

**PASSING THE TEST:
New York's Newborn HIV Testing Policy, 1987 to 1997**

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Introduction

This case study traces the evolution of policy in New York State regarding the screening of newborns for HIV antibodies, from the introduction of the blinded newborn seroprevalence survey in November 1987 through the implementation of the mandatory newborn testing and notification begun in February 1997. It is intended to provide a reader with the context in which key policies were debated or enacted and a sense of who the key players were. A caveat for the reader: since this case study spans over a decade's worth of activity and discourse around a highly-charged emotional issue, as a chronological accounting it can only touch upon key events and personalities. Moreover, an effort has been made to present the issues and decisions objectively by outlining the arguments advanced for certain decisions or policies, rather than arguing the merits of one point-of-view over another.

Data for this case study were collected through confidential key informant interviews, literature reviews, and archival material review (such as program documentation and newspaper reports). Because many of the informants are currently involved in policymaking and public health activities, and might otherwise feel constrained from being completely candid if their comments would be publicly attributed, individuals' insights and comments have been intertwined within the narrative without identifiable attribution.

This particular case of newborn screening policy in New York offers insights into the state's broader politics and policy making surrounding HIV/AIDS. Several of the key lessons include the following:

- Policies and advocacy efforts from the 1960s through the 1990s produced a confluence of the patients' right movement, community engagement models, and categorical funding streams that produced a public health environment far more sensitive to individual privacy rights, patient autonomy, special interests and particularized communities than the more traditional mandate of public health operating solely for a majoritarian "public good";
- Advocates for people affected by HIV/AIDS have consistently challenged the traditional public health roles of surveillance, resource distribution, and case-finding -- and particularly the consequences of these traditional policies and programs for disenfranchised populations -- and in so doing have compelled "exceptionalist" policies regarding HIV/AIDS that differ in many important aspects from other communicable or sexually-transmitted diseases. New York's newborn screening debate embodied the struggle between the traditional and exceptionalist approaches;
- As the issue of newborn surveillance evolved from an insular public health issue to one of political moment, who framed the issue and how the issue was framed became the two most important predictors of public opinion;
- The locus of decision-making shifted over the course of a decade, as did the arena in

which debate was engaged. Once public health policy was being debated in a political arena (and particularly once it reached a certain crescendo), the ultimate decisions and considerations were more often related to their political consequences than to their health consequences. When the testing policy changed in 1996 and 1997 (first with “consented” testing and then with mandatory testing), it occurred because of shifting political winds and not because of any scientific sea change;

- As originally conceived, the state’s newborn screening program addressed “public health uncertainty” about the epidemiology of HIV but it could not resolve the “medical uncertainty” of a clinician unaware of a patient’s status, and it therefore reinforced the divide between the population-orientation of the state and the patient-orientation of the clinician;
- Although New York’s initial newborn testing policy revolved around surveillance and its epidemiological utility for charting the epidemic and program planning, the legislative battle focused on newborn testing for the purposes of case-finding. *When the political debate was first engaged in 1993 there was scant evidence that mandatory testing would result in any decrease in perinatal transmission.* Even as the scientific landscape changed (particularly concerning the clear evidence for intervening in the prenatal period) the terms of the newborn testing debate remained fixed. Given the advent of rapid testing and the potential value of AZT therapy antenatally, medical science is only now beginning to demonstrate any evidence for proactively identifying HIV-antibody-carrying infants at birth. The cornerstones of the political discourse on the testing policy, though, were predicated on emotional and political issues, not scientific ones. Furthermore, as a case-finding tool, newborn testing was principally effective only in identifying the mother. When the issue was first raised legislatively in 1993 there was no system of follow-up care or any reliable way to assure that all HIV-positive babies were accurately identified when they seroconverted;
- Given the players, the program, and the shifting political environment, it is likely that mandatory testing was inevitable in New York State. The mandatory newborn testing policy has also facilitated the successful passage of other HIV legislation in New York, such as mandatory partner notification and named HIV reporting.

The chronology of newborn testing policy unfolded in a shifting context of decision-making and debate: from insular public health (the pragmatic era), to the population/clinical split (the era of mounting clinical frustration), to the political arena (marked by polarization, issue-framing, and political “processes” of negotiation and pressure), to clinical optimism (retroviral therapy and protease inhibitors), and a return to public health pragmatism (the implementation of a political decision)

There were two points of strong federal-state interaction regarding newborn screening, and the nature of each reveals a great deal about the shifting eras. In 1987, the CDC strongly

supported New York's surveillance efforts as a complement to its "Family of Surveys," and provided half the ongoing funding for New York's newborn screening program. This was clearly the era of public health pragmatism, particularly in the face of uncertainty about the epidemic's future path. In 1995-1996, there was increasing political momentum at the federal level (evidenced by amendments to the Ryan White Reauthorization Act proposed by Congressmen Coburn and Ackerman) for mandatory newborn testing. With the sweep of Republicans into Congress, and similar Republican inroads in the New York State legislature (and the change at the executive level from a Democratic to a Republican governor), the Democratic-controlled Assembly faced increasing political pressure to conform to the governor's wishes for a mandatory newborn testing program. In 1996, after quiet negotiations between several key legislative players, the New York State Assembly Speaker reversed his three-year opposition to mandatory testing and helped pass the "Baby AIDS" bill.

The framing and marketing of the issue of newborn screening and testing played a significant part in the decisions and actions taken. The early blinded screening program publicized its findings of high seroprevalence rates among women in inner-city communities, and the news was presented as that of epidemiologic discovery. The emerging pattern of HIV transmission -- with its growing impact on communities of heterosexual women and their offspring, in some neighborhoods as high as 4% -- served as the impetus for a number of prevention and education efforts. In contrast, once the issue entered the political arena, the debate was waged in the realm of public opinion. Those who favored mandatory newborn testing presented the issue as one of villains and victims. The villain in this case was "Big Brother" government, armed with specific knowledge about a baby that could save her life, thwarting the victims -- dedicated doctors and caring mothers -- from saving HIV-infected babies. The counter-arguments were far subtler, often relying upon biostatistical arguments, legalistic or ethical frameworks, or advocacy on behalf of minority women. Although those opposed to mandatory testing advocated a model of voluntary HIV testing, which presumably worked to foster trust between a health care provider and a mother and capitalized on maternal instincts to protect a baby's welfare, the images could not compete with those of HIV-infected babies being denied treatment by an uncaring government.

Finally, what state public health officials had recognized early on -- that using the sentinel event of birth as a primary epidemiological marker because it was universal, occurred in an institutional setting over which the state had considerable regulatory power, and built upon a successful newborn genetic screening program -- carried equal appeal for policymakers. Whether the state was interested in HIV surveillance or case-finding, the birth of a baby appeared to provide a perfect opportunity.

The Public Health Environment, 1980-1986

New York's city and state health departments confronted a number of sensitive issues in the first few years of the AIDS epidemic: the regulation of sexual behavior in commercial bathhouses, clean needle exchanges for intravenous drug users, and the development of voluntary

HIV testing programs, among others. Each issue posed its own policy challenge. In considering bathhouse closures, public health officials weighed the benefit of using their police powers against the consequence of threatening a particular group's civil liberties. With proposed needle exchange programs, they tried to balance the moralism of anti-drug policies and politics with the pragmatism of stemming an avenue of transmission. As HIV tests became available in 1985, officials had the task of inspiring trust among groups who were wary of a government's ability to preserve an individual's privacy and confidentiality. From the debates that arose among public health officials, interest groups and affected individuals, health care providers, and political leaders, a general strategy of voluntary risk reduction and HIV prevention programs emerged. Rather than use their prerogative to close gay bathhouses, bars, and other public venues public health officials first sought voluntary compliance from the gay community. Only after the voluntary effort had failed did the state compel the closure of the commercial bathhouses. The health commissioners had less success with needle exchange programs. Although sequential city health commissioners David Sencer and Stephen Joseph both endorsed needle exchange programs, and state health commissioner David Axelrod was also willing -- albeit reluctantly -- to experiment with such approaches, the proposed programs generated too much political opposition. It wasn't until 1989 that a limited needle exchange demonstration was approved for New York City. The lessons reinforced by these two issues were clear: individual rights matter and politics matter. To craft strategic programs, public health officials had to appease civil libertarians and advocacy groups at one end of the political spectrum and political conservatives at the other end.

The HIV antibody test developed in 1985 as a means of safeguarding the blood supply raised the greatest specter of governmental intrusion into an individual's private domain. Although public health officials did not universally endorse a voluntary HIV testing program initially (it was, in fact, opposed initially by the city health commissioner and a national association of state health officers), by the end of 1985 most health officials acknowledged the test's utility for preventing transmission of the virus. The HIV test, however, was regarded by its opponents as the linchpin for a number of potentially intrusive measures -- registries of HIV-infected individuals (which could both stigmatize and lead to discrimination if the names were ever revealed), mandatory partner notification programs, impingement of women's reproductive choices, and the potential deportation of infected immigrants. In response to these concerns, public health officials and policymakers reinforced the exceptionalist nature of AIDS policy -- rather than using the traditional reporting requirements and contact tracing associated with sexually-transmitted and other communicable diseases, New York health officials carved out explicit informed consent requirements and voluntary HIV testing and notification policies. Behind such policies was an implicit quid pro quo. In return for relying upon various risk groups' voluntary compliance with these prevention strategies, public health officials would withhold a compulsory approach. Given the absence of any reliable treatment in the mid 1980s, public health officials' reliance upon voluntary prevention efforts seemed the most prudent course of action.

New York's innovative administration of its AIDS programs further reflected its awareness that this disease required a different approach than others. The AIDS Institute was

established as an independent center within the state health department in 1982, at first reporting to the director of the Center for Community Health (an umbrella unit for all community-based public health activities), and later split out so as to report directly to the Commissioner of Health. The broad mandate of the AIDS Institute included strategic planning, the oversight of community and clinical programs, the synthesis of epidemiological and evaluation data for planning purposes, and policy development. The Bureau of HIV/AIDS Surveillance operated separately from the AIDS Institute, and worked as a component of the state's epidemiology unit. The surveillance group was responsible for analyzing the data provided by the state's Wadsworth Laboratory, which represented the third leg of the administrative tripod. Finally, the state legislature created the AIDS Advisory Council (staffed by the AIDS Institute) as a forum to provide the health commissioner with input from both health care providers and communities affected by AIDS. The AIDS Advisory Council served as a buffer between vocal community advocacy groups, program planners within the health department, and the state legislature. Among the Council's roles were developing proposed statewide AIDS budgets, identifying special needs populations, and lobbying the politicians on designated "Legislators Days." According to one state health official, "the AIDS budget is unique. It is laid out in lines that are more specific than the overall department's budget, because of visibility and political action. Each group of constituencies is represented in a separate line, such as a budget line for 'High risk women and children.'" Prior to the current administration, which began in 1995, the AIDS Institute also had its own Policy Office, distinct from the health department's, which oversaw an interagency policy committee coordinating the AIDS policy work of a number of state agencies and units. AIDS policy in New York was clearly exceptional and political, and the locus of decision-making was foremost in the hands of Dr. David Axelrod, the state's health commissioner.

Public Health Pragmatism, 1987 - 1990

At the Third International AIDS Conference in Washington DC in the Summer of 1987, the State of Massachusetts reported on its anonymous newborn screening program for HIV antibodies, which had been operational for a year. The first state in the nation to conduct such surveillance, Massachusetts had capitalized on its newborn screening program for genetic and metabolic disorders in order to test for the presence or absence of maternal HIV antibodies in a baby's blood. Two high-ranking New York public health officials, Lloyd Novick, the director of the Center for Community Health (which oversaw both the epidemiology unit and the AIDS Institute at the time), and Donald Berns, the assistant director of the state-run Wadsworth Center for Laboratories and Research, were very impressed by Massachusetts's presentation. Berns assured Novick that they had the laboratory capacity to conduct such a surveillance effort in New York. They returned to New York intent on developing an even more sophisticated screening program. The two met with health commissioner David Axelrod and Herbert Dickerman, the head of the Wadsworth Labs, and began planning the newborn surveillance program. From the onset, the four determined to improve on the Massachusetts surveillance program by also collecting demographic data, including the zip code of the mother (or the hospital if the mother's zip code was unavailable), maternal age, and the race/ethnicity of the infant.

Although the planners' principal concerns at first were those of logistics and capacity -- securing a sufficient blood sample from a newborn heel-stick; designing the data form for accurate coding; removing identifiers; developing the epidemiological framework to use the data collected by the labs, conduct small-area and large-area analyses, and report findings -- the health department officials acknowledged in their meetings that the issue of dealing with HIV-positive results was of some concern. The universal newborn screening program had to be built on research conducted on anonymous blood samples. If they approached mothers for consent to test their newborn's blood it would raise issues of potential bias, since not all mothers would consent and the resultant sample might not be representative of the population of child-bearing women. Since the surveillance therefore had to be conducted in anonymous fashion, "blinded" to those drawing the blood and those analyzing the blood, the health department had no legal authority or capacity to then identify those babies testing HIV-positive and notify the mother. In addition to the planned newborn serosurvey, the New York public health officials were also designing serosurveys that provided epidemiological data among population "windows" for whom blood was routinely collected -- drug users, state prisoners, runaways and homeless teens referred to medical examinations, and family planning and STD clients, in addition to newborns.

The decision to launch the blinded newborn seroprevalence survey and the related serosurveys rested with these four public health officials, and principally with Health Commissioner Axelrod. As one of Governor Cuomo's most trusted cabinet members, Axelrod was afforded a great deal of latitude in formulating public health policy and was well-respected by members of the state legislature. Axelrod's management style was such that he relied upon a close circle of high-ranking deputies for their counsel, and all major decisions funneled up to him. To assure himself that his strategies were sound both scientifically and ethically, Axelrod often convened committees of outside experts to consider the effectiveness, consequence, or significance of particular policies or programs. In mid-September, 1987, Axelrod brought together clinicians and ethicists to review the gamut of proposed seroprevalence surveys -- the "windows" into various populations -- and particularly the newborn screening study. The Advisory Committee (composed of Elaine Abrams of Harlem Hospital, Daniel Callahan of the Hastings Center, Victor DeGruttola of Harvard SPH, NIAID's Richard Kaslow, the CDC's Magarite Pappaioanou, and UC Berkeley's Warren Winkelstein) unanimously supported the universal newborn screening program.

The blinded newborn seroprevalence study built upon the state's established Newborn Screening Program (NSP), which tested infants at hospital discharge for seven inherited disorders (phenylketonuria, congenital hyperthyroidism, and maple sugar urine disease, among others) by drawing blood through a heel-stick. The NSP had been developed in New York State in the early 1960s by a Buffalo microbiologist, Dr. Robert Guthrie. He had watched in horror as his niece had gone undiagnosed with PKU until she was 16 months old, as a result of which she grew up retarded and schizophrenic. If PKU was detected early enough after birth, babies could be put on a special low-protein diet, and they would go on to lead perfectly normal lives. On average, New York screens over 300,000 infants each year and identifies approximately 12 children with PKU. In contrast, from Nov 30, 1988 through Nov 30, 1989 there were 1,816 infants born with

maternal HIV antibodies, of whom approximately 700 developed AIDS.

The state health department began collecting newborn HIV seroprevalence data on Nov 30, 1987. "What I recall quite vividly," said one of the study planners, "is that after the first two weeks we were taken aback by the results. They had quite an impact on us." Several earlier newborn studies conducted in municipal hospitals in New York City had revealed seroprevalence rates of 2.4 to 2.5%. The study planners expected to find similar data in high-risk neighborhoods, and were stunned to find rates of 4% seroprevalence in Harlem, the South Bronx, and the Bedford Stuyvesant section of Brooklyn. "This meant that 1 of every 25 women [delivering a baby] was infected," noted a public health official, "and when we reported that we expected a big outcry, and a large media push, for us to immediately unblind the survey." To their surprise, the newspaper coverage focused on the epidemiological significance of the findings -- on the spread of HIV infection across the state and the depth of HIV seroprevalence in particular communities.

Within four weeks of starting the newborn seroprevalence study, the state health department had amended the contracts of state-regulated family planning programs and prenatal care clinics, which served over 300,000 women annually, requiring them to provide on-site HIV counseling and testing services. The state also stepped up its efforts to reach pregnant women in high-risk neighborhoods through its Community Health Worker program and through targeted education campaigns, and advised obstetricians and other physicians throughout the state of the compelling need to provide HIV counseling and testing services to women of reproductive age. In his State of the State message on Jan 6, 1988, Governor Mario Cuomo told the assembled legislators, "There is no greater tragedy than the birth of a child condemned to death, yet estimates indicate 1,000 infants will be born with the AIDS virus in 1988... The initial results of the prevalence studies have only served to heighten our sense of urgency and to focus dramatically upon our most vulnerable populations. Results on the first 11,000 newborn blood specimens demonstrate an alarming statewide HIV seroprevalence rate of almost 1% among women of childbearing age."

At the same time that New York was beginning its seroprevalence studies, the Centers for Disease Control (CDC) was initiating its Family of Surveys, seroprevalence sample studies in 45 states. The CDC funded states to conduct anonymous seroprevalence studies on representative samples of intravenous drug users, STD and tuberculosis clinic patients, hospital admissions, patients at clinics serving women of reproductive age, and newborns. New York public health officials decided to conduct universal, anonymous screening rather than sampled screening, since it was piggybacking the study on the universal Newborn Screening Program and the additional cost was warranted by the greater predictive power of conducting a universal test. The CDC contributed funding that covered half of New York's seroprevalence studies and the state made up the difference (by 1996, the state was paying three-quarters of the cost of the seroprevalence surveys, and CDC one-quarter of the \$2 million program).

As Novick was to later write (Novick, 1991), the newborn seroprevalence survey

provided the state health department with three critical elements: currency, relevance, and focus. The "currency" allowed the state to monitor the real-time spread of the infection without having to account for the lag time between HIV infection and a reported AIDS case (and it enabled the state to conduct analyses of HIV trends over time without adjusting for the CDC's expanded definition of AIDS in 1993); the "relevance" of the universal screening test enabled the state to report actual, rather than projected, infection rates among childbearing women, and to closely estimate the rate among all women ages 15 to 44; and the "focus" derived from the small-area planning that could be conducted given the sociodemographic variables of maternal age, race/ethnicity, and zip code. The last was perhaps the most important to the state public health officials, since it served as an early-warning system that alerted them to what communities the virus was moving into, and thereby provided an opportunity for targeted prevention and education efforts.

In March, 1988, Commissioner Axelrod reconvened a special advisory committee to review the preliminary results of the newborn serosurvey. The committee (composed of Elaine Abrams and Margaret Heagarty of Harlem Hospital, NIAID's Richard Kaslow, the CDC's Timothy Dondero and Margaret Oxtoby, Myron Essex and Harvey Fineberg of Harvard School of Public Health, Keith Krasinski of Bellevue Hospital, Peter Selwyn of Montefiore, and Isaac Weisfuse of the New York City Department of Health) strongly recommended continuing the serosurvey, particularly for purposes of monitoring the epidemic.

Only days before the advisory committee met, a newspaper article in *Newsday* (a major New York daily) featured an interview with Dr. Rodney Hoff, the architect of the Massachusetts health department's blinded newborn survey. Even as he presented the rationale for the blinded serosurvey, "...so that we can monitor HIV infection trends in women," he did sound a cautionary note, saying, "there is a trade-off here between the legal issue of consent and ethical issue of duty to inform." Since there was no accepted treatment at the time, Hoff said he considered it ethically acceptable to not identify individual patients (a position adopted by Bayer, Levine, and Wolf in a 1986 *JAMA* article, and by the journal *Nature's* editorialists in a 1987 article). "Once there is an effective treatment for infected infants," he concluded, "we will very quickly convert to a case-detection system."

Between 1988 and 1990, the New York State health department pursued a number of measures predicated on voluntary adherence to primary and secondary prevention practices. In the absence of a treatment or vaccine, public health strategies focused first on preventing initial infection (primary prevention) by modifying risk behaviors, and for those infected, preventing the further spread of the virus (secondary prevention). Tertiary prevention efforts, focused on limiting the progression of the disease within an infected individual, were for the most part limited to PCP prophylaxis and experimental antiretroviral therapies. As has been extensively documented, since HIV/AIDS raised so many issues of the authority of the public health authorities to intervene in the private affairs of selected communities (e.g., gay bathhouse closures, mandatory partner notification), and since there had been sufficient numbers of cases of HIV/AIDS discrimination in housing, public schools, and employment to warrant a genuine

concern, public health officials generally believed the most expeditious prevention strategy had to be voluntarily elicited, rather than coerced or mandated. Furthermore, such an approach followed the principle of the "least restrictive alternative" in gauging appropriate public health action¹. Particularly given some of the early successes in persuading the gay male population to voluntarily reduce risky behaviors, it seemed sensible to public health officials and legislators to pursue measures that educated and engaged the communities most at risk, rather than potentially alienating these communities and driving them away from the health care system.

In keeping with this approach, the state legislature passed New York State's confidentiality statute in 1988, which imposed strict penalties for disclosure of confidential HIV information and required written informed consent prior to any HIV testing. According to one of the key legislators involved in drafting the law, "We recognized that there was an urgent public health need to have people come forward and be tested, to be counseled, and to cooperate, and since there was no lure of treatment we had to offer a guarantee of confidentiality." One key provision of the statute gave physicians treating HIV-infected individuals the "power" to warn others who might be at risk of HIV infection, but not the "duty" to warn. This was in keeping with the balance between prevention and case-finding, as was the language of the informed consent as well. Rather than adopting a "directed" approach which recommended HIV testing, the language of the informed consent was "non-directed," spelling out all the potential negative consequences of testing and leaving the formulation of a decision entirely up to the individual. This approach to informed consent was based on twenty years of success in the field of genetic counseling, and was driven by various consumer movements promoting both patient's rights and autonomy, as well as a shared medical decision-making model which regarded a patient as an active partner along with his or her health-care provider.

The state health department codified its strategy in two key planning documents: the January 1989 five-year interagency plan, "AIDS: New York's Response," which introduced a number of new initiatives aimed at education (such as HIV/AIDS education incorporated into the core curricula of all public schools and colleges), voluntary counseling and testing, expansion of health services, and preservation of human rights through anti-discrimination legislation and adherence to the principles of informed consent; and the "New York State Principles for the Care of Women and Children with HIV Infection," drafted after a 3-day symposium in 1990 at the Mohonk Mountain House in New Paltz, and thereafter known as the "Mohonk Principles." The Mohonk symposium, led by the AIDS Institute's Nick Rango, brought together key staff from a number of state agencies, as well as health professionals involved in AIDS-related services and women affected by the epidemic. The document clearly stipulated the state's voluntarist approach. The consensus document urged "routine counseling and voluntary testing of all women

¹ In one of the most cogent articles examining the legal capacity of public health authorities to constrain individual behavior through the regulation of public meeting places or contact tracing, Gostin and Curran concluded in 1987 that, "Even stricter scrutiny will be applied to public health measures which affect liberty, autonomy, or privacy of human beings. These measures should not be promulgated without searching examinations as to public health need, specificity of the targeted population, and adherence to the principle of the least restrictive alternative." *AJPH* Feb 1987, 77 (2): 217.

of reproductive age," which should be provided in all health care settings; it asserted each woman's right to make her own reproductive choices; and it recommended a program of routine counseling and voluntary testing of postpartum women who may not have received adequate counseling or testing opportunities prior to giving birth. The document further clarified a consensus position opposing mandatory newborn screening, arguing that the involuntary testing of the mother (the practical consequence of newborn testing) must be weighed against the state's interest in safeguarding the health and welfare of the infant. It presented the criteria that had to be met before unblinding the newborn screening: "(1) substantial clinical benefit of treatment in HIV-infected newborns has been demonstrated; (2) appropriate clinical services are available to all HIV-infected family members regardless of family resources; (3) a definitive laboratory test becomes available allowing for the detection of HIV infection in newborns (as opposed to the presence of maternal antibodies), or the indicated clinical intervention for infants with HIV infection has been proven to be sufficiently non-toxic to uninfected infants who would receive it because of the presence of maternal HIV antibodies; and (4) a system of voluntary counseling and testing of all women of reproductive age has failed to be effective."

The voluntary counseling and testing program at family planning clinics and prenatal care programs was emblematic of this approach. The state intended that every woman of reproductive age seen in a state-regulated facility would be provided with sufficient information to protect herself from being infected, and that every woman would also voluntarily take the HIV test in an effort to inform reproductive choices (such as whether to have an abortion or to pursue future pregnancies) and to encourage other secondary prevention efforts. In 1990, state health officials also rejected the CDC's 1989 recommendation for risk-based assessments -- which attempted to concentrate efforts at encouraging testing among individuals in specific self-reported high risk categories -- in favor of a broader, universal approach that sought to gain the consent to test among all women at the state-regulated clinics. In September, 1990, the health department sent out a "Dear Colleague" letter to all physicians in the state, urging them to counsel any patient who had sex with more than one person in the last ten years, or who had ever used illicit drugs, to be tested for HIV. Furthermore, the state launched the OB Initiative in 1990, a postpartum program at 24 hospitals in high seroprevalence areas to counsel and test women who indicated they had not been tested during their pregnancies.

The results of these voluntary programs, though, proved disappointing. Testing rates in 1991 and 1992 ranged from 14 to 66% (Healton, 1996) at the women's clinics, and except for Harlem Hospital's program, which persuaded over 90% of postpartum women to test, the OB Initiative was equally ineffective. Although the merits of case-finding versus prevention were debated, it was increasingly evident to public health officials in the early 1990s that such voluntary case-finding strategies needed strengthening.

At the same time that these programs directed at individual behavior change were being initiated, a number of efforts were undertaken by the state health department to more accurately focus community-wide prevention and treatment efforts. One innovation developed by the AIDS Institute and the state's epidemiology unit was a Community Needs Index, which took into

account newborn seroprevalence rates and hospital discharge data in constructing a profile of high-, medium-, and low-risk neighborhoods. The index was then used in program development, the expansion of specially-designated AIDS centers at hospitals and community health centers, and the distribution of state funds to community-based organizations in high-risk neighborhoods. From an epidemiological perspective, the universal newborn screening was still regarded as effective and relevant. Beginning in 1990, though, as treatment options for HIV-infected infants became more widely accepted, the tension between the epidemiological and the clinical utility of the newborn screening (in very broad terms, the polarization of surveillance and prevention versus case-finding and treatment) grew within the state health department. These issues had percolated within the larger health care community since 1988 (see Krasinski et al, 1988), but now they were gaining a wider audience. What began as an internal debate within the health care community in the late 1980s evolved into a very public debate by 1993.

The Seeds of Discontent, 1990 - 1993

By 1990, Commissioner Axelrod was having second thoughts about the state's blinded seroprevalence study. The Fifth International AIDS Conference in Montreal the previous summer had featured a number of promising studies suggesting the value of specific prophylactic therapies directed at infants, and the CDC was in the process of formulating new guidelines for PCP prophylaxis for infants and children that would be released in 1991. The efficacy of such treatment, as with antiretroviral therapy in adults, was dependent upon early detection of the viral infection. Axelrod convened his chief deputies and discussed the possibility of replacing the blinded newborn screening program with one in which newborns carrying the HIV antibody would be mandatorily identified and a parent notified. The AIDS Institute director, Nick Rango, was vehemently opposed, and urged Axelrod instead to redouble his efforts on the voluntary testing program. As the data continued to show, though, women were not voluntarily stepping forward to be tested. In late 1990, Axelrod asked one of his key deputies to assemble a small team and draw up a plan for unblinding the newborn study. The plan was to include how notification would be made, how to bring women back for comprehensive care and treatment, and how to assure sufficient capacity at existing designated AIDS centers to care for the women and children. At first, the team considered an approach that involved giving each woman the "right of refusal," but rejected that as having too many problems. They settled instead on a plan of mandatory newborn testing and notification, along with assured treatment for all who tested positive. The AIDS Institute's Rango continued to object to the approach.

In February, 1991, Axelrod suffered an incapacitating stroke. Despite its advocates within the health department, the plan to unblind the newborn testing was shelved. "We had no commissioner," said one veteran public health official who favored the plan, "and no one with the political resources to pull it off."

Outside the health department, indeed outside the medical community, there was an increasing interest in revisiting the newborn testing issue. In mid-1991, Gretchen Buchenholz, the executive director of the Association to Benefit Children (ABC), a New York City-based foster

care agency, approached her legal counsel to lead a lobbying campaign to unblind the newborn screening study. After several cases in which foster children had gone undiagnosed with the HIV-infection despite their caregivers' interest in obtaining an HIV test for the infant, and which they attributed to the restrictiveness of the state's confidentiality statute in not allowing the foster parents to order an HIV test without the natural parents' consent², the agency decided the most effective strategy would be mandatory HIV screening of all newborns, with a guaranteed provision of care for all who tested positive. The special counsel and the executive director of ABC approached a number of agencies to enlist them in the campaign. According to their published accounting of these lobbying efforts, they were rebuffed by the state AIDS Institute, the Lambda Legal Defense and Education Fund, and the Gay and Lesbian Rights Project of the American Civil Liberties Union. But they did receive positive support from certain children's rights groups. For three years, ABC continued to seek common cause with other HIV/AIDS providers, and it wasn't until 1994 that they decide to use a litigation strategy to advance their position.

Some of the strongest dissenting voices opposed to blinded newborn screening study in 1992 came from Nassau County on Long Island, a predominantly conservative area just east of New York City, and in the reportage of the area's leading daily newspaper, Newsday. In the summer of 1992, the Nassau HIV Commission recommended to the local Board of Health that it petition the state to allow mothers to consent to be notified if their infants tested positive for HIV. The Commission also lobbied the Nassau Board of Health to recommend to the state that all physicians throughout the state be required to offer an HIV test to their pregnant patients. One of the Nassau County Board of Health members, Dr. Larry Ravich, said during the board meeting at which the Commission's recommendations were presented, "I think we are approaching this with little slippers on." He pressed for mandatory HIV testing for all pregnant women, a position adopted by the board. Several days later, Newsday columnist Bob Wiemer endorsed the Board of Health's push for mandatory HIV testing. He referred to the 1988 confidentiality statute that stood in the way of such mandatory testing as "criminally foolish," and argued that under the existing laws, "the rights of the carrier are held superior to the rights of the uninfected." Although the Nassau County Board of Health's recommendations did not alter state policy, they did demonstrate a public breach within the public health community. And the columnist's sentiments, however inflammatory they appeared at first glance, would soon gain currency in the legislative efforts to unblind the newborn screening.

In January, 1993, Newsday ran a series of articles by reporter Nina Bernstein that documented the failure of voluntary partner notification to protect unsuspecting women from HIV-infected husbands. The articles were powerful and dramatic, and the stories the reporter recounted of women learning their husband's diagnoses as they lay on their deathbeds --

² This was actually an artifact of rule-making by the local governmental child-welfare agency, and not the state statute, which in fact gave each local governmental child-welfare agency the authority to test foster children without the natural parents' consent. The New York City Child Welfare Administration's policy was to require every effort be made to acquire the natural parents' consent prior to testing the foster child.

sometimes as a result of an inadvertent slip by a social worker or physician caring for the husband -- made a strong case for stronger partner notification policies. The state health department and the state legislature were implicated in the failure to protect these women, and it so infuriated state Assemblywoman Nettie Mayersohn as she read the newspaper series that she grew determined to change state law. Within weeks of reading the newspaper articles, at the start of the legislative session, Mayersohn, a Democratic majority member of the Assembly's Health Committee, proposed amending the public health code. Her proposed legislation would require named reporting of HIV-infected individuals to the local health department, and mandatory partner notification if the infected individual voluntarily released the names of sexual contacts. As a politician and community activist with a long history of supporting women's rights, Mayersohn perceived herself to be operating from a similar position, that of protecting women from unfair policies and inequitable relationships. She sought support for her position from a variety of women's groups and gay activists, and was surprised at their rebuff. Next, she went to the medical community. After a presentation at the Medical Society of the State of New York, a physician approached her and told her about the state's policy of blinded newborn screening. He presented it as the greatest travesty of the state's confidentiality statute -- that the state knew the HIV-status of infected babies, but wouldn't let either the mothers or the physicians know. Notwithstanding the inaccuracies of such a portrayal -- the state did not maintain the identities of the HIV-infected babies, nor was it preventing or denying the ability of mothers to test or physicians to strongly counsel their patients to test -- this captured Mayersohn's attention completely. After verifying the facts of the blinded newborn screening policy, she decided to shelve her partner notification legislation and devote all her legislative energy towards the passage of the "Baby AIDS Bill" she introduced in May 1993, which would unblind the newborn screening and mandatorily notify the parents of the baby's status. "The secret is out," Mayersohn wrote in one of her first newsletters on the subject in 1993, "the State of New York has been using babies for statistical purposes -- but has been denying them treatment and the protection they need to save their lives." Her legislation was mirrored in the state senate in a bill sponsored by Guy Velella, a Republican from the Bronx.

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Given the response to her partner notification legislation, Mayersohn was hardly surprised by the vehement opposition she encountered from gay activists, civil libertarians, and feminist groups. Still, she was confident her constituency of middle-class, mostly Jewish homeowners in Queens, would support her position as one consonant with her "pro-family" stance. She set aside virtually all other legislative business to focus on the newborn testing issue. According to Mayersohn, "This was an issue that people would respond to. I was horrified. I couldn't focus on any other political agenda." Her doggedness was not overlooked by her fellow Assembly members, especially those who opposed her legislation. According to one legislative leader, "It is rare to see a legislator focus her career down to one question. She was irrelevant to the legislative process [once she began pursuing the Baby AIDS legislation], but that fixation contributed to her success. It was clear to me from the start that it would be extremely difficult to overcome her position."

Mayersohn's proposed legislation to unblind the newborn screening proved to be a turning

point in the evolution of policy. Whereas the locus of decision-making control over newborn testing had resided within the state health department from 1987 through 1992, the debate and decision-making over newborn testing now entered the public and political realms. Public health officials had become secondary actors in the policy-making process. Whatever their personal inclinations to advocate or oppose mandatory newborn testing, their role became one of functionaries rather than trusted advisors. Public health officials would provide the legislators and advisory committees with data, and would work on the implementation of the interim and final policies regarding newborn testing, but they would no longer steer the process.

Political Maneuverings, 1993-1994

Mayersohn introduced her 1993 legislation in the political environment of a Democratic Assembly (100 of 150 seats), a Republican Senate, and a three-term liberal governor, Mario Cuomo, as the state executive. Both state houses operate under protocols of centralized leadership: the Assembly Speaker and the Senate majority leader each have the power to move legislation out of committee for a floor vote, or to block votes from coming up for floor votes. Until procedural reforms were enacted in the 1998 legislative session, the legislative leaders also controlled budgetary decisions; the state budget was determined by negotiation among the Assembly Speaker, the Senate majority leader, and the governor. In 1993, Mayersohn had little influence with either Speaker Sheldon Silver, a Manhattan Democrat, or with Governor Cuomo.

A former community activist who first ran for political office when she was in her mid-fifties, Mayersohn's greatest political assets were her persistence and the image she presented of herself as a plain-speaking Jewish grandmother. In her home district in Queens, Mayersohn had been a tenant organizer, president of the PTA, and a Democratic district leader. She had returned to college after raising a family, and graduated from Queens College alongside her youngest son. Although she had run against a Democratic incumbent to gain her Assembly seat, Mayersohn fostered some key political ties amongst fellow Queens Democrats. When she was a district leader, Mayersohn helped Gary Ackerman campaign successfully for a State Senate seat, and the two kept in contact after he later became a US Congressman. In 1995, Ackerman would play a pivotal role in the shifting national debate about newborn testing when he introduced a bill modeled on Mayersohn's New York bill.

The populist image Mayersohn cultivated was that of an independent thinker, not beholden to the party line, who was devoted to protecting those without power (such as women and babies). Also, based on the relative homogeneity of her home district and her strong record of constituent service Mayersohn enjoyed very strong electoral support. In order to bolster her position and gain the endorsement of her fellow legislators, Mayersohn would photocopy relevant medical journal articles and newspaper reports that supported her arguments and circulated them to all her colleagues.

Mayersohn was well aware that her bill faced an uphill battle, particularly given what she called the "Manhattan constituency," by which she meant legislators whose most vocal leftist