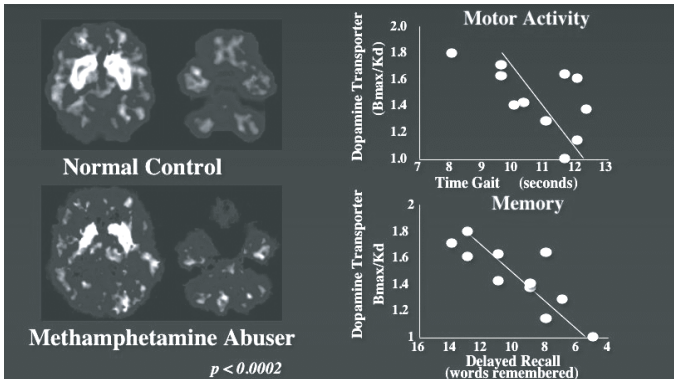


Emergent Stabilization of Methamphetamine Toxicity

Anthony Dekker, DO, Associate Director, Phoenix Indian Medical Center, and Chief Clinical Consultant, Addiction Medicine and Chronic Pain Management, Phoenix, Arizona

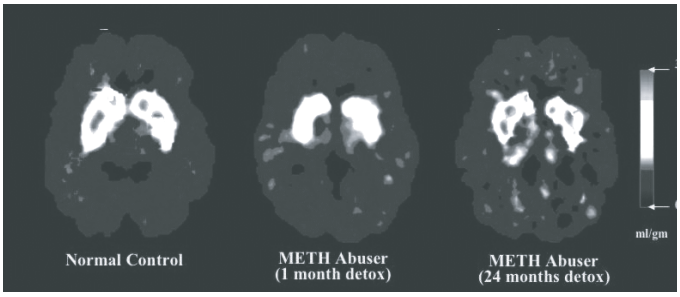
Methamphetamine toxicity is commonly seen in emergency rooms and primary care offices throughout Indian Country. Methamphetamine abuse rates have steadily increased over the past ten years.[1] Evaluation and treatment of methamphetamine toxicity requires skills in emergency and behavioral medicine, and pharmacotherapy. Methamphetamine is toxic to the brain. Damage to the nerve terminals in the dopamine- and serotonin-containing regions of the brain have been documented in animal models and are suspected in human models. Chronic methamphetamine abusers have significant abnormalities with decreased motor speed and impaired verbal learning. Studies have demonstrated increased psychiatric severity with methamphetamine abuse and deficits in the brain areas of emotion (e.g., depression and anxiety). Memory deficits are also associated with methamphetamine abuse[2] (see Figure 1).

Figure 1. Dopamine transporters in methamphetamine abusers



The loss of dopamine function in brain cells seems similar to disorders like Parkinson's disease, but the motor areas of methamphetamine abusers seem to be spared the damage seen on autopsy in Parkinson's patients. There is a suspicion that moderate methamphetamine induced effects in early life may predispose and individual for Parkinson's disease. Methamphetamine's effects in the cognitive areas, however, reveal damage that is as severe as the changes in chronic Parkinson's disease patients. Cellular death does not seem to be as common, and this may explain the recovery some methamphetamine abusers have experienced with sustained abstinence from methamphetamine[3] (see Figure 2). The evidence of brain recovery is not uniform, as there are areas of dopamine function demonstrated on neuroimaging that do not improve over two years of abstinence.

Figure 2. Partial recovery of brain dopamine transporters in methamphetamine abusers after protracted abstinence



Acute methamphetamine toxicity is exemplified with agitation, violence and psychosis.[4] Medical stabilization is needed and a concise, but comprehensive evaluation is warranted. An old mnemonic, the six B's, can help to evaluate an emergent patient.

Breathing	CPR and ACLS
Blood and Circulation	CV Evaluation, Trauma Assessment
Brain and Spinal Cord	Evaluation for Injury and Behavioral Health Impairment and Toxicity
Bowel And Bladder	Mouth to Anus and Evaluate for Urinary Retention
Bugs	Infectious Disease Evaluation
Bones	Evaluate for Fractures

Evaluation will be difficult as methamphetamine toxicity may decrease the sensation of pain from an injury or infection. After excluding medical reasons for acute agitation and psychosis, intervention will be necessary. A quiet, but secure and safe setting is necessary. The patient must be protected from items that could be used to harm themselves or others. Non-confrontational interviewing should be used. If the patient is paranoid and delusional or psychotic, stabilization with an antipsychotic may be necessary. Clinical history is difficult as the patient may not recall details or may be unable to cooperate. Patient safety may justify capture of information from other parties present with the patient. Adolescents and young adults often mix other drugs of abuse with methamphetamine. Alcohol in lower doses is a sedative, but toxicity occurs early and increased agitation may follow. Opioids in the form of heroin or prescription opioids are often mixed with methamphetamine toxicity. This may complicate the therapeutic options as opioid overdose should not be treated with benzodiazepines.

Urine toxicology screening is important. The immunoassay provided by most hospitals will detect amphetamines in addition to PCP, cannibinoids, cocaine, opioids (but not oxycodone, methadone, fentanyl or buprenorphine), benzodiazepines (but not lorazepam or clonazepam) and barbiturates. Confirmatory tests with Gas Chromatograph/Mass Spectrometry (GC/MS) will be needed in significant toxicities. There is significant cross reactivity of the immunoassays for amphetamines.

Efforts should be made to avoid physical restraints in the methamphetamine toxic patient. There will be times when physical restraints cannot be avoided, but close monitoring needs to be continuous as several untoward events are possible, including asphyxia.

Methamphetamine abusers may have several chronic and acute disorders secondary to the drug abuse and related behaviors. Many times addressing these issues will calm the patient and assist in cooperation. Skin lesions are common, caused by the hypersensitivity to puritus. Excoriated skin is the rule rather than the exception. If the patient has been injecting, cellulitis, abscess formation, and septicemia may be present. Dental lesions secondary to the direct effects on the enamel or poor hygiene are common. Anemia and cachexia may be present from anorexia and the increased metabolism.

Methamphetamine is a DEA approved Schedule II medication for weight loss. Because patients overexert themselves with methamphetamine toxicity, musculoskeletal injuries are often seen, including rhabdomyolysis. Cardiac dysrhythmias, ventricular hypertrophy, hypertension, and, on a long-term basis, renal damage may occur. High-risk behaviors associated with methamphetamine abuse seem to center on violence and sexual activities. Genital assessment in a psychotic patient is at best, difficult. Gonorrhea and chlamydia screens can be done with urine LCR. Viral hepatitis, syphilis and HIV are evaluated with sera.

Antipsychotic choices include oral and injected formulations. Patients who are able to cooperate and consent for oral medications have a better prognosis compared to those who refuse any pharmacologic intervention. None of the typical or atypical antipsychotics are indicated for methamphetamine psychosis. The following is opinion and is not supported by any controlled study. For patients who are able to consent and swallow tablets, quitiapine (Seroquel) 100mg, titrated from two to four tablets has been helpful in our patients. Some patients are more likely to take the newer mint flavored, rapidly dissolving tablets such as olanzapine (Zyprexa Zydis) 10 to 15 mg or respirdone (Risperdol M tabs) 2 to 4 mg. Patients who are uncooperative and a danger to themselves or others may require parenteral antipsychotics. The old standby, haloperidol, 10 to 20 mg IM will provide significant sedation, but if the patient is sent home without further treatment, recurrence is likely.

Injectable atypical antipsychotics include olanzapine (Zyprexa) and respirdone. Recently there have been reports of pharmacologic therapies for methamphetamine detoxification and withdrawal. The Prometa protocol is a branded intervention. There is not sufficient evidence in controlled trials to support this intervention over other non-pharmacologic interventions, such as the Matrix Protocol. Off-label use of amantadine and other dopamine agonists also lacks scientific evidence of efficacy. Many providers will not inject a patient unless consent is obtained.

In conclusion, more research is needed to establish evidence for treatment of acute methamphetamine intoxication. There also needs to be research in the areas of treatment of methamphetamine withdrawal.

Concurrent with the methamphetamine epidemic, there has been a rise in frustration that there are no FDA approved interventions for methamphetamine dependence. Seizing this opportunity, a publicly owned company, Hythiam, has promoted an intervention strategy called Prometa. Prometa was initially developed by Juan Josi Legarda, PhD in 1988 when it was one of the HANDS treatment protocols in Spain. Prometa incorporates the use of three medicines that were originally approved by the FDA for other disorders. These combinations are now used off-label in the treatment of alcohol, cocaine, and now, methamphetamine dependence. The antihistamine, hydroxyzine is combined with flumezanil, which diminishes the effects of benzodiazepines and the anticonvulsant gabapentin, and given intravenously daily for three days. The patients then participate in a 90 day therapeutic program. Several of the Hythiam-employed physicians report that the neuronal-chemical damage and imbalances caused by addictions are reversed with the treatment. The neurochemical activity of these medications is not understood, and science does not have any controlled trials to support the claims made by Hythiam. The treatment is expensive. Physicians are "licensed" by Hythiam to provide the treatment. Previously published information reveals licensees typically will charge $12,000 for the HANDS/Prometa Protocol for Alcohol and $15,000 for the HANDS/Prometa Protocol for Stimulants. Hythiam receives $6400 a treatment for alcohol and $7450 per treatment for stimulants. I would not recommend the Prometa protocol for treatment of methamphetamine dependence until controlled trials document benefit to the patient. More information is at *www.prometainfo.com/pi/about-dependence/index.jsp.*

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