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DOCUMENT NO. AND TYPE	SUBJECT/TITLE	DATE	RESTRICTION
001. memo	Shirley Sagawa to Mrs. Clinton re: Column idea [partial] (1 page)	05/05/2000	b(6)

COLLECTION:
Clinton Presidential Records
Domestic Policy Council
Ann O'Leary
OA/Box Number: 19581

FOLDER TITLE:
Infant Screening

2013-0436-S
rc1289

RESTRICTION CODES

Presidential Records Act - [44 U.S.C. 2204(a)]

P1 National Security Classified Information [(a)(1) of the PRA]
P2 Relating to the appointment to Federal office [(a)(2) of the PRA]
P3 Release would violate a Federal statute [(a)(3) of the PRA]
P4 Release would disclose trade secrets or confidential commercial or financial information [(a)(4) of the PRA]
P5 Release would disclose confidential advice between the President and his advisors, or between such advisors [a)(5) of the PRA]
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b(9) Release would disclose geological or geophysical information concerning wells [(b)(9) of the FOIA]

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re: Newborn Screening

MEMORANDUM FOR MRS. CLINTON

From Shirley
re: infant hearing screening

From: Shirley Sagawa

Re: Column idea – Newborn Infant Hearing Screening

Date: May 5, 2000

cc: Carol Beach, Ann O'Leary

I know you have been looking for "evergreen" topics for the column. I wanted to propose a column to educate parents about the importance of screening infants for hearing. Due to new technology that reduces the cost to screen newborns for hearing loss (under $30) and a greater understanding of the importance of the first years of life, a growing number of experts, including NIH and the American Academy of Pediatrics, recommend universal newborn hearing screening.

I wanted to call this issue to your attention for several reasons. First, it is an important early childhood issue that affects many children. Each year, 20,000 babies are born deaf or hearing impaired, but most are not diagnosed until they are between two and three years old. Most hospitals only screen newborns with high risk factors, even though data shows that 50% of children diagnosed with permanent hearing loss never exhibited any initial factors.

Due to late detection of their condition, deaf children miss out on early language development and most never catch up. In fact, half of the children with severe to profound hearing losses read below the fourth grade level at the time they leave school. Early detection would enable deaf children to receive services right away – hearing aids, exposure to sign language, speech therapy, or other interventions. One study estimates that taxpayers would save $40,000 in lifetime education costs and $55,000 in lifetime medical, therapy, and auxiliary medical costs for each hearing impaired child identified early.

(b)(6)

[001]

Although the deaf community is divided on many things, this is one issue all agree on. Rep. Jim Walsh of Syracuse introduced legislation, which passed last year, to authorize federal funding for newborn hearing infant screening. Last year, $3.375 million was appropriated for grants to states for this purpose and this year; the President's budget for FY2001 requested the same amount. In addition, 27 states have adopted laws that either expand access to newborn hearing screening programs, or mandate hospitals to test hearing in all newborns before discharge. Infant hearing screening bills are pending in twelve states.

Please let me know if you would like more information. I have a lot of research that I could pass on to Carol if you agree a column on this topic would make sense.

file: Infant Screening

Big Gap in Screening U.S. Infants for Hereditary Ills

By CAREY GOLDBERG

Two babies: Mubashir Younis and Bryce Burke. Both were born with rare metabolic diseases. But one was lucky in the time and place of his birth, and one was not.

Mubashir was born last April in Massachusetts, just two months after the state expanded the **screening** for **hereditary** diseases that it does on newborns. The test picked up his propionic acidemia, which can cause coma, brain damage and even death. Treated and watched carefully, he is growing normally, his "unbelievably lucky" father, Waheed Younis, said.

Bryce, who has a metabolic disorder called MCAD, was not tested for it when he was born in Fort Worth in 1996, and Texas still does not routinely screen newborns for it. When he was 19 months old, Bryce's blood sugar levels suddenly plunged, he had massive seizures and fell into a coma. Brain damage left him unable to walk or talk.

"He'll never be a normal child or person again," said his father, Robert Burke. "It's just so frustrating in this day and time to have a test that's available and people not know about it." And states do not mandate it, he added.

Massachusetts, using complex new technology called tandem mass spectrometry, now subjects the drops of blood drawn from the heels of almost every newborn to tests for MCAD and nearly 30 other inherited diseases. A handful of other states are starting similar programs. But in some states, like Texas, babies are tested for fewer than a half-dozen such **hereditary** diseases. In some cases, a lack of diagnosis can lead to health disasters and death.

State-to-state disparities exist in many areas of health care. But the gap in newborn **screening** is so great that federal health officials, parents' groups, some doctors, a private laboratory and some state legislators are trying to step in.

"We think infants, regardless of where they're born, should have equal

access to **screening** and services," said Dr. Claude Earl Fox, the administrator of the federal government's Health Resources and Services Administration.

His agency and the American Academy of Pediatrics are sponsoring a task force on newborn **screening**, and the group is expected to issue a report in the next few weeks that advocates reducing the **screening** gap between states.

Newborn **screening**, experts say, varies so much from state to state because it presents a classic, politically charged public health dilemma: whether money directed to fight rare or incurable diseases might be better spent on other programs.

They see the current grappling with that dilemma as an excellent rehearsal for an even bigger one in years to come: what to test for when DNA-based technology makes it possible to screen newborns for thousands of genetic diseases.

"Public health departments have to be very careful how they spend their dollars so they get the biggest bang for the buck," said Dr. Brad Therrell, director of the National Newborn **Screening** and Genetics Resource Center.

Public health is a states' rights issue, said Dr. Edward McCabe, who is chairman of the task force, but national decisions should be made on a "core of disorders" to be screened for. "It's a very difficult situation to have a child who may be born across the street from another child and yet have a very different **screening** experience," Dr. McCabe said.

Dr. Fox noted that "there are states that screen for galactosemia, and that incidence is 1 in 60,000, and states that don't screen for sickle cell anemia, and that incidence is 1 in 600."

"That's a reason to have this task force," Dr. Fox added.

Another reason is the march of technology. Tandem mass spectrometry, which can precisely and efficiently count blood components that become elevated with certain disorders, is catching on. And as some states start using it, the gap between them and states that do not may become a chasm. New parents can ask their hospitals to order the testing, but most do not even know to ask, and most hospitals do not offer it routinely.

Dr. Edwin W. Naylor, president of Neo Gen **Screening** Inc. of Pittsburgh, the leading private laboratory specializing in spectrometry testing, estimates that, based on data he has collected, of the four million babies born in the United States every year, about 1,000 suffer from conditions, mainly metabolic disorders, that can only be screened for by using tandem mass spectrometry.

"That's 800 to 1,000 babies a year that are not being diagnosed, and I'd say probably a quarter of those are dying," Dr. Naylor said. Although some people question those numbers, they are not out of line with what Massachusetts has found in its first year of expanded **screening**.

"You have a baby every day or two that's dying of it," Dr. Naylor added. "But the education process, the overcoming the politics of it," come slowly.

The politics varies from state to state.

In New York, Gov. George E. Pataki is seeking $5 million to expand the state's newborn screening program. New Jersey screens infants for just four disorders, the most common among states: phenylketonuria, which can cause retardation if not detected; hypothyroidism, which can stunt growth and brain development, sickle cell anemia and galactosemia, a defect in the breakdown of a sugar in milk. Connecticut screens for seven, a middling number among states.

Dr. Therrell said, "In any particular state, the disorders screened for are directly proportional to the number of proponents for that particular disorder in that particular state, and also to the public health dollars available."

Dr. Naylor said he and his colleagues have successfully used tandem mass spectrometry to detect rare hereditary diseases in newborns since 1992, and Neo Gen has screened nearly one million babies. But it takes time for the technology to gain credibility and for states to decide whether detecting such rare diseases is worth the money.

It costs hundreds of thousands of dollars for state laboratories that choose to do the testing themselves rather than join with a private laboratory like Neo Gen to buy tandem mass spectrometry equipment. Some states deem newborn screening such a basic public health service that they pay for it themselves; others, like Massachusetts, charge for it.

To the families and doctors of children with sometimes fatal disorders that can be screened for but are not, this process is heartbreakingly slow.

"Ten years ago, I could say to such families that there was no way we or anyone could have prevented these deaths or injuries," Dr. Richard I. Kelley, an expert on metabolic disease and an associate professor at Johns Hopkins University, wrote to the Newborn Screening Advisory Committee of the Massachusetts Department of Public Health. "Today I am faced with the same tragedies, but I can no longer say that the death or injury was unavoidable, only that bureaucracies and the resistance to change have prevented the adoption in this country of proven screening techniques for treatable metabolic disease."

Advocates of expanded testing contend that it is also cost-effective: testing may cost from $20 to $50 per newborn, they say, but babies left undiagnosed could require hundreds of thousands of dollars in medical care over a lifetime.

But some remain unconvinced, wanting to wait for more data.

Tandem mass spectrometry "is promising, it's intriguing, but we need to know whether going in this direction, and going to this expensive technology, in the long run will pay off," said Dr. George Cunningham, chief of the genetic disease branch of the California Department of Health

Services. His department has bought a tandem mass spectrometry machine but still needs more financing to start a pilot program.

Also, he said, public health officials must decide whether, for example, it is better to expand the newborn **screening** program to pick up a rare disorder or to provide expanded prenatal care or provide folic acid to all pregnancies.

Massachusetts is already seeing the first-year results of its expanded **screening**. Out of the first 75,000 babies screened, it has turned up 10 with metabolic disorders that would have gone undetected without tandem mass spectrometry. The state also began **screening** for cystic fibrosis, and detected an additional 21 babies.

State health officials deem this first year a technical success, but that does not solve the economic question. It cost Massachusetts about $800,000 to start up the expanded **screening**, said Dr. Roger Eaton, director of the New England Newborn **Screening** Program, and though subsequent years will cost much less, "it is expensive for 10 people."

"If you're the family of one of those 10, then it's worth it," Dr. Eaton said. "But there are a lot of needs competing for the same dollar."

Despite the price, the new technology seems to be gaining acceptance. Some laboratory directors predict that regional labs will be set up for states that cannot afford the new technology.

Colorado's newborn **screening** managers want to expand **screening**, but first they need approval to raise their fees to $50 from about $33, they say.

In Alabama, which tests newborns for just four disorders, the state laboratory director sounded less enthusiastic, though he predicted that the state would eventually move to tandem mass spectrometry. "The equipment is very expensive," the director, William J. Callan, said, and newborn **screening** also requires extensive ancillary services, including follow-up tests and counseling.

One of the nation's leading parent-run Web sites on newborn **screening**, www.tylerforlife.com, describes the consequences of imperfect **screening** programs. It was founded last year by a couple in Georgia whose son, Tyler, died of galactosemia when he was 10 days old. They did not receive the results of his **screening** test until three days after his death.

"We had never heard of galactosemia and have since found out that a lot of other people, including health care professionals, have not, either," the couple, Tera and Brendan Mize, wrote on the Web site.

Theirs is a common refrain from parents and doctors of children with rare metabolic disorders. They say the rarity of the diseases often leads to misdiagnoses of cerebral palsy or "birth trauma." There are also indications that some cases of sudden infant death syndrome may be caused by undiagnosed metabolic diseases, experts say.

MCAD, or Medium Chain Acyl-CoA Dehydrogenase deficiency, the disorder Bryce has, is one of the more common "inborn errors of

metabolism." An associate professor of genetics at Yale University, Piero Rinaldo, testified to the Massachusetts panel on newborn **screening** that it affected about one baby in 10,000 and led to death 30 percent to 50 percent of the time when a baby had its first crisis, "fatalities which would be prevented with almost no exceptions by simple dietary treatment and basic preventive measures."

The question of just how treatable these disorders are is one of many that states must wrestle with as they consider expanding testing. Their rule of thumb tends to be that a disorder must be prevalent and treatable to be worth **screening** for, but those lines can blur and move.

Dealing with such issues now is good practice, many say, for the great debates to come as it becomes possible to decipher a newborn's genes and determine tendencies toward all kinds of diseases.

"I see us as moving and now gathering speed toward a whole new world of newborn **screening**," said Dr. Philip Reilly, a clinical geneticist and lawyer on the Massachusetts panel. "Mass spectrometry will take the world by storm in the next couple of years, and we'll begin to go down the road toward DNA-based **screening**," raising new issues like privacy and use of the samples in research.

"I would say Massachusetts and a few places are setting a new standard of care," Dr. Reilly said. "And yes, babies unlucky enough to be born in states five years late may suffer."

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