One approach for addressing these issues is to involve social scientists (behavioral scientists, anthropologists, sociologists, etc.) or sexuality researchers in the design, implementation, and analysis of behavioral surveillance systems. They have the experience in designing, pre-testing, and training needed to ensure quality. Rarely does a national program have the capacity to undertake this work alone, but instead it should draw in partners with the relevant experience, which might include university researchers, external consultants, community members from surveillance sub-populations, local NGO or clinic staff who have worked with these sub-populations, etc. And while the interviews (or self-administered questionnaires) may be done in clinic settings or other consistent sampling sites by existing staff, these staff must be trained in asking about sensitive issues and those uncomfortable with the material not assigned interviewing duties.

Thus, issues which arise in terms of data quality include how to design a locally relevant instrument, how to validate the findings, who administers it, how best to train them, and who to involve in this process.

3. *Building a sustainable behavioral surveillance system.*

Behavioral surveillance is an activity that is expected to go on for many years. This means that it must be "institutionalized" in a way which makes it sustainable. Two issues arise in this regard. First, is how often should behavioral surveillance be conducted – if only done once every second year or so, it will be difficult to maintain a team able to conduct the work consistently. Thus, some balance needs to be reached between the rates of change of behavior and the needs of sustaining an effective team. Second is where to base the behavioral surveillance system. Basing it in the national program gives it sustainability, but only if the national program has the capacity and staff needed to conduct it. Placing it in a local setting (clinic or provincial level, e.g.) can improve local utilization of the findings, but then additional training must be undertaken to build the capacity at those levels to collect quality data. A university might make a good base, but it would probably need to be tied into other behavioral studies to sustain the interest of researchers. A commercial firm or NGO might take it on, but then issues of financial sustainability must be addressed. Each national program implementing behavioral surveillance needs to think about these issues.

4. *Keeping the cost within reason.*

As with epidemiological surveillance, there are opportunity costs associated with behavioral surveillance. The money spent on conducting behavioral studies is money not spent on prevention or care activities or improved epidemiological tracking of HIV and STDs. A number of cost-related issues then arise. How many sub-populations should be tracked and how do we prioritize them? Behavioral monitoring is not inexpensive if done well – this automatically limits the number

of groups one can afford to track. What are the methodological versus quality issues? For example, face-to-face interviews are more expensive than self-administered questionnaires, but does it improve the quality enough to justify the additional cost. How often do we conduct behavioral surveillance? Each round is going to come at a cost and this will directly influence how often one can do it. This must be balanced against issues of maintaining capacity, rates of behavioral change, and the number of groups one tracks. There is a clear need for better documentation of how these trade-offs have been decided in real world surveillance systems and for better estimates of the costs of behavioral surveillance in developing country settings to feed into the planning of future systems.

5. *Linking epidemiological (HIV and STD) and behavioral surveillance systems.*

To date, we have not had very much experience in linking epidemiological and behavioral data. This applies both at the time of data collection and at the time of analysis. The question then is how best to combine epi and behavioral systems so that they synergistically improve our understanding of the national situation and our ability to interpret trends in HIV prevalence (and incidence, when available).

On the data collection end, a number of issues arise. Should we collect epi and behavioral data from the same people, different members of the same population, or totally different populations? In each case, what new biases does this introduce and how do we link the epi and behavioral data in a meaningful fashion? How does one ensure that the two data sources are sampling from the same pool? How do we link STD data with behavioral data? Why do high STD levels not always correlate with high HIV levels, and is their correlation better with behavioral data? These are still largely unresolved questions in most settings.

To date, epi and behavioral data have generally been treated as independent sources, with little effort expended triangulating them and determining their level of consistency, that is, analyzing them together. To the greatest extent this is due to the lack of epi and behavioral data over the same time periods in the same sub-populations. But it is also related to the fact that the relationships between epidemiology and behavior can be quite complex, especially if confounded by other STDs, changes in protective behaviors over time (either positive, e.g., rapid growth in condom use among sex workers, or negative, e.g., increased anal intercourse with the advent of combination therapies), and self-reporting biases. These issues need to be explored more closely and simple models developed to be applied at the national level, which allow program managers to use their epidemiological and behavioral data to maximum benefit.

6. *Adapting behavioral surveillance systems as the epidemic progresses.*

And a final critical issue, that will just be put on the table here since it is currently under active discussion, is how should behavioral surveillance systems change as the epidemic evolves? Are there general guidelines and principles which can be developed to guide national programs in keeping their systems relevant to their current situation and needs?

The Role of Behavioral Surveillance in Catalyzing Action

If surveillance is to catalyze action, it must be locally relevant. This relevance must not only be in terms of the important populations behaviorally and epidemiologically, but also in terms of the populations which are likely to move policymakers to respond. In choosing sub-populations for surveillance or disseminating surveillance findings it may sometimes be necessary to factor in what is likely to produce action. This might include choosing politically important populations such as youth, or it may involve documenting and carefully explaining to policymakers the linkages between key vulnerable populations and the population at large (as for example with commercial sex in countries where a large fraction of adult men are clients of sex workers). This means that behavioral surveillance systems should be implemented flexibly with a good understanding of the local epidemiological and risk behavioral landscape, the social, religious, economic and cultural constraints faced by the country, and the political factors which limit action by leaders and policymakers.

Assuming that the behavioral surveillance system has been designed to reflect the true epidemiological situation in a country, however, its real impact will depend primarily on the dissemination of its findings. Findings which are not relevant to actions or do not reach the people who can act on them are futile and meaningless data collection exercises. Thus, having a clear plan of action based on the findings and a well defined dissemination strategy is crucial. These should be decided and agreed upon at the time the system is designed.

As each sub-population is chosen or each question is considered for the behavioral surveillance system, the question should be asked: can someone act on this finding to improve prevention and care? If the answer is no, other actionable data should be collected. For example, many early questionnaires asked about anal sex or oral sex among heterosexual populations, but unless one anticipates implementing programs to address these issues (unlikely in general population campaigns), there is little point in tracking them in a behavioral surveillance system. On the other hand, for MSM a question on anal sex would be not only appropriate but essential to directing prevention efforts. It should be kept in mind that every question asked increases the time and cost associated with the surveillance system, so the system should focus on things that make a difference.

In disseminating findings, efforts should be made to reach everyone who can act on the findings. This includes the policymakers, the sub-populations included in the surveillance system, and the population as a whole. However, what is disseminated to each of them should depend upon their needs, be sensitive to local concerns, and relate to things they

can act upon. Policymakers should be provided targeted policy briefs which summarize one or two key findings relevant to their own activities, which discuss the implications of these findings for their programs and recommend possible courses of action which follow from them. Meetings should be held or small media prepared providing feedback to the leaders and members of the sub-populations in the surveillance system. Otherwise, they will have little motivation to change behavior or make incorrect assumptions about their current levels of risk. The general public needs to know what risks are relevant to them and be made aware of the existence of risk behaviors among their sexual and needle sharing partners. However, in preparing targeted materials, one should always be careful to only provide information on which they can act. This is the concept of market segmentation – you don't tell everybody everything, you only tell them what is relevant to them. This will let them focus on what is important to them and minimize unintended side effects such as increased negative attitudes or discrimination. For example, publicizing high levels of anal sex among MSM in general population forums will have little prevention benefit and most likely contribute to increased stigmatization and discrimination. But, presented in forums which reach primarily MSM it can contribute greatly to behavioral change.

Thus critical issues to be considered in producing action include what factors go into a good dissemination strategy? What information should be collected and to whom should each piece of data be disseminated? How can the information be best presented in ways that produce action (at an individual, community, and national level)? And how can we minimize the harm done to marginalized populations?

This paper has scratched the surface of a number of issues which must be carefully considered as behavioral surveillance systems are implemented on a wider scale. At present, we have many questions but few answers. However, as experience is gained and shared at the national scale with the implementation of behavioral surveillance systems, the design and implementation of these systems should move onto firmer foundations. The result will be an expanded synergy between epidemiological and behavioral data collection and improved national responses to the HIV epidemic.

USEFUL REFERENCES

NOTE: This paper has only scratched the surface of the issues facing countries implementing behavioral surveillance systems. A number of recent papers and documents explore these issues in more depth and are of value to those interested in the current state of thinking on behavioral surveillance. These include:

Mills S, Saidel T, Bennett A, Rehle T, Hogle J, Brown T, and Magnani R, *HIV risk behavioral surveillance: a methodology for monitoring behavioral trends,* **AIDS 1998, 12** (suppl 2): S37-S46.

Mills S, Ungchusak K, Srinivasan V, Utomo B, and Bennett A, *Assessing trends in HIV risk behaviors in Asia,* **AIDS 1998, 12** (suppl B): S79-S86.

FHI and collaborators are currently preparing a manual on behavioral surveillance. This will expand on the considerations in the report:

> HIV risk behavioral surveillance surveys (BSS): Methodology and issues in monitoring HIV risk behaviors, Summary from the workshop "HIV risk behavioral surveillance: country examples, lessons learned, and recommendations for the future" held in Bangkok, Thailand August 11-14, 1997, Family Health International, 1998.

UNAIDS is currently preparing documents on behavioral research needs of national programs and 2nd generation surveillance systems, which incorporate behavioral components.

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HIV 母子感染に関する国際ワークショップ
「HIV 母子感染の現状と対策」

日時: 平成 11 年 2 月 16 日(火)午後 1～6 時

場所: 国立感染症研究所・共用第一会議室

開会の辞 中谷比呂樹(厚生省保健医療局エイズ疾病対策課)

座長 川名尚 (東京大学)

喜多恒和 (防衛医科大学校)「日本における母子感染の現状と対策」

吉野直人 (国立感染症研究所)「国立感染症研究所での母子感染検体の解析」

戸谷良造 (国立名古屋病院)「分娩周辺期の死への母体血曝露減少を重視した HIV 母子垂直感染防止策」

高山直秀 (都立駒込病院)「輸入感染症としての HIV 母子感染」

早川智 (日本大学医学部)「胎盤・脱落膜における局所免疫と HIV 垂直感染」

杉浦亙 (国立感染症研究所)「母子感染における薬剤耐性 HIV -1 の問題点」

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「タイにおける母子感染の現状と対策」

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「米国における母子感染の予防対策の進歩」

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総合討論

閉会の辞 木原正博 (神奈川県立がんセンター)

Progress in preventing vertical transmission of HIV in the USA

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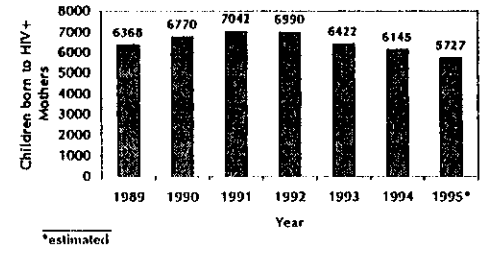
Epidemiology of Perinatal HIV Infection in the USA

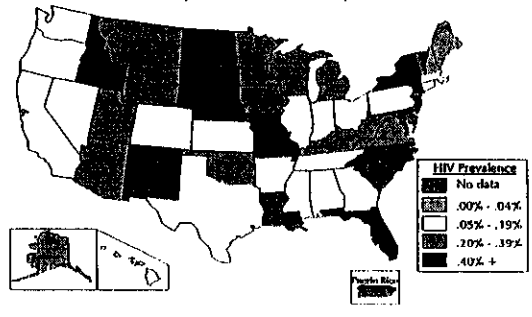
Between 5000 and 7000 children were born to HIV-infected woman in the USA each year from 1989 to 1995, when the last national estimates were made. This number has been declining since 1991 [Fig.1].

The prevalence of HIV infection among childbearing women is greatest in the Eastern part of the country, with the highest rates in Florida and New York State [Fig.2]. Whereas in the early epidemic, the mothers of most children with perinatal HIV infection were injecting drug users, recently a larger proportion of infected mothers have acquired their infections sexsually [Fig.3]. The incidence of AIDS in children is highest among Hispanics and Blacks (1.3 and 4 per 100,000 children aged < 13 years old), with rates in these groups several times higher than in white or other groups.

Number of Children Born at Risk for Perinatal HIV Infection, USA, 1989-1995

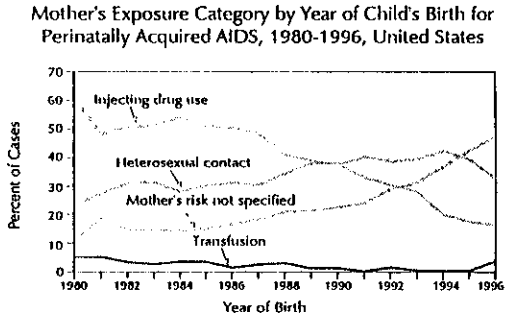


HIV Prevalence among Childbearing Women, United States, 1995



Transmission Rate and Risk Factors

Based on data from several large multi-site studies of HIV-infected women who do not breast feed their children, the rate of perinatal HIV transmission is about 20%. Several factors have been identified in pregnant women in these studies that appear to make the risk higher, including high plasma viral load, low CD4 cell count, or AIDS. Additional factors about the delivery make the risk higher, including premature delivery, long duration of ruptured membranes, and vaginal delivery.



Other factors that may play a role in increasing transmission risk include unprotected sex, injecting drug use, or smoking during pregnancy; chorioamnionitis; and absence of such host genetic factors as the CCR5 gene. However, no single factor can determine whether a woman will or will not have an infected baby.

Research on Preventing Perinatal HIV Transmission

In 1994, the resultt of a very important clinical trial on preventing perinatal HIV transmission was announced. This trial, called the AIDS Clinical Trials Group 076 trial, compared a regimen of ZDV (AZT, zidovudine) with placebo. The ZDV regimen consisted of 100 mg 5 times a day from 14-34 weeks gestation until delivery, a 2 mg/kg loading dose followed by 1 mg/kg infusion intravenously during labor, and 2 mg/kg/dose 4 times a day for infants starting at 8-12 hours of life until 6 weeks of age. HIV-infected pregnant women could participate in the trial if they were 14-34 weeks gestation. Had minimal or no HIV symptoms, had a CD4 count < 200 cells/μl, and did not take antiretrovirals during the current pregnancy. The transmission rate in the ZDV group was 7.6%, and in the placebo group was 22.6%, representing about a 2/3 reduction in transmission. The only short term adverse event associated with this ZDV regimen was mild anemia in some of children, which resolved without treatment in all cases. Moreover, after 4 years of follow up, these have been no long-term immunologic, growth, or developmental effects and no evidence of carcinogenicity among children exposed to ZDV *in utero*. Resistance to ZDV has not appeared to be an important problem.

Early Recommendation for Perinatal HIV Prevention

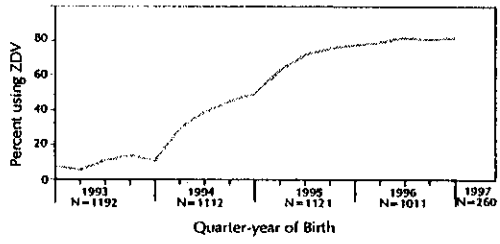
Shortly after these results were announced in 1994, the US Public Health Service issued guidelines in 1994 that recommended this regimen for all women with characteristics similar to the women who participated in the trial, and gave guidance for using ZDV for women with different characteristics (e.g., CD4 count < 200 cells/μl). A second set of

guidelines was issued in 1995 that recommended offering voluntary HIV counseling and testing to all pregnant women in the United States.

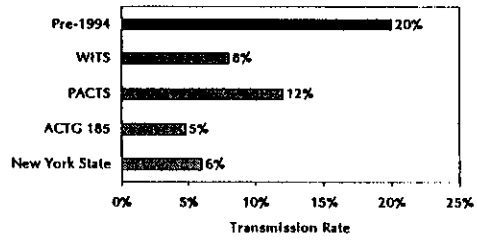
Impact of Early Recommendations

The use of ZDV by HIV-infected pregnant women and their newborns increased quickly after these recommendations, such that by 1997, more than 80% had used at least some part of the ACTG 076 ZDV regimen [Fig.4]. As a result, the risk for perinatal transmission declined from about 20% before 1994 to between 5 and 10% among women using ZDV after 1994 [Fig.5]. This also led to a decline in the overall number of perinatally acquired AIDS cases in the US of more than 40%.

Percent of Perinatally HIV Exposed or Infected Children who Received or whose Mothers Received any ZDV, Born 1993-March 1997 in 29 States, USA



Transmission Rates after 1994 among U.S. Women Using 076 AZT Regimen



Current Recommendations for Preventing Perinatal Transmission in the USA

Since 1994, substantial advances have been made in understanding HIV pathogenesis and in treatment and monitoring of HIV infection, In particular, more aggressive combination drug regimens are now recommended to treat HIV infection in the US. Although therapy during pregnancy requires unique considerations, pregnancy is not considered a reason to defer antiretroviral therapy. Unique considerations for use of antiretroviral therapy during pregnancy include: potential need to alter dosing due to pregnancy; potential for adverse effects on the fetus and newborn; and effectiveness for reducing perinatal transmission. Data to address many of these considerations are not yet available for many drugs.

Nonetheless, revised recommendations for antiretroviral therapy in pregnancy were made in early 1998. These recommendations state that the use of the 3-part ACTG 076 ZDV regimen, alone or in combination with other antiretrovirals, should be discussed and offered to all HIV-infected pregnant women. In addition, use of other antiretrovirals recommended to treat the mother's HIV infection should be discussed. This discussion

should include what is known and not known about 1) the effects of antiretrovirals on the fetus, including lack of long-term outcome data on pregnancy use; 2) what treatment is recommended for the woman's health; and 3) the efficacy of ZDV for reducing perinatal transmission.

Summary and Future

In summary, recommendations for preventing perinatal HIV transmission in the USA include providing antenatal care and prenatal HIV counseling and testing for all pregnant women, using antiretroviral therapy that includes the ACTG 076 ZDV regimen, minimizing exposure of the fetus to blood and other infected fluids, avoiding breast feeding, and assuring appropriate follow up care for HIV-infected women and their children. In addition, recent data have also suggested that the use of elective cesarean section may also reduce the risk for perinatal transmission, even among women using the ACTG 076 AZT regimen. However, no recommendations have been made yet for the routine use of cesarean section to prevent perinatal transmission.

Current issues remaining for perinatal HIV prevention in the US include 1) determining the short and long term safety of the variety of antiretrovirals used by women during pregnancy; 2) whether use of cesarean section offers additional reduction in transmission risk for women using combination therapy and if it is safe for HIV-infected women; 3) whether interventions can be developed for women not in antenatal care; and 4) if it might be possible to completely eliminate perinatal transmission in the US some day.

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厚生省エイズ動向委員会

目次

概 要

1. エイズ発生動向調査(サーベイランス)報告の概要

エイズ**発生動向調査(サーベイランス)**は昭和 59(1984)年から開始され、後天性免疫不全症候群の予防に関する法律が平成元(1989)年に施行されることによって整備され現在に至っている。報告の流れとしては、HIV 感染者あるいは AIDS 患者を診断した医師が都道府県・政令市に「エイズ病原体感染者報告票」(以下、初回報告票と呼ぶ)を7日以内に提出し、その報告票が都道府県・政令市から厚生省保健医療局エイズ疾病対策課に集められる。初回報告票がすでに提出された HIV 感染者あるいは AIDS 患者に病状の変化(HIV 感染者が AIDS 発病または死亡、AIDS 患者が死亡)があった場合、「エイズ病原体感染者報告票(病状に変化を生じた事項に関する報告)」(以下、病変報告票と呼ぶ)が同様の流れで集められる。いずれの報告票もエイズ動向委員会による審査を通して確定される。なお、凝固因子製剤による感染はこの報告の対象外である。

初回報告票の内容は、HIV 感染者・AIDS 患者の別、国籍、感染経路、性、年齢、感染地(日本国内・海外)、居住地(都道府県・政令市)、診断年月日、報告年月日などである。病変報告票の内容は、病状の変化の状況とその年月日が入ることを除けば、初回報告票とほぼ同じである。なお、いずれの報告票でも、氏名、生年月日などの個人を特定できる情報は含まれていない。

2. 発生動向調査(サーベイランス)のための AIDS 診断基準は下記の通りである

I　HIV 検査で感染が認められた場合

酵素抗体法(ELISA)又はゼラチン粒子凝集法(PA 法)といった HIV の抗体スクリーニング検査法の結果が陽性で、かつ Western Blot 法又は蛍光抗体法(IFA)といった確認検査法の結果も陽性であった場合、または抗原検査、ウイルス培養、PCR 法などの病原体に関する検査(以下、「病原検査」という。)により HIV 感染が認められた場合であって、下記の特徴的症状(indicator Diseases)の1つ以上が明らかに認められるときは AIDS と診断する。

II　周産期に母親が HIV に感染していたと考えられる生後 15ヶ月未満の児の場合

周産期に母親が HIV に感染していたと考えられる生後 15ヶ月未満の児については、HIV の抗体確認検査が陽性であっても、それだけでは HIV 感染の有無は判定できないので、さらに以下の①または②のいずれかに該当する場合で免疫不全を起こす他の原因が認められないものを AIDS と診断する。

① HIV 抗体検査、ウイルス分離、PCR 法などの病原検査法が陽性で、特徴的症状の1つ以上が明らかに認められるとき

② 血清免疫グロブリンの高値に加え、リンパ球数の減少、CD4 陽性Tリンパ球数の減少、CD4 陽性Tリンパ球数／CD8 陽性Tリンパ球数比の減少といった免疫学的検査所見のいずれかを有する場合であって、特徴的症状の1つ以上が明らかに認められるとき

（特徴的症状）

1　カンジダ症（食道、気管、気管支又は肺）
2　クリプトコックス症（肺以外）
3　クリプトスポリジウム症（1ヶ月以上続く下痢を伴ったもの）
4　サイトメガロウイルス感染症（生後1ヶ月以上で、肺、脾、リンパ節以外）
5　単純ヘルペスウイルス感染症（1ヶ月以上継続する粘膜、皮膚の潰瘍を呈するもの又は生後1ヶ月以後で気管支炎、肺炎、食道炎を併発するもの）
6　カポジ肉腫（年齢を問わず）
7　原発性脳リンパ腫（年齢を問わず）
8　リンパ性間質性肺炎／肺リンパ過形成：LIP/PLH complex　(13 歳未満)
9　非定型抗酸菌症（結核以外で、肺、皮膚、頸部もしくは肺門リンパ節以外の部位、又はこれらに加えて全身に播種したもの）
10 ニューモシスチス・カリニ肺炎
11 進行性多発性白質脳症
12 トキソプラズマ脳症（生後1ヶ月以後）
13 化膿性細菌感染症（13歳未満で、ヘモフィルス、連鎖球菌等の化膿性細菌による敗血症、肺炎、髄膜炎、骨関節炎又は中耳・皮膚粘膜以外の部位の深在臓器の腫瘍が2年以内に、二つ以上、多発あるいは繰り返して起こったもの）
14 コクシジオイデス症（肺、頸部もしくは肺門リンパ節以外に又はそれらの部位に加えて全身に播種したもの）
15 HIV 脳症（HIV 痴呆、AIDS 痴呆又は HIV 亜急性脳炎）
16 ヒストプラスマ症（肺、頸部もしくは肺門リンパ節以外に、又はそれらの部位に加えて全身に播種したもの）
17 イソスポラ症（1ヶ月以上続く下痢）
18 非ホジキンリンパ腫（B細胞もしくは免疫学的に未分類で組織学的に切れ込みのない小リンパ球性リンパ腫又は免疫芽細胞性肉腫）
19 活動性結核（肺結核（13歳以上）又は肺外結核）
20 サルモネラ菌血症（再発を繰り返すもので、チフス菌によるものを除く。）
21 HIV 消耗性症候群（全身衰弱又はスリム病）
22 反復性肺炎
23 浸潤性子宮頸癌

※　19 のうち、肺結核、22、23 は 1994 年の新たな診断基準で採用された特徴的症状である。
※※ 肺結核及び浸潤性子宮頸癌については、HIV による免疫不全を示唆する症状または所見がみられる場合に限る。

（厚生省エイズサーベイランス委員会、1994）