HOUSE COMMITTEE ON PUBLIC HEALTH

TEXAS HOUSE OF REPRESENTATIVES

INTERIM REPORT 2004

A REPORT TO THE

HOUSE OF REPRESENTATIVES

79TH TEXAS LEGISLATURE

REPRESENTATIVE JODIE LAUBENBERG

CHAIRMAN

COMMITTEE CLERK

SUZANNE BOWERS

Committee On
Public Health

January 18, 2005

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Chairman

P.O. Box 2910
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The Honorable Tom Craddick
Speaker, Texas House of Representatives
Members of the Texas House of Representatives
Texas State Capitol, Rm. 2W.13
Austin, Texas 78701

Dear Mr. Speaker and Fellow Members:

The Committee on Public Health of the Seventy-Eighth Legislature hereby submits its interim report including recommendations and drafted legislation for consideration by the Seventy-Ninth Legislature.

Respectfully submitted,

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HOUSE COMMITTEE ON PUBLIC HEALTH

INTERIM STUDY CHARGES

Charge 1 Study the need to regulate products containing dietary supplement ephedra. Include a review of other state actions. No interim study was conducted on Charge #1 as it was addressed at the federal level (H.RES.435).

Charge 2 Examine the demographics and cost of diabetes in Texas. Assess the impact diabetes will have on Texas' population, budget, and health care system in the future and recommend appropriate policy changes.

Charge 3 Investigate the practice of allowing corneal tissue to be taken and used for transplantation without prior consent. Recommend appropriate state policy changes.

Charge 4 Collect, review and report on the statistics and statewide impact of drug and alcohol abuse by pregnant women on the unborn.

Charge 5 Review the current operations of the Texas Immunization and Kidney Health Care programs. The review should determine if the operational and administrative changes made to the Medicaid Vendor Drug Program will continue to meet the needs of Texans who do not qualify for Medicaid,

Children's Health Insurance Program, or private insurance and recommend any necessary changes.

Charge 6 Monitor the agencies and programs under the committee's jurisdiction.

CHARGE 2

Examine the demographics and cost of diabetes in Texas. Assess the impact diabetes will have on Texas' population, budget, and health care system in the future and recommend appropriate policy changes.

LEAD MEMBER

Representative Jodie Laubenberg

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INTRODUCTION

On August 11, 2004 the House Committee on Public Health held a public meeting to assess the future impact diabetes will have on the Texas population, budget, and healthcare system. Numerous healthcare professionals, as well as representatives from Texas Department of State Health Services and Health and Human Services, were invited to bring testimony on the seriousness of this disease.

BACKGROUND

There are three kinds of diabetes: Type I, Type II, and gestational diabetes. Type I is an autoimmune disease that accounts for 5-10% of all diabetes.[1] Type II is associated with poor diet, lack of exercise, aging, and obesity, as well as other factors and accounts for 90-95% of all diabetes.[2] Gestational diabetes is associated with pregnancy.

Type I diabetes is caused by the autoimmune destruction of pancreatic islets that produce insulin and can occur throughout life, but more frequently in childhood and adolescence. It is a condition of very low to undetectable insulin levels in the body that result in elevated blood glucose levels. Type II diabetes is caused by the development of resistance to the effects of insulin on metabolic pathways in the body (the metabolic syndrome). It is a condition where insulin concentrations in the body may be higher than normal, but blood glucose levels are still elevated because of resistance. The cause of insulin resistance is unknown but it worsens with increasing obesity and lack of exercise. While different in pathology, both Type I and II diabetes lead to the same complications including retinopathy (the leading cause of blindness), heart disease and stroke, loss of peripheral nerve function predisposing people with diabetes to lower extremity amputations, and end stage renal disease with dialysis. The focus of this report is on Type II diabetes and how to treat and prevent its progression through community involvement, education and management. However, the same information is also applicable to people with Type I diabetes.

The Demographics of Diabetes in Texas

Based on surveys by the Behavioral Risk Factor Surveillance System, an estimated seven percent of adult Texans have either Type I or Type II diabetes.[3] This percentage totals around an estimated 1.3 million individuals with diagnosed diabetes.[4] The Texas Department of State Health Services (TDSHS) estimates that an additional 3.3 percent may have diabetes that has yet to be diagnosed.[5] The Texas rate of diabetes is higher than the estimated national average of 4.8 percent.[6] Diabetes is the sixth leading cause of death in Texas and the fourth leading cause of death in both African Americans and Hispanics[7]. The contributory role of diabetes to other causes of death is more than three times as high as the number of direct fatalities.[8] This is especially significant where heart disease is concerned as heart disease is the leading cause of death in Texas.[9]

African Americans in Texas experience a disproportionately higher rate of diabetes (9.5 percent) compared with rates found in white and non-Hispanic whites (6 percent) or Hispanic (7.1 percent) populations.[10]

The Cost of Diabetes in Texas

The American Diabetes Association has estimated that nationally, direct and indirect expenditures for diabetes was approximately $132 billion. This estimate consists of $92 billion in direct medical costs and $40 billion in indirect costs.[11] The average cost per person per month for each person with diabetes is an estimated $1,000 both in direct healthcare costs and indirect costs.[12] This monthly cost amounts to approximately half a million dollars per person with diabetes over a lifetime.[13] Annual per capita health care

costs are estimated at $13,242 for individuals with diabetes and approximately $5,640 for individuals without diabetes.[14]

The direct and indirect costs of diabetes in Texas are estimated at $9.2 billion for 2002.[15] Using the national breakdown formula, 70% of this amount, or $6.4 billion, was spent on medical care, $2.8 billion was associated with lost productivity, and $5.6 million attributed to permanent disability.[16]

Texas spent $3.8 million on diabetes control in FY 2002 and $3.9 million in FY 2003.[17] The state budgeted approximately $2,895,000 million for diabetes control in FY 2004.[18] Funds are used to coordinate and implement programs to prevent diabetes and subsequent complications through four key functions: surveillance, health communications, health care systems support, and community interventions with one direct service support, the Diabetic Eye Disease Program.[19]

In FY 2003, there were 95,332 Medicaid clients with diabetes diagnosis.[20] CHIP clients with diabetes diagnosis numbered 2210.[21] Diabetes- related expenditures by Medicaid totaled $408.14 million in FY 2003.[22] For the CHIP program the expenditures totaled $8.87 million in FY 2003.[23] Cases of diabetes may actually be underreported because physicians may not always indicate on claims forms whether the treatment was administered for a diabetes-related condition.[24]

Hospital charges for Type II diabetes in Texas totaled $426 million in 2001 and rose to $500 million in 2002.[25] For Type I diabetes these amounts totaled $201 million and $221 million, respectively.[26] The majority (sixty percent) of the costs for hospitalizations for Type II are paid by Medicare.[27]

FINDINGS

1. The future impact of diabetes on Texas' population

The rate of diabetes in Texas continues to rise, up 2.2 percent from 1995 to 2002.[28] This increase is due in part to a continuing rise in Type II diabetes relating to greater childhood-onset in Texas.[29] Twenty years ago ten percent of Texas school children were considered overweight or obese. Today, an estimated 35% of children in Texas are overweight or obese.[30] In a single generation the number of overweight children has tripled.[31]

Type II diabetes used to be called "adult-onset diabetes" but now pediatricians report this diagnosis in children as young as age six.[32] This number is expected to grow. By 2025 Texas could have an estimated 47,000 children with either Type I or Type II diabetes.[33] These children could face the common complications of diabetes such as cardiovascular disease, kidney disease, neurological disease, blindness, and amputations of the lower extremities.[34]

Other demographical shifts in Texas are also likely to increase the prevalence of diabetes. The increasing population of aged individuals will contribute to the prevalence of diabetes.[35] Another indicator for increased prevalence of diabetes is the growing population of Latinos.[36] Currently, the Texas' population is 33% Latino but this number is projected to grow to 51% by 2040.[37] In Texas, Latinos as an ethnic group have the highest lifetime risk for diabetes of any ethnic group.

2. The future impact of diabetes on Texas' budget

The increasing cost of diabetes results from the increasing numbers of children with the disease. The current estimation of the 30,000 Texas children with diabetes could carry a tab of $15 billion dollars in healthcare costs.[38] Based on current projections, the estimated 47,000 Texas children with diabetes by 2025 could potentially carry a tab of $23.5 billion dollars.[39] Based on these projected estimates, Texas will not be able to afford the diabetes-related medical care or indirect costs from diabetes such as loss of a productive, competitive workforce if change does not occur.

3. The future impact of diabetes on Texas' healthcare system

Patients with diabetes need a variety of services to maintain their health and intervene in health crises. These services include physician services, inpatient services, outpatient services, laboratory and x-ray, and diabetic supplies. Additionally, those children with diabetes may require case management services. Thus, diabetics can be expected to access a broad range of healthcare services in Texas with greater frequency.

The impact of diabetes on the healthcare system will depend in part on coverage by Medicaid. This is a real concern as diabetes treatment continues to drain resources. This fact was highlighted by one study that estimated that $192 million of the Medicaid long term budget is directly attributable to diabetes.[40]

Recent legislative changes could help improve diabetes care as it relates to the healthcare system in Texas. HB 727 establishes disease management programs for certain Medicaid recipients.[41] The goals of the legislation include an increased focus on

preventative care, increased compliance with physician guidelines, potentially decreasing unnecessary hospital and outpatient services.[42] HB 1735 expands disease management in managed care to assist children who suffer from a chronic disease.[43] This legislation will also assist individuals who are both diagnosed and at-risk for the development of diabetes.[44] The focus for diagnosed clients will be on self-management techniques and compliance with the treatment plan of the physician.[45] The focus for at-risk clients will involve both education and targeting youth to identify diabetes precursors such as obesity.[46]

CONCLUSION

Diabetes is a slow and often silent destroyer of human life. In many cases, diagnosis is not detected until the disease is at a crisis level. Even with early warning signs, the patient may not fully understand the future impact of this disease, thus not always following the advice of medical experts.

Prevention and self-management are long term strategies for fighting diabetes. Lifestyle choices and behavioral changes are less costly, safe, and effective compared to the actual dollars spent on healthcare and the loss of quality of life associated with diabetes.[47] Additionally preventative measures can be taken to reduce diabetes in Texas and have the additional benefit of being good preventative measures for other costly, chronic conditions that threaten the lives of Texans and burden the healthcare system. HB 727 and HB 1735 are a good start. However, prevention requires the development of a network that will sustain itself and support long term change. A good investment in the healthcare of Texans today could help offset a catastrophe in the future.

POLICY OPTIONS

Policy Option 1:

Target children. School physical health programs are vital in the fight against obesity in children. Currently these programs are under the monitoring of the Texas Education Agency (TEA). TEA should continue to monitor the school districts to assure that they are actively pursuing the full intent of SB19.

Policy Option 2:

On-site diabetes care resource. The role of the school nurse, licensed vocational nurse, or other school staff or volunteer affiliated with the school's health program could be expanded to act as a facilitator of self-management and a resource for performing procedures and administering treatment.

Policy Option 3:

Physical education. Improving physical education (PE) is another means of targeting childhood obesity and Type II Diabetes. Currently children receive PE through only grade six. The time may either be spent watching other children or is structured in such a way that in one week only one PE class will actually occur. PE should be managed in a way that ensures that all participants actually receive the benefit of exercise during the class. Schools might also enlist the aid of private industry in rolling out such programs as "Step With It" and "Go Kids".

Policy Option 4:

Support lifestyle changes with education and community outreach. Education should be made available to all Texans regarding lifestyle changes regarding healthy eating and exercise. UTMB's Stark Diabetes Center has successfully implemented community partnerships in traditionally underserved areas with an eye towards meeting the individual needs of the community. The state should study the UTMB Stark Diabetes Center as a model for possible partnerships with existing community-based organizations. Potential partnerships could include senior citizen centers, Weight Watchers, schools, and worksites. Educators could include physicians, nurses, registered dietitians, and other members of the community.

Policy Option 5:

Make diabetes a reportable disease in Texas. The state needs a repository of information for reporting diabetes, including pediatric diabetes. This would result in better data that could perhaps assist academic institutions with obtaining federal grants to do research. This resource does not have to be built from scratch. The Bureau of Primary Health Care (BPHC), also known as the Health Disparities Collective (HCD), created a registry using the Patient Electronic System (PECS) which collects outcomes and information on up to eight chronic conditions. The registry can track individual progress of an entire population, as well as provide more accurate numbers of Texas' total diabetic population. This information is currently not available statewide, rather, it is only available to HCD partners. Cost and privacy concerns will have to be addressed.

Policy Option 6:

Reinstate podiatry services and ophthalmology services for adults who are enrolled in Medicaid as funds allow. This measure could prevent more costly and debilitating complications down the road, such as blindness and amputations.

ENDNOTES

(1) Paul Handel, M.D., Vice President, Medical Division, Blue Cross Blue Shield, Texas House Public Health Subcommittee Testimony, August 11, 2004

(2) Ibid

(3) Don Warren, Program Director, Statistical Research Section, Texas Legislative Council, Memorandum to the Honorable Jodie Laubenberg, House of Representatives, July 01, 2004 (Source: Texas Behavioral Risk Factor Surveillance, Centers for Disease Control), page 1

(4) Jan Ozias, PhD, R.N., Texas Diabetes Program, Texas Department of State Health Services, Texas House Public Health Subcommittee Testimony, August 11, 2004

(5) Ibid (Memorandum of Don Warren)

(6) Ibid

(7) Eduardo Sanchez, M.D., M.P.H., Commissioner, Texas Department of State Health Services, Texas House Public Health Subcommittee Testimony, August 11, 2004

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(10) Texas Department of Health, Diabetes in Texas: A Risk Factor Report 1999-2002 Survey Data, Publication No. 16-11164, August 2003, page 4

(11) Randall J. Urban, M.D., Director, Endocinology Fellowship Program, Chairman, Department of Internal Medicine, University of Texas Medical Branch at Galveston, Texas House Public Health Subcommittee Testimony, August 11, 2004

(12) Ibid (Testimony of Eduardo Sanchez)

(13) Ibid

(14) Ibid (Testimony of Jan Ozias)

(15) Ibid (Testimony of Randall Urban)

(16) Ibid

(17) Warren, page 2

(18) Ibid

(19) Texas Department of State Health Services

(20) Jason Cooke, State Medicaid and CHIP Director, Texas Health and Human Services Commission, *Presentation to the House Committee on Public Health,* February 18, 2004, page 3

(21) Ibid, page 3

(22) Ibid, page 5

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(24) Olga Garcia, Texas Health and Human Services Commission, Texas House Public Health Subcommittee Testimony, August 11, 2004

(25) Ibid (Testimony of Jan Ozias)

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(40) Ibid (Testimony of Jan Ozias)

(41) Cooke, page 11

(42) Ibid

(43) Cooke, page 13

(44) Cooke, page 12

(45) Ibid

(46) Ibid

CHARGE 3

Investigate the practice of allowing corneal tissue to be taken and used for transplantation without prior consent. Recommend appropriate state policy changes.

LEAD MEMBER

Representative Glenda Dawson

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INTRODUCTION

The committee held a public hearing to investigate the practice of allowing corneal tissue to be taken and used for transplantation without prior consent and recommend appropriate state policy changes on August 4, 2004. At the hearing, the committee heard invited testimony from the directors of the eye banks in Texas. The witnesses provided the committee with a general overview and history of the legislative consent law. The committee recognizes the assistance of the eye banks in Texas to collect data. Based on the testimony and research, the committee is able to appropriately recommend changes to current law.

BACKGROUND

Prior to 1977, there was a shortage of viable corneas available for transplantation to patients who were at or near legal blindness. In that year the 64th Texas Legislature passed House Bill 307, the "Gift of Sight" legislation filed by Representative John Bryant. The law did not require the medical examiner to ask whether or not a relative objected to the removal of corneal tissue. However, removal was only permitted if the medical examiner was not aware of an objection and, if the cause of death required an investigation by the medical examiner or justice of the peace, the removal could not interfere with an autopsy or alter the post-mortem facial appearance. Time is a critical factor to the effective recovery of corneal tissue. Corneas remain viable for six (6) hours after the time of death and recovered corneas must be transplanted within six (6) days from recovery. Additionally, thousands of corneas are destroyed each year during the course of routine forensic autopsies. Autopsies can destroy the tissue when the fluid in the back of the eye is withdrawn for serological and toxicology testing. However, because the cornea is so small (roughly three-eighths of an inch across), its removal causes essentially no disfigurement. Recognizing these facts, the Texas Legislature enacted the current cornea law, permitting medical examiners and justices of the peace to authorize cornea recovery prior to autopsy.

STATISTICS NATIONWIDE

The Eye Bank Association of America (EBAA) represents approximately 99 percent of the United State' eye banking community with a membership of 88 eye bank organizations. The EBAA reported 46,436 total numbers of corneal grafts nationwide last year. Of those, 14,196 (30%) were exported internationally. A small number of eye banks which export a large volume of tissue internationally do not identify the destination. Thus, "destination not specified" as a category trumps all others; 5,953 tissues exported to international destinations are in the unspecified category. 88.9% of donors are Caucasian and 63.3% are male throughout the nation. Nearly, the same number of corneas has been reported by U.S. banks for transplant over the last four years. The number of transplants performed in the U.S. over that period has seen a decline by almost 1,000 (32,144 in 2003 vs. 33,020 in 1999). Last year, there were 81,502 total corneas donated, a decrease from 83,408 reported in 2002. 20,991 corneal tissues were used for research and training down from 25,467 in 2002. Corneal defects (7,776 or 38.6%) and donor history (4,882 or 24.2%) were the leading reason tissue intended for surgery were not suitable for transplantation.

EYE BANKS IN TEXAS

There are seven (7) eye banks in the state of Texas. They are located in Dallas, Galveston, Houston, Lubbock, Austin/Manor, San Angelo, and San Antonio. These eye banks are members of the EBAA, which include over 80 eye banks nationwide.

The data below was provided voluntarily by the seven Texas eye banks to the EBAA. These statistics are annual numbers for 2003. (Note: "Exported corneas" refers only to corneas delivered from an eye bank serving a particular service area to an eye bank serving another service area.)

Total number of corneas recovered:	5,311
Total number of corneas useable for transplantation:	3,306
Total number of cornea transplants:	1,851
Total number of corneas exported for transplant:	1,455

There have been numerous lawsuits generated in Texas due to the tissue and eye banks procuring tissue without the expressed consent from the next-of-kin. There are currently two eye banks and medical examiner offices in Texas that allow removal without consent: the Lions Eye Bank of Central Texas in Austin and the Lions Eye Bank of Texas at Baylor College of Medicine in Houston, which is the ninth in the nation for corneas procured. The eye banks in Austin and Houston account for 3,046 (57%) of the 5,311 donations in Texas. Both eye banks estimate that 50% of their donations are recovered under the legislative consent law, also referred to as the medical examiner (ME) law. At times other eye banks in Texas request corneal tissue from Austin and/or Houston. Of the 1,455 corneas exported for transplant outside Texas eye banks' service areas, 843 are exported internationally. Corneal tissue is distributed by: 1) an eye bank's service area; 2) throughout the state; 3) regionally; 4) nationally; and 5) internationally. Emergency cases take precedence over this standard practice by eye banks.

OTHER STATES

The Eye Bank Association of America (EBAA) reported in 2000 that thirty-one (31) states, containing fifty-nine (59) eye banks, have medical examiner laws similar to Texas. Only six (6) of those eye banks in three (3) different states reported use of their state's medical examiner laws. It should also be noted that the EBAA no longer reports data on the medical examiner law. Recently, California repealed the legislative consent law and has not shown a decrease in the number of donations. In 2001, the California legislature passed a bill that requires the Department of Motor Vehicles (DMV) to coordinate with the Health and Human Services Agency to develop educational materials and a standardized form to be supplied by the DMV to create an organ and tissue registry. With 7,838 corneal donations, Florida has the highest number in the nation attributed to a state registry and the legislative consent law. Utah and Illinois are declared model leaders in organ and tissue transplants. Utah's Lion's Eye Bank attribute the increase in donor numbers (175 total donors in 2002 and 299 total donors in 2004) for their eye bank to full time educated staff, great support from the community partners, their OPO, Tissue Bank, Coalition and Independent Foundation, increase focus on research tissue and their Utah Donor Registry. Illinois is said to have commitment from the organ and tissue community and good training for DPS that makes their state registry a success. Illinois continues to increase donor awareness through the state's "Life Goes On" program, instituted in 1993. Illinois' organ donor education program has earned a national reputation, having created the largest state registry in the country, with nearly 5 million participants as of 2000. Each month, an additional 40,000 people sign up for the registry.

Illinois is also making minority awareness a particular focus. Other efforts include a statewide media campaign, outreach to senior citizens and teenagers, and a program to education donor awareness and education. The Illinois General Assembly also provides $2 million each year for donor awareness and education programs.

SAFETY & FDA

The EBAA sets the standards of practice for tissue procurement, preservation, storage, and transplantation through its medical advisory board and the association is endorsed by the American Academy of Ophthalmology. The United States Food and Drug Administration regulates the eye banks under 21 C.F.R. Part 1270. A major concern is whether corneas are tested adequately to ensure that no disease is transmitted to recipients of transplants.

The FDA states the major reason for making it a requirement that eye banks conduct a medical/social history for all donor tissue to be utilized for transplant is the increased risk of disease transmission via corneal transplant namely, Creutzfeldt-Jakob disease (CJD). CJD transmissions have been reported in the United Kingdom, where corneas and sclera from a donor subsequently determined to have CJD were transplanted into, and then removed from three recipients. It is a well-known fact that corneal tissue has a greater ability to transmit this disease, more so than other tissues recovered by tissue banks. However, if a serological screening test or an adequate screening exam is developed to detect this disease in blood drawn for corneal tissue donors, this disease would be

detected and the corneal tissue destroyed prior to distributing for transplant. This is how HIV, hepatitis B, and hepatitis C are currently detected and screened out.

In the past, US Food and Drug Administration (FDA) regulations contained an exception from the donor medical history interview for corneas procured under legislative consent. Under a proposed rule 1271.3(o), a "donor medical history interview" means a documented dialogue with the donor, if the donor is living. If the donor is not living or is unable to participate in the interview, the interview takes place with an individual who is knowledgeable about the donor's medical history and relevant social behavior, such as the donor's next of kin. The FDA recognizes that, when corneal tissue is procured without the consent of the donor's next of kin, a donor medical history interview with the donor's next of kin does not necessarily occur. However, the agency notes that the proposed definition of donor medical history interview would permit the interview to be conducted with an individual knowledgeable about the donor's medical history and relevant social behavior and would not require and interview with the next of kin. For that reason, FDA considers the proposed regulation and state legislative consent laws may coexist, and does not intend at the time to preempt those laws. While there is a possibility that there may be changes to this FDA rule, it is scheduled to take effect in May 2005.

EVALUATING POLICY OPTIONS

An ad hoc legislative workgroup composed of representatives from each Organ Procurement Organization (OPO), and six (6) of the seven (7) eye banks and others met on August 17, 2004 to address this charge. The eye banks in attendance indicated that

their organizations would support efforts to eliminate legislative consent. In order to ensure that the cornea supply is not interrupted, the workgroup further recommends that medical examiners and eye banks streamline communication in a timely manner in order to facilitate donation and contact information for next-of-kin, medical and social history of potential donor and medical examiner findings. The group also noted that specific training to organ and tissue donation should be included in the training required of Justices of the Peace and medical examiners to educate them if any changes were made to current law.

This workgroup discussed a donor registry and presumed consent as ways to increase donation participation in Texas. While Texas has attempted a state sponsored registry in the past, the problems confirmed by the health care community caused the donor registry to be abandoned in lieu of correcting the flaws in the old process. An "Opt In" registry should be adopted, but failure to be registered should be construed as an objection to being a donor. During the past donor registry, failure to register indicated you did not want to be a donor. This was not necessarily the case for a potential donor who was not registered as an affirmative donor in the registry. Another issue with the past registry is that some of the Department of Public Safety (DPS) clerks were uncomfortable talking with people about donations and were not trained to address organ donation. The database defaulted to "No" when a licensee did not designate either "Yes" or "No" and created problems with obtaining consent through the appearance that the individual had expressed opposition to being a donor.

Several methods of registration should be available such as registration via the internet, vehicle registration, driver education and mail. These methods would prevent the problems caused by the previous registry program and is believed to eliminate the need for human interaction and keep fiscal costs at a minimum. The workgroup also suggests an advisory committee composed of transplant professionals to oversee the registry and that the data should be owned by the state and not by an independent organization.

On the issue of presumed consent, Senate Task Force 862 unanimously recommended that a presumed consent approach should be attempted. The workgroup recommends that the state fund and conduct a state-wide survey to learn public attitudes and opinions toward donation and presumed consent.

CONCLUSION

Before the legislative consent law, patients had to wait six to 18 months before receiving a corneal transplant. Corneal Transplants have been performed since 1905, with a success rate above 90%. Eye banks charge fees for obtaining, storing and distributing corneas. The national average is $1,800 per corneal. Because of better cataract techniques, improved technology and improved treatment, corneal transplants are on a gradual decline even though there is a growing population. Currently, **there are no patient waiting lists and no national database for corneal transplants as there is for solid organs.** People that undergo LASIK or other refractive surgery are not suitable corneal donors. With the number of people undergoing such procedures growing, the number of possible donors is decreasing. In 2004, data will be collected by the Eye Bank Association of America on the number of corneas deemed not suitable due to refractive eye surgery.

Today, with the increase in available tissue, assured quality and safety, improved donor procurement procedures and corneal storage techniques as well as surgical techniques by doctors and advancements in technology, corneal transplantation is now an elected and scheduled procedure. The transplant community in Texas is united behind any legislative efforts that are proven to increase organ and tissue donation.

POLICY OPTIONS

Policy Option 1: Eliminate legislative consent for the removal of corneal tissue.

Policy Option 2: Include cornea transplantation under the Anatomical Gift Act.

Policy Option 3: Create a state sponsored registry for organ and tissue donation.

Policy Option 4: Create a first-person consent law that allows hospitals legal authority to proceed with organ procurement.

Policy Option 5: Improve education and public awareness for tissue/organ donation throughout the Texas health care community.

Policy Option 6: Streamline communication between medical examiners, hospitals and organ and tissue banks.

Policy Option 7: Require documentation and/or attempt to reach next-of-kin.

Policy Option 8: If changes occur in current statute, require donor awareness training for medical examiners and Justices of the Peace.

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CHARGE 4

Collect, review, and report on the statistics and statewide impact of drug and alcohol abuse by pregnant women on the unborn.

LEAD MEMBER

Representative Larry Taylor

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INTRODUCTION

The Subcommittee conducted one hearing on August 25, 2004 on the charge addressing drug and alcohol abuse by pregnant women. Witnesses from a variety of perspectives were invited to bring testimony on the issue. The hearing included testimony on the State's lack of data collection and the state-wide impact of the various problems surrounding drug and alcohol abuse by pregnant women. Witnesses agreed this tragic situation must be addressed. In addition, agency staff provided statistical information for the state, indicating a need for prenatal care education among mothers of all socio-economic backgrounds. The hearing also included an overview of prenatal and women's health concerns by several doctors, child advocates and legal professionals. Increased public awareness, improved prenatal care and law enforcement options were often mentioned with ideas varying on how to achieve the goals.

BACKGROUND

While both alcohol and drug abuse by pregnant women are grave problems with grim consequences, there seems to be more information concerning alcohol abuse and Fetal Alcohol Spectrum Disorder (FASD). The tragedies of FASD and babies born drug affected are completely preventable. Upon becoming pregnant women should immediately stop any activities potentially harmful to the fetus . However, the number of substance abusing pregnant women is growing.

According to Dr. Meganne Walsh, the number of women drinking during pregnancy has increased in recent years.

> Four times more pregnant women drank frequently in 1995 than in 1991…In 1999, 12.8% of pregnant women reported having had at least one drink during pregnancy, compared to 16.3% in 1995. But alarmingly, the rates of binge drinking (more than 5 drinks on one occasion) and frequent drinking (more than 7 drinks per week) did not decline and remained high…130,000 pregnant women consumed risky levels of alcohol in 1999.[1]

Also, there is no safe amount of alcohol a woman can ingest when pregnant, as the fetus receives the alcohol ingested by the mother through the placenta, Carolyn Smith said.

> Research shows that exposing a fetus to alcohol is more damaging than exposure to other illegal drugs, including cocaine. Alcohol destroys brain

[1] Dr. Meganne Walsh, Public Health Subcommittee Testimony, Texas March of Dimes, Aug.. 25, 2004, page 3

cells that can not be repaired. About 20% of pregnant women drink alcohol compared to about 1% who use cocaine. Individuals who present for treatment for illegal drug abuse, probably also use alcohol.[2]

Fetal Alcohol Spectrum Disorders are one possible consequence of alcohol consumption during pregnancy. These disorders are the leading cause of mental retardation in western civilization, including the United States, and are 100 percent preventable. FASD is also the major cause of numerous social disorders such as learning disabilities, school failure, juvenile delinquency, homelessness, unemployment and mental illness. Dr. Walsh testified that,

> FAS is characterized by stunted growth (before and after birth), facial abnormalities (small eyes, flattened cheeks, small jaw, etc.), and central nervous system defects that include mental retardation, hyperactivity, delayed development of gross motor skills (rolling over, sitting up, and crawling), delayed development of fine motor skills (finger coordination), impaired language development, memory problems, problems in learning, and seizures. According to the U.S. Department of Health and Human Services, FAS affects an estimated 1 out of every 1000 newborns and is the leading known cause of mental retardation. It is the only cause that is entirely preventable. At least 10 times the number of babies born with

[2] Carolyn Smith, Texas House Public Health Subcommittee Testimony, Texas Office for Prevention of Developmental Disabilities, Aug. 25, 2004, page 1

FAS are born with lesser degrees of alcohol-related damage. This condition is sometimes referred to as Fetal Alcohol Effect.[3]

Statistics

All witnesses concurred that in Texas there is not enough existing empirical statistical data relating to and examining the range of birth defects attributed to Fetal Alcohol Spectrum Disorder (FASD) and drug use by pregnant women. Texas does not maintain accurate, extensive short or long term records from which the true magnitude of the problem facing our state could be extrapolated. Many obstacles present themselves when collecting information on the effects of FASD and drug abuse by pregnant women.

Women do not readily admit alcohol and substance abuse to their prenatal specialist or OB/GYN. Therefore, many babies go on to suffer the damaging effects that could have easily been prevented. Tragically, many of the most severe cases of women abusing alcohol and drugs during pregnancy never receive any prenatal care and then arrive at the hospital only to give birth.[4] The subcommittee discussed many different options on how to begin collecting more data on the subject.

However, some data does exist, albeit sparse, at the state level and is still not extensive at the national level. Dr. Lisa Hollier of the University of Texas - Houston

[3] Walsh, page 2
[4] Smith, page 3

Medical School and LBJ Hospital testified that 3-5% of all pregnancies have birth defects.[5] She also added that

> During each prenatal visit, we ask our pregnant patients about substance abuse, including tobacco, alcohol and other drugs. While we do not have exact data regarding the prevalence of substance abuse in our population, it is approximately 5%. According to data from Texas birth certificates in 2002, 6.2 % of women in Texas smoked during their pregnancy. The national Survey on Drug Use and Health reported that approximately 3.3 % of pregnant woman between the ages of 15 and 44 reported using an illicit drug in the month before being interviewed.[6]

According to the Texas Office for the Prevention of Developmental Disabilities, women who give birth to one infant with FASD have an approximate 75% chance of having additional children with birth defects. Joe Vesowate with the Texas Commission on Alcohol and Drug Abuse (TCADA) testified that "According to the 2002 National Survey on Drug Use and Health, 9 percent of pregnant women reported drinking alcohol in the past month, 3 percent reported binge drinking and less than 1 percent reported heavy alcohol use in the month prior to the survey."[7] Mr. Vesowate also testified that TCADA calculated the economic cost of FASD in Texas to be $305 million.

[5] Dr. Lisa Hollier M.D., University of Texas - Houston Medical School and LBJ Hospital, Texas House Public Health Subcommittee Testimony, Aug. 25, 2004, page 3

[6] Hollier, page 1

[7] Joe Vesowate, Texas Commission on Alcohol and Drug Abuse, Texas House Public Health Subcommittee Testimony, Aug. 25, 2004, page 1

Many women in Texas are simply not aware of the potential implications of consuming alcohol during pregnancy. "The Texas Women's Health Survey, conducted by the Texas Department of Health in 2001, revealed that about one-half of Texas women of childbearing age may not be aware of the risks posed to the unborn child by maternal alcohol consumption during pregnancy."[8]

Legal

In several ways, the same problems that present themselves in the lack of statistical data present themselves in the legal arena. Just as there is little data with which to observe the situation, the law is equally silent when presenting possible ways of improving the lives of the pregnant women and the children impacted by negative behaviors.

Several witnesses referred to, if only in passing, legal solutions and options for curbing drug and alcohol abuse by women during pregnancy. Former Representative Patricia Gray and Associate District Judge Susanne Radcliff both testified on specifically the legal aspects of the interim charge, legal pitfalls and possible legislative solutions. Yet, many different issues must be considered before deciding on a public policy that could include a law enforcement and/or legal aspect. For instance, one must consider the current set of legal precedents put forth by Texas and Federal courts as well as the rights of the women in question.

In Texas, Senate Bill 319 passed during the regular legislative session of the 78th Legislature. It changed the definition of an "individual" in the Texas Civil Practices and

[8] Vesowate, page 1

Remedies Code and the Texas Penal Code. In response to the new definition and the law change, Rebecca King, District Attorney for the 47th district, which includes Potter, Randall and Armstrong counties, wrote a letter to all physicians in Potter county notifying them that "Based on the new laws, it is now a legal requirement for anyone to report a pregnant woman who is using or has used illegal narcotics during pregnancy."[9]

The house sponsor of SB 319, Representative Ray Allen, has requested an opinion from Texas Attorney General Greg Abbott regarding the correct interpretation of the law and its subsequent application. Rep. Allen cites language in the bill that specifically exempts from prosecution the actions of the mother while pregnant that cause harm or death to the fetus.

District Attorney King submitted a follow up letter clarifying her position August 23, 2004. In her letter she states,

> By creating a new legal entity the legislature did not 'amend' the Health and Safety Code, it merely extended the reach of § 481.122 in a reasonably foreseeable way. The legislature obviously was aware of how to limit the parameters of the new entity and it chose not to do so in relation to § 481.122. The legislature expressly limited the State from prosecuting a mother or physician for murder by enacting § 19.06 and re-defining the term 'individual' in the Kidnapping statute, e.g. Tex. Penal Code § 20.01(5). These provisions express a clear understanding by the

[9] Rebecca King, 47th District Attorney, Texas, Letter to Physicians in Potter County, September 22, 2003

legislature that new definition of 'individual' was to be broadly applied and that would act in the specific areas that they did not wish it to apply. Otherwise, the more prudent course would have been to simply re-define the term 'individual' only in chapters 19, 22 and 49 of the Penal Code in a manner similar to the way it did act in Chapter 20. No limiting language was added to Chapter 481 or other provisions of Texas law. Therefore, a fetus under current law must be able to enjoy all the rights, privileges and protections afforded any other legal entity under the laws of the State of Texas, unless the Legislature has expressly limited them.[10]

Still, contending that a fetus is an "individual" is not necessarily mandatory in order for the law to deem the actions of the mother illegal. However, if Texas Attorney General Greg Abbott, in response to Representative Ray Allen's request for an A.G.'s opinion, finds SB 319's definition of an "individual" applicable to all of Texas law then, according to District Attorney King, physicians in Texas will be required to report illegal drug use by expectant mothers to the proper authorities.

Involuntary Treatment for Pregnant Women

Involuntary treatment and intervention in situations of drug and/or alcohol are addressed by Texas Statute, which applies to use by anyone, including expectant mothers. If a person, by drug or alcohol use, creates a situation in which they could cause injury to

[10] Rebecca King, Texas 47th District Attorney, Letter to Texas Attorney General Greg Abbott, August 23, 2004, page 4

themselves or others they can be placed in treatment without the person's permission. Texas statute states:

> 462.062. APPLICATION FOR COURT-ORDERED TREATMENT.
>
> (a) A county or district attorney or other adult may file a sworn written application for court-ordered treatment of another person. Only the district or county attorney may file an application that is not accompanied by a certificate of medical examination for chemical dependency.
>
> … (2) a statement that the proposed patient is a chemically dependent person who:
>
> (A) is likely to cause serious harm to himself or others; or
>
> (B) will continue to suffer abnormal mental, emotional, or physical distress, will continue to deteriorate in ability to function independently if not treated, and is unable to make a rational and informed choice as to whether to submit to treatment;…[11]

If a county or district attorney felt that an expectant mother was a danger to herself, he or she could order treatment today. The outcome of the debate regarding the revised definition of an "individual" in SB 319 could then be in the Texas statute in question; if it is concluded that the new definition of an "individual" applies to all statutes, save where specifically exempted, the Texas legal system has the lawful ability to place an expectant mother in treatment for placing her unborn fetus in danger.

[11] Texas State Statute, Health and Safety Code 462.062

Other states have passed laws specifically imposing involuntary treatment on pregnant women. Both South Dakota and Wisconsin have laws on the books protecting the unborn fetus from the actions of the mother. South Dakota State Codified Laws Ann. Section 34-20A-63 reads:

> Emergency commitment--Grounds. An intoxicated person who:
>
> (1) Has threatened, attempted, or inflicted physical harm on himself or herself or on another or is likely to inflict physical harm on another unless committed; or
>
> (2) Is incapacitated by the effects of alcohol or drugs; or
>
> (3) Is pregnant and abusing alcohol or drugs;
>
> may be committed to an approved treatment facility for emergency treatment. A refusal to undergo treatment does not constitute evidence of lack of judgment as to the need for treatment.[12]

Wisconsin State Statue Section 48.01(1)(a) reads:

> (a) While recognizing that the paramount goal of this chapter is to protect children and unborn children, to preserve the unity of the family, whenever appropriate, by strengthening family life through assisting parents and the expectant mothers of unborn children, whenever appropriate, in fulfilling their responsibilities as parents or expectant mothers. The courts and agencies responsible for child welfare, while assuring that a child's health and safety are the paramount concerns, should assist parents and the expectant mothers of unborn children in

[12] South Dakota State Codified Laws Ann. Section 34-20A-63

changing any circumstances in the home which might harm the child or unborn child, which may require the child to be placed outside the home or which may require the expectant mother to be taken into custody. The courts should recognize that they have the authority, in appropriate cases, not to reunite a child with his or her family. The courts and agencies responsible for child welfare should also recognize that instability and impermanence in family relationships are contrary to the welfare of children and should therefore recognize the importance of eliminating the need for children to wait unreasonable periods of time for their parents to correct the conditions that prevent their safe return to the family.[13]

Involuntary Commitment and Drug Testing

Only one state has passed laws giving the state power to incarcerate an expectant mother. Minnesota did this by changing the definition of the term "chemically dependent person" to include pregnant women who habitually use specific controlled substances. Minnesota State Statue Section 253B.02(2) states:

> Chemically dependent person. "Chemically dependent person" means any person (a) determined as being incapable of self-management or management of personal affairs by reason of the habitual and excessive use of alcohol, drugs, or other mind-altering substances; and (b) whose recent conduct as a result of habitual and excessive use of alcohol, drugs, or other mind-altering substances poses a substantial likelihood of

[13] Wisconsin State Statue Section 48.01(1)(a)

> physical harm to self or others as demonstrated by (i) a recent attempt or threat to physically harm self or others, (ii) evidence of recent serious physical problems, or (iii) a failure to obtain necessary food, clothing, shelter, or medical care. "Chemically dependent person" also means a pregnant woman who has engaged during the pregnancy in habitual or excessive use, for a non-medical purpose, of any of the following controlled substances or their derivatives: cocaine, heroin, phencyclidine, methamphetamine, or amphetamine.[14]

Involuntary drug testing of women suspected of such abuse has been used in some states. However in her testimony, Ms. Gray advised against state mandated drug testing of pregnant women suspected of drug abuse. Her testimony included information on the public hospital in Charleston, South Carolina that used such measures.[15] In 1988, the hospital she spoke of began testing expectant mothers for cocaine without their knowledge. Those women testing positive were then referred for prosecution under the existing statutes for drug offenses and/or child abuse and neglect. Crystal Ferguson and other women subsequently filed suit, claiming violation of the Fourth Amendment's prohibition against warrantless and nonconsensual searches. While the hospital triumphed at the trial and initial appellate court levels, the Supreme Court ruled that "using the threat of criminal sanctions to deter pregnant women from using cocaine is a violation of

[14] Minnesota State Statute Section 253B.02(2)

[15] Patricia Gray, J.D., LL. M., Texas House Public Health Subcommittee Testimony, Aug. 25, 2004, page 3

the Fourth Amendment's prohibition against an official nonconsensual search that is not authorized by a valid warrant."[16]

The Court also examined the question of whether such testing might fall under the "special needs" exception serving certain non-law-enforcement ends. This exception is used to protect the public interest. However, the Court said that the exception did not apply in *Ferguson* because the information obtained from the involuntary, nonconsensual testing was given to the police, therefore not serving a non-law-enforcement purpose.

Ms. Gray also brought testimony concerning state prosecution of pregnant alcohol and drug abusers whose abuse directly causes stillbirth or other negative effects to the child.[17] Testifiers such as Ms. Gray and Dr. Walsh advised against prosecution fearing that pregnant women might avoid prenatal care because of the danger of prosecution for their substance abuse. She said while several women have been prosecuted for prenatal substance abuse, such a conviction has only been upheld once in a 2003 South Carolina case. [18]

Before this case, courts have traditionally rejected the criminal prosecution for several reasons. Courts have been unwilling to criminalize the act of a pregnant woman ingesting harmful substances because such an act cannot be assumed to be an intentional act to harm the child. Also, several states "have explicitly excepted prosecution of mothers in such circumstances in their feticide and child homicide statutes, suggesting

[16] *Ferguson v. City of Charleston*, 532 U.S. 69
[17] Gray, pages 9 - 12
[18] *McKnight v. South Carolina*, 124 S. Ct. 101 (2003)

that the issue is one which states have chosen to deal with in their health care systems."[19] Prosecution under statutory theories of drug delivery or possession of drugs has also been rejected by the courts. Reasons for that rejection include the fact that mothers may not receive fair warning from the statutes that prosecution could result if their newborns have controlled substances in their systems. Denial motives also involve the public health concerns of driving women away from treatment.

Concerning such situations in Texas, there are two reported cases involving the prosecution of substance abuse during pregnancy. In *Jackson v. State* 833 S. W. 2d 220 (1992), Tracy Jackson was convicted for possession of a controlled substance because she delivered a stillborn child who had traces of cocaine in his system. Her conviction was overturned because the Court said "this was insufficient evidence to establish that the defendant possessed cocaine within the meaning of the criminal statute."[20] In *Collins v. State of Texas* 890 S.W. 2d 893 (1884) the court convicted Tracy Collins of reckless injury to a child based on the fact that her child was born displaying cocaine withdrawal symptoms. Then, the Court overturned her conviction, ruling that the statute did not give fair warning to the defendant that she could be prosecuted for injury to her child if she did cocaine while pregnant.

[19] Gray, page 10
[20] Gray, page 11

CONCLUSION

Too many infants are brought into this world already at a disadvantage to not take actions to protect those severely and perhaps permanently handicapped by someone else's reckless choices. Substance abuse by pregnant women is one of the most preventable causes of developmental disabilities.[21] Other states have already begun exploring possible legal and legislative answers. Something can be done in Texas to impede the growth of this problem. While the issue is filled with controversy and presents a long and difficult path, there are already some policy options to help find the road to resolution.[22] Hesitation is not advised, as the longer it takes to formulate a proper legislative solution the greater and more widespread the harm experienced by innocent young lives.

[21] Vesowate, page 1

[22] Interim Report on the House Committee on Public Heath Subcommittee on Interim Charge #4, Policy Options, page 4

POLICY OPTIONS

Policy Option 1:

Expand the authority of Department of Family and Protective Services (DFPS) fatality review teams to specifically review stillbirths and deaths that may be attributed to substance abuse by the mother, and report on their findings to the legislature.

Policy Option 2:

Require DFPS to create a database of families in which substance abuse has been a factor in their referral to DFPS with the goal of facilitating early intervention for treatment.

Policy Option 3:

Assist state schools of public health in conducting a long term tracking study of children born exposed to drugs and/or alcohol in utero in order to help gain understanding of developmental and other problems these children may have and help develop treatment options to assist the children. The study should also specifically include children exposed to methamphetamine.

Policy Option 4:

Promote cooperation between the Department of State Health Services and the schools of public health in the state to develop model programs for identifying, tracking and treating pregnant substance abusers.

Policy Option 5:

Create treatment options that specifically focus on caring for pregnant substance abusers in a number of sufficient geographic locations in the state to allow for meaningful access to care.

Policy Option 6:

Clarify the provisions of the Texas Health & Safety Code to specify that pregnant substance abusers are specifically included in provisions related to emergency detention, protective custody and commitment to treatment.

Policy Option 7:

The Texas Department of State Health Services should enhance public awareness about the impact of substance abuse on the developing fetus, including the impact of male substance abuse. This public awareness campaign should specifically include high schools and college campuses.

Policy Option 8:

Enhance penalties against drug dealers who knowingly sell to pregnant women. Enhance penalties against bartenders who knowingly serve an intoxicated pregnant woman.

Policy Option 9:

The Legislature should engage the restaurant/bar industry in a plan to promote awareness of alcohol abuse on fetal development.

Policy Option 10:

The Texas Council on Alcohol and Drug Abuse (TCADA) should engage the medical community in developing protocols for treatment referral of pregnant substance abusers.

Policy Option 11:

If prosecution of pregnant substance abusers is developed as an option, engage the county and district attorneys association, the criminal defense lawyers association and representatives of the social service community to develop an educational program for prosecutors about appropriate use of such statutes.

CHARGE 5

Review the current operations of the Texas Immunization and Kidney Health Care programs. The review should determine if the operational and administrative changes made to the Medicaid Vendor Drug Program will continue to meet the needs of Texans who do not qualify for Medicaid, Children's Health Insurance Program, or private insurance and recommend any necessary changes.

LEAD MEMBER

Representative Vicki Truitt

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INTRODUCTION

Two public hearings were conducted to address interim charge #5, reviewing the current operations of the Texas Immunization and Kidney Health Care(KHC) programs. The witnesses testified to the status of the Immunization and Kidney Health Care programs and identified the recent modifications to these programs that were mandated by the 78th Legislature.

The first hearing conducted by the House Committee on Public Health, Subcommittee on Immunizations and Kidney Health took place June 16, 2004. At the hearing, the committee took invited testimony from Dr. Sharilyn Stanley and Phillip Walker from the Texas Department of State Health Services; Dr. Jane Rider from the Texas Medical Association; Olga Garcia, Lisa Carruth, Trey Berndt and Sharon Carter from the Health and Human Services Commission; and Dr. Glen Stanbaugh and Rita Littlefield from the Texas Renal Coalition. The committee also took public testimony from Sister Michele O'Brian from Christus Santa Rosa Healthcare and Laura Waters from DaVita, Inc.

The House Committee on Appropriations, Subcommittee on Health and Human Services, conducted the second hearing relating to this charge on June 28, 2004. At this hearing, the committee took invited testimony on Immunizations and Kidney Health Care programs from Phillip Walker, Dr. Nick Curry, Dr. Dave Wanser and Machelle Pharr from the Texas Department of State Health Services, as well as Cindy Mueller from the Texas Department of Transportation.

KIDNEY HEALTH CARE

BACKGROUND

The Texas Legislature established the Kidney Health Care Program (KHC) in 1973 to provide limited financial assistance for the care and treatment of persons suffering from endstage renal disease (ESRD)[1]. KHC provides medical, transportation and drug services to eligible clients.

In fiscal year 2003, the total budget for client services was $24,321,630. Of the total, the medical benefits which include access surgery and dialysis services for 785 recipients accounted for $1,855,839. The expenditure for transportation services to recipients for ESRD treatments accounted for $4,201,992 of the total client services spending. The KHC drug benefit program makes up the majority of spending for client services with $18,263,799 which is 75 percent of the total dollar amount allocated to these services.

The KHC Reimbursable Drug List (RDL) includes about 1,000 drug products that represent about 28 therapeutic drug categories. These categories include antihypertensives (for high blood pressure), analgesics, antacids, antiemetics, antihyperlipidemics (for high cholesterol), antibiotics, antivirals, immunosuppressants (anti-rejection drugs for transplant recipients). phosphate binders, hypoglycemic agents, vitamins, and mineral supplements.

In fiscal year 2003, more than 24,000 clients were enrolled in the KHC program. About 16,858 of those clients received a drug benefit. Of the 16,858 clients who received a drug benefit, 8,767 of these clients had only Medicare coverage and 5,854 had both Medicare and Medicaid. The remainder (about 2,237 clients) were ineligible for Medicare, or were transplant recipients whose Medicare coverage expired and who did not qualify for lifetime coverage of immunosuppressive drugs. KHC does not provide drug coverage for KHC clients with health insurance that covers prescription drugs unless they exhaust the drug coverage limits in their health insurance policy.

OPERATIONAL AND ADMINISTRATIVE CHANGES

During the 76th Legislative Session, H.B. 494 mandated the KHC program to consolidate their drug claims processing functions with the Medicaid Vendor Drug Program. Appropriations Rider 38 of the General Appropriations Act, 76th Legislative Session, also created a voluntary manufacturer rebate program for the KHC program.

The KHC program is funded from general revenue funds. Due to a shortfall in appropriations available to the state, the ability to maintain the same level of services for the program participants was not possible. The projected growth rate in caseload and increased demand for services has created estimated client service expenditures for Fiscal Year 2004 and 2005 to be $55.9 million. KHC was appropriated $38.7 million for the entire program which includes $33.9 million for client services for Fiscal year 2004 and 2005.

MEDICAID RECIPIENT DRUG COVERAGE

Due to a projected funding shortfall, the KHC program implemented certain cost containment measures. One cost containment measure was to discontinue KHC's coverage of one prescription per month for Medicaid recipients. It is estimated that with the elimination of this benefit forMedicaid clients, there will be a cost savings of $900,000 per year to the state. As a result of this cost containement measure, along with other measures taken, the number of projected total recipients to be served will be reduced in Fiscal Year 2004 from 25,666 to 19,316. Therefore, Medicaid recipients that relied on the KHC program to provide a supplemental prescription will no longer receive that prescription. The elimination of this benefit amounts to an average out-of-pocket cost of 12 dollars per month for those who no longer receive this benefit and is not anticipated to have a large impact on these Medicaid recipients.

KIDNEY HEALTH CARE PRESCRIPTION CO-PAY

The General Appropriations Act of the 78th Legislative Session mandated the implementation of KHC drug co-pay during the Fiscal Year 2005 and 2005 biennium. The implementation of a $6 co-pay for each prescription claim has an estimated savings to the state of $1.5 million. It has also been observed that recipients of prescription drug benefits who pay the $6 co-pay have become more conscientious about use of prescribed drugs, have taken the medications in a more timely manner, and have ensured that it is consumed thoroughly. [2]

VOLUNTARY MANUFACTURER'S DRUG REBATE

KHC participates in a voluntary manufacturer's drug rebate program with drug manufacturers to provide rebates on specific prescriptions used for the program. Historically, the rebate funds have been used by the KHC program to supplement program funding that is not covered by the general revenue appropriations. For Fiscal Year 2004 and 2005 it was estimated that $6.4 million of Kidney Health Care funding would be acquired through the drug rebates.

In addition to the discontinuation of Renagel coverage in December of 2003. The implementation of the cost containment measure mentiond above is estimated to reduce KHC funds from the rebate revenue from 6.4 million to 5.1 million for the biennium.

The implementation of the cost containment measure mentioned above to eliminate the drug benefit for those who receive Medicaid for the 2004 and 2005 biennium will have a negative impact on KHC funding. The funds lost through the elimination of the rebates associated with these clients has lowered the amount available from $6.4 million to $5.2 million for the biennium.

The implementation of the Medicare Part D drug benefit that will go into effect in 2006 is estimated to cover the prescription needs of 80 percent of Kidney Health Care participants. Medicare Part D will shift cost of drug coverage for eligible KHC clients.[3] Therefore, although the program will still receive funds from general revenue

appropriations, they will lose much of this supplemental funding source that will limit the programs ability to maintain current service levels.

Medicare Discount Card Program

In June of 2004, a new Medicare discount drug card program became available. This new program offers eligible Medicare beneficiaries the opportunity to enroll in a single discount card program offering discounted prices on selected drugs. Low-income beneficiaries who enroll in a card program may also be eligible for a subsidy of $600 (for the remainder of 2004, and again during calendar year 2005) to be used toward the purchase of prescription drugs.

There have been some start up difficulties with the interim Medicare discount drug card program, especially with the complexities involved with the enrollment process for seniors and the many different discount card programs from which to choose.

Medicare Part D

In January 2006, the new Medicare Part D prescription drug benefit will replace the Medicare discount drug card program. It is anticipated that a significant portion of KHC clients will be eligible for the new Medicare Part D drug benefit. Although this benefit will be available to all Medicare beneficiaries, it has significant cost sharing, and gaps in coverage that may be particularly problematic for clients suffering from end stage renal disease. Many low-income Medicare beneficiaries will be protected from high cost

sharing and coverage gaps, but Medicare beneficiaries ineligible for these subsidies will face substantial out-of-pocket costs.

In 2006, "standard coverage" will have a $250 deductible, 25 percent coinsurance for costs between $250 and $2,250 in drug expenses, and catastrophic coverage after out-of-pocket expenses of $3,600. After the beneficiary reaches the catastrophic limit, the Medicare drug benefit program will pay all costs except for nominal cost sharing. Low-income subsidies will be available for persons with incomes below 150 percent of the federal poverty level.

TRANSPORTATION SERVICE

KHC transportation service reimburses patient for allowable travel for end stage renal disease related treatment. Travel benefits are limited to an estimated reimbursement rate of 13 cents a mile, round trip mileage on record, and a monthly maximum. As a result of H.B. 2292, all TDSHS transportation services were transferred to the Texas Department of Transportation(TxDOT). KHC is continuing to process travel claims for this benefit under a HHSC Interagency Agreement with TxDOT. For Fiscal Years 2004 and 2005, the KHC program received approximately $9 million from the State Highway Fund to provide funding for transportation of KHC recipients.

IMMUNIZATIONS

BACKGROUND

Immunizations have been hailed as one of the most important achievements in modern society. Vaccines save millions of lives each year in the United States alone and have significantly lowered healthcare costs related to the diseases that the vaccines defend against. Therefore, "Vaccines are one of the greatest achievements of biomedical science and public health".[5] In order to identify the importance of vaccinations for disease prevention in our society today, one must look at disease outbreaks that occurred in the twentieth century and the reduction of such outbreaks with the increased utilization of vaccines in Texas and the United States. The twentieth century annual morbidity for diseases that include diphtheria, measles, mumps, pertussis, polio, rubella, congenital rubella syndrome, tetanus and H. influenzae amounted to over a million reported cases. During 2003, the morbidity decreased 1,000 fold, from 1,044,845 average annual morbidity during the twentieth century to 8,957 average annual morbidity for 2003.[6,7,8] The improvement in disease prevention is due to the understanding that immunizations are the best way to prevent the spread of communicable diseases.

Vaccines have proven to be one of the most cost effective and safe developments in public health. The benefit-cost ratio for the use of common childhood vaccines is a testament to the benefits that vaccines produce for society. For every dollar spent on DTaP (diphtheria, tetanus, and pertussis) alone, $27 is saved in indirect and direct costs.[9]

Children who are un-immunized are not only placed at risk but also place a higher risk of disease infection on the children and adults with whom they come into contact. Therefore, when immunization rates go down, the potential for serious disease outbreaks greatly increase. During 1989, measles broke out with 18,193 cases reported, and there were 41 deaths in the United States. During 1990, the epidemic spread to 27,786 cases reported and 64 deaths.[10] Eighty percent of the cases that occurred during 1989 and 1990 among children 16 months of age to five years of age could have been prevented by timely vaccinations. The threat of vaccine preventable diseases has prompted continuous efforts to improve immunization rates in the United States.

During 2000, Texas ranked 50th in the nation for state vaccine coverage of 19-35 month-old children. During 2002, Texas had improved to 45th in the nation with an immunization rate of 71.3 percent in comparison to the national average of 78.5 percent. [11] The statistical comparisons above pertain to the vaccination series 4:3:1 which is four doses of diphtheria-tetanus-acellular pertussis (DTaP) vaccine, three doses of polio vaccine, and one dose of a measles-containing vaccine.[12,13] Immunizations rates in 2003 for 19-35 month-old children hit a record high of 78.1 percent of Texas children who were fully vaccinated against five diseases in 2003.[14] The national average increased from 78.5 percent to 82.2 percent. This improvement can be attributed to many different factors, yet a major factor is legislation passed in 2003 that improved immunization rates in the state.

LEGISLATION PASSED TO IMPROVE IMMUNIZATION RATES IN TEXAS

In 2003 the 78th Texas Legislature adopted H.B. 1920, H.B. 1921, H.B. 2292(Sections 2.160-164), S.B. 42, S.B. 43 and S.B. 486 that have a significant impact on immunizations. Major components of this legislation include:

- Establish a continuous, statewide education program for parents and physicians.
- Establish methods to streamline enrollment and reporting for the Texas Vaccines for Children program.
- Establish methods to increase participation in the immunization registry (ImmTrac).
- Establish methods to increase the utility of immunization registry (ImmTrac) data.

ESTABLISH A CONTINUOUS, STATEWIDE EDUCATION PROGRAM FOR PARENTS AND PHYSICIANS

As directed by legislation passed during the 78th Legislature, TDH began to collaborate with public and private local, regional and statewide entities with an interest in immunizations. The purpose of this is to form a workgroup of stakeholders to support statewide efforts to improve immunization rates and develop continuing education materials.[15] In the fall of 2003, TDH initiated a statewide multimedia advertising campaign aimed at educating parents about the value of fully vaccinating children against preventable and sometimes life-threatening illnesses by promoting the message, "Vaccines. Build your child's health." Also, beginning in August 2004, TDH launched an enhanced media campaign to reach African American communities in Houston and

Dallas to encourage parents of children two years old and younger to get their children immunized.

It is evident that these efforts to educate Texans about the importance of vaccines are vital steps to continuously improving Texas immunization rates. In the effort to educate Texans about the importance of vaccines, it should also be noted that Respiratory Syncytial Virus (RSV) is the most common cause of serious respiratory infection in infants and young children, [16] and is the number one cause of hospitalization of children under one year of age. [17] Educating Texans about the prevention of RSV and the importance of appropriate prophylaxis should also be included in education materials whenever possible.

IMPROVE EDUCATION RELATING TO THE DANGER OF PERTUSSIS INFECTION

The improvement of Texas immunization rates in 2003 can be partially attributed to the increased awareness of the need for immunizations by parents and providers. The enhancement of immunization rates in Texas is the beginning of a continuous campaign strategy to improve the level of coordination between the TDSHS and external partners and stakeholders. In order to continuously improve immunization rates in Texas, it is vital to identify areas in which we can improve education to better inform Texas parents of the dangers related to disease. The vaccine preventable disease pertussis (commonly known as whooping cough) accounted for 670 of the 689 total cases of vaccine preventable diseases infections in Texas during 2003. In the past five years alone, 20 Texas infants have died from pertussis infection. The vaccine protection dissipates in

time; thus, teenagers and adults become infected with the disease. Since the immune system is much more resilient at older ages, those who contract the disease do not have the identifiable whooping sound in their cough, and therefore, do not realize the seriousness of the infection. The infected adult then comes into contact with infants whose bodies' cannot defend against the infection. The goal of the enhanced education campaign should emphasize the danger of pertussis infection and inform new parents to keep all coughing individuals away from newborn children.

ESTABLISH METHODS TO STREAMLINE ENROLLMENT AND REPORTING FOR THE TEXAS VACCINES FOR CHILDREN PROGRAM

Methods have been identified to improve enrollment and reporting for the Texas Vaccines for Children program(TVFC). TDH, now TDSHS has been directed to work with the Texas Health and Human Services Commission to ensure that providers can enroll in TVFC on the same form when applying to become a Medicaid provider. Reporting methods have been improved and simplified, and a process is being put into place to allow providers to report vaccines administered under TVFC program to ImmTrac.[18]

ESTABLISH METHODS TO INCREASE PARTICIPATION IN THE IMMUNIZATION REGISTRY (IMMTRAC)

Due to legislation passed in the 78th legislature, beginning January 1, 2005, all providers and payors will be required to report to ImmTrac all vaccines administered to children. Providers authorized to use ImmTrac can see what immunizations their child has already

had, even if they were given in another city or county. So when a child comes in for shots, that child gets only those that he or she needs. By using ImmTrac, immunization providers can also remind parents to bring their child in for shots that are due, or notify parents about shots that are overdue. Thus, the ImmTrac registry will help improve immunization reporting techniques. Physicians are no longer responsible for obtaining and verifying permission to report immunizations into the registry, now it is done by signatures on birth certificates or written communication between parents and TDSHS. This use of the ImmTrac registry will result in a more complete and accurate database for Texas immunizations. It will also allow better access to records, decrease duplicative reporting, and enable the state to plan and better develop its immunization strategy by enhancing utilization of the registry.[19]

ESTABLISH METHODS TO INCREASE THE UTILITY OF IMMTRAC DATA

Legislation passed during the 78th legislature has allowed for greater data collection that will provide the TDSHS, local health departments and other providers with information vital for understanding immunization patterns in the state. Legislation that went into effect on September 1, 2003, allowed registry information to be released to several authorized entities such as: any provider authorized to administer vaccines, insurance companies, health maintenance organizations or payors and state agencies having legal custody of a child. This sharing of immunization information will allow for better identification of children who do not have complete vaccination records. By enhanced utilization of the registry, TDSHS can use the ImmTrac data to identify areas in the state with low immunization rates, and take the necessary actions to improve the rates in these

areas. Until now, the state lacked the accurate data to differentiate between areas that have high levels of immunizations and areas with low levels of immunization. This information will allow the state to better coordinate resources in those areas that are under-vaccinated and improve immunization rates throughout the state.

PNEUMOCOCCAL DISEASE

Vaccines purchased by TDSHS are funded through a combination of federal grant funds and general revenue; the program is called the Texas Vaccines for Children (TVFC) Program.

The federal Vaccines for Children (VFC) Program is an entitlement program that provides vaccines for administration to children through 18 years of age who are enrolled in Medicaid, have no health insurance, are underinsured, or who are Alaskan Native or American Indian. Underinsured children can be vaccinated in the VFC only if they present for services at a federally qualified health center (FQHC) or rural health center (RHC.)

Texas general revenue funds are combined with federal dollars to pay the cost of vaccines in an attempt to ensure that any provider can vaccinate underinsured children whether or not the provider is a FQHC or a RHC. This allows children and families to receive all needed vaccines from their primary health care provider.

TDSHS recruits physicians and other vaccine providers in Texas to enroll in the TVFC Program. Enrolled TVFC providers are then furnished vaccines at no charge to vaccinate all children through 18 years of age regardless of their insurance status; this is referred to as a one-tiered vaccination system.

In 2000, a new vaccine was licensed for administration to infants to protect against invasive pneumococcal disease. This is a potentially life-threatening infection that most commonly causes ear infections, but can also cause serious complications such as pneumonia and meningitis. The vaccine is called the pneumococcal conjugate vaccine, Prevnar. Although Prevnar is included in the federal Vaccines for Children (VFC) program there are insufficient state funds to purchase this vaccine for underinsured children who are otherwise eligible for the Texas VFC (TVFC.) Because of this funding gap, the Texas Department of State Health Services (TDSHS) instituted a two-tiered vaccine system in 2001. That is, underinsured children cannot be vaccinated against invasive pneumococcal disease by all TVFC providers; these families must travel to a Federally Qualified Health Center (FQHC) or a Rural Health Center (RHC) which may be hundreds of miles from their home in order to receive free vaccine funded by the federal government.

Any TVFC provider can vaccinate children who are eligible for the federal VFC against pneumococcal disease, but children who are underinsured and rely on state funds to pay for their vaccines cannot. TDSHS shall make its best efforts to improve funding for Prevnar and other newer, more-targeted vaccines.

POLICY OPTIONS

Policy Option 1: Identify the options to increase appropriations allocated to the KHC program to accommodate the growing number of KHC clients in the state including the consideration of funding the program with tobacco tax dollars.

Policy Option 2: Identify and encourage opportunities for coordinated efforts between the Kidney Health Care program and parties with an interest in diabetes to create collaborated efforts to educate Texans on the relationship between diabetes and endstage renal disease.

Policy Option 3: Direct the Appropriations Subcommittee on Health and Human Services to monitor the revenue loss to the KHC Voluntary Manufacturer's Drug program due to anticipated adoption of the Medicare part D drug benefit and supplement through an alternative funding source, possibly restructuring the voluntary rebate program.

Policy Option 4: Initiate a public awareness campaign relating to the importance of kidney donations in collaboration with the overall public awareness and education campaign relating to organ/tissue donation.

Policy Option 5: Determine the percentage of KHC clients who will be ineligible for the New Medicare Part D drug benefit program and consider alternative funding sources.

Policy Option 6: Measure personal financial costs for KHC clients who are not protected from high cost sharing and who experience coverage gaps associated with the Medicare Part D drug benefit program.

Policy Option 7: Identify and monitor the entity within the Health and Human Services Commission that will oversee the transfer of transportation services from the Kidney Healthcare program to the Texas Department of Transportation under the Health and Huma

Policy Option 8: Monitor Texas Department of State Health Services' Immunizations public awareness campaign and identify ways to further enhance immunization rates in Texas.

Policy Option 9: Direct the Department of State Health Services' Immunizations public awareness multimedia campaign to specifically focus on pertussis (whooping cough) and educate parents and providers on the importance of keeping young children isolated from coughing adults.

Policy Option 10: Increase utilization of the ImmTrac registry by identifying and targeting geographic areas with low vaccination rates.

Policy Option 11: Identify the options to increase appropriations allocated to the Immunization program for the purchase of enough vaccine to implement a single (one-tiered) system for all recommended vaccines.

END NOTES

(1) End Stage Renal Disease: Also known as chronic kidney failure, which is a health condition where patients require dialysis treatments or a transplant to perform lost kidney function.

(2) House Committee on Public Health Testimony of Dr. Glen Stanbaugh, Texas Renal Coalition. Presented June 16, 2004.

(3) House Committee on Public Health written materials provided by the Texas Department of Health for the Subcommittee Hearing on Immunizations and Kidney Health Care. Presented June 16, 2004.

(4) Kidney Health Care Rules. Texas Department of Health Publication #41-10978. July 22, 2004. http://www.tdh.state.tx.us/kidney/rules.htm

(5) CDC. Impact of vaccines universally recommended for children--United States, 1990-1998. MMWR 1999; 48:234-8

(6) CDC. MMWR April 2,1999. 48:242-264

(7) CDC. MMWR January 9, 2004.52:1277-1300

(8) House Committee on Public Health, invited testimony of Dr. Sharilyn Stanley, Associate Commissioner, Disease Control and Prevention, Texas Department of Health. Presented June 16, 2004.

(9) Indirect costs include costs related to: Work loss, death, disability, etc.

(10) National Vaccine Advisory Committee. "The Measles Epidemic: The Problems, Barriers, and Recommendations," January 8, 1991.

(11) Texas Department of Health Immunization Division, News Release, July 29, 2004.

(12) Ibid

(13) Vaccine coverage levels are most commonly reported as a 4:3:1 rate. The 4:3:1 rate refers to four doses of diphtheria-tetanus-pertussis vaccine(DTP/DTaP), three doses of poliovirus vaccine, and one dose of measles, mumps, rubella vaccine. Rates for the 3:3:1, other vaccine combinations, and individual vaccines are sometimes reported.

(14) Texas Department of Health Immunization Division, News Release, July 29, 2004.

(15) House Committee on Public Health Testimony of Dr. Sharilyn Stanley, Associate Commissioner, Disease Control and Prevention, Texas Department of Health. Presented June 16, 2004.

(16) United States Centers for Disease Control National Center on Infectious Disease.

(17) Pediatric Infectious Disease Journal, Volume 1, Number 7, July 2002, 629-632.

(18) ImmTrac is designed to access and utilize a statewide immunization database. This registry is part of a TDSHS initiative to increase vaccination coverage for children across Texas. Beginning in the summer of 1993, research was started to evaluate the requirements and impact of a statewide Immunization Tracking System (ITS). On Aug. 17, 1994, Electronic Data Systems (EDS), a private information technology provider, was awarded the ITS project, and the ImmTrac project was initiated.

(19) http://www.dshs.state.tx.us/kidney/khcmain.htm