Nurkle: Mccains

Addendum to the White House News Report for March 2, 2000

HEALTH

Vaccine Giants to Pledge Third-World Offensive

By RICARDO ALONSO-ZALDIVAR
TIMES STAFF WRITER

WASHINGTON—The four biggest vaccine makers will announce today at the White House that they are donating millions of doses of their products and stepping up research to cure diseases that plague African countries and other developing nations.

The announcement reflects a growing realization by governments, public health doctors, medical researchers, foundations and pharmaceutical company heads in industrialized countries that the "neglected diseases" of the Third World pose a threat to continued global economic development.

"There is a global crisis around the big, killer diseases: pneumonia, tuberculosis, HIV and malaria," said Dr. Richard Feachem, director of the Institute for Global Health at UC San Francisco and a participant in the effort. "We have a major problem in that incentives are not in place for the pharmaceutical industry to invest in finding cures."

President Clinton, in his new budget, is proposing a tax credit to encourage drug companies to find vaccines for these diseases. He is also proposing steep increases for federal research through the National Institutes of Health and a $50-million U.S. contribution to a global fund for distributing vaccines to poor countries. In Congress, Sen. John F. Kerry (D-Mass.) has introduced legislation calling for a broader package of incentives to drug companies.

"We can really have a big wallop here," Dr. Anthony Fauci, the government's leading AIDS researcher, said of today's White House meeting. "It's something that's actually happening, not talk. This initiative has not only galvanized the drug companies, but foundations and other organizations."

The donations and commitments from the drug industry include:

- A million doses of hepatitis B vaccine, worth $100 million, by Merck. The company will also commit to developing AIDS vaccines for strains of the virus found in poor countries.
- Ten million doses of influenza type B vaccine by American Home Products. The vaccines should provide protection for more than 3 million children.
- Fifty million doses of polio vaccine by Aventis Pasteur. The donation will support an effort to eradicate polio in five African countries that have been engulfed in civil wars.
- A commitment by SmithKline Beecham to expand its malaria vaccine program and begin vaccine trials for children in the African nation of Gambia later this year.

Although the pharmaceutical industry is among the most consistently profitable, the vast bulk of its research goes into finding treatments for diseases and conditions that afflict the developed world, such as cancer or high cholesterol. The infectious diseases that are the main killers in the Third World get much less attention.

Indeed, less than 10% of all public and private research funding goes to addressing the primary health problems that affect 90% of the world's population.

Clinton's combination of tax credits for private research and funding for international organizations to buy and distribute vaccines is a strategy aimed at developing both new products and a market for them.

"The tax credit is an incentive to go in and do the research," Fauci said. "No matter how wealthy a drug company is, this is important to them."

Under Clinton's budget proposal, the government would match every dollar of vaccine sold by a manufacturer to international health organizations with a dollar of tax reduction. Vaccines for malaria, tuberculosis and HIV/AIDS would be eligible.

LOS ANGELES TIMES
THURSDAY, MARCH 2, 2000

Drug firms boost vaccine donations

By Steve Sternberg
USA TODAY

Several of the world's largest vaccine makers will pledge today to donate millions of doses of vaccines to people in needy countries, government officials say.

The drug firms are to make the announcements today at a White House session called by President Clinton to urge vaccine makers, health groups and other organizations to join forces to save the lives of needy people worldwide.

The meeting follows last month's launch of Clinton's Millennium Vaccine Initiative, which calls for a major boost in vaccine research efforts, new funding for the purchase and delivery of existing vaccines, and a $1 billion tax credit for drug firms that invest in vaccine development.

Three million children die of vaccine-preventable illnesses each year worldwide. The firms announced:

▶ Merck & Co. will donate 1 million doses of hepatitis B vaccine over five years and enhance efforts to develop vaccines including one against HIV, the AIDS virus.

▶ American Home Products Corp. will contribute 10 million doses of Haemophilus influenza B to UNICEF to prevent pneumonia and meningitis.

▶ SmithKline Beecham will expand its malaria vaccine program and begin a trial in Gambia this fall.

▶ Aventis Pasteur will donate about 50 million doses of polio vaccine to Africa and will continue to work on an AIDS vaccine.

"We're very excited about what can be done in next decade to accelerate the development of new vaccines to address critical diseases killing millions today," says Patty Stonesifer, president of the Bill and Melinda Gates Foundation. The foundation recently gave $750 million to support the Global Alliance for Vaccines and Immunization (GAVI), a public and private partnership that aims to get existing vaccines to poor people as well as develop new ones.

"This is really good news," says Tore Godal, GAVI's director. He urged the drug firms to develop combination vaccines to enhance coverage of poor populations efficiently and at low cost.

To: Ruby, Ann, Tom, Heather file: Mtgs

Fr: Deborah

UPDATE ON PREVNAR

I wanted to send around some information detailing the current status of the Prevnar issue.

PREVNAR

Prevnar is a vaccine for a type of pneumonia which can cause meningitis in children. Children receive the vaccine in stages -- an initial course of three shots and then a booster shortly thereafter, depending on how old the child is when the vaccine course is started.

The private sector price for this vaccine is $55 per dose, and a full course of the vaccine costs approximately $220 per child. The public sector price that CDC has negotiated for the VFC and 317 programs is approximately $45 a dose -- so a full course of the vaccine costs these programs $180 per child.

The 11 states who have universal access programs can also access the reduced price negotiated by CDC – I am trying to get a list of those states. In states with universal access programs, the state purchases all vaccines for all children – regardless of their insurance status.

This vaccine essentially doubles the cost of fully immunizing a child. Previously, the cost of fully immunizing a child under the VFC program was $160 -- it's now $340.

ACIP RECCOMENDATION

ACIP recommended that this vaccine be provided to all children under the age of two, and be provided to children at risk aged two to five years. Children at risk include those with depressed immune systems, such as those with sickle cell disease, HIV, or renal failure. ACIP did a cost benefit analysis that took into account lost time at work for parents. It concluded that the vaccine would be cost-effective at $46 a dose. Since that time, ACIP has since reviewed some of the assumptions made in the initial cost-benefit analysis and raised the break-even point slightly -- to about $50 per dose.

DISEASE BURDEN

There are approximately 18,120 children out of the approximately 20 million children under the age of 5 who develop this type of pneumonia (less than one percent of one percent).

Out of these children, 80 percent of the cases are in children under the age of two. ACIP's recommendation supports routine vaccination for these children.

Right now, CDC does not have an estimate for the number of children who are at increased risk of developing this type of pneumonia. We will try to get find an estimate.

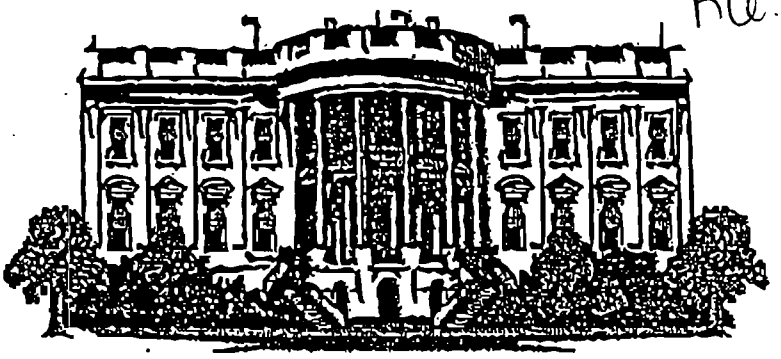
CDC ACTION

CDC is preparing to accept the recommendations of ACIP, unaltered. When that happens, these recommendations will be accepted by AAFP, APA, and other clinical organizations so it becomes the standard of care for the field.

ACCESS

Once the CDC recommendation is released, children who are on Medicaid can receive the vaccine from their provider. Children who are uninsured can receive the vaccine from public health clinics for free; if they are low-income and under-insured, they can access the vaccine for a sliding-scale payment.

file: vaccines



THE WHITE HOUSE

Domestic Policy Council

DATE: 7/26

FACSIMILE FOR: Ann O'Leary

FAX: 6-2878
PHONE:

FACSIMILE FROM: Andrea Kane

FAX: 202-456-7431
PHONE: 202-456-5573

NUMBER OF PAGES (INCLUDING COVER): 22

COMMENTS: Some welfare/immunization info -- I confess I haven't read the actual study yet. Note ethical concerns. Also, consider calling Marc Greenberg @ CASOA pediatrician brain 328-5740 x24

Class size doesn't ensure better grades, studies say

By Andrea Billups
THE WASHINGTON TIMES

Reducing class size has not made a dramatic impact on student achievement, according to two new studies of an educational issue that has polarized lawmakers, parents, teachers and researchers.

A report from the Heritage Foundation in Washington, using data from a national reading test, found that on average, smaller classes don't increase the likelihood that students will post higher scores.

Children in classes with 20 or fewer students per teacher did no better on reading exams than those in classes with 31 or more students, said Heritage researcher Kirk Johnson, who analyzed data from the 1998 National Assessment of Educational Progress (NAEP) tests.

The NAEP exams are given in core subjects every two years to students in the fourth, eighth and 12th grades in 39 states. Mr. Johnson analyzed the NAEP data on six factors: class size, race and ethnicity, parents' education, reading materials in a student's home, gender and participation in free or reduced-price lunch programs.

"Class size ... pales in comparison with the effects of many factors not included in the NAEP data, such as teacher quality and teaching methods," Mr. Johnson said. "It is certainly not the cure-all for academic achievement."

President Clinton has continued his push for hiring 100,000 new teachers to lower the student-teacher ratio in the nation's classrooms, an initiative supported by Al Gore, the likely Democratic presidential nominee. The National Education Association and the American Federation of Teachers also have been outspoken supporters of class-size reduction as an important step in boosting student achievement.

But Mr. Johnson and Heritage education policy analyst Nina Shokraii Rees found that hiring 100,000 new teachers would barely make a dent in lowering the number of students per teacher. With 46.8 million public school students and 2.8 million teachers, they said, the current ratio stands at 16.8 to 1. Even with the additional teachers wanted by Mr. Clinton, that figure would only drop to 16.2 to 1.

Average class sizes, they added, have dropped steadily in the past 30 years, but student achievement on reading tests has remained fairly constant.

"Federally mandating more teachers will not necessarily boost scores," Mr. Johnson said.

In California, a statewide class-size reduction initiative for students in kindergarten through the third grade has yielded modest gains in student achievement, according to a report released last week by a consortium of evaluators led by the American Institutes for Research and RAND.

The California plan began in 1996 at a cost of $4 billion after the state's fourth-graders finished last on national reading tests. Researchers evaluating its progress found that third-grade students posted incremental gains for the second year in a row, with only a slightly greater percentage of those students who are in smaller classes scoring above the national median on the Stanford 9 exams than their peers in larger classes.

While researchers call the improvements "encouraging," a problem has emerged as a result of the class-size reduction program: a widening shortage of qualified teachers, which is more pronounced in schools that serve low-income and minority students.

RAND senior social scientist Brian Stecher called the issue "critical" for California educators.

"We have begun to see lower teacher qualifications in middle schools and high schools as well," he said.

Mr. Johnson at Heritage acknowledges that his research, as well as other widely reported studies on class size, including findings from the Student Teacher Achievement Ratio program in Tennessee, will not end the debate. More studies are necessary.

"I think it's going to be an issue this year, next year and the year after, so long that parents demand accountability and are trying to find whatever means possible to get their children to do better in school," he said.

Welfare requirement boosts immunizations

Georgia 'incentive' helps, study find

By Cheryl Wetzstein
THE WASHINGTON TIMES

A Georgia welfare program that required families to have their children immunized or lose some of their benefits has increased immunizations, a study has found.

"The results of our evaluation suggests that when low-income families are given the incentive to keep their children up to date on immunizations and are reminded regularly of this, they are able to do so," said Larry C. Kerpelman, lead author of the study that appears in today's issue of the Journal of the American Medical Association (JAMA).

However, a JAMA editorial questioned the ethics of the practice.

Financial "penalties for delayed immunization were threatened only to individuals already at risk for economic deprivation: low-income, predominantly minority (black) families with a high proportion of single parents and young children who were dependent on welfare support," said the JAMA editorial written by Drs. Matthew M. Davis and John D. Lantos, both pediatricians.

Without a full evaluation of the families' lives, they said, the benefits of the welfare reforms may be overestimated.

At least 10 states, including Maryland and Virginia, have required immunization of children as a condition to receive welfare benefits, either as a statewide policy or demonstration project, according to groups that track welfare reform.

During 1993 and 1996, Mr. Kerpelman and colleagues David B. Connell and Walter J. Gunn studied 2,500 welfare families in Muscogee County, Georgia.

Some 1,500 families were r domly selected to be regularly minded that they had to immuni their children or lose some of t welfare benefits.

The vaccinations included th for diphtheria, tetanus, pertus polio, measles, mumps, rube Haemophilus influenzae Type and Hepatitis B.

The researchers found that 7 percent of 2-year-olds whose p ents were regularly reminded the immunization rules receiv all their vaccinations. This co pared with 60.6 percent of the tc dlers whose parents were not re ularly reminded about immu zations.

Eleven families lost some their benefits because they didi get their children vaccinated in timely manner. However, eight the 11 families reapplied for ben fits and were reinstated, mo within a month.

The tough immunization polic has been criticized as unfair an punitive — Medicaid provider may be scarce, clinics may hav limited hours, parents may n know the schedules for immuniz tions, advocates have said.

Mr. Kerpelman and his co leagues considered some of thes things in their study, even measu ing the burden of providing doc umentation, time lost in work t visit the doctor and out-of-pocke transportation costs.

There was "relatively little in creased burden on the part of fam ilies to comply with the require ments," the researchers found.

"Linking welfare payments t health-related actions ... is argu ably unfair," often because of prob lems in the health delivery system the researchers wrote.

The Washington Times
WEDNESDAY, JULY 5, 2000

Child Immunization Rose in Ga. Program Of Welfare Linkage

Associated Press

CHICAGO, July 4—Threatening to withhold welfare payments to low-income families unless their children got regular vaccines significantly increased immunization rates in Georgia, a study found.

Several states implemented similar measures in the 1990s, when the federal government encouraged testing of innovative welfare programs, including those that improved the health of public aid recipients.

At the time, critics slammed the practice as unfair, and an editorial accompanying the study in Wednesday's Journal of the American Medical Association questions the ethics of the practice.

"The ethical stumbling block . . . rests in the fact that financial penalties for delayed immunization were threatened only to individuals already at high risk for economic deprivation," wrote Matthew Davis and John Lantos. Lantos is a medical ethicist at the University of Chicago. Davis, formerly of UC, is at the University of Michigan.

But the study's authors said poor children face a higher risk of "vaccine-preventable" diseases. "It is both a public health obligation to encourage low-income parents to have their children immunized for these diseases and a benefit to these families and to the public as a whole," they said.

States with similar programs were required to assess their impact, though only Georgia and Maryland have completed their evaluations, said co-author David Cornell of Abt Associates Inc. of Cambridge, Mass.

At Georgia's request, the social science research firm evaluated the program from its start in 1993 through 1996, when it, like many others, was revamped under President Clinton's welfare reform legislation.

Maryland's program was evaluated by another firm, which found no evidence that the threatened sanctions increased immunization rates, Cornell and colleagues said.

Report on Medical Errors Called Erroneous

Fueling Debate, Researchers Challenge Data Indicating Thousands Die Because of Mistakes

By Rick Weiss
Washington Post Staff Writer

An alarming and highly influential 1999 report which concluded that as many as 98,000 Americans die every year from preventable medical errors is itself being criticized as erroneous by some experts.

The debate, which has been simmering for months, attains prominence today with the publication of dueling opinion articles in the prestigious Journal of the American Medical Association. The articles highlight the difficulty of accurately tallying medical errors and underscore the extreme sensitivity of the topic in today's litigious medico-legal environment.

In one of the articles, three critics assert that the medical error figures used in last year's Institute of Medicine (IOM) report were greatly exaggerated and that the subsequent flurry of efforts to increase oversight of medical professionals was "premature."

"The available data do not support IOM's claim of large numbers of deaths caused by adverse events, preventable or otherwise," write Clement J. McDonald and two colleagues from the Indiana University School of Medicine in Indianapolis.

In the opposing article, a Harvard University public health specialist who helped write the IOM report, and who conducted some of the original research upon which it is based, defends the error figures as, if anything, conservative.

The researcher, Lucian L. Leape, reiterates the report's conclusion that health care professionals, lawyers, regulators and patients must rise above the long tradition of blame and denial and uncover together the systematic flaws in the U.S. health care system that lead to repeated errors.

"Rather than attempting to assuage guilt or outrage about errors by punishing, disconfirming, or self-flagellation, physicians need to look to preventing recurrence of errors," Leape writes.

The headline-grabbing 1999 report, "To Err is Human: Building a Safer Health System," was released last November by the IOM, a branch of the independent, congressionally chartered National Academy of Sciences. It concluded that errors cause between 44,000 and 98,000 deaths in U.S. hospitals every year—more than the number caused by breast cancer, highway accidents or AIDS.

The response from many quarters was quick. Hospitals and insurers launched task forces to examine the problem while federal agencies quickly funded new research. In February President Clinton said he would create a new federal office to study and promote patient safety. He also called for new legislation that would allow hospitals and doctors to investigate their errors and publicize their findings without fearing that the information would later be used in malpractice suits against them.

But the legislative approach collapsed last month. Republicans and Democrats, failing to agree on how uniformly and openly hospitals should investigate errors, introduced competing bills that many on Capitol Hill predict will remain stymied indefinitely by congressional deadlock.

Now the growing debate over the validity of the IOM report, some experts said, could affect other nascent efforts to understand and prevent medical errors.

The dispute began when word got out that one of the studies that the IOM had relied upon had been criticized previously in a medical journal article for counting deaths due to drug abuse as "medication errors."

Then, in April, a Harvard researcher, who with Leape and others had conducted the two most important studies upon which the IOM report had relied, wondered aloud in the New England Journal of Medicine whether the IOM report might itself be erroneous and harmful.

The author, Troyen A. Brennan, who holds degrees in both medicine and law, noted that those two key studies looked not at medical errors per se but at "adverse events," or bad outcomes—many of which may not have resulted from errors or even have been preventable. For example, some patients with liver damage must be returned to surgery because of persistent bleeding. That is an adverse event of surgery, but not necessarily the result of an error.

"A careful reader must have some reservations about the IOM report," Brennan wrote in the April 13 New England Journal.

In the newest contribution to this debate, McDonald and his Indiana colleagues go further, claiming that the original studies upon which the IOM report relied assumed wrongly that all patients who experienced errors or "adverse events" and then died might have lived if not for those adverse events.

"The implication is that if it were not for the adverse event they would have lived," McDonald said in an interview. "But there's a reason these people were in the hospital. My fear is we'll start spending money on error accountants instead of on more nurses or other ways to help patients."

But Leape, in his published rebuttal, says the original research took into account patients' underlying risk of death. He also notes that the studies looked only at hospital patients. With more than half of all surgeries now occurring on an outpatient basis, he writes, these studies, if anything, underestimate the total number of medical errors.

In a telephone interview, Brennan said that the original studies may have overestimated hospital errors by as much as 20 percent, but that outpatient errors like those cited by Leape almost certainly make up for and exceed that margin.

Brennan said he was concerned that the debate over the scale of the medical errors problem—and some legislators' refusal to ensure that investigations of medical errors be conducted confidentially—could break the recent positive momentum toward improving the situation for patients.

"People are finally starting to pay more attention," Brennan said. "But there's still a lot of room for improvement. We can't stop now."

Staff researcher Lynn Davis contributed to this report.

The Washington Post
WEDNESDAY, July 5, 2000

Effect of a Monetary Sanction on Immunization Rates of Recipients of Aid to Families With Dependent Children

Larry C. Kerpelman, PhD; David B. Connell, PhD; Walter J. Gunn, PhD

Context Immunization rates among low-income families have lagged behind those for the general community, with several possible barriers cited in the literature.

Objective To evaluate the effect of an initiative aimed at improving immunization rates among low-income preschool children by imposing a sanction on families who failed to provide proof of up-to-date immunization status.

Design and Setting Randomized, controlled before-after trial conducted from January 1, 1993, through December 31, 1996, in Muscogee County, Georgia.

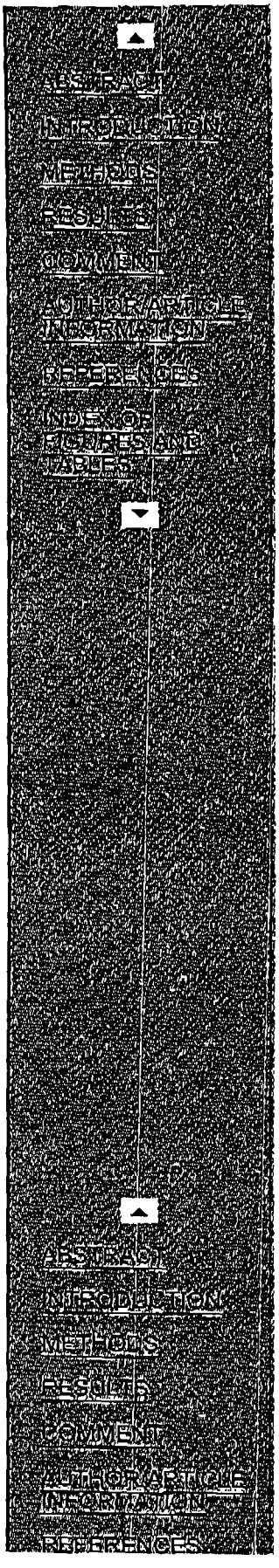
Participants A total of 2500 families with children aged 6 years or younger who received Aid to Families with Dependent Children assistance.

Intervention Families in the intervention group (n=1500) were informed that receipt of the welfare benefit for any preschool-aged children was contingent on provision of proof of up-to-date immunization status at the beginning of welfare eligibility and, subsequently, semiannually or annually. Case families in the control group (n=1000) were encouraged to immunize their preschool children but were not informed of any aid sanctions nor did such sanctions apply to them.

Main Outcome Measure Age-appropriate rates of 5 immunizations (measles-mumps-rubella; poliovirus; diphtheria and tetanus toxoids and pertussis; *Haemophilus influenzae* type b; and hepatitis B), based on examination (with family's written consent) of medical provider records, compared among intervention-group vs control-group families.

Results There were no significant differences at baseline between intervention and control families in immunization rates of preschool children. Families in the intervention group were significantly more likely than families in the control group to have up-to-date immunization status in all 4 years of the study for all 5 immunizations (with 3 exceptions). At age 2 years, 72.4% of children in the intervention group vs 60.6% of those in the control group achieved vaccine series completion, which included 4 diphtheria and tetanus toxoids and pertussis, 3 poliovirus, and 1 measles-mumps-rubella ($P<.001$). Sanctions were implemented only 11 times. There was relatively little increased burden on the part of families to comply with requirements.

Conclusion In our study, a monetary sanction in a population receiving welfare benefits stimulated a significant increase in childhood immunization rates, suggesting that when welfare recipients are given an incentive to keep their children's immunizations up-to-date, most are able to do so.



immunizations up-to-date, most are able to do so.

JAMA. 2000;284:53-59

Although immunization rates have increased in general over the last decade,[1, 2] the rates for poor and minority children have not kept pace.[3, 4] Robinson and colleagues[5] have identified several risk factors that highly correlate with failure to immunize children on schedule, including having low parental education level, large family size, low socioeconomic status, or ethnic or minority group membership; receiving services through public health clinics; being a single parent; starting the immunization series late; and having inadequate insurance coverage for immunizations. Others have indicated that the difficulties poor families have in keeping their children's immunizations up-to-date result from deficiencies in the health care system,[6, 7] and a lack of transportation, social support, and understanding of immunization schedules.[8, 9] These factors strongly suggest that families receiving welfare assistance are at risk of not having their children immunized in a timely fashion.

In the 1990s, the federal government encouraged states to seek waivers of federal welfare rules to test innovative programs and policies, including those that aimed at improving the health of public aid recipients. These waivers, which carried with them an obligation to evaluate the effects of the innovative programs and policies, allowed states to engage in experiments to encourage behaviors among welfare recipients that would lead, among other things, to better family health. Twenty-one states applied for health-related welfare waivers.[10] After the passage of the Personal Responsibility and Work Opportunity Act of 1996, which gave states greater flexibility in administering their welfare programs, many states ceased evaluation activities. To our knowledge, of the states that received waivers for encouraging immunization, only Georgia and Maryland have completed program evaluations.

We present herein the results of a 4-year evaluation of the effect of the Preschool Immunization Project (PIP), a large-scale immunization initiative. The PIP was designed and implemented by the Georgia Department of Human Resources, Division of Family and Children Services, the agency responsible for administering that state's Aid to Families with Dependent Children (AFDC) program. Although the 1996 welfare reform legislation replaced AFDC with Temporary Assistance for Needy Families midway through our evaluation, we refer to Georgia's welfare program as AFDC for the purposes of consistency.

METHODS

Intervention

On January 1, 1993, all families (except for 1000 families in the control group) who either applied or reapplied for AFDC benefits in Georgia were told that they had to provide proof of up-to-date immunizations for their preschool-aged children (≤6 years). They were reminded of their obligation both when they applied and when they were recertified for welfare eligibility, which was required semiannually until 1996, when it became an annual requirement. If the family did not present such proof without good cause, such as having religious objections or known allergic reactions, a sanction could be applied after oral or written warnings were issued. The sanction was losing AFDC benefits normally provided for the nonimmunized child. Medicaid benefits and those for Early Periodic Screening, Diagnosis, and Treatment were not affected.

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Screening, Diagnosis, and Treatment were not affected.

Study Design

To evaluate the effect of the sanction, a randomized controlled trial was instituted in Muscogee County, Georgia, using a systematic random sampling method, by which 1500 families were randomly selected as the intervention group and 1000 families were randomly selected as the control group. Although families in the control group were encouraged to immunize their preschool children, they were neither told about the sanction nor penalized for failure to immunize them. Families in the intervention group, as all the other families receiving AFDC in Georgia, were told about the sanction for not immunizing their preschool children.

Muscogee County, Georgia, consists mainly of the city of Columbus (1995 population 178,681) and the Fort Benning Military Reservation. Almost all of the sample cases were from Columbus. The PIP was approved by the US Department of Health and Human Services, which mandated a randomized assignment evaluation of the project by an independent organization. In doing so, the US Department of Health and Human Services counsel indicated that the project and its evaluation were exempt from human subjects review.

The Georgia Department of Administrative Services used a systematic random sampling method to assign families into the intervention and control groups in November 1992, before the project began on January 1, 1993. Data from the state's Public Assistance Reporting and Information System files indicated that 3600 families receiving AFDC in Muscogee County were subject to the PIP. From those families, every third family was assigned to the control group until 1000 cases were selected. Every third family from the remaining 2600 was assigned to the intervention group until 1500 cases were selected (Figure 1).

Sanctions

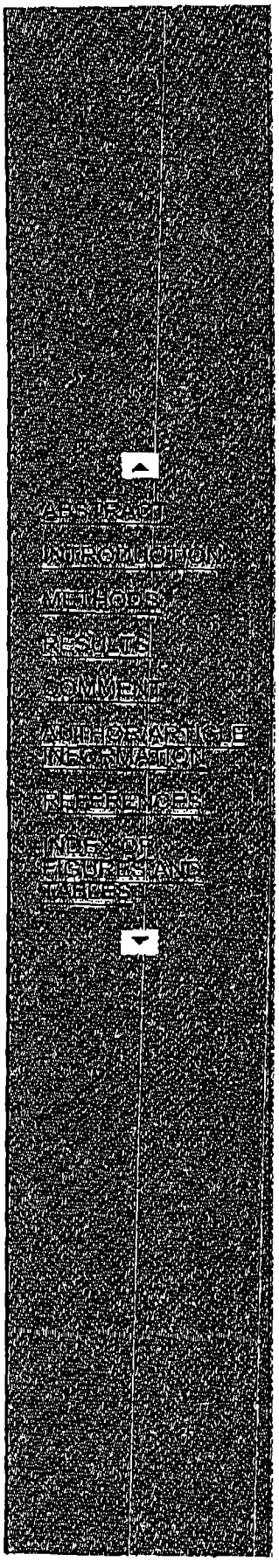
To assess the incidence of the application of sanctions, we reviewed the Muscogee County AFDC case record files of 2265 of the 2500 cases in the study. The remaining 235 case records were not available in the Muscogee County AFDC offices.

Outcome Measures

Age-Appropriate Immunization Rates

The main outcome measure entailed examination of medical records of preschool-aged children to assess whether they had received their diphtheria and tetanus toxoids and pertussis (DTP), poliovirus, measles-mumps-rubella (MMR), *Haemophilus influenzae* type b (Hib), and hepatitis B (HBV) vaccines when required. Children were considered to be *up-to-date* if they had received age-appropriate immunizations based on the recommendations of the Advisory Committee on Immunization Practices and on Georgia PIP requirements in effect at that time. A 1-month grace period was allowed before categorizing a child as not up-to-date. We considered each immunization separately, as well as series completion at age 2 years (4 DPT, 3 poliovirus, and 1 MMR immunizations).

Conditions for review of children's immunization records were: (1) the child's parent or guardian gave written informed consent for the review of medical records; (2) a local immunization provider or providers (whether private physician or county health department) could be identified; and (3) the medical provider(s) gave permission to examine the records. For each child old enough to be eligible for at least 1 immunization at each time point examined, immunization records were recorded from all providers that could be identified as having immunized the child at any point since birth.



Five trained abstractors, from Columbus State University's Health Science Department, recorded all vaccinations. The abstractors were blinded to the status of the children. The record abstracts were edited, entered, verified, and checked for internal consistency and obvious errors.

The collection of children's immunization data (through review of their medical records) began in 1995 and continued into early 1998. All medical record reviews completed before December 1996 were updated during 1997 and 1998. The resulting immunization data for this evaluation were current as of December 31, 1996. Analyses of the medical records file were completed for the children in the sample, even those whose families no longer received AFDC benefits.

Client Burden

Ten-minute-long telephone interviews were conducted between October 1995 and December 1996. Forty families in the intervention group were asked about the extra burden imposed on them by the PIP. These interviews attempted to determine the annual amount of time spent, time lost from work, and out-of-pocket transportation costs required to address the immunization documentation requirements.

Statistical Analysis

Rates of participation (in AFDC and in the study) were compared using χ^2 analysis. The effect of the intervention on immunization rates was assessed using logit (or log of the odds) analysis, with 4 variables entered into the equations: intervention status (intervention/control), age (in months), sex (male/female), and ethnicity (minority/nonminority). Children's up-to-date immunization status was evaluated at 5 points: baseline (January 1, 1993), after 1 year (December 31, 1993), 2 years (December 31, 1994), 3 years (December 31, 1995), and 4 years (December 31, 1996) of the demonstration's operation. All available immunization records were included in each analysis reported herein whether or not the child remained subject to PIP requirements (ie, active AFDC status and age ≤6 years). Series-completion rates by age 2 years were assessed. For this analysis, records of children who turned 2 years old during the study period (January 1, 1993-December 31, 1996) were examined for these immunization series.

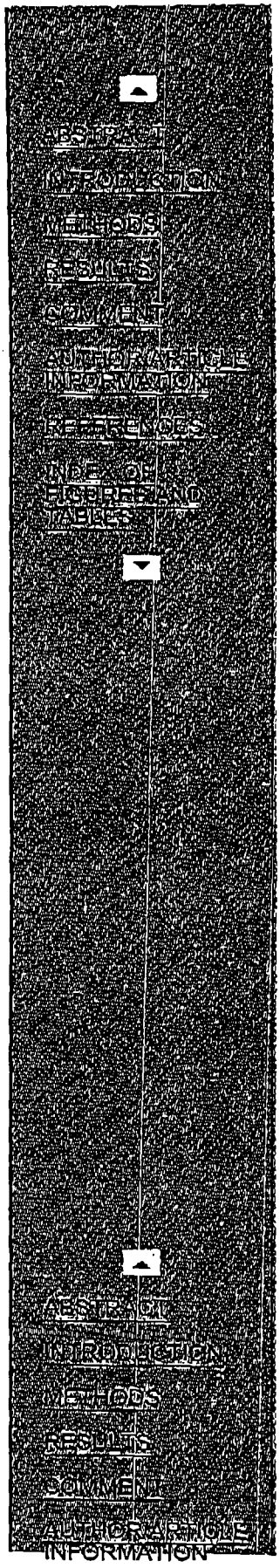
RESULTS

Sample Size and Participation

Sample Characteristics

As of January 1, 1993, the intervention group included 2488 children (1.66 per family); the control group included 1662 children (1.66 per family). At that time, the average age of the preschool-aged children was 3.22 years for the intervention group and 3.34 years for the control group (Table 1). In each group 85% were black and 14% were white. The intervention group had the same proportion of males and females, but the control group had slightly fewer males proportionally (48.5%). During the study, the 278 infants born in the control group families and 483 in the intervention group families were included in this study. Toward the end of the study, the average number of preschool-aged children in intervention group families was 1.98 and 1.94 in the control group families. Age breakdowns indicate that similar proportions of children were in each age group for the 2 groups.

Participation in AFDC



Participation in AFDC

Over the 4-year course of this evaluation, families in both intervention and control groups left the Muscogee County AFDC program, either by income ineligibility or by moving out of the county. In December 1993, 86.3% of the control group and 82.8% of the intervention group remained active. That difference in the percentages remaining active is statistically significant (x^2=5.8, P<.02). By December 1994, 76.4% of the control group vs 71.6% of the intervention group remained active (x^2=7.3, P<.01). By December 1995, however, that difference narrowed with 68.2% in the control group vs 66.9% in the intervention group remaining active recipients (x^2=0.6, P<.50). As of December 31, 1996, 65.5% of the control group vs 61.7% in the intervention group remained active (x^2=3.8, P<.05).

Study Participation Rates

The ability to collect information from the entire research sample for the duration of an evaluation affects the reliability of observed results. If a segment of the original sample were not involved in the analysis and if that segment were different in important ways relevant to the measures of interest, the final results could be biased. In this study, written consent to review medical records was obtained for 3001 (61.1%) of the 4911 sampled children: 1864 children (62.7%) in the intervention group and 1137 children (58.7%) in the control group. This difference is statistically significant (x^2=5.24, P<.05).

Preexisting differences between families in the intervention group that did and did not provide consent to review records were assessed by analyzing demographic characteristics at baseline. Families providing consent had more children and were more likely to be ethnic minorities.

Children in the intervention group for whom permission to review medical records was received were younger than those in the control group for whom permission was received, but all other demographic characteristics were similar for the 2 groups. The difference in children's ages observed in this analysis contrasts with the lack of difference in average age of children in the intervention and control groups at the time of original family selection (Table 1).

Sanctions

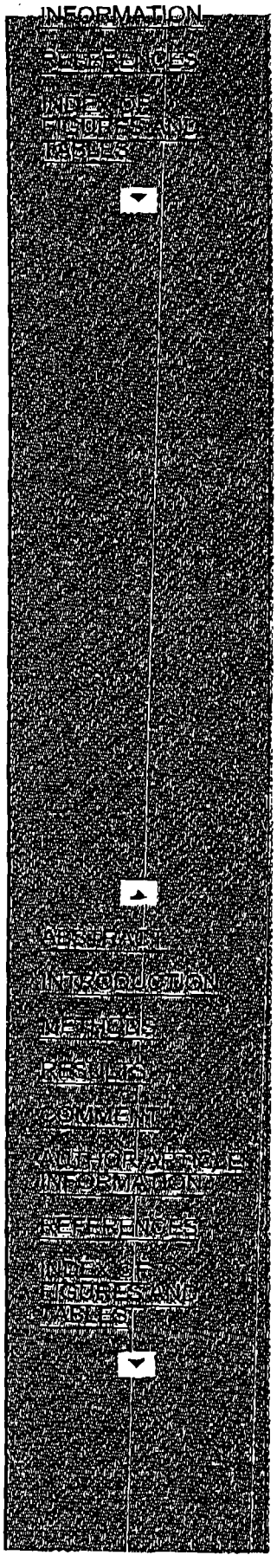
Families in the intervention group received 17 warnings that benefits would be decreased if parents continued not to provide proof of immunization. Families in the control group mistakenly received 3 warnings. Of the 20 warnings, 11 resulted in sanctions being applied, all to families in the intervention group, affecting a total of 18 children. Eight of the 11 sanctioned families reapplied and were approved for benefits. The period required for reactivation ranged from 1 month (as was the case for 5 families) to 6 months.

Immunization Rates

Up-to-Date Immunization Rates

There were no differences between the immunization rates of intervention and control groups at baseline. After baseline, immunization rates were higher for intervention group children for all immunizations in each year. Differences after the project's first year are statistically significant for all immunizations (P<.05), with the lone exception of Hib in the second year (Table 2). Observed intervention effects generally increased each year for the first 2 years, as the PIP regulations took root in the intervention population and were maintained in the succeeding 2 years (Figure 2).

Children's age was significantly related to up-to-date status for each immunization at each time point, with 2 exceptions (poliovirus in the third year and MMR in the first year). For DTP, poliovirus, and MMR vaccine, older children were more likely to be fully immunized. However, for Hib and HBV vaccines younger children were more



However, for Hib and HBV vaccines younger children were more likely to have completed the series requirements.

Sex was unrelated to immunization status at all time points except for the baseline Hib vaccine, for which males were more likely to be up-to-date. Ethnicity was unrelated to immunization for all vaccinations except HBV. For HBV, nonminority children were more likely to be up-to-date after baseline regardless of intervention status, age, or sex.

Analyses conducted of only those children aged 6 years or younger provided equivalent results; in fact, stronger intervention effects were observed for that sample alone.

Series Completion

Of the 510 intervention group children who became 2 years old from January 1, 1993, through December 31, 1996, 369 (72.4%) achieved series-completion. Of the 340 control group children, 206 (60.6%) achieved series-completion. This difference is statistically significant (χ^2=13.4, P<.001).

Client Burden

The interviews with 40 families showed that the level of additional annual burden of being required to provide immunization documentation was 0.66 hours in time spent, 0.13 hours in time lost from work, and $0.41 in out-of-pocket transportation costs.

COMMENT

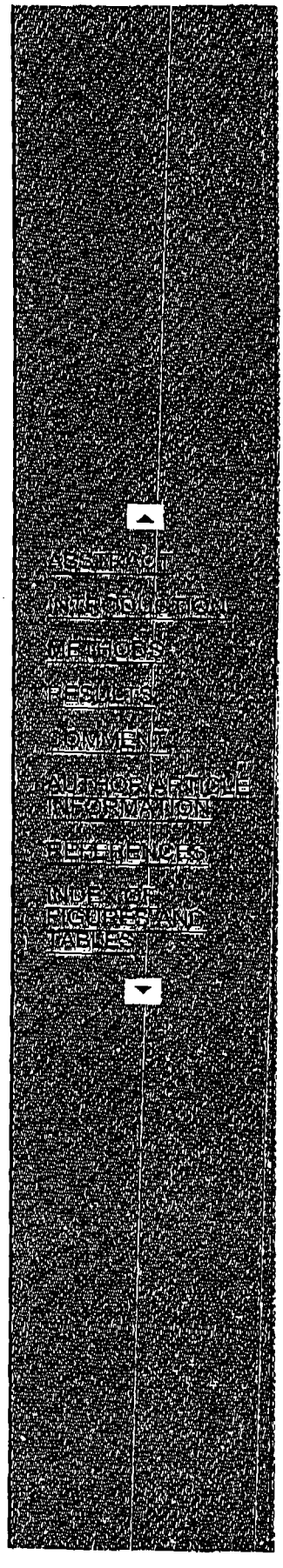
Effect of the Intervention

Age-appropriate vaccination coverage rates, although virtually identical at baseline, increased in the intervention group after 1 year and remained level for the remainder of the study. With just 3 exceptions, the intervention group had statistically significant and clinically meaningful higher coverage rates (by about 6-7 percentage points) for all 5 of the vaccines from the project's first through fourth years.

Immunization rates for MMR and poliovirus are high (≥80% after the first year), and the rate for DTP approaches that of these 2 immunizations (≥70%). For the Hib and HBV vaccinations, rates are far lower (<30%). The Hib and HBV vaccines have been a relatively recent requirement, so it might be expected that compliance on these 2 immunizations might take several years to reach high levels. A study of HBV vaccination rates in a similar population for which intensive in-person efforts were made to improve immunization coverage found similar rates of HBV coverage but with a more rapid rate of increase in up-to-date levels.[11]

Given that the already high levels of immunization rates for MMR, poliovirus, and DTP present a potential ceiling effect, the increase of as much as 7 percentage points in immunization up-to-date rates achieved with these 3 vaccinations is all the more remarkable. Finally, not only are the PIP's effects positive, but the burden on families to adhere to the PIP requirements was low.

Although age of a child is significantly related to all immunization rates, the direction of the relationship is different depending on the immunization. A positive relationship between age and immunization rate was found for MMR, poliovirus, and DTP, whereas a negative relationship was found for Hib and HBV immunization rates. At the outset of the PIP, up-to-date rates for Hib and HBV immunizations were extremely low, no doubt because inclusion of these 2 in the



were extremely low, no doubt because inclusion of these 2 in the immunization series was fairly new. It appears that as the original sample of children aged, little attempt was made to bring them up-to-date for these vaccines, but children born into the sample as the PIP progressed were being immunized more routinely with Hib and HBV vaccines.

The finding that minority children were significantly underimmunized with HBV vaccines appears contrary to 1997 data from the National Immunization Survey.[4] In our study, that difference progressively decreased with time, so it is possible that had data been obtained in our samples for 1997, that difference would have disappeared.

Selection Bias

Comparison of the intervention and control groups' demographic data indicate that the systematic random assignment procedure was performed correctly and had the desired result. That the intervention and control groups can be considered statistically similar at baseline makes the intervention effects found all the more compelling. On the other hand, given that the intervention-control group difference among families actively participating in AFDC at most points in the time studied is statistically significant, it is conceivable that the intervention may have influenced some families to leave AFDC.

Consent Bias

The net effect of the potential bias that may have resulted from families not consenting to let their children's medical records be examined was determined by analyzing family demographics. Although the ages of the children in the intervention and control groups for whom medical records were examined were different, unlike the ages of the groups in the entire sample, when adjusted for in the logit analysis, that difference did not appear to have an effect on the intervention results. Despite the potential bias inherent in obtaining family consent, a record check of immunizations yields a more valid and reliable indication of immunization status than does health care clinician or parental recall,[12] measures that are often used in other studies of childhood immunization rates.

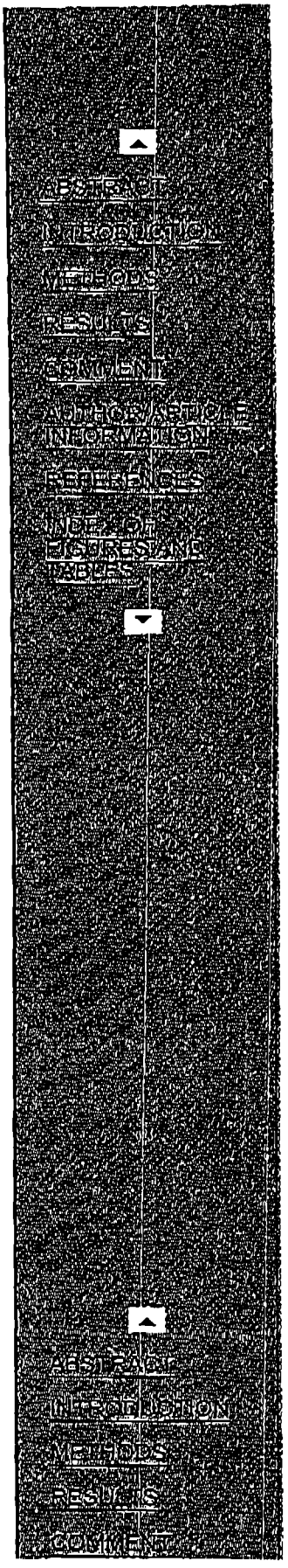
Other Factors

In any project requiring additional activities from the administering agency and the program recipients, program implementation cannot be expected to be perfect. Results from a process evaluation of the program showed some difficulties in implementation. Case workers said (or at least remembered) that they received relatively little training, and the sanction was not applied according to agency procedures in some instances. Among the difficulties in administering the study were (1) some control group families were treated like intervention group members; (2) other unrelated immunization promotional efforts were operating in the community during the same period diluting the effect of the intervention being evaluated; and (3) during the 4-year evaluation period, national welfare policy changes occurred that affected all state welfare programs.

Factors such as treatment crossover and dilution of the treatment intervention operated to mitigate the purity of this evaluation. Yet the intervention accomplished its objectives despite these adversities, for the efforts of the PIP are decidedly positive for ensuring childhood immunizations.

The Role of Sanctions

In the Georgia PIP, sanctions were seldom implemented, yet the families to whom the threat of sanctions were made had their children immunized at higher levels than did the families not subject to such sanctions. The sanction intervention undoubtedly served several purposes. Semiannually, at first, then annually, it focused



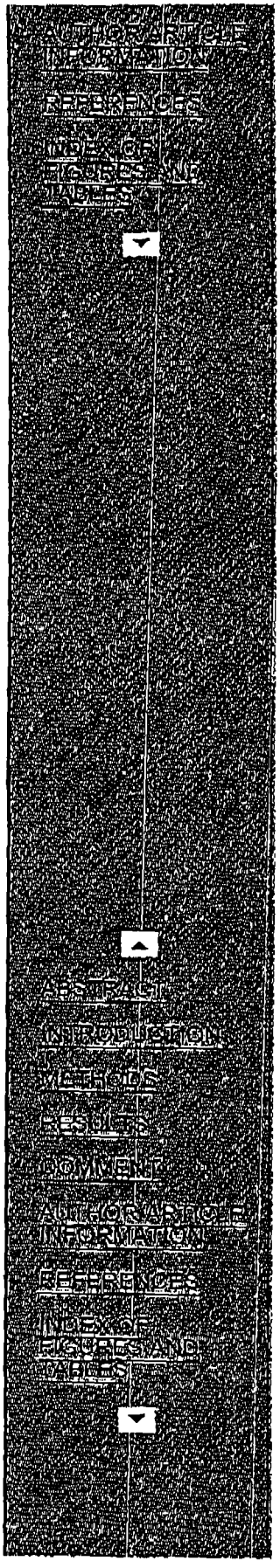
several purposes. Semiannually, at first, then annually, it focused attention on a desired health behavior, imparted information about what was expected of families, and threatened monetary loss for not carrying out the desired health behavior.

We found only 1 other completed welfare waiver evaluation of the role of sanctions on the immunization behavior of persons receiving public assistance, namely, Maryland's Primary Prevention Initiative (PPI). Even though many welfare waiver projects like the PIP were initiated in the early 1990s, with planned evaluations, changes in the 1996 welfare reform legislation caused many states to drop both their demonstration projects and their evaluations of them.

The Maryland PPI aimed at changing a more comprehensive range of behaviors than did Georgia's PIP, including requirements related to preventive health care (over and above immunizations), prenatal care, and attendance at school on the part of school-aged children in the family. Concerning immunization, the Maryland PPI evaluation found "no consistent evidence that PPI contributed to an increase in immunization coverage,"[13] nor did it find an effect on any of the other desired health behaviors, nor on school attendance. The evaluators of the Maryland program attributed the total lack of effect of that program to several factors, including weaknesses in implementing the sanction, compensatory increases in other aid to families that were sanctioned, and inadvertent exposure of control families to 1 or more intervention components.[14]

In Georgia's PIP, there were, similarly, weaknesses in implementing the sanction, little overall intrafamilial economic impact of the sanctions, and inadvertent exposure of control families to the intervention. However, the PIP's improvement in immunization rates is the opposite of those found in Maryland. It is plausible to conclude that the Georgia project achieved its desired ends because it focused on 1 aspect of health behavior (immunizations), which was easy to understand and required clear actions from participants. Clients subjected to the requirements of Georgia's PIP more than likely could comprehend readily what was expected of them to avoid being penalized and found it relatively easy and convenient to have their children immunized. Maryland's PPI, on the other hand, aimed its efforts at a broader range of health (and nonhealth) behaviors. Participants in PPI may have found it harder to understand what was required of them, to effect that broader range of health behaviors, and thus to adhere to that project's requirements.

Linking health activities to welfare benefit payments and concomitantly placing responsibility for their children's immunizations on the recipients of welfare was somewhat controversial when this project was launched (and remains so). Linking welfare payments to health-related actions on the part of welfare recipients is arguably unfair, in that the problems it intends to address are due more to problems in the health care delivery system than to the family itself.[15] Families receiving welfare may have particular difficulties keeping their children up-to-date on immunizations due to the relative scarcity of Medicaid providers, systemic barriers (such as restricted clinic hours), and lack of relevant information. In fact, the Center for Law and Social Policy called for a moratorium on the AFDC grant reduction approach "until evaluations of it and other approaches provide information about the relative effectiveness of different approaches."[16] Yet the fact remains that poor children are at higher risk of vaccine-preventable illnesses. It is both a public health obligation to encourage low-income parents to have their children immunized for these diseases and a benefit to these families and to the public as a whole. There are other advantages, as well. Although immunization rates are high at school entry,[17] there are delays in vaccine administration before school entry that a program like this addresses. Furthermore, immunization visits provide an opportunity for other well-baby or well-child services to be provided. Although vaccine-preventable illnesses may pose no obvious danger now, the



vaccine-preventable illnesses may pose no obvious danger now, the recent measles outbreak suggests that the public health armamentarium should include effective means to increase immunizations by implementing programs similar to the PIP.

The results of our evaluation suggest that when low-income families are given the incentive to keep their children up-to-date on immunizations and are reminded regularly of this, they are able to do so. The threat of a penalty and regular reminders about the important positive measure they could take for their children provided enough of an incentive and focus for parents to have their children immunized. Even though very few families were actually penalized by having their welfare benefits reduced, the overall effect of the PIP was decidedly beneficial for this population.

Author/Article Information

Author Affiliations: Abt Associates Inc (Drs Kerpelman and Connell) and Arlington Associates (Dr Gunn), Cambridge, Mass.

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Corresponding Author and Reprints: Larry C. Kerpelman, PhD, Abt Associates Inc, 55 Wheeler St, Cambridge, MA 02138-1168 (e-mail: larry_kerpelman@abtassoc.com).

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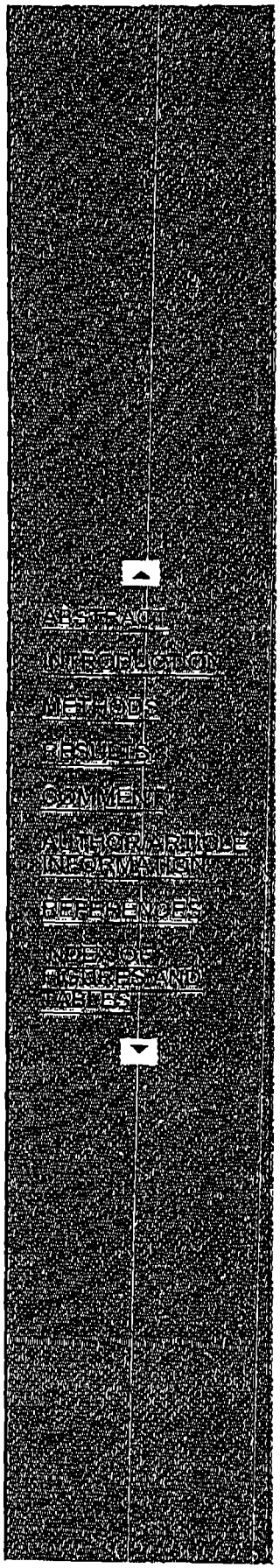

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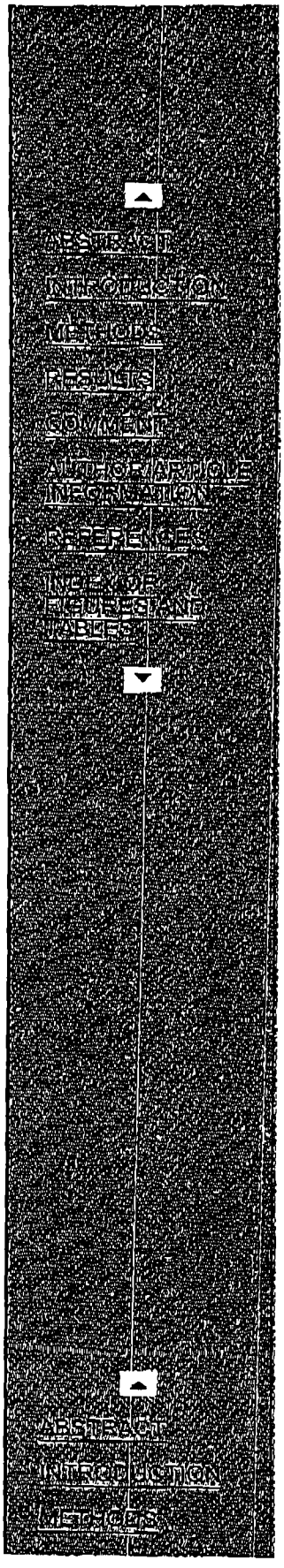

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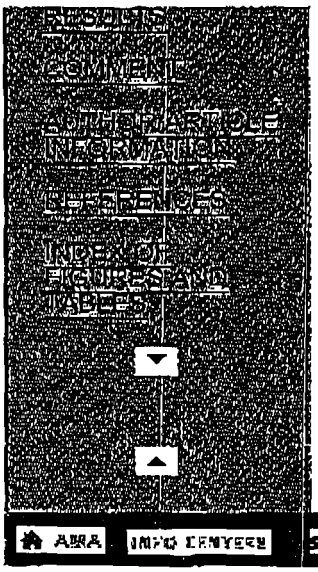


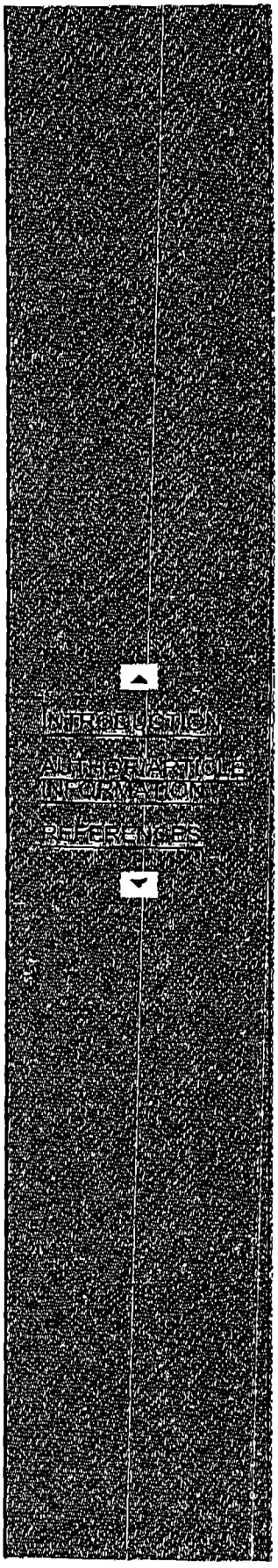
Ethical Considerations in the Public Policy Laboratory

Matthew M. Davis, MD; John D. Lantos, MD

Standards for evaluating clinical innovations are very different from standards for evaluating policy innovations. In the case of the former, the research community appropriately insists on exquisite attention to fair participant selection, a favorable risk-benefit ratio of the intervention, informed consent, and respect for enrolled subjects.[1] Conversely, innovations in public policy are initiated by legislative action or agency dictate; evaluation (if it occurs) is often retrospective and conducted without the oversight of an institutional review board (IRB) or without informed consent. In this issue of THE JOURNAL, Kerpelman et al[2] describe an admittedly controversial program that used the threat of sanctions of welfare benefits to encourage compliance with early childhood immunizations. Their evaluation highlights some of the ethical problems involved in policy evaluations.

In 1993, the state of Georgia began to require that all families receiving Aid to Families with Dependent Children (AFDC) provide proof of up-to-date immunization status for all children aged 6 years and younger. According to the policy, families that did not provide this proof would be warned about sanctions if they failed to obtain immunization documentation for a child and would ultimately lose benefits for persistently underimmunized children. To evaluate this initiative (called the Preschool Immunization Project [PIP]), 1500 families enrolled in AFDC in Muscogee County, Georgia, were randomly chosen as the intervention group and received the "incentive" of the threatened loss of their AFDC benefits. For comparison, 1000 AFDC-beneficiary families from the same county were exempted from the new statewide policy. Though the latter group of families were encouraged to immunize their children, they received no information regarding sanctions. Over a 4-year period of follow-up, Kerpelman et al found that immunization rates were significantly higher (6%-7% for single immunizations; 12% for combined series completion at age 24 months) among children whose parents knew that their AFDC benefits were at risk. Positive effects of the intervention were most apparent during the first 2 years and were generally maintained subsequently.

On the surface, the PIP improved immunization rates among preschool-aged children. But was the threat of sanctions ethical, as a policy directed toward improving children's health? Negative incentives, although their effectiveness may be debated, are common in public policy: eg, financial penalties for late filing of taxes, loss of licensure for severe traffic offenses, or restricting school attendance for underimmunized grade school–aged children. The ethical stumbling block in a program like PIP rests in the fact that financial penalties for delayed immunization were threatened only to individuals already at high risk for economic deprivation: low-income, predominantly minority (black) families with a high proportion of single parents and young children[3] who were dependent on welfare support. Research involving racial minorities and among vulnerable populations in general raises particular ethical issues that have been the focus of concern and reform over the last half century. While reducing persistent health disparities

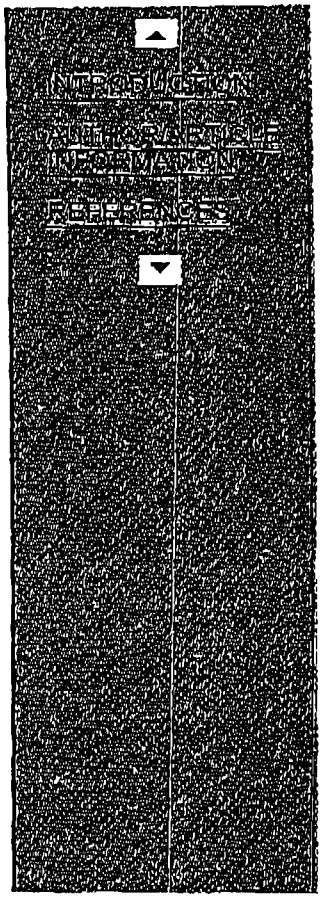


the last half century. While reducing persistent health disparities among minority populations (including significant inequalities in childhood immunization rates) is now a national research priority,[4] the ethical imperative in research efforts is to decrease—not potentially increase—the overall risk borne by individuals more likely to experience poor health. Programs that link AFDC sanctions to immunizations have prompted concern about placing parents and children at heightened risk for deprivation, and critics have called for a thorough investigation of the untoward effects of such programs.[5,6]

How much is known about the untoward effects of the PIP? As Kerpelman and colleagues[2] report, only 17 warnings were given, and very few families (11 of 1500; <1%) ever received actual sanctions. Of these 11 sanctioned families, 8 reapplied for AFDC and their benefits were reinstated within a period of 1 to 6 months. The authors suggest that the sanction intervention worked by providing the threat of sanctions, but that, because the threat was seldom carried out, no harm was done. However, other than tracking changes in immunization status and surveying 40 families (<3%) about the additional burden of requiring immunization documentation, the investigators did not evaluate more fully the impact of the threat of sanctions on parents' behavior. For example, significantly more families dropped out of the intervention group than the control group (38.3% vs 34.5% at 4 years). The authors present no data on whether these rates are attributable to differences in follow-up AFDC eligibility, family relocation outside the county, or families' responses to the punitive nature of the intervention. Information on whether parents left AFDC simply because of the threat of monetary sanctions, whether sanctions were applied or not, or how threats of sanctions changed parents' perceptions of the process of obtaining preventive health care for their children would help to characterize more completely the possible negative consequences of this Georgia program and judge whether the increase in immunization rates justified the overall burden imposed on families.

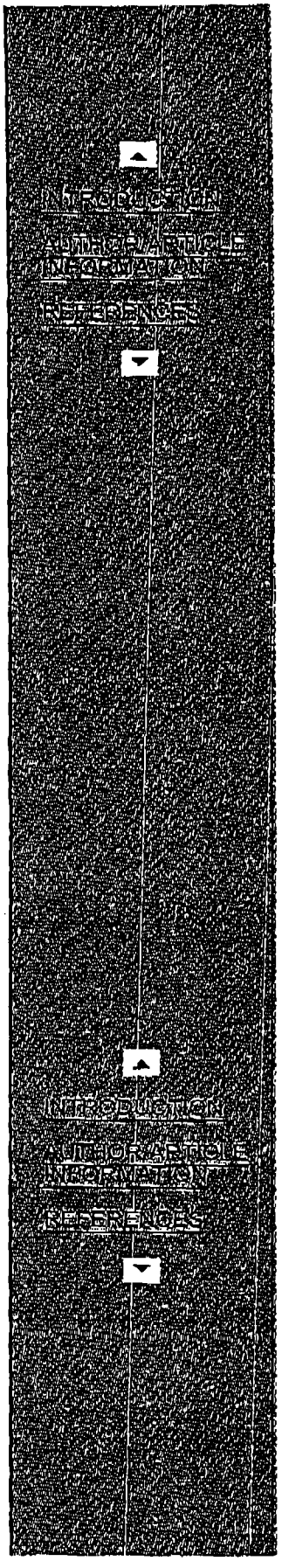
Over the past decade, several studies have established the effectiveness of less controversial programs that improve immunization rates among low-income children. Provider reminder-recall systems, provider feedback interventions, and multicomponent programs that include educational and motivational elements as positive incentives for parents have improved immunization rates in multiple studies (as reviewed by Shefer et al[7]). In addition, a few studies have promoted adherence to immunization for families enrolled in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC),[8-10] in which program beneficiaries were required to attend WIC sites more often than usual if their children were not up-to-date on immunizations (ie, negative incentives were used). In contrast to AFDC beneficiaries in the PIP, however, WIC beneficiaries in these studies did not receive the threat of reduction in their overall benefits. Rather, more frequent visits ensured that benefits would be provided, despite noncompliance with immunization recommendations. For example, Birkhead et al[8] conducted an intervention trial in 6 WIC sites in New York City between April and September 1991. Parents of children whose immunizations were up-to-date were issued the usual 2-month supply of food vouchers; parents of children not up-to-date with immunizations received a 1-month supply of vouchers. Children in the intervention group were 2.9 times more likely than controls to have received measles immunization overall and to have been immunized against measles more rapidly (26 days vs 45 days) after an index WIC visit.

When the Georgia legislature enacted the PIP initiative in 1992, the standard of care for improving immunization rates among poor children was not as clear as it is today. As states attempted to address inadequate immunization rates among preschool-aged children 8 to 10 years ago, many state governments opted not to use punitive measures but rather decided to strengthen the links



use punitive measures but rather decided to strengthen the links between welfare and health programs. Several states, such as Alabama, Connecticut, Delaware, Hawaii, Nebraska, and South Dakota, established a broad range of interventions, including home visits to families of participants in job training programs, on-site immunizations at job-training offices, referrals for underimmunized children from welfare agencies to health care providers, and links to immunization clinics for beneficiaries of AFDC, Medicaid, and food stamps.[5] Such programs targeted systemic barriers to access that affected poor families and sought to ameliorate them. In contrast, programs with AFDC sanctions exposed common barriers to health care access for poor families (eg, lack of a regular source of care,[11] lack of child health insurance,[12] or both in the era before the State Children's Health Insurance Programs) and then threatened to sanction the families for failing to resolve those barriers.[5]

The PIP also was controversial because, unlike a clinical investigation, the evaluation did not seek IRB approval or the prior informed consent of study participants. Instead, because the PIP was a federally sanctioned, state-level welfare innovation, the US Department of Health and Human Services (HHS) waived the need for IRB review or informed consent (although all parents included in the analysis gave written informed consent for the release of their children's immunization records). Under Section 1115 of the Social Security Act,[13] the secretary of HHS may waive compliance with core AFDC legislation (namely, the requirements for states to provide welfare benefits for certain individuals) so that states may carry out projects "judged likely to promote the objectives of AFDC."[3] During the past 7 years, such AFDC waivers were approved for more than 40 states,[3] as a means of encouraging states to serve as "laboratories" for welfare policy innovation.[14] Although the waiver legislation calls for evaluations of demonstration projects by objective investigators, with random assignment if possible, little mention is made of participant



protections, except in the case of child support initiatives.[13]

The Office for Human Research Protections, which is expected to replace the Office for Protection from Research Risks by July 2000, is responsible for ensuring the safety and welfare of individuals who participate in HHS-sponsored investigations.[15] As did the Office for Protection from Research Risks, the Office for Human Research Protections works under the auspices of HHS to oversee the work of local IRBs to maximize the benefits of clinical research while minimizing risks to subjects.[15] Accordingly, the goals of Section 1115 and the Office for Human Research Protections should be consistent under the common oversight of HHS. An assistant secretary of HHS who recently testified before Congress said, "[HHS] must never lose sight of this department's responsibility to families who depend on our programs for assistance . . . and who deserve to be protected when they become subject to demonstrations."[14] This perspective, expressed in 1999, unites the goals of welfare reform and responsible research, but it is not clear whether the same degree of attention to subjects' rights was part and parcel of welfare demonstration projects at the time the PIP was initiated. Of note, a similar, contemporaneous program with AFDC sanctions implemented in Maryland (which failed to demonstrate improvement in immunization status) also had an IRB waiver but indicated in their published evaluation that their protocol met local institutional requirements for clinical studies.[16]

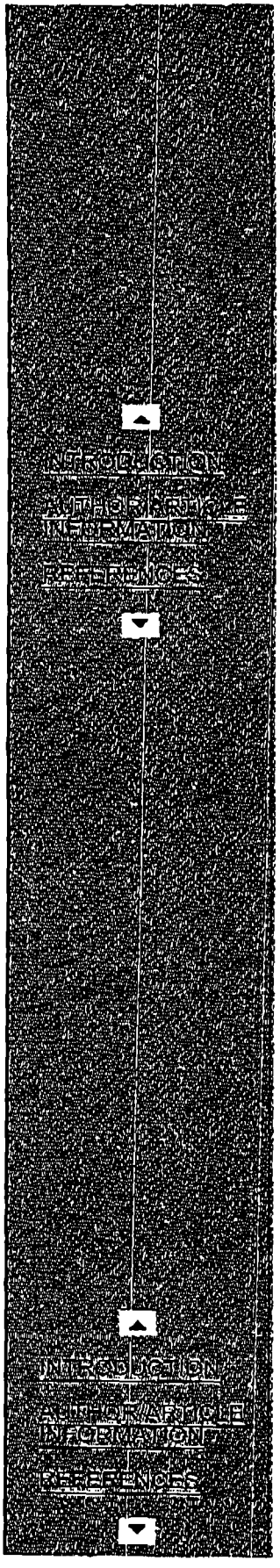
Although the study by Kerpelman et al can be criticized for not examining extensively enough the potential negative impacts of the PIP's threatened sanctions, the ultimate responsibility for Georgia's AFDC beneficiaries lies squarely with the state's Department of Human Resources and also with HHS. In granting waivers for demonstration projects that permit program evaluations to proceed without IRB oversight or without obtaining prior informed consent, state and federal agencies are obliged to take responsibility for protecting participants and ensuring that evaluators attempt to measure not only positive outcomes of interest but also outcomes that adversely affect families' well-being. While not every program granted an HHS waiver will succeed, the process for evaluating waiver programs should accurately identify innovations that are safe. Lawmakers and their constituents should recognize that evaluations that fail to characterize fully the negative consequences of welfare policy innovations may overestimate eventual programmatic benefit and may underestimate worsening health status among eligible program beneficiaries.

The image of states as local laboratories of public policy innovation has certain appeal. However, when the public policy in question is welfare support for impoverished children and their families, investigators and citizens share a collective responsibility to make certain that each state's public policy laboratories meet the highest ethical standards. Evaluations of welfare programs are research and should be held to the same ethical standard as clinical evaluations.

Author/Article Information

Author Affiliations: Departments of Pediatrics (Drs Davis and Lantos) and Medicine (Drs Lantos and Davis), Robert Wood Johnson Clinical Scholars Program (Drs Davis and Lantos) and McLean Center for Clinical Medical Ethics (Dr Lantos), University of Chicago, Chicago, Ill. Dr Davis is now with the Division of Pediatrics at the University of Michigan Medical Center, Ann Arbor.

Corresponding Author and Reprints: Matthew M. Davis, MD, Division of Pediatrics, University of Michigan, D3202 MPB, 1500 E Medical Center Dr, Ann Arbor, MI 48109 (e-mail: ketravis@med.umich.edu).



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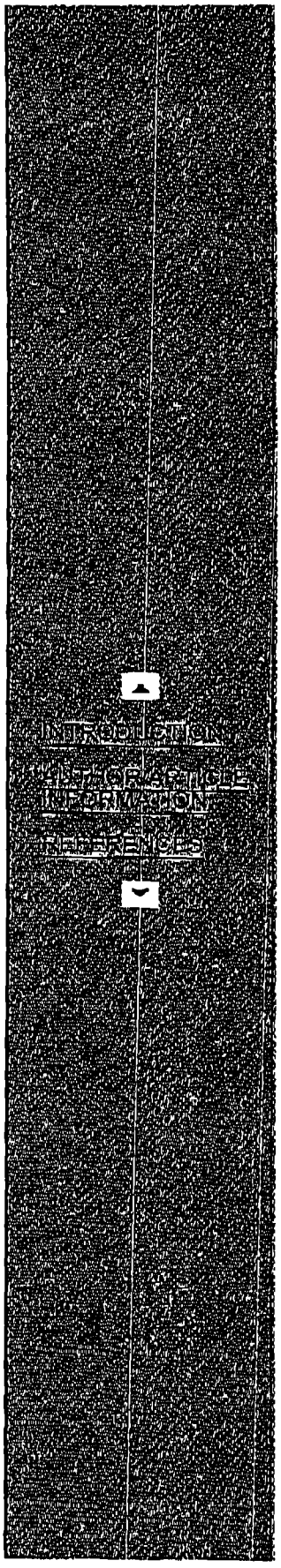

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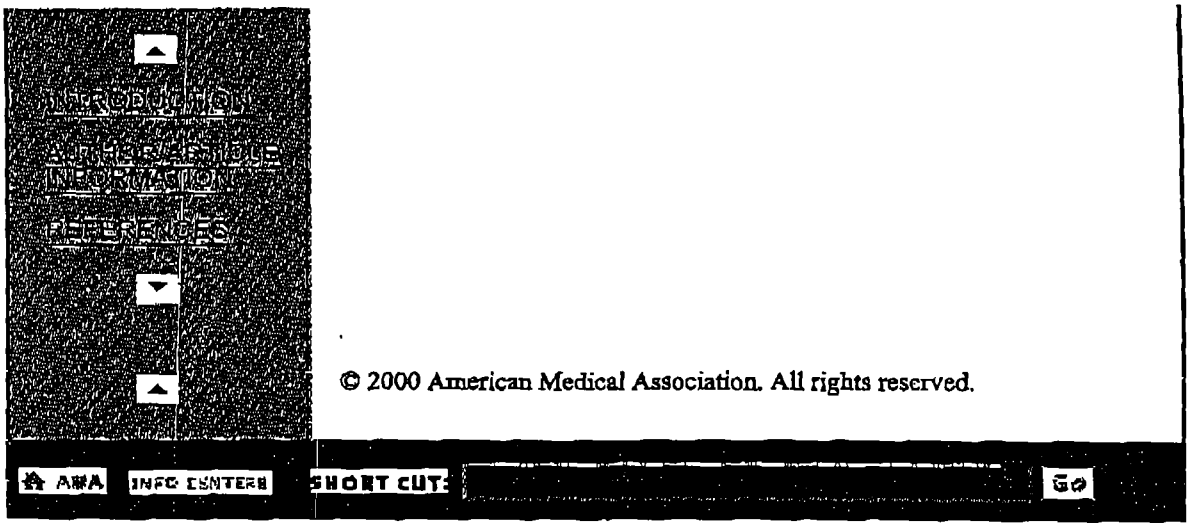
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July 5, 2000, Wednesday, Final Edition

SECTION: A SECTION; Pg. A02

LENGTH: 302 words

HEADLINE: Child **Immunization** Rose in Ga. Program Of **Welfare** Linkage

DATELINE: CHICAGO, July 4

BODY:

Threatening to withhold **welfare** payments to low-income families unless their children got regular vaccines significantly increased **immunization** rates in Georgia, a study found.

Several states implemented similar measures in the 1990s, when the federal government encouraged testing of innovative **welfare** programs, including those that improved the health of public aid recipients.

At the time, critics slammed the practice as unfair, and an editorial accompanying the study in Wednesday's Journal of the American Medical Association questions the ethics of the practice.

"The ethical stumbling block . . . rests in the fact that financial penalties for delayed **immunization** were threatened only to individuals already at high risk for economic deprivation," wrote Matthew Davis and John Lantos. Lantos is a medical ethicist at the University of Chicago. Davis, formerly of UC, is at the University of Michigan.

But the study's authors said poor children face a higher risk of "vaccine-preventable" diseases. "It is both a public health obligation to encourage low-income parents to have their children immunized for these diseases and a benefit to these families and to the public as a whole," they said.

States with similar programs were required to assess their impact, though only Georgia and Maryland have completed their evaluations, said co-author David Connell of Abt Associates Inc. of Cambridge, Mass.

At Georgia's request, the social science research firm evaluated the program from its start in 1993 through 1996, when it, like many others, was revamped under President Clinton's **welfare** reform legislation.

Maryland's program was evaluated by another firm, which found no evidence that the threatened sanctions increased **immunization** rates, Connell and colleagues said.

LANGUAGE: ENGLISH

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ACIP vote regarding pneumococcal conjugate vaccine

On June 21, 2000, the CDC, Advisory Committee on Immunization Practices (ACIP) voted to recommend the pneumococcal conjugate vaccine for all children 23 months of age and younger, and for children 24 to 59 months of age who are at high risk of serious pneumococcal disease, which includes children with sickle cell disease, HIV infection, chronic illness or weakened immune systems.

The vaccine is highly effective in preventing invasive pneumococcal disease in young children. Pneumococcal infections cause approximately 700 cases of meningitis, 17,000 cases of bacteremia (blood stream infections) and 200 deaths each year in children under age 5 in the United States. *Streptococcus pneumoniae* is the most common cause of community-acquired pneumonia in young children. Meningitis is the most severe type of pneumococcal disease. Of children under 5 years old with pneumococcal meningitis, about 5% will die of their infection. Many children with pneumococcal pneumonia or blood stream infection will be hospitalized and about 1% of children with blood stream infections or pneumonia with a blood stream infection will die of their illness.

The committee voted that the vaccine be given to all infants at 2, 4, and 6 months of age, followed by a booster dose at 12-15 months of age. Children who are unvaccinated and are 7 to 11 months of age should be given a total of 3 doses and children who are unvaccinated and are 12 to 23 months of age should be given a total of 2 doses. Healthy children who are unvaccinated at 24 months of age or older only need one dose of the vaccine.

The ACIP also recommended that the vaccine should be considered for all children age 24 to 59 months, with priority given to children at moderate risk of invasive pneumococcal disease. This includes all children aged 24 to 35 months, children of American Indian, Alaskan Native or African American descent, and children who attend out-of-home group child care.

The vote will become a final recommendation when it is published in the *Morbidity and Mortality Weekly Report* (*MMWR*).

The committee also voted to include this vaccine in the Vaccines For Children program, which provides free vaccines to children who are enrolled in Medicare, are not insured, underinsured or are American Indian or Alaskan Native.

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February 18, 2000, Friday, Late Edition - Final

SECTION: Section A; Page 20; Column 1; National Desk

LENGTH: 739 words

HEADLINE: F.D.A. Approves Costly **Meningitis** Shots

BYLINE: By SHERYL GAY STOLBERG

DATELINE: WASHINGTON, Feb. 17

BODY:

The first **vaccine** to prevent a leading cause of **meningitis** in infants and toddlers was approved today by the Food and Drug Administration, one day after a panel of scientific experts recommended against giving it to all children under the age of 5 in part because of its high cost.

The **vaccine,** Prevnar, manufactured by Wyeth-Ayerst Laboratories, a division of the American Home Products Corporation in Philadelphia, protects youngsters against the pneumococcus bacteria, which each year causes an estimated 1,400 cases of **meningitis** and 16,000 cases of blood poisoning in children under 5, as well as 40 percent of all childhood ear infections.

The approval is important because **meningitis,** while not very common, kills several hundred children each year and leaves others with brain damage and other neurological problems. But prevention will come at a price; a four-dose course of Prevnar will cost $232, roughly the same as all other childhood immunizations combined.

With that high cost in mind, a panel of advisers to the Centers for Disease Control and Prevention recommended on Wednesday that the **vaccine** become part of the routine immunization schedule for the roughly 3.8 million babies born each year, but given immediately on a catch-up basis only to children under the age of 2.

Among 2- to 5-year-olds, the panel called for vaccinating only those children at high risk, specifically blacks, American Indians, Alaska Natives and youngsters with H.I.V., sickle-cell anemia or other disorders that weaken the immune system.

The decision marked the first time that the panel had given special consideration to black children, and only the second time that it had taken cost into account. The panel conducted a cost-benefit analysis for Prevnar, taking into account lost time at work for parents. It concluded that the **vaccine** would be cost-effective at $46 a dose, $12 less than the $58 the company has set.

In an interview today, Dr. Peter Paradiso, vice president of scientific affairs and research strategy for Wyeth-Ayerst, defended the price, but said the company was pleased with the committee's decision. He also said the company spent 14 years developing the **vaccine** and tested it in more than 50,000 children, which drove up the cost.

"Our goal for this **vaccine** was for it to become part of the routine immunization schedule for all kids, and it will," Dr. Paradiso said, adding that "the amount of disease you are preventing and will prevent for years to come justifies the price."

The panel's advice is not binding, but the C.D.C. is likely to follow it. Government-financed health programs would then use the guidelines to determine how to put Prevnar into medical practice, meaning

those in the programs are likely to have limited access to the **vaccine.** While doctors and health insurance companies are also likely to follow the advice, people who want their children vaccinated could pay their doctors to do so.

While some doctors say it troubles them to offer **vaccines** to some children and not to others, Dr. Gary Overturf, a University of New Mexico authority on infectious diseases, said a committee of the American Academy of Pediatrics had reached the same conclusion.

"We are uncomfortable making decisions strictly on cost, but I don't think this was strictly on cost," he said. "We had to set a priority to put those children at highest risk first."

Dr. Overturf said it would be logistically impossible to vaccinate all children under the age of 5. In any event, once all newborns have gotten the **vaccine** over the next five years, the issue will become moot.

In approving Prevnar, the food and drug agency said it was extremely effective in preventing cases of pneumococcal **meningitis,** a dangerous infection of the spinal cord and central nervous system that often leaves children with neurological damage, including deafness and learning disabilities.

In clinical trials, the **vaccine,** which is targeted against seven of the most common strains of pneumococcus, proved 100 percent effective in preventing infection with those strains, and 90 percent effective in preventing infection with all strains, the agency said.

The agency said infants could receive the **vaccine** at 2, 4 and 6 months of age, and at a year to 15 months. For children under 2 years old who have missed the initial doses, the vaccination schedule will be determined by health care providers.

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