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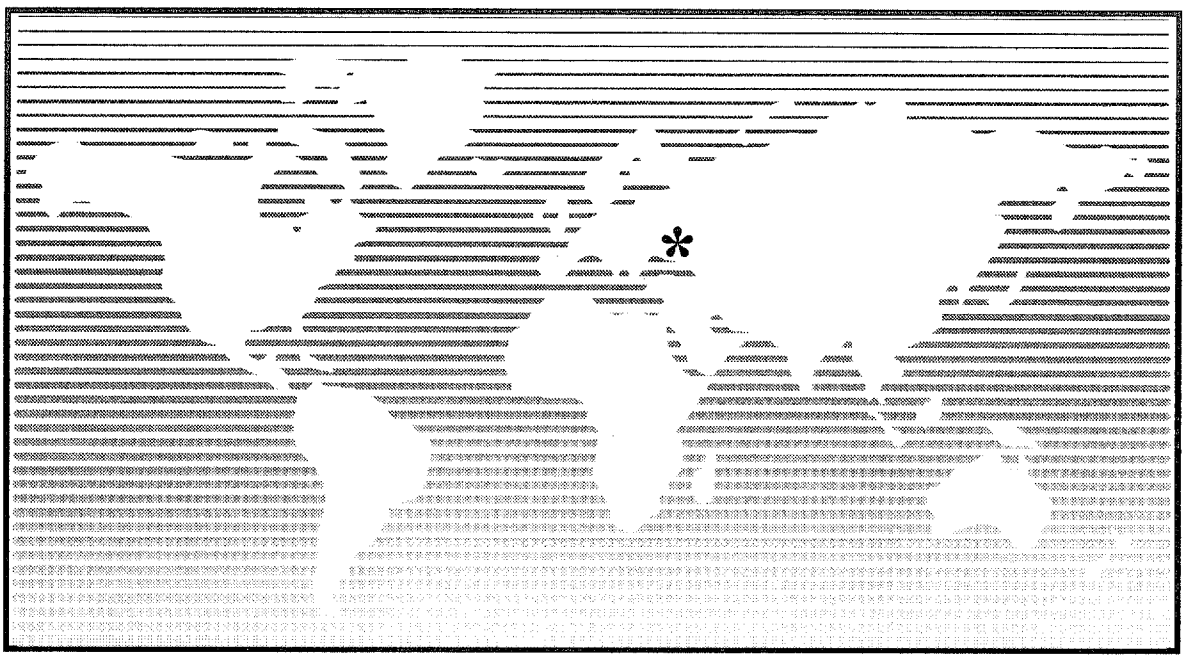

Submitted by:
Program for Appropriate Technology in Health (PATH)
4 Nickerson Street
Seattle, Washington 98109 U.S.A.
Tel: (206) 285-3500/Fax: (206) 285-6619/E-Mail: info@path.org

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EXECUTIVE SUMMARY

PATH was awarded a Cooperative Agreement (CA) by USAID in May 1994 to provide assistance to Ukraine with three important health problems previously identified by Ukrainian health authorities:

- The Diphtheria Epidemic
- Bloodborne Infection Control among Health Care Workers
- Diabetes Mellitus among Children

DIPHTHERIA CONTROL

Course of the Diphtheria Epidemic

Diphtheria had once been endemic to Ukraine, but with the introduction of Soviet immunization in the 1960s, the number of diphtheria cases fell sharply. In the mid-1980s, following several years of decline in the public health infrastructure, diphtheria began to surge again in the Soviet Union. By 1991, epidemic diphtheria had returned to Ukraine. By 1993, the epidemic had spread to over half the oblasts in the country and by 1995 virtually the entire country was affected. Further information on the characteristics of the epidemic are described in the report.

Evolution of USAID/PATH Collaboration with the Ministry of Health (MOH)

The initial objectives of the PATH diphtheria project component were primarily humanitarian, providing to Ukraine 22 million doses of tetanus diphtheria toxoid (Td) vaccine, as well as antitoxin, antibiotics, and diphtheria diagnostic laboratory materials.

In collaboration with the MOH and WHO, the USAID/PATH immunization strategy evolved and expanded, leading to provision of 10 million additional doses of Td vaccine.

Early discrepancies in data provided to PATH by the MOH and the oblasts led to the establishment of the PATH Technical Assistance Group (TAG), to upgrade technical support to PATH Ukraine project management. The work of the TAG is explained in detail in the report.

By the end of 1995, the project's scope had extended far beyond humanitarian assistance activity to include enhanced monitoring of vaccine consumption, collaborative assessments of vaccine coverage and seroconversion, a case-control study, and epidemiologic impact analyses.

The Ukrainian Response and USAID/PATH Program Accomplishments

Mass Campaign Strategy: The Ukrainian adult mass immunization strategy against diphtheria was the first time since the 1976 swine flu immunization program in the U.S. that such a national strategy had been adopted. It represents the only time in history that universal adult immunization had been adopted to arrest an epidemic already in progress. Over 18 months, campaigns were conducted in all 27 oblasts and administrative regions of the country.

High Coverage Achieved: Approximately 85 percent of the adult population were immunized during the two-year mass immunization period.

Td Vaccine Efficacy Demonstrated: Case data show that even a single dose of Td vaccine seems to confer marked protection for all ages, that two doses provide more protection, and that three doses virtually eliminate age-specific risk differences.

Case data analysis shows clearly that the overwhelming majority of new cases continues to come from among the unimmunized and partially immunized population.

A PATH/MOH case-control study estimated that disease risk was decreased by over 70 percent for individuals who had received three or more recent doses of vaccine.

Impact: It is clear that the diphtheria epidemic is abating in Ukraine. In all but one oblast, disease incidence was lower in 1996 than it had been in 1995. This decrease is consistent across all age groups and accelerated as 1996 progressed. Preliminary MOH data for 1997 confirm that these decreases continue. Data for the first eleven months of 1997 show a 59 percent reduction in incidence over that of the same period in 1996.

Although PATH cannot say absolutely that the decreases seen since late 1995 stem from the Ukrainian immunization program rather than natural epidemic burn-out, a number of observations discussed in this report give strong support to the conclusion that the immunization program has been effective.

This pronounced abatement of the epidemic was achieved through an infusion of 32 million Td vaccine doses under the USAID/PATH program, 23 million doses provided by the IFRC, and an unknown but substantial quantity of Ukrainian-procured Russian and European vaccine.

Lessons Learned

Despite the exceptional relationship of cooperation that PATH enjoyed with the MOH, certain problems persisted throughout the project. These included a persistence of inaccurate vaccine management information, vocal resistance from certain quarters within the medical community to the use of the Western Td vaccine, and decentralization of public health management decision making. Please see the report for fuller discussion.

Major Supporting Program Subcomponents

Other vigorous efforts toward strengthening sustainability of Ukrainian public health capacity were instituted under this project. Here are some highlights from the full report:

- Information, Education, Communication (IEC) Regional Seminars introduced a PATH curriculum translated into Ukrainian and trained over 75 master trainers and health educators.

- Diphtheria Diagnostic Laboratory Supplies for toxigenicity testing were supplied in quantities sufficient for two years.

- PCR Lab Equipment provided by PATH outfitted the first laboratory in Ukraine to be able to perform this versatile molecular biological procedure (Polymerase Chain Reaction).

- Cold Chain Monitoring electronic equipment was provided to the central and all oblast vaccine cold stores.

- Assessment of BIOLEK Vaccine Facility in Kharkiv was carried out, and a report was transmitted to USAID.

- Vaccine Procurement Training for 63 central and oblast procurement managers and 13 vaccine specialists was carried out.

BLOODBORNE INFECTION CONTROL (BBIC)

Overview

The original impetus for the bloodborne infection control (BBIC) component was the high prevalence of hepatitis B among Ukrainian health care workers (HCWs). Although hepatitis B (HB) vaccination is the cornerstone of HB prevention among health care workers, the provision of HB vaccine by this project was never feasible because of the cost of U.S.-source HB vaccine that would be required under USAID procurement regulations, nor desirable because of its nonsustainability.

Accordingly, PATH provided assistance to improve control of all bloodborne infections in the health care setting, including hepatitis B, that did not depend on HB vaccine procurement. This more comprehensive approach diminishes exposure to other bloodborne pathogens such as hepatitis C virus, human immunodeficiency virus, and cytomegalovirus for which no vaccines yet exist.

Project Goals

PATH approached the improvement of BBIC through the following:

- the application of the COBEX (COllaborative Blood Exposure) study methodology: COBEX is an applied epidemiological survey technique that permits a hospital staff to analyze the incidents of blood exposure among its personnel in order to define the kinds of risk the health care workers are encountering in their work. From the COBEX study, a hospital staff can devise a risk reduction strategy specific to the problems revealed by the study. The COBEX study can be repeated and the results can reveal issues in compliance or other problems in risk management.

- the production and distribution of educational materials: PATH developed and distributed a monograph, a brochure, slide talks, and a poster in Russian and Ukrainian for use by health care professionals and students.

- establishing a sewing workshop for the production of surgical barrier clothing: PATH identified a partner in Kyiv and procured sewing equipment and some early production supplies for the facility. Territorial Medical Amalgamation (TMA) has demonstrated they have the ability to design and manufacture western-style medical barrier garments of good quality. However, early production output is low. TMA now needs to focus its efforts on developing a marketing strategy and system to promote and distribute its products.

- the study of glove use and failure in the hospital setting: The study assessed the impact of introducing purpose-specific gloves on glove usage and glove failure rates among hospital workers and estimated future glove commodity needs. The study showed strikingly that where there is an inadequate supply of gloves, both in quality and quantity, health workers are at risk for bloodborne infection exposure. Two possible approaches to projecting future glove requirements are described in the report.

Implementation of COBEX Strategy and Use of Educational Materials

PATH collaborated with two AIHA partnership hospitals, the Lviv Railway Hospital (LRH) and the Odessa Oblast Clinical Hospital (OOCH), where the COBEX studies were first carried out and personnel trained in their use. Through two regional conferences, three additional hospitals were identified to do COBEX studies. PATH then disseminated the COBEX methodology to a broader circle of 30 hospitals. These participating hospitals were given a limited supply of gloves and goggles as incentive and compensation for the investment of their time and effort. Trainer-coordinators from the initial COBEX study hospitals assisted the 30 new hospitals. COBEX study findings and blood exposure risk reduction strategies are discussed in the report.

PATH sponsored a national summation conference in March 1997. Recommendations for lowering blood exposures were prepared, which emphasized broader and more specific education in BBIC for HCWs at all levels; greater access to adequate barrier materials through more effective procurement and local production; and access to hepatitis B vaccine for all HCWs.

The USAID/PATH BBIC educational materials were distributed at the conference and later delivered to other hospitals and educational institutions. Taking advantage of these materials, they conducted training for each level of medical worker—physician, nurse, midwife, and sanitary personnel. Three quarters of the 35 participating hospitals reported completion of the first COBEX study and compilation of a risk reduction strategy based upon the results; nearly half of this group reported completion of a second COBEX study.

PATH believes that this project activity has significantly raised the awareness of the dangers of blood exposures and need for prevention strategies among HCWs in Ukraine. As a result of the COBEX study in their hospitals, they discovered the need to change some techniques, especially in laboratory practice (handling of blood samples), surgical practice (finger-guided suturing, passing of instruments), starting IVs, and in labor and delivery practice (internal examination).

Lessons Learned/Concluding Observations

The BBIC project was challenged by the sustained support required for implementing the COBEX methodology and the lack of consistent support from central health officials. Nevertheless, interest in BBIC increased substantially over the course of the project, perhaps because the acute rise in HIV infection in Ukraine posed a real threat to the underprotected HCWs. The BBIC educational materials were very popular.

DIABETES MELLITUS IN CHILDREN

Overview

This program component had three main goals:

1. To provide diabetic children with insulin and diabetic supplies for one year.

   Approximately 4,000 children to the age of 15 registered as having diabetes were served during the course of PATH project activity in Ukraine. They received a one-year supply of insulin, needles and syringes, and glucose and ketone monitoring supplies.

2. To provide diabetic educational materials to patients and health care professionals.

   A popular American instructional manual for children written by Dr. Luther Travis, Professor of Pediatrics of the University of Texas Medical Branch , Galveston, Texas, was adapted for Ukraine, translated into Ukrainian, published, and delivered to oblast endocrinologists for distribution to the children.

   In September 1996, PATH and the MOH sponsored an educational conference on the care of children with diabetes near Kyiv for oblast pediatric endocrinologists and other interested specialists.

3. To assess and document the ongoing needs of diabetic children at the end of the project.

   The educational conference allowed the visiting PATH team to assess the current status of diabetic care for the children and related supply issues. The resultant report was submitted to USAID in November 1996.

Parent Telephone Survey

To gather some updated information, PATH conducted a telephone survey of the parents of 71 children who were listed in the patient registry. Some of the information follows:

- All 71 parents reported receiving the raion to patient transfer form with their insulin, indicating that the distribution system PATH designed was used correctly.
- A total of 94.4 percent reported no problems in getting their USAID/PATH insulin and supplies. The remainder reported not getting their insulin on time.
- All 71 received their blood glucose and urine ketone strips and 87.3 percent reported they had used them as needed.
- Price for a vial of insulin among the 56.3 percent of 71 telephone respondents who pay for their insulin varied from 8 hryvnyas to 41 hryvnyas (US$4.25-$21.80). A large number apparently depend on humanitarian or governmental aid.

Conclusions and Recommendations

The PATH/USAID project in humanitarian assistance to the children with diabetes in Ukraine was much appreciated by the physicians of the children, and by the parents. As temporary humanitarian assistance, the project has been a success.

As this project ended, PATH was not aware of any international donor programs of similar scope for Ukraine's diabetic children. PATH makes a series of recommendations in the report concerning international donor activity.

CROSS-CUTTING ISSUES

Implications of Increasing Decentralization

PATH observed a growing tendency toward decentralization of power and decision-making in each of the three program components. PATH sought to collaborate intensely with the central government, represented by the MOH, but came to understand that the periphery, represented by the oblasts, was taking independent actions and assuming initiative. Accordingly, PATH took a "both-and" approach, working collaboratively with the center but also going to great lengths to meet the periphery.

A listing of all procurement is found as Attachment 1. A listing of all publications and materials produced is found as Attachment 2.

INTRODUCTION

PATH was awarded a Cooperative Agreement (CA) by USAID in May 1994 to provide assistance to Ukraine with three important health problems previously identified by Ukrainian health authorities:

- The Diphtheria Epidemic
- Bloodborne Infection Control among Health Care Workers
- Diabetes Mellitus among Children

This final report of PATH activities under this CA will consider each of these three components separately.

CONTRACTUAL HISTORY/FINANCIAL REPORT

- PATH's proposal submitted April 13, 1994, in response to USAID's Request for Application (RFA) was approved verbally April 28, 1994.

- The CA was signed June 9, 1994, effective April 29, 1994, for a term of two years and an award of $11,340,000.

- The first cost extension was granted on July 1, 1995, for an extension through October 31, 1996, to permit procurement of an additional 10 million doses of diphtheria vaccine, with an increase in funds of $1,965,000, for a total award of $13,305,000.

- The second cost extension was granted September 30, 1996, for an extension through April 30, 1997, to permit continuation of technical assistance in diphtheria control and bloodborne infection control. Additional funds in the amount of $95,270 for technical training in vaccine procurement increased the the total award to $13,400,270.

- The third and final extension was granted April 14, 1997, through October 31, 1997, to permit completion of technical assistance in bloodborne infection control and vaccine procurement training, technical support to the new PCR laboratory, and start-up of the surgical barrier clothing sewing workshop, both equipped by PATH. The total award remained at $13,400,270.

- A total of $9,537,317 was expended for commodities and freight for the three project components, and $3,856,246 for programmatic activities. The final financial report will be submitted under separate cover.

DIPHTHERIA CONTROL

Historical Introduction: Evolution of USAID/PATH Collaboration with the Ministry of Health (MOH)

Initial Operative Assumptions

At its inception, the stated objectives of the PATH diphtheria project component were clearly humanitarian and relatively short term. The project would procure and deliver to Ukraine 22 million doses of tetanus diphtheria toxoid (Td) vaccine, as well as antitoxin, antibiotics, and diphtheria diagnostic laboratory materials. In addition, assistance in social mobilization for the immunization campaign would be forthcoming from the information, education, communication (IEC) activities of the overall project. PATH was guided by the principle that the Ukrainian authorities would control and direct the diphtheria campaign. For its part, PATH would provide the commodities and seek collaboration in the sharing of information and data needed for the accountability of this humanitarian assistance project.

Shifts in Diphtheria Control Strategy

Prior to USAID/PATH involvement, the Ministry of Health (MOH) of Ukraine had a strategy for diphtheria control focusing on vaccinating adults in "high-risk" groups. At the time there was no official World Health Organization (WHO) diphtheria control policy in the Newly Independent States (NIS). The initial USAID/PATH response supported a strategy of immunization of the urban adult population with two doses, each one month apart, in the ten oblasts with the highest incidence of diphtheria. This focus on adults was a tactical decision based on the observation that around 80 percent of all cases were adults, and the fact that children were receiving UNICEF vaccine coverage. This early strategy turned out to be too restrictive and was unresponsive to the dynamics of the epidemic. It was never implemented by the MOH.

Meanwhile, the World Health Organization (WHO) policy for adult diphtheria immunization was formulated over the course of a series of consultative meetings and released in April 1995. It recommended one dose of Td vaccine for all adolescents and adults, 16-59 years of age, to be administered in 10-day mass immunization campaigns. In addition, adults 30-49 years of age were to receive two booster doses at one month and 6-12 months following the initial campaign dose. The decision to include these second and third doses was based upon United States Centers for Disease Control (CDC) field studies which found that a significant proportion of adults in this older age group, particularly those over 40 years of age, did not develop a sufficient protective immune response to a single dose of Td. The one campaign dose would be provided by international donors, including USAID/PATH, while second and third doses would be derived by Ukrainian government procurement. This expanded coverage strategy led to the first modification of this CA, which enabled the provision of 10 million additional doses of Td vaccine.

PATH's Response to Technical Issues

Throughout the early period of the project, discrepancies in data provided to PATH by the MOH and the oblasts made interpretation of strategy compliance and monitoring of the commodities very difficult. As these problems arose, PATH became intensely involved with the MOH in an array of technical questions related to the diphtheria control effort. During this time, PATH helped organize and support a joint WHO/MOH assessment conference (February 27-28, 1995) and lent substantial logistical support to the CDC for carrying out field studies. USAID's mid-course project review report in August 1995 documented the data problems and concluded that PATH was hampered in its ability to monitor progress.

In response to these concerns, PATH established a Technical Assistance Group (TAG) comprised of three epidemiologists and one physician (Drs. David Mercer, Vivien Tsu, James Maynard, and Roscius Doan) based in PATH Seattle, to upgrade technical support to PATH Ukraine-based project management (Mr. John Pott and Dr. Dmitri Tyshchenko). From September 1995, members of the TAG made regular, frequent trips to Ukraine to establish a system for obtaining distribution and consumption data on the Td vaccine. The TAG enjoyed an exceptional collaborative relationship with the MOH, but nevertheless experienced problems with accurate assessment of vaccine distribution, consumption, coverage, and wastage throughout the project.

While this activity was originally conceived as a humanitarian assistance activity, by the end of 1995 the project's scope had extended far beyond that, even beyond enhanced monitoring of vaccine consumption, to include collaborative assessments of vaccine coverage and seroconversion, a case-control study, and epidemiologic impact analyses.

Course of the Diphtheria Epidemic

Following is a summary description of the course of the epidemic. A fuller account can be found as Attachment 3.

Historical Background

Diphtheria has long been recognized as endemic to the Ukraine region. Beginning in the 1960s, following the introduction by the Soviet Union of immunizations with diphtheria toxoid vaccines (DTP,DT,Td), the number of diphtheria cases in Ukraine decreased sharply by the late 1970s to fewer than one case per 1,000,000 population. Transmission was never completely interrupted, however. Isolated outbreaks persisted throughout the 1970s and 1980s, primarily among children. In the mid-1980s, following several years of decline in the public health infrastructure, diphtheria began to surge again in the Soviet Union, primarily in the major urban centers of western Russia. This Russian epidemic, which reached a peak incidence in 1995 of more than 50 cases per 100,000 population, differed from previous ones in that it primarily affected adults. By 1991, the first year of Ukrainian independence, epidemic diphtheria had returned to Ukraine, with a sharp rise in

incidence in the cities of Kyiv, Lviv, and Odessa. By 1993, the epidemic had spread to over half the oblasts in the country and by 1995 virtually the entire country was affected (see Figure 1 of Attachment 3).

Description of Epidemic

Epidemic Dynamics

The spread of the diphtheria epidemic from Russia into Ukraine was first recognized in 1991 in major urban areas of the country. Following a brief decline in early 1994, a second epidemic wave hit the country in late 1994 and 1995, peaking in the fourth quarter of 1995 with an annualized crude incidence of 15 cases per 100,000 population. Incidence began dropping in late 1995, following the introduction of mass immunization campaigns, and by December 1996 crude incidence was the lowest it had been in over two years (Graph 1 of Attachment 3). The last quarter of 1996 saw the lowest fourth quarter incidence in four years (Graph 2 of Attachment 3).

Age and Sex Differences

A distinctive feature of the Ukrainian epidemic was the sharp age and sex-specific differences in risk and severity of disease. Over 80 percent of the cases were among adults over 15 years old, and as the epidemic progressed, adolescents 16-19 years old and adults 40-49 years old shared the highest incidence rates (Graph 3 of Attachment 3). Graph 3 also shows the marked difference in sex-specific risk of disease. While disease incidence differed little between males and females below the age of 10 years, among adolescents it increased sharply in females relative to males. By the age of 25, cases among women were almost twice as common as among men, a differential that remained into old-age. Possible explanations for this age and sex pattern of disease are presented in the report as Attachment 3.

Mortality

Between 1993 and 1996 there were 519 deaths attributed to diphtheria, reflecting an overall case-fatality ratio (CFR), i.e., the proportion of cases resulting in death, of 3.6 percent. As the epidemic increased during this period, so too did CFR, from 2.6 percent in 1993 to 4.0 percent in 1995 before dropping slightly in 1996 to 3.6 percent.

Deaths from diphtheria were concentrated among children under 10 years and adults, particularly men, over 35 years of age. Graph 4 of Attachment 3 superimposes these two patterns, showing the strong bi-modal age distribution of diphtheria deaths and the over-representation of non-fatal cases relative to fatal cases among those aged 10-35 years. While stable for most age groups, between 1993 and 1996 the risk that a case would be fatal increased by as much as 175 percent among those over 40 years old.

The CFR was higher for males in every age group except the very youngest. This sex difference in case-fatality ratio was greatest for adults over 30 years old, and among the oldest cases, death resulted almost twice as often for men as for women (Graph 5 of Attachment 3).

Case fatality rates differed markedly between urban and rural areas. The cases in the latter areas were, overall, more than two times more likely to result in death than were cases from urban areas (CFR 6.2 percent vs. 2.8 percent).

The Ukrainian Response and the USAID/PATH Program

Mass Campaign Strategy

In February 1995, at an international conference called by the Government of Ukraine (GOU) and WHO; organized by PATH and the MOH; and attended by advisors from the MOH, USAID, PATH, WHO, CDC, the International Federation of Red Cross and Red Crescent Societies (IFRC), and UNICEF, Ukraine adopted an ambitious mass-immunization strategy in which all adults between the ages of 16 and 59 years were to receive at least one dose of Td vaccine through regional mass immunization campaigns. Those between 30 and 49 years of age were to receive subsequent additional doses following recommendations by WHO and CDC.

The first campaigns were organized and carried out in April 1995 in four oblasts (Odeska, Khersonska, Zaporizka, Mikolaivska), the Republic of Crimea, and the cities of Kyiv and Sevastopol. Over the next 18 months, campaigns were conducted in all 27 oblasts and administrative regions of the country. However, it became clear that the use of a considerable proportion of USAID/PATH vaccine was not in compliance with the established one-dose campaign strategy, but was distributed to oblasts and used during noncampaign periods for routine immunizations and for second and third follow-up doses. As noted earlier, because data deficiencies made project accountability for vaccine distribution, consumption, and coverage nearly impossible, PATH established a TAG to enhance monitoring and evaluation. By the end of 1995, PATH had reached agreement with the MOH on a new reporting system. These new reporting requirements became effective in January 1996 and formed the basis for subsequent PATH estimates of vaccine consumption and coverage.

Coverage

PATH has carefully examined oblast reports for 1996, along with retrospective vaccination numbers provided by oblasts for 1995, and estimates that approximately 85 percent of the adult population were immunized, using the official Ukrainian definition of three Td doses within a year, during the two-year mass immunization period.

One measure of increasing coverage is, curiously, a rising proportion of cases who had been fully or partially immunized. The proportion of cases who received two or more

doses in the two years prior to onset of disease has increased almost seven fold since 1993, from 3.4 percent to 23.2 percent. This is consistent with expected vaccine efficacy, which is less than 100 percent (see also Graph 6 in Attachment 3, and discussion).

Case data from 1995 and 1996 show clearly that the overwhelming majority of new cases continues to come from among the unimmunized and partially immunized population (Graph 7 of Attachment 3). This population provides the pool of circulating toxigenic *C. diphtheriae* which allows the epidemic to continue, albeit at decreasing levels over time. Graph 7 is especially important in that it shows that even a single dose seems to confer marked protection for all ages, that two doses provide more protection, and that three doses virtually eliminate age-specific risk differences.

Impact

It is clear that the diphtheria epidemic is abating in Ukraine. In all but one oblast, disease incidence was lower in 1996 than it had been in 1995, and for many oblasts, particularly those that were hardest hit by the epidemic in 1995, 1996 incidence was lower than it had been in 1993 (Table 2 of Attachment 3). This decrease is consistent across all age groups (Graph 8 of Attachment 3) and accelerated as 1996 progressed. The change in the rate of decrease has been largely exponential over time, approximating a mirror image of the exponential rate of increase witnessed between June 1994 and June 1995 (Graph 9 of Attachment 3).

Incomplete data for 1997 confirm that these decreases continue. The preliminary MOH report for the first eleven months of 1997 registers 1,222 diphtheria cases, whereas the same period in 1996 registered 2,988 cases. This represents a 59 percent reduction in incidence over the previous year.

Summing Up

PATH cannot say with absolute certainty that the decreases seen since late 1995 stem from the Ukrainian immunization program rather than the natural epidemic burnout associated with infectious disease outbreaks. However, the following observations give strong support to the notion that the immunization program has been effective:

- The incidence in Ukraine never approached the levels seen in neighboring Russia, although there is no apparent distinguishing demographic or immunologic history to explain why Ukraine's experience should have been different.
- The incidence began to decrease within six months of the initiation of the mass campaigns.
- The rate of decrease has been greatest in those oblasts where mass campaigns were conducted.
- A case-control study conducted by PATH in 1996 estimated that disease risk was decreased by over 70 percent for individuals who had received three or more recent doses of vaccine (see case-control study provided as Attachment 4).

- Government statistics and coverage surveys show that since the initiation of mass campaigns in the spring of 1995, adult coverage with three or more doses of vaccine has increased to over 80 percent. This was achieved through an infusion of 32 million Td vaccine doses under the USAID/PATH program, 23 million doses provided by the IFRC, and an unknown but substantial quantity of Ukrainian-procured Russian and European vaccine.

The Ukrainian effort of adult mass immunization against diphtheria was the first time since the 1976 swine flu immunization program in the United States (U.S.) that such a national strategy had been adopted. It represents the only time in history that universal adult immunization had been adopted to arrest an epidemic already in progress. The immunization strategy has had success. Yet the persistence of lower levels of diphtheria despite these massive efforts speaks to the poor cost-efficiency of adult immunization in the prevention of disease outbreaks. The current Ukrainian epidemic started among children who had been inadequately immunized and spread quickly to inadequately protected adults. The cost of prevention by universal childhood immunization and periodic boosters is far less than that of arresting an established epidemic.

Ukraine will require universal EPI coverage of her children, rigorous adult immunization, and rapid case investigation with prophylactic treatment of case contacts for years to come. But the current evidence justifies optimism that diphtheria is coming under control in the country, and that the massive public health response mounted by the Ukrainian MOH, with support from international donor agencies, is in large part responsible.

Lessons Learned

Despite the exceptional relationship of cooperation that PATH enjoyed with the MOH, certain problems persisted throughout the project:

Persistence of Inaccurate Vaccine Management Information

- Local preparation and capacity for accurate vaccine tracking was often lacking.
- Many details of immunization strategy and campaign implementation changed over the course of the project.
- Statistical definitions and reporting standards were disparate among oblasts.

In retrospect, USAID/PATH underestimated the readiness of the Ukrainian public health structure to respond to the needs of donors for reliable monitoring data on vaccine distribution, consumption, and coverage.

- Although PATH implemented new reporting forms in collaboration with the MOH, the oblasts had little opportunity to prepare for the reporting changes.
- Furthermore, oblasts had little input into these changes, received little feedback, and perceived few benefits from the new information requirements.

- Consequently, compliance with the new informational procedures was uneven, especially in the early months.

Resistance from Vocal Quarters within the Ukrainian Medical Community to the Use of the Western Td Vaccine

- Concerns were expressed about the efficacy of Western vaccination because of its lower diphtheria toxoid antigen content, as measured by Lf (flocculation units).
- Some ardent opponents rejected the mass immunization strategy, or even the effectiveness of immunization altogether. But this vocal minority did not prevail at the MOH.

This distrust of immunizations had spawned negative publicity in both Ukraine and elsewhere in the NIS. It served as a major impetus to PATH's participation in the field studies mentioned earlier and contributed to the urgent importance of IEC support to the mass immunization campaign.

Economic Distress and Concurrent Decentralization of Public Health Management

- PATH often found demoralized but willing public health staff who had not been paid for several months.
- Increasing decentralization of management eroded the central authority of Kyiv.

Major Supporting Program Subcomponents

The procurement, delivery, and distribution of 32 million doses of Td vaccine together with its monitoring by the TAG was the crucial element of the USAID/PATH diphtheria project. However, other vigorous efforts toward strengthening sustainability of Ukrainian public health capacity were instituted under this project. These included the following:

Information, Education, Communication (IEC) Activities

Initially, PATH's IEC Specialist, Ms. Barbara Crook, produced and scheduled broadcast of four TV spots and collaborated with and provided some financial support to Dr. Movchaniuk, Director of the Republican Health Education Center, to support the social mobilization campaign strategy for the 1995 winter diphtheria immunization campaign. Concomitantly, Ms. Crook spearheaded four regional IEC seminars developed specifically to ensure sustainability of IEC capacity within the MOH. To conduct these IEC regional seminars, PATH developed, translated, and pretested a comprehensive IEC curriculum that focused on the design and development of public health mass media campaigns and informational materials development. The overall purpose of the IEC seminars was to train a core of master trainers and the Chief Physicians of Oblast and City Health Education Centers throughout Ukraine to conduct social mobilization campaigns that would support immunization and other public health campaigns.

The four regional IEC seminars took place in Kherson, Uzhhorod, Kharkiv, and Ternopil. The most unique feature that distinguished the last seminar from the previous three was that the Ukrainian master trainers had overall responsibility for conducting the seminar, with Ms. Crook playing primarily an advisor role. Seventy-five health educators were trained through the four seminars.

Additional IEC support was provided during the April-May 1996 diphtheria mass immunization campaign when Ms. Crook, Ms. Marcia Rock of BASICS, and Ukrainian collaborators implemented a social mobilization strategy in support of the three eastern oblast campaigns. They were part of the PATH/USAID/CDC Consultative Team that worked closely with oblast health officials to determine immunization and social mobilization strategies. PATH produced and scheduled broadcast of two new TV spots, and produced and distributed, in collaboration with a local NGO and the local Health Education Centers, thousands of copies of posters, leaflets, a press release, and a general fact sheet throughout the immunization campaign areas.

For a fuller account of IEC/social mobilization efforts, see Attachment 5.

Laboratory Supplies and PCR Lab Equipment

Laboratory Supplies Provided

PATH provided basic materials to supply the diphtheria laboratory diagnostic capacity of Ukraine. These materials consisted of Hoyles medium, needed for culture before the Elek test for *C. diphtheriae* toxigenicity is performed, and Rosco PZA test kits, a confirmatory biochemical test system.

Ukraine's First PCR Laboratory Equipped.

PATH consultant Dr. Marie Coyle, Professor of Laboratory Medicine at Harborview Medical Center, Seattle, Washington, traveled to Ukraine twice to help define the needs for laboratory diagnostics and to assess the status of laboratory support for diphtheria diagnosis. It was one of Dr. Coyle's recommendations that PATH consider supporting the upgrading of the central laboratory of the Ukrainian Center for Disease Surveillance, formerly the Republican Sanitary Epidemiological Station (SES) Laboratory, to give it PCR capability.

PCR is a laboratory technique which allows for amplification (replication) of small, defined DNA fragments in a test tube, enabling a wide range of subsequent analyses. The equipment and technique can be applied to many diagnostic problems in microbiology.

PATH procured and delivered the equipment needed to install the first PCR laboratory in Ukraine. Parallel with the provision of equipment, PATH arranged for Drs. Androulla Efstratiou and Kathy Engler of the Public Health Laboratory Services' (PHLS) Central Public Health Laboratory in London to give technical support in the installation of the equipment and provide training to laboratory personnel on PCR techniques. This PCR training seminar for twelve participants took place in Kyiv on June 2-6, 1997.

Cold Chain Monitoring

In the early phase of the diphtheria project, PATH Ukraine Representative Mr. John Pott, an engineer and expert in cold chain management, conducted an assessment of the vaccine storage capacity in Ukraine prior to the initial shipment of Td vaccine. He found the system functional but precarious. In August 1994, Mr. Pott taught a WHO-sponsored cold chain instruction course in Odessa to 30 participants representing all the oblasts of Ukraine.

Under this project, USAID/PATH also provided electronic cold chain monitoring equipment (Tiny TTMs and TempTales) to Ukrvaccina, storage facilities at Obukhov, and to all oblast central vaccine stores. (Ukrvaccina is the government's designated central procurement agent.) These devices record at frequent intervals the ambient temperature on a small computer chip, which can be downloaded with appropriate software installed on a computer.

The electronic cold chain monitoring equipment has been very useful. The first cold chain break was detected during vaccine transport from Kyiv to Poltava (six hours at 24 degrees C), reported in August 1994. Also, in the Obukhov central stores temperatures very close to freezing were detected. The MOH took steps to correct these deficiencies.

PATH routinely included electronic cold chain monitors in all vaccine shipments. The monitors were downloaded on delivery of the vaccine to Ukrvaccina to check for thermal breaks. It should also be noted that this cold chain monitoring technology averted a mishap during one of PATH's insulin procurement deliveries, when insulin was found to have been exposed to freezing conditions and was immediately replaced by the manufacturer, Eli Lilly. (See PATH's Quarterly Report submitted January 31,1995, for further details.)

Assessment of BIOLEK Vaccine Facility in Kharkiv

Development of a base for local manufacture of vaccines can be seen as a major element in the national strategy of a sovereign state for achieving sustainable vaccine security. Accordingly, Dr. James Maynard of PATH and Dr. Alexis Shelokov, USAID consultant, made an assessment visit to the BIOLEK vaccine production site in Kharkiv in April 1996. They found a competent facility that under the appropriate circumstances could fully produce diphtheria combination vaccines and become the primary provider of these vaccines to Ukraine and perhaps neighboring countries. However, they felt there was a need for further technical assistance to determine the financial and technical feasibility for full production of an adequate line of vaccines.

For any international donor, support for such an enterprise may be controversial. If a given international agency determined that it favored local production of vaccine in Ukraine, focused technical assistance to BIOLEK could facilitate its achieving

international Good Manufacturing Practices standards. At the same time, technical assistance to the newly established national control authority (the National Committee on Biologics) could enhance its effectiveness and strengthen vaccine quality assurance.

Vaccine Procurement Training

PATH identified procurement of safe, effective vaccines at the lowest possible price to be an essential element in the achievement of national vaccine security as it assisted Ukraine in the diphtheria epidemic and participated in early discussions on national hepatitis B control strategy. Based on her previous experience in vaccine procurement training elsewhere in the NIS, PATH proposed to USAID that its procurement specialist, Ms. Dian Woodle, organize similar training in Ukraine. The proposal was accepted and funding for vaccine procurement training was granted. While the original training plan called for intensive, hands-on assistance to the government's designated central procurement agent, Ukrvaccina, the detailed assessment and evaluation during the planning phase revealed a widespread practice of decentralized vaccine procurement. With the encouragement of USAID/Kyiv, PATH developed an alternate program designed to reach many of the actual purchasers of vaccine as well as support the important role of Ukraine's newly developing national control authority for biologics in the procurement of safe, effective vaccine.

Subsequently, PATH organized a seminar on International Practices of Vaccine Procurement and Organization of Quality Assurance which was held at Pushcha Ozernaya near Kyiv July 14-16, 1997. Seminar participants included 63 national and oblast level specialists, including representatives of several commercial enterprises. Foreign faculty included representatives from USAID/PATH, WHO/EURO, and the United States Food and Drug Administration (USFDA). On July 17-18, 1997, following the main seminar, PATH procurement specialists convened a two-day working group on the Process for International Procurement of Vaccines for 13 national and oblast level specialists.

The purpose of the main seminar was to:

1) develop a common understanding of vaccine procurement and supply as it is currently practiced in Ukraine;
2) provide a forum for discussion of current practices and problems;
3) provide an opportunity for the MOH to disseminate directions, rules, and new developments applicable to vaccine procurement in Ukraine; and
4) furnish information on international vaccine procurement issues, practices, standards, and regulatory procedures, international sources, and relative pricing.

The purpose of the working group was to provide in-depth information on the international procurement process to personnel who are oriented toward hands-on procurement work.

Each participant of the main seminar received a large notebook containing Russian language overheads and text from each presentation plus relevant supplementary material.

Each working group participant received an additional compendium of training and reference materials, in Russian, aimed at guiding their efforts to obtain vaccine on the international market.

Recommendations from the seminar were that:

- USAID should continue to coordinate with international donors to address the potential shortfall in EPI vaccines for the near future.
- The MOH should be encouraged to seek the assistance of an economist to undertake an evaluation of Ukrvaccina's dual role as a government agent with national responsibilities and self-supporting vaccine supplier, and make recommendations for improving its competitiveness in the market and/or effectiveness as a government unit.
- Collaboration between the new Ukrainian Committee on Immunobiological Drug Control and the USFDA should be encouraged. Ukraine is facing the challenge of regulating vaccines in a political environment of increasing decentralization. The U.S. model of federal rules setting for local implementation in the U.S. is relevant to Ukraine.
- Ukrvaccina is charged with soliciting international vaccine donations, but regularly encounters problems with obtaining necessary data from the oblasts on a consistent, systematic basis. Assistance with inventory and reporting systems should be encouraged.
- A similar conference should be held yearly to enhance communication among the regions and with the central level.

The full report of the seminar transmitted to USAID on September 5, 1997, may be referred to for further details.

Conferences and Workshops

Over the course of the project, PATH sponsored or helped organize several important conferences and workshops under the diphtheria component. These included:

- August 8-10, 1994, Cold Chain Workshop held in Odessa by PATH Ukraine representative Mr. John Pott, using WHO curriculum. Taught to 30 participants from all the oblasts of Ukraine.

- December 5-9, 1994, Ukrainian Health Education Conference entitled "Clinical overviews of the problems pertaining to Diphtheria, Hepatitis B, and Juvenile Diabetes health education programming in Ukraine" held in Kyiv, facilitated by Ms. Anne Sochan.

- February 27-28, 1995, International Diphtheria Consultation held at Pushcha Vodytstya, called by the GOU and WHO, organized by PATH and the MOH, and attended by advisors from the MOH, PATH, USAID, WHO, CDC, IFRC, and UNICEF. At this meeting, Ukraine adopted an ambitious mass-immunization strategy

in which all adults between the ages of 16 and 59 years were to receive at least one dose of Td vaccine, and those between 30 and 59 years were to receive additional doses.

- March 11-13, 1996, International Diphtheria Consultation held at Pushcha Ozernaya. In follow-up to the conference the year before, PATH and the CDC presented data that demonstrated a favorable effect of the mass immunization strategy on the epidemic. The GOU made a commitment to continue the campaign. PATH offered to organize a consultative team for the oblast mass campaigns held in succeeding months.

- April 15- July 2, 1996, Mass Immunization Campaign Consultative Team. A team of six consultants with representation from USAID, CDC, BASICS, and PATH provided intensive technical support and consultation in social mobilization and policy issues during the campaign in Donetsk, Dnipropetrovsk, and Luhansk oblasts.

- December 12, 1996, MOH Meeting to Discuss Diphtheria Strategy held in Kyiv, attended by PATH, USAID, and IFRC. Although it was proposed by the international representatives that an international follow-up assessment meeting be organized, such a meeting did not occur.

- Four Regional IEC Seminars for 75 health educators and a core of master trainers, led by Ms. Barbara Crook and held in Kherson in July 1995; in Uzhhorod in October 1995; in Kharkiv in March 1996; and in Ternopil in October 1996.

- June 2-6, 1997, PCR Laboratory Techniques Seminar for 12 laboratory scientists held at the Ukrainian Center for Disease Surveillance in Kyiv, led by Drs. Androulla Efstratiou and Kathy Engler.

- July 14-18,1997, Seminar on International Practices of Vaccine Procurement and Organization of Quality Assurance held at Pushcha Ozernaya for 63 national and oblast level specialists, and on July 16-17, 1997, a Working Group on the Process for International Procurement of Vaccines for 13 national and oblast level specialists. Both seminars were led by Ms. Dian Woodle.

Project Spin-offs

TAG Activity Leads to Health Information Systems and Management Reform Activity

During the three years of this project, the PATH TAG observed a number of problems in information gathering and dissemination related to vaccine distribution, monitoring, and disease surveillance. In response to this situation, USAID is supporting a program to strengthen health information systems (HIS) for management. This new program is now in its first year of work; focused in Lvivska oblast; and implemented by a team from PATH, BASICS, and the CDC.

IEC Training

Through this project a core of master trainers and over 75 chief physicians from Health Education Centers throughout Ukraine have been trained in qualitative research and IEC methodology, including how to design and conduct mass media campaigns, and are capable of applying their knowledge to health areas other than diphtheria. For example, PATH's breast cancer screening project in Chernihiv includes a health educator who was trained at the Ternopil regional IEC training seminar.

National PCR Laboratory Capability

The PCR laboratory in the Ukrainian Center for Disease Surveillance has tested the use of the PCR technique for characterization of Cholera vibrio strains.

Follow-on Needs in Ukraine

Develop Ukrainian Transitional Strategy: Moving from Diphtheria Epidemic Control to Routine Disease Prevention

- Mop-up immunization of remaining unprotected populations.
- Case control and contact prophylaxis.
- Routine EPI and adult Td boosters.

Strengthen the Response to Public Health Issues

- Continued support for technical assistance in health information systems.

Increase Public Support for and Understanding of Childhood Immunization

- IEC methodology to enhance public acceptance of immunization.

Provide Support for National Vaccine Security

- Technical support to Biologics Committee.
- Enhance knowledgeable vaccine procurement in the oblasts, as procurement decentralizes.
- Develop a focus on national vaccine need forecasting within the MOH.
- Maintain adequate cold chain in the oblasts.

BLOODBORNE INFECTION CONTROL (BBIC)

Overview

The original impetus for the bloodborne infection control (BBIC) component was the high prevalence of hepatitis B among health care workers (HCWs), confirmed by the first PATH assessment of the problem in July 1994. As a result of the assessment, PATH proposed alternatives to the original preassessment proposal to provide "barrier protection kits" for HCWs because this was felt to be an unsustainable response to a long-term problem. In September 1994, PATH was asked by the MOH of Ukraine for assistance in the development of a working meeting on a national hepatitis B strategic plan which would include an approach to achieving sustainable access to hepatitis B vaccine using their own resources and a curriculum for the training of medical workers in BBIC. Hepatitis B (HB) vaccination is the cornerstone of HB prevention among health care workers in the hospital environment where blood contact takes place. This is clearly true in the U.S. and is part of OSHA recommendations. The provision of HB vaccine by this project was never feasible because of the cost of U.S.-source HB vaccine that would be required under USAID procurement regulations, nor desirable because of its nonsustainability.

PATH felt, however, that the project could provide assistance to Ukraine in the control of hepatitis B that did not depend on HB vaccine procurement. Assistance to improve control of all bloodborne infections in the health care setting is effective in diminishing the spread of hepatitis B among HCWs regardless of the availability of hepatitis B vaccine. Moreover, BBIC measures diminish exposure to other pathogens such as hepatitis C virus, human immunodeficiency virus, and cytomegalovirus for which no vaccines yet exist.

At a consensus meeting held at USAID/Washington on October 12, 1994, it was concluded that the response to HB vaccine access should take place within a broadened context of vaccine self-sufficiency which might include the broader spectrum of expanded EPI vaccines. Once started, HB immunization must be continued to establish disease control. Sustainable national procurement of HB vaccine would be necessary for hepatitis B control to succeed. In later conversations with the MOH, it was agreed to subsume the discussion of HB vaccine under the broader rubric of bloodborne infection control.

On March 1-3, 1995, PATH cosponsored with the MOH a meeting to discuss bloodborne infection control and hepatitis B national control strategy which resulted in the initiation of a project in BBIC to be carried out in two sites. PATH was encouraged by USAID/Kyiv to consider American International Health Alliance (AIHA) partnership hospitals as sites for the proposed project. In May 1995, a PATH assessment team visited two AIHA hospitals, Odessa Oblast Clinical Hospital and Lviv Railway Hospital, where it was agreed to initiate the project.

Project Goals

The BBIC demonstration project had the following goals:

- Improve BBIC through research and education.
- Improve access to and utilization of barrier supplies needed for the prevention of bloodborne infection.
- Disseminate the experience of the demonstration project for replication in other sites.

Research and Education

This objective was approached by application of the COBEX (COllaborative Blood Exposure) study and the production and distribution of educational materials.

COBEX Methodology

Under this project PATH introduced an applied epidemiological survey technique that permits a hospital staff to analyze the incidents of blood exposure among its personnel in order to define the kinds of risk the health care workers are encountering in their work, the COBEX study. From the COBEX study, a hospital staff can devise a risk reduction strategy specific to the problems revealed by the study. This is the Phase I study.

After the risk reduction strategy is implemented by the staff, the COBEX study can be done again and the results can form the basis for discussion of issues in compliance or other problems in risk management. This is the Phase II study. This survey technique can thus be used to monitor further blood exposure risk among the health care workers.

For further details on this study methodology, please see the COBEX assessment materials for monitoring blood exposures in operating rooms (Attachment 6), and for reporting occupational blood exposures (Attachment 7).

Educational Materials

PATH developed and distributed the following educational materials for use by health care professionals and students:

- Monograph (bilingual Ukrainian/Russian) for physicians and teachers of medical personnel.
- Brochure (in separate Ukrainian and Russian versions) for middle level personnel, including nurses and medical students.
- Slide Talk (in separate Ukrainian and Russian versions) for medical staff teaching, in two versions, 45-minute and 2-hour.
- Poster (in separate Ukrainian and Russian versions) suitable for clinics and procedure rooms.

English versions of these productions were submitted to USAID in June 1997.

Implementation Strategy

PATH collaborated with two AIHA partnership hospitals, the Lviv Railway Hospital (LRH) and the Odessa Oblast Clinical Hospital (OOCH), where the COBEX studies were first carried out and personnel trained in their use. These studies were completed and presented at two regional BBIC conferences, hosted by the institutions in Lviv and Odessa in April 1996.

At the two regional conferences, three additional hospitals (two in Kherson, and the Institute of Clinical and Experimental Surgery in Kyiv) were identified to do COBEX studies. COBEX coordinators from the three hospitals were trained by personnel from OOCH and by PATH Ukraine project manager, Dr. Katya Gamazina. In April 1996, PATH proposed to the MOH to disseminate the COBEX methodology to a broader circle of approximately 30 hospitals. These participating hospitals would be given a limited supply of gloves and goggles as incentive and compensation for the investment of their time and effort.

Eight COBEX coordinators from the five participating hospitals met with PATH staff and infection control consultant, Ms. Pat Lynch, in December 1996 at the Institute for Clinical and Experimental Surgery in Kyiv. The meeting permitted a detailed review of COBEX methodology and prepared these trainer-coordinators to assist 30 new hospitals in implementing the BBIC program. The December meeting participants also provided input into planning for the national summation conference held in Kyiv in March 1997, where nearly all the oblasts of Ukraine were represented.

Representatives of 22 oblast hospitals, the MOH, and program presenters from the Kyiv Institute for Epidemiology and Infectious Diseases and the Institute for Post-Graduate Medical Education of Physicians attended the March 1997 national summation conference. Progress in application of COBEX methodology to blood exposure monitoring was reviewed. Small group discussions on means for effective BBIC were held. Recommendations for lowering blood exposure were prepared by the discussion groups, assuming that all work in the future would be carried out without outside assistance. The key recommendations emphasized broader and more specific education in BBIC for HCWs at all levels; greater access to adequate barrier materials through more effective procurement and local production; and access to hepatitis B vaccine for all HCWs.

The USAID/PATH BBIC educational materials were distributed at the conference and delivered to other hospitals and educational institutions in the months following. (For a fuller report of the national summation conference, see the Quarterly Report of April 30, 1997.)

COBEX Study Findings

PATH followed closely the first COBEX studies done at the two AIHA hospitals in Odessa and Lviv. At the OOCH, an Operating Room study and a Delivery Room study were done. At LRH, an Accident Report study and a "Do-It-Yourself" Operating Room study were done. The first three studies tested COBEX methodology in three distinct clinical site types. The fourth study tested whether hospital staff on their own, with only

written instructions, could carry out an Operating Room study. Each is summarized below

These first four studies were analyzed by PATH and became teaching material at various times throughout the subsequent BBIC conferences. The full reports can be found as Attachments 8 through 11.

During the interval between the two regional BBIC conferences (April 1996) and the national summation conference in Kyiv (March 1997), the three additional volunteer COBEX hospitals carried out COBEX studies. This work is described below.

OOCH OPERATING ROOM COBEX STUDY

Methodology:

Specific personnel were assigned to watch for blood exposures and to ask at the end of every surgical procedure, "Did anyone have a blood exposure?" The assigned nurses also asked the question when personnel acted as if an exposure might have occurred: flinching, needing glasses cleaned, etc. They recorded information on a form about the time, length of the procedure, emergency case, job classification, type of case, activity and devices in use, anatomic location, and whether a patient was exposed to blood of punctured personnel.

Main Findings:

- Blood contact occurred 98 times during 2,300 surgical cases (4.3 percent). Over half, 56 percent were contacts with intact skin; one contact was with nonintact skin. Mucous membrane was involved in 7 percent of the occurrences and punctures in 36 percent.

- Surgical blood contacts occurred 50 percent of the time during 364 emergency cases. The blood contact rate was 13 percent for emergencies and 2.5 percent for non-emergencies. Punctures occurred almost three times as frequently during emergency cases.

- Physicians had 77 percent of the punctures and 6 of 7 of the mucous membrane exposures.

- Activities and devices associated with punctures included managing suture needles, passing instruments, and sharp power equipment.

- Fingers and hands were the anatomical location for 77 percent of blood contacts, and facial mucous membranes for 8 percent.

- Four of 35 punctures (11 percent) resulted in an exposure for the patient.

Discussion:

In this study, management of suture needles and transferring instruments are practices that need change. Changes in practice cannot eliminate all risk, however. Adequate barrier precautions are required, such as wearing double gloves if possible in emergencies or surgical cases where sharp wire or bone fragments are present. Proper masking of the face, including goggles, prevent mucous membrane exposures. (See full report as Attachment 8.)

OOCH DELIVERY ROOM COBEX STUDY

Methodology was identical to the Operating Room Study, q.v.

Main Findings:

- There were 183 blood contacts and exposures: 66 percent with intact skin, 3 percent with nonintact skin, 10 percent with mucous membranes, and 21 percent were punctures. Exposures occurred at a rate of 41/100 vaginal deliveries and 37/100 C-sections.

- No punctures occurred among vaginal deliveries during emergency procedures, but 14/16 punctures occurring during C-sections involved emergency procedures.

- Of 38 punctures, physicians sustained 47 percent and nurses sustained 50 percent.

- Most (74 percent) of the blood contacts did not involve a medical device, but of those that did, 39/47 (83 percent) were with suture needles.

- Fingers and hands accounted for 65 percent of contact locations, and facial mucous membranes for 12 percent. Approximately 22 percent of the contacts and exposures could be prevented by improved facial protection.

- Only one puncture (0.5 percent) was reported to have resulted in a patient exposure, far below other reports (9-29 percent). Possible underreporting?

Discussion:

Again, as in the previous study, management of suture needles and instrument transfer are important areas for staff review. In addition, personnel should wear gloves more frequently for intravenous (IV)administrations and IV injections. Cleaners could reduce contact with blood by wearing appropriate utility gloves. (See full report as Attachment 9.)

LRH ACCIDENT REPORT STUDY

Methodology:

Personnel throughout the hospital and clinics were asked to anonymously self report all blood exposures for a short period of time by completing a report form. Boxes were placed in 14 locations around the facility so that personnel could put their exposure reports in any of the boxes privately.

Main Findings:

- There were 274 reports describing 26 punctures (9 percent), 2 mucous membrane exposures (1 percent), and 246 intact skin contacts with blood (90 percent).
- Nurses, physicians, and laboratory staff had 94 percent of the blood contacts. Nurses sustained 20 of 26 punctures reported.
- High-risk departments included intensive therapy, bandage and procedure rooms, dental department, and laboratory. High-risk activities included drawing blood and giving IV injections. Hollow needle sticks accounted for 19 of 26 punctures.
- Activities associated with increased risk for exposure were phlebotomy, IV starts, and IV port injections, and dental extractions.

Discussion:

The study showed that glove use should be increased for activities involving sharp tools or invasive procedures, or predictable bloody fluid contact, such as in dental clinics. Utility, examination, and surgical gloves should be available. Education should be targeted to physicians, nurses, and laboratory personnel, since they have the highest incidence of blood exposure. Better disposal methods for sharps might reduce post-use injuries and blood contact.

The personnel demonstrated that this method could be used to describe the epidemiology of blood exposures. Similar methods may be effective in other Ukrainian hospitals. (See full report as Attachment 10.)

LRH "DO-IT-YOURSELF" OPERATING ROOM COBEX STUDY

The methodology for this study was identical to that of the OOCH Operating Room COBEX Study, q. v. supra. This study was implemented in a suite of small operating rooms doing largely scheduled procedures.

The primary purpose of the study was to determine whether the COBEX written instruction materials would be sufficient explanation for a hospital staff to carry out a COBEX study independently.

PATH concluded that the hospital staff was able to use the COBEX methodology satisfactorily. (See also Attachment 11.)

COBEX STUDIES IN KHERSON HOSPITALS AND THE KYIV INSTITUTE OF CLINICAL AND EXPERIMENTAL SURGERY

The Komsomolsky Raion Hospital in Kherson completed a COBEX study in their labor and delivery department. Their report was reviewed by PATH consultant Ms. Pat Lynch and is included as Attachment 12. Of note is the need for accuracy of data, a problem discussed at the December 1996 meeting in Kyiv.

The Kherson Oblast Hospital BBIC coordinator submitted a summary report on their operating room COBEX study, which is attached as Attachment 13. Of interest is the high incidence of blood exposures at peak surgical activity in the hospital daily routine. A great percentage of blood contacts occurred because of glove failures and surgical needle punctures.

The Institute of Clinical and Experimental Surgery completed a COBEX study in their microvascular operating room and submitted a risk reduction strategy in lieu of a report. See Attachment 14.

Risk Reduction Strategies

Derived from the results of the COBEX studies, each hospital site developed its conclusions in the form of a strategy for reducing the risk of blood exposure among its health care workers. The risk reduction strategy developed at OOCH is included as Attachment 15. See also Attachment 14, mentioned earlier.

By the conclusion of the working meeting in Kyiv in December 1996, PATH had prepared a composite summary of risk reduction strategies. This summary can be found as Attachment 16.

Ukrainian Response to BBIC Project

PATH believes that this project activity has significantly raised the awareness of the dangers of blood exposures and need for prevention strategies among HCWs in Ukraine. Most of the chief physicians of the participating hospitals were very cooperative. PATH received many reports of enthusiasm for the BBIC educational materials. Many found the results of the COBEX study useful for teaching medical workers about BBIC and said that they now have a greater appreciation of the issue and will continue to pay attention to it.

Although the hospitals were glad to receive the gloves and goggles distributed by the project, it was perhaps more meaningful that as a result of the COBEX study in their hospitals they discovered the need to change some techniques, especially in laboratory practice (handling of blood samples), surgical practice (finger-guided suturing, passing of instruments), starting IVs, and in labor and delivery practice (internal examination).

Several of the chief physicians were interested in the results of the LRH glove study, a summary of which had been presented at the March national summation conference. They mentioned that the presentation suggested quite a new approach for Ukraine in managing glove procurement and estimating necessary supplies (see page 23 for further details of this PATH-sponsored study).

Some of the doctors expressed an interest in management of post-exposure prophylaxis, referring to the paper PATH released at the March conference. This seemed most important in their opinion because it is impossible to avoid blood contacts and exposures in routine medical practice.

The main emphasis was laid on the education and training of medical personnel. The physicians stressed that all the educational materials they received are appropriate to Ukrainian Directives and Guidelines. Taking advantage of these materials, they conducted training for each level of medical worker: physician, nurse, midwife, and sanitary personnel. Specific accounts of educational activities carried out by certain oblast hospitals follow:

RIVNE: Organized conferences for all levels of medical workers.

KHARKIV: Used BBIC educational materials for several discussions in the hospital and also at the oblast level.

ZHYTOMYR: Used the materials for lectures to specialist groups and chief nurses.

SIMFEROPOL: Although this center did not send a representative to the March national summation conference, the deputy director had carried out a COBEX study and organized a meeting reviewing the results.

LUHANSK: Completed a COBEX study, although no representative had been sent to the March conference, so they had no BBIC educational materials.

SUMY: Finished the COBEX study. Conducted BBIC training in the hospital and at an oblast level meeting.

IVANO-FRANKIVSK: Completed the COBEX study and used educational materials for conferences in the hospital and at the oblast level.

KHERSON: Have used the results of the COBEX studies in oblast-level meetings of physicians and nurses and in the oblast and two raion city hospitals for training nursing students.

ZAKARPATSKA: Conducted trainings for both hospital personnel and oblast medical workers.

TERNOPILSKA: Completed the COBEX study. Using the materials for training. Have discussed the possibility of extending BBIC study to the raion hospitals of the oblast.

KHMELNYTSKY: Organized conferences on BBIC for each level of medical worker.

LUTSK: Conducted conference for oblast surgeons. Organized nurses' training for each department of the hospital.

CHERNIHIV: Set up a hospital committee on BBIC. Organized conferences for each level of medical worker in the oblast hospital. Provided training for surgeons and traumatologists of all the raion hospitals in the oblast. Use the test in the BBIC brochure as a control test for nurses and sanitary workers on the issue of BBIC. Plan to reprint the brochure in order to provide a copy to each worker.

ODESSA: Organized an oblast-wide conference on BBIC. Dr. S. Posokhova of OOCH is also a Docent in the Odessa Medical Institute and uses the BBIC slides and monograph in her presentations to medical students.

PATH distributed monographs and brochures to additional teaching institutions, including 25 nursing schools and four institutes for postgraduate medical education.

Attachment 17 gives a listing of the status of hospitals participating in COBEX studies. Of the 35 hospitals selected by the MOH to participate, 26 have reported completing Phase I studies (74 percent), and 15 have reported completing Phase II studies (43 percent) by mid-November 1997.

Access to and Utilization of Barrier Supplies

Under this objective, PATH was able to help establish a sewing workshop for the production of surgical barrier clothing and study the use of gloves in a hospital setting under two conditions, before and after receiving an adequate supply of use-specific gloves.

Lviv Railway Hospital (LRH) Glove Study

In collaboration with the LRH, PATH conducted a study of glove use and failure rate. The study was undertaken because appropriate use of reliable gloves is an essential element in successful bloodborne infection control among health care workers, and little was known of the magnitude of risk as it related to current glove practices.

Prior to the study, LRH relied on donated sterile surgical gloves for all applications—clinical exam, surgical care, laboratory and pharmacy work, and utility purposes (housekeeping, etc.).

New sterile gloves were first used for surgery, then reprocessed and passed on to the remaining services where they were repeatedly reprocessed until no longer functional. Utility workers generally received gloves in their last stages of effectiveness.

The study purpose was to assess the impact of introducing purpose-specific gloves on glove usage and glove failure rates among hospital workers, and to help estimate future glove commodity needs. After a baseline observation period of usual glove use, the hospital was supplied with purpose-specific gloves. Data were collected. The study shows strikingly that where there is inadequate supply of gloves, both in quality and quantity, health workers are at risk for bloodborne infection exposure. Two possible approaches to projecting future glove requirements are described. (See full study as Attachment 18.)

Surgical Barrier Clothing Sewing Facility

PATH initially spent considerable time and effort to attempt establishment of a sewing facility for the production of surgical barrier clothing at LRH. For a number of reasons, it was ultimately decided that proceeding further with LRH was not a viable option. After consulting with USAID in February 1997 and receiving an extension of time to identify a new partner, PATH established criteria for evaluating potential candidates. Out of five candidates in Kyiv, PATH selected the Territorial Medical Amalgamation (TMA) in the Dnipro Raion of Kyiv. Minor renovations of a suitable work space at TMA were completed by early summer and sewing equipment procured earlier for the LRH site were cleared through customs and transferred to the new base of production. The new workshop at TMA was inaugurated in September 1997. (A full history can be found in Quarterly Reports for April 30, July 18, and October 31 of 1997.)

Following the September opening ceremony, PATH made arrangements for the provision of the final equipment and material supplies to be provided under the project. These items consisted of a button sewing machine and a seam/hem sewing machine to eliminate production bottlenecks, and over 10,000 yards of U.S.-made and locally made fabric.

TMA has produced the following garments since inaugurating production in September: 164 surgical operating gowns; 84 surgical scrub suits; 47 surgical caps; 177 surgical shoe covers; 10 full hood surgical masks; and 298 nose/mouth face masks. Using its own funds, TMA has also purchased material and produced 3,500 bed sheets/napkins for a maternity hospital in Kyiv.

Of the surgical garments produced since inauguration, TMA has reported having sold 14 surgical scrub suits, 4 surgical operating gowns, and 3 surgical caps. The low number of products sold reflects perhaps the biggest challenge the TMA sewing facility will face in becoming a viable business operation—to make the transition in focus and operating structure from a command-based economy to a market-based economy. Through garment

samples provided to PATH, TMA has demonstrated they have the ability to design and manufacture western-style medical barrier garments of good quality. Where TMA needs to focus its efforts is on developing a marketing strategy and system to promote and distribute its products.

PATH personnel and the project consultant, Mr. Sergey Tytarenko, have discussed with TMA staff the importance of developing a marketing plan to identify potential customers, the competition, and an effective sales strategy. TMA had planned to hire an experienced business manager to develop the marketing plan and manage the sewing facility; however, they were unable to offer a sufficient salary and the qualified candidate accepted a position with another company.

TMA has currently placed one of their hospital administrators in charge of managing the sewing facility. Without direct experience in managing a small production facility, and having to support his previous responsibilities along with his new position, the appointed manager has not been able to provide the management and marketing guidance needed for a start-up business. TMA will need to resolve their management and marketing problems if the sewing facility is to achieve any measure of success.

The sewing facility is also facing the challenge of selling its products to customers (medical institutions and hospitals) that have seen a significant reduction in recent years in the amount of state funding they receive for medical supplies.

PATH is inquiring into the possibility of local business support organizations, such as NEWBIZNET, that might be able to provide marketing and management technical assistance to the TMA sewing facility.

Dissemination of the BBIC Demonstration Activity

This objective was addressed in two ways:

- Hospitals and a variety of educational institutions received the COBEX methodology and the BBIC educational materials.
- Two regional BBIC conferences and one national BBIC summation conference were held in which the COBEX methodology and the studies were discussed. All conferences were attended by MOH representatives, and the national summation conference report was transmitted in Ukrainian translation to the MOH.

PATH-AIHA Collaboration

In addition, PATH has collaborated throughout the project with the AIHA hospital partnership program:

- AIHA partnership hospitals (OOCH and LRH) provided the initial bases for the COBEX studies and hosted the two regional conferences held in April 1996.

- In July 1996, PATH DC briefed a Russian/Ukrainian delegation on an HIV/AIDS study tour to Canada and the U.S. under AIHA auspices.
- In August 1996, PATH project director Dr. Doan participated in a working meeting in Moscow sponsored by AIHA for preparation of an infection control curriculum for Russia. The PATH BBIC program was presented.
- In October 1997, Dr. Doan participated in the AIHA Annual Conference for the NIS held in Atlanta, Georgia. He presented the outlines of the BBIC program in Ukraine, including a summary of the LRH Glove Study. He distributed copies of BBIC Russian language materials, which were avidly received.
- PATH has enjoyed continuous contact with the AIHA/Kyiv office, and has shared its results and materials with the AIHA/Kyiv staff.

Lessons Learned/Concluding Observations

COBEX and Clinical Practice

Through the USAID/PATH BBIC project, hospital personnel have demonstrated an increased awareness of the risk for bloodborne exposure in their work and can take appropriate steps to reduce risk. Hospital administrators have been brought to full engagement with the specific issue of BBIC among their HCWs and were provided the methodology and the educational materials needed for this work.

PATH knew from the outset that the implementation of the COBEX methodology into clinical practice would require sustained support for optimal results. The COBEX coordinator would have to be properly trained and motivated to achieve reliable findings. This coordinator should have a counterpart to assist. These efforts are labor intensive and require the commitment of management for their success.

Follow-through, however, was uneven within the diverse group of participating hospitals beyond the first two demonstration sites in Odessa and Lviv. The COBEX regional coordinators for various reasons could not provide the level of supervision needed to maximize results. In retrospect, PATH and the participating hospitals underestimated the time and effort required to overcome the complicated logistics of poor telecommunications and mail service, and long summer vacations. PATH could not confirm the quality of the COBEX work because data was not submitted in time in most cases. Despite these difficulties, PATH staff and the regional coordinators believe most sites made a sincere effort. Since the MOH never transmitted a formal directive in support of this activity, it is speculated that some hospitals may have been reluctant to disclose their participation openly.

Nevertheless, PATH was pleased by the overall response to the COBEX methodology. Three quarters of the 35 participating hospitals reported completion of the first COBEX study and compilation of a risk reduction strategy based upon the results; nearly half of this group reported completion of a second COBEX study. Verbal reports of risk reduction strategy discussions indicated that the hospital staffs were identifying the needed

corrective measures. The national summation conference in March 1997 was well attended by representatives from 22 oblasts, in addition to the MOH and several academic institutions. Lastly, regional centers that previously were not in direct collaboration with PATH in this project have taken the initiative to use the materials (Simferopol, Sumy, Chernihiv, among others).

Lack of Consistent Central Support

PATH was only partially successful in garnering support for BBIC activities through central authorities. In the early stages, First Deputy Minister of Health Dr. Viktor F. Marievsky, who had a professional interest in the subject, strongly endorsed the activities presented. However, enthusiasm for the COBEX methodology was not always shared by others in the MOH. Some expressed resistance to COBEX from a belief that the main approach to BBIC should be the provision of more barrier materials, not education or assessment of clinical practices. Others seemed to place BBIC as a lower priority among competing urgent issues. In addition, PATH suspects also that for some people the COBEX methodology may have departed too sharply from established infection control procedures in the hospitals. COBEX permitted autonomous in-house assessment by the hospital personnel themselves, independent of MOH infrastructure initiative. Moreover, the subsequent rapid turnover of MOH officials coincident with Dr. Marievsky's departure from the MOH disrupted support for the project. For these reasons, PATH failed to achieve support for the integration of COBEX methodology into the SES system of hospital infection control review and was unsuccessful in establishing a Central Advisory Panel as originally intended. Nevertheless, MOH officials were cooperative in responding to specific PATH requests for advice or no-cost support for workshops or conferences.

Changing Attitudes and Increasing Interest

PATH perceived a definite increase of interest in the topic of BBIC over the course of the project. This was evident between the time of the two regional BBIC conferences in April 1996 and the national BBIC conference eleven months later in March 1997. One probable reason for the rising interest was the acute increase in HIV infection in Ukraine during the time interval. The rising threat of AIDS has heightened concern among HCWs for their own safety. The PATH-produced educational materials have been very popular.

Vaccine Self-Sufficiency

At the outset of this project component, the focus was on hepatitis B and the need for a national strategy of hepatitis B immunization. PATH addressed the issue of vaccine self-sufficiency for hepatitis B vaccine at the national summation conference on BBIC and in more detail during the vaccine procurement training seminar, discussed earlier.

Follow-on Needs in Ukraine

- Build on COBEX methodology. This useful approach needs time and ongoing support to be institutionalized. Ukraine may have to adapt further the methodology to its local needs.
- Support implementation of universal precautions, in technique and in adequate procurement of barrier supplies.
- Support local production of disposable supplies: upgrade latex technology for glove and condom manufacture and enhance quality of disposable needle and syringe manufacture.
- Enhance competent hepatitis B vaccine procurement for HCWs in the oblasts, as procurement decentralizes. Integrate hepatitis B vaccination of HCWs into a comprehensive national hepatitis B immunization strategy.
- Support marketing research and management assistance to the TMA surgical barrier clothing sewing workshop to enhance prospects for long-term success.

DIABETES MELLITUS IN CHILDREN

Overview

Approximately 4,000 children to the age of 15 registered as having diabetes were served during the course of PATH project activity in Ukraine. They received a one-year supply of insulin, needles and syringes, and glucose and ketone monitoring supplies. In addition, a popular American instructional manual for children written by Dr. Luther Travis, Professor of Pediatrics of the University of Texas Medical Branch, Galveston, Texas, was adapted for Ukraine, translated into Ukrainian, published, and delivered to oblast endocrinologists for distribution to the children.

In September 1996, PATH and the MOH sponsored an educational conference on the care of children with diabetes near Kyiv for oblast pediatric endocrinologists and other interested specialists. Team members included Dr. Doan, Project Director; Dr. Martha Spencer, pediatric endocrinologist of the International Diabetes Center in Minneapolis, Minnesota; Ms. Broatch Haig, Dietitian of the International Diabetes Center; and Dr. Travis. The conference and the meetings surrounding it provided an opportunity for the visiting PATH team to take stock of the current status of diabetic care for the children of Ukraine. The assessment report prepared by the PATH team reviewed the conference proceedings and supply and care issues. That report was submitted to USAID on November 27, 1996, and will be referred to in the current report as the Diabetes Assessment Report.

Project Goals

This program project had three main goals:

- To provide diabetic children with insulin and diabetic supplies for one year.
- To provide diabetic educational materials to patients and health care professionals.
- To assess and document the ongoing needs of diabetic children at the end of the project.

Provision of a One-Year Supply of Diabetic Materials

Early in the project PATH established a distribution plan which would allow documentation of the receipt of supplies from the central receiver (Ukrvaccina) at Obukhov through succeeding distributions to the oblast endocrinologist, the raion endocrinologist, and to the patient's family. This distribution system was a modification of a similar plan recommended to PATH by USAID that had been successfully used by another NGO working in humanitarian assistance in the Caucasus. The PATH system utilized three transfer forms to document the distribution of product. In Ukraine, PATH considers that the distribution plan was quite successful. It provided secure documentation of the flow of diabetes materials to the patient.

Ukrvaccina remained the internal shipping agency throughout the project. The one-year supply of diabetic materials was distributed throughout Ukraine by a refrigerated Ukrvaccina truck approximately every four months. Each of the three four-month distributions was accomplished as divided shipments through three established oblast circle routes to the eastern, western, and southern regions of Ukraine.

Products supplied were Lilly Humulin regular and NPH insulin, needles and syringes, blood glucose and urine ketone monitoring strips, and lancets. The recipients were diabetic children registered with the MOH. Throughout the project, PATH cooperated with the MOH and the Kyiv Institute of Endocrinology and Metabolism to create a computerized patient register. This database was critical for determining the number of children with diabetes in each oblast. At the end of the project, the computer database was turned over to the MOH.

Total insulin and syringe distribution as reported to USAID in the Quarterly Report dated October 31, 1996, is provided as Attachment 19.

Parent Telephone Survey

PATH undertook a telephone survey of parents of 4,078 diabetic children listed in the registry. The goal was to interview a random selection of 5 percent (204) of the registry in two-month's time from the PATH Ukraine office.

The logistics of the process proved very difficult due to incorrect or out-of-date phone listings, busy signals, reaching adults who could not respond to the questions, and other reasons. Because of limited staff time, the sampling was stopped after 71 interview questionnaires were completed. A total of 284 completed calls were needed to complete 71 questionnaires. On average, 1.6 hours of telephone effort were expended to complete one questionnaire. The average age of the child whose family was interviewed was 12.4 years. The age range was 4 to 17 years.

The summary results of the telephone survey are recorded in Attachment 20. The questions to the parents centered in four general areas:

1) impressions of the PATH insulin provision;
2) impressions and use of the instructional manual PATH distributed;
3) impressions of the health of their child with diabetes; and
4) impressions of the most pressing needs for their child, including how easy or difficult it is to get insulin in their particular region of Ukraine.

Information from the telephone survey which is of relevance to the product distribution follows:

- All 71 parents reported receiving the raion to patient transfer form with their insulin, indicating that the distribution system PATH designed was used correctly.

- A total of 94.4 percent reported no problems in getting their USAID/PATH insulin and supplies. The remainder reported not getting their insulin on time.
- All 71 received their blood glucose and urine ketone strips and 87.3 percent reported they had used them as needed.
- A total of 97.2 percent reported no problems with using the Lilly insulin; 93 percent reported that the Lilly insulin had had a positive effect on their children's health; and 2.8 percent reported that it "didn't agree" with their children (not further explained).

Provision of Diabetic Educational Materials

Instructional Manual

The principal educational product was Ukrainian translation of the self-care guide for children with diabetes written by Dr. Luther Travis, entitled *An Instructional Aid on Insulin-Dependent Diabetes Mellitus* which was systematically reviewed by Ukrainian endocrinologists to be adapted the needs of Ukrainian children. This Ukrainian version was released by PATH and Dr. Travis at the PATH/MOH conference on the care of the child with diabetes held in Kyiv in September 1996. The use of the manual was discussed at that conference. It was agreed that the manuals would be distributed through the oblast endocrinologists, who in turn would give the manuals to their pediatric patients.

The manuals have been distributed throughout the country to the oblast endocrinologists. In general, each endocrinologist received about 25 percent more manuals over the count of patients on the registry in order to cover additional subsequent patients. In addition, certain sites and individuals received consignments for their special needs. Many of the physicians view the manual as a scarce resource and distribute it only to new patients or preadolescents. In general, they do not think the book is as suitable for older diabetic children. Figures related to distribution of the manuals through the country are provided in Attachment 21.

Of the 71 parents reached by the telephone survey described above, 36 (50.7 percent) had received the manuals so far; 30 of the children (83.3 percent) had read it; and 33 of the parents (91.7 percent) had read it. Thirty-three parents reported that their doctors were using the book for teaching with their children. They found it to be very useful and easy to read.

Treatment and Practice Guidelines

At the conference on the care of the child with diabetes, practice guidelines for diabetes care were developed conjointly by the PATH consultant Dr. Spencer and the conference participants. These were translated into Russian and sent to the MOH (for a copy see the Diabetes Assessment Report, Attachment C referenced earlier).

Assessment and Documentation of Ongoing Needs

Supply and Equipment Issues

INSULIN

The PATH assessment team in September 1996 spoke with many Ukrainians concerning the status of insulin supply in the country. The consensus judgment at that time was that the situation was bad, and probably worse than two years previously. One favorable development in the past three years has been market reform permitting imported insulin to be freely available in the pharmacies. The price appears to be quite variable.

The parent telephone survey conducted by PATH in October 1997 asked for an opinion of how difficult it was for the respondent to obtain insulin locally. Approximately 20 percent reported that it was usually difficult. The remaining felt it was easy to get, or sometimes difficult. When asked what the major problems are with getting sufficient insulin for their child, 40.8 percent responded availability was sometimes a problem, 38 percent said they had no difficulties, and nearly 20 percent said cost was a problem.

Price for a vial of insulin among the 56.3 percent of 71 telephone respondents who pay for their insulin varied from 8 hryvnyas to 41 hryvnyas (US$4.25-$21.80). A large number apparently depend on humanitarian aid.

Ukraine currently imports all of its insulin requirement. The German pharmaceutical company, Hoechst, is planning to establish an animal insulin plant in Kyiv and has made interim progress in 1997; start-up of production is expected in 1998. Reportedly the plant will produce pork insulin and semisynthetic human insulin derived from pork. The Hoechst project received negative press in 1996 because the Ukrainian public does not trust insulin of animal derivation, a sentiment shared by certain diabetes advocates.

During the 1996 PATH/MOH diabetes conference, the American presenters more than once affirmed that insulins of animal origin are safe for children. Under the circumstances of poor accessibility to insulin, the Americans were concerned that the Ukrainians would reject a viable alternative source of insulin, purified animal insulin. (Please see the Diabetes Assessment Report for more technical discussion of insulin types and their use.)

SUPPLIES AND EQUIPMENT FOR MONITORING

Most patients have no testing materials of their own and rely entirely on monthly laboratory blood glucose and urine aliquot testing done at scheduled clinic visits. Almost all areas have some blood glucose test strip supplies obtained from

humanitarian assistance. The areas around Kyiv and Kharkiv seem to be best supplied. Most blood glucose strip testing is by visual means. Glucose meters exist in small numbers but they are expensive and are difficult to maintain properly. The availability of urine ketone strips is variable across the country.

Care and Treatment Issues

In addition to developing diabetes practice guidelines and affirming the importance of good nutrition and nutritional education, the September 1996 conference participants expressed support for the training of nurses, dietitians, and psychologists who could assist them in the care of children with diabetes.

An important set of observations of the PATH team in September 1996 focused on normalization of the life of the child with diabetes. The team was impressed at the difference in the approach to meeting the psychological and social needs of the child with diabetes, comparing the U.S. to Ukraine. Whereas in the U.S. the emphasis is to integrate the child into full participation in a normal life, in Ukraine the emphasis is to protect the child with diabetes who is seen as handicapped and vulnerable.

The papers presented by the Ukrainians at the conference emphasized the level of poor growth, delayed sexual maturation, and hepatomegaly seen among Ukrainian diabetic children, all of which are the direct result of poor control of their diabetes. It would appear that this appearance of vulnerability fosters restrictive structures that serve to isolate these children, presumably for the purpose of protecting them from further harm. The rationale of the approach to rendering psychosocial support to children with diabetes is unique to conditions within any given country. Much more exchange of experience and information is needed for a clearer understanding.

At the September 1996 diabetes conference, Drs. Travis and Spencer challenged the participants to be advocates for the child with diabetes. They suggested that health care professionals need to join forces with the parents and with each other to petition the government for necessary supplies and services and to form private voluntary organizations for support of these children. Dr. Travis emphasized that advocacy is a process that requires a continuous effort and a constant commitment. The parent telephone survey suggests that much more could be done; only 8.5 percent of respondents had ever had any contact with a diabetes organization.

Conclusions and Recommendations

The PATH/USAID project in humanitarian assistance to the children with diabetes in Ukraine was much appreciated by the physicians of the children, by the parents that PATH met during and after the September 1996 conference, and through the telephone survey one year later. As temporary humanitarian assistance, the project has been a success.

In September 1996, the PATH team found its task of assessment difficult because objective supporting information was often not available. The overarching recommendation of the PATH assessment team is that all additional aid for the diabetic children in Ukraine should be directed toward helping Ukraine overcome obstacles to good care and treatment. Further international donor support of diabetes commodities should be linked to assistance in alleviating the supply problem and in education. The recommendations that follow are abridged from the Diabetes Assessment Report. It is advisable that the findings on which they are based be confirmed and expanded by further inquiry and observation.

Supply Issues

PATH is not aware of any international donors currently providing or planning to provide insulin and diabetes supplies to Ukraine on a scale approaching that which was provided under this program. If an international donor were to propose provision of such product to Ukraine in the future, PATH would recommend that the distribution of the product be organized as was the USAID/PATH product distribution through an independent delivery system controlled by the donor, featuring transfer documentation at every point in the distribution, and with the insulin transferred directly to the oblast endocrinologists for dispensing to the patients. In the PATH delivery system, Ukrvaccina provided reliable cold storage and transport of the diabetes supplies.

Resolution of the problem with shortages awaits in large part satisfactory corrections and improvements in the economy of the country. The newly emerging nongovernmental organizations (NGOs) may become effective advocates to their government. Perhaps an alternative mechanism for meeting needs of children with diabetes would be collaboration between indigenous NGOs and oblast officials toward local financial support for the provision of supplies.

Resource conservation should be a priority strategy. For example, the pros and cons of vial vs. pen insulin could be considered; cutting blood glucose strips lengthwise could double the number of tests feasible for a given supply of strips; and using visual blood glucose strips rather than glucose meters for monitoring is more cost effective.

International donor organizations could assist through education and training. For example, training in competitive international tendering and procurement of essential supplies might be offered to appropriate MOH and/or oblast officials.

Education

Educational programming in diabetes care should be separately focused for health care workers, and for patients and their families. International donors should be encouraged to enlist the collaboration of the MOH in the cosponsoring of conferences. New Ukrainian NGOs with diabetes as their focus should be supported to develop joint programs with interested international diabetes organizations.

Emphasis on Good Diabetic Control over Secondary Treatment Issues

The primary focus of treatment efforts should be metabolic (blood glucose) control. Emphasis should be placed on adequate monitoring of insulin therapy, together with dietary control appropriate to level of activity. For such an approach to be effective, education of the patient and his/her family is essential.

If fewer resources were spent on procedures of marginal or unproven value, resources theoretically could be saved for expenditure on better metabolic control. Examples include the use of oral pills for treatment of liver enlargement as if it were a liver pathology independent of the basic diabetes process, rather than a manifestation of poor metabolic control due to lack of adequate insulin therapy and ultrasound imaging of the pancreas, or the screening for early diabetes in children when there are no known effective methods for disease prevention.

Contact by Ukrainian Diabetes Specialists and NGOs with International Organizations

The PATH team recommends and encourages the Ukrainian pediatric endocrinologists to seek contact with international professional groups or programs that offer conferences or courses of specialty training, such as the International Society for Pediatric and Adolescent Diabetes (ISPAD) which has available subsidized memberships and travel grants to its conferences, and McMasters University, Faculty of Medicine, Hamilton, Ontario, Canada, which offers a four-month study program in pediatric endocrinology.

The PATH assessment team also encourages the parents and patients active in Ukrainian NGOs for children with diabetics to make contact with like-minded groups in other countries.

Follow-on Needs in Ukraine

- Support for adequate insulin supply. Further international donor commodity support should be linked to assistance in patient and HCW education.
- Encourage adequate self-monitoring (blood glucose) to enhance diabetes control.
- Encourage more education of medical management of diabetes for health care workers.
- Enhance patient education for self care.
- Support for diabetic NGOs and advocacy groups.

CROSS-CUTTING ISSUES

Implications of Increasing Decentralization

PATH encountered a recurring dynamic clustered around the growing tendency toward decentralization of power and decision making observed in each of the three program components.

Much effort is required to institutionalize change. In both the BBIC and diphtheria activity, PATH early on came to recognize that fundamental changes in practice and policy were implicit in the work at hand. To introduce the new strategies, PATH sought to collaborate intensely with the central government, represented by the MOH, but came to understand that the periphery, represented by the oblasts, was taking independent actions and assuming initiative. Accordingly, PATH took a "both-and" approach, working collaboratively with the center but also going to great lengths to meet the periphery. In all three program components, it meant that it was important to encourage regional and national conferences to bring together oblast administrators and medical professionals with their MOH colleagues.

The prevailing process of decentralization of control meant that PATH could not always count on a central decision to emerge coherently, nor a central order or command to be obeyed by the periphery. This dynamic was vividly manifest during the struggle to mount a national mass diphtheria immunization campaign. The BBIC program went forward to over thirty hospitals in the country, with the blessing of the MOH, but often was supported more vigorously by the initiative of regional centers, such as the original BBIC sites in Odessa and Lviv, and the subsequent voluntary efforts of sites in Kherson, Simferopol, Chernihiv, and Sumy, to name a few centers. Examples of oblast nonresponse to central requests or orders were common during the early efforts to accumulate diphtheria immunization data. In the diabetes program component, the MOH issued an order for information to be passed to PATH about the consumption rates of the last distribution of diabetes supplies. Only four oblasts responded.

In many cases the decentralizing tendency means that local resources must be found to support programs and commodities that once were financed by the central government. In the process of casting off financial responsibility, the central government has tended to lose control of its systems, and countrywide implementation of programs is uneven, often according to the financial health of a given oblast. On the other hand, decentralization has encouraged local initiatives to be employed as during the regional IEC training seminars. In addition, local resources have been used successfully at the local level to obtain vaccine through barter arrangements.

PROGRAM INDICATORS

The final chart showing achievements under this CA can be found as Attachment 22.

Attachment 1

Ukraine Humanitarian Health Assistance Activity
Commodities/Freight and Printed Materials

December 30, 1997

Commodity	Item/Supplier	PATH P.O. Number	Quantity	Ship Date	Expenditures
DIPHTHERIA					
Td Vaccine	Td vaccine-Swiss Serum	94-0036, 94-0030	6.8 million doses	Jul-94 to Oct-94	$ 377,243.00
	Td vaccine-Pasteur Merieux	94-0035	1.0 million doses	Aug-94 & Sep-94	90,000.00
	Td vaccine-Connaught	94-0034	14.52 million doses	Sep-94 to Dec-95	3,630,000.00
	Td vaccine-Connaught	95-0109	10 million doses	Dec-95 to May-96	2,631,000.19
Antitoxin	Antitoxin-Connaught	94-0034	350 vials	Sep-94	58,709.00
Diagnostics	Oxoid Hoyle medium base-Difco	94-0068	3,060 kgs	May-96	181,306.06
	Pyrazinamidase test kits-Rosco	94-0100	36,456 kits	Jun-95	97,994.00
	Oxoid Hoyle medium base-Difco	96-0200	3,240 kgs	Sep-96	185,250.00
PCR Laboratory Supplies	VWR brand dry block heaters	97-0032	1 each	May-97	279.31
	Modular heating blocks, 20 hole	97-0037	1 each	May-97	36.14
	Eppendorph centrifuge 5415C	97-0032	1 each	May-97	2,012.00
	Micropipettor - 1000 ul	97-0033	1 each	May-97	244.50
	Micropipettor - 2 - 20 ul	97-0033	1 each	May-97	244.50
	Micropipettor - 200 ul	97-0033	1 each	May-97	244.50
	Perkin-Elmer DNA Thermal Cycler 480	97-0045	1 each	May-97	8,235.00
	Repipettor	97-0037	1 each	May-97	351.00
	Aeroseal Filter Pipette Tips 1000 ul	8897	1 case	May-97	70.50
	Aeroseal Filter Pipette Tips 20 ul	8897	3 cases	May-97	165.00
	Aeroseal Filter Pipette Tips 200 ul	8897	1 case	May-97	55.00
	Bleach 1gallon	97-0037	1 each	May-97	2.00
	Combitip Reservoirs 5ml	97-0037	1 pack	May-97	83.66
	dNTP Set, 100 mM solutions	10397	2 each	May-97	360.00
	Kimwipe tissue, 4 1/2 x 8 1/2	97-0037	1 case	May-97	103.60
	Latex Gloves pwdr free (L)	97-0037	10 boxes	May-97	113.40
	Latex Gloves pwdr free (M)	97-0037	10 boxes	May-97	113.40
	Latex Gloves pwdr free (S)	97-0037	10 boxes	May-97	113.40
	Microfuge storage box 0.65	9597	1 pack	May-97	18.00
	Mineral Oil 500g	10297	1 each	May-97	18.10
	Taq DNA Polymerase, 5000 U	97-0045	1 each	May-97	2,803.95
	2ml boilproof microtube (natural)	11797	4 packs	May-97	59.60
	Thin wall reaction tubes	8897	2 bags	May-97	58.00

Ukraine Humanitarian Health Assistance Activity
Commodities/Freight and Printed Materials

December 30, 1997

Commodity	Item/Supplier	PATH P.O. Number	Quantity	Ship Date	Expenditures
	Primers - specific for amplified gene	10197	2 each	May-97	129.62
	Sterile water, 1 l (or Baxter 2F7114)	97-0037	1 each	May-97	18.14
	Day Glow Asst. Rainbow Racks	9597	2 packs	May-97	52.00
	10 ml screw cp vial (500)	8897	1 pack	May-97	50.00
PCR Product Detection Equip.	DS-34 Camera, lens, pistol grip	97-0037	1 each	May-97	446.25
	DS-34 Camera Cable release	97-0037	1 each	May-97	9.80
	DS-34 Electrophoresis filter kit	97-0037	1 each	May-97	33.25
	DS-34 Hood 13"	97-0037	1 each	May-97	147.60
	667 film, B&W, 20 exp/Twin Pk	97-0037	5 each	May-97	122.60
	DNA minigel system	9897	1 each	May-97	265.00
	Casting chamber	9897	1 each	May-97	48.00
	Gasketed UVT gel tray	9897	2 each	May-97	96.00
	14 Tooth Comb	9897	5 each	May-97	120.00
	Micropipettor - 2 - 20 ul	97-0033	1 each	May-97	244.50
	Micropipettor - 200 ul	97-0033	1 each	May-97	244.50
	Power supply - 220 VAC	97-0032		May-97	292.00
	Single intensity ultraviolet transilluminators, ultra-lum, 15x15 230V, 50Hz	97-0032	1 each	May-97	680.00
PCR Product Detection Supplies	Ethidium Bromide, 10 mg/ml	10197	1 each	May-97	29.00
	Kb DNA Ladder (250ug)	10197	1 each	May-97	105.00
	Latex Gloves pwdr free (L)	97-0037	3 boxes	May-97	34.02
	Latex Gloves pwdr free (M)	97-0037	3 each	May-97	34.02
	Latex Gloves pwdr free (S)	97-0037	3 boxes	May-97	34.02
	Agarose (125g)	10197	1 each	May-97	263.00
	10 X TAE buffer	10197	1 each	May-97	21.00
	Blue-Orange 6X loading dye, 3mls	11697	1 each	May-97	25.00
	Earthstak 96 tip stock rack	8897	10 packs	May-97	224.00
	Microfuge tubes clear 0.65	9597	5 packs	May-97	125.00
	Face shields	14397	3 each	May-97	125.82
	Hot plate stirrer	14397	1 each	May-97	352.92
	Stir bars	14397	2 packs	May-97	31.38
	Whatman Grade No. 1 filter paper	14397	2 packs	May-97	73.28

Ukraine Humanitarian Health Assistance Activity
Commodities/Freight and Printed Materials

December 30, 1997

Commodity	Item/Supplier	PATH P.O. Number	Quantity	Ship Date	Expenditures
	One liter flask	14397	1 pack	May-97	31.75
	Six liter flask	14397	1 each	May-97	71.76
	Safety glasses	14397	1 pack	May-97	29.88
	Cryovial storage tubes - 2ml	14497	1 bag	May-97	27.00
	Charcoal (EB disposal)	14797	500 grams	May-97	14.35
Misc. Supplies	Labels and temperature monitors				5,919.00
	Cold room monitors-Remonsys	94-0088	28 systems	Aug-94	6,175.00
	Serosurvey supplies	95-0046	1 lot	Jul-95	4,246.00
	Vaccine unloading cart		1 each	Sep-94	219.10
Freight/Insurance	Antitoxin, vaccine, misc.				86,259.00
	PCR supplies shipping/handling				4,466.14
Office Equipment	PATH Ukraine computer equipment	94-0105	1 lot	Dec-94	3,660.00
	Misc. office equipment				549.00
Total Diphtheria					**$ 7,383,431.51**

Ukraine Humanitarian Health Assistance Activity
Commodities/Freight and Printed Materials

December 30, 1997

Commodity	Item/Supplier	PATH P.O. Number	Quantity	Ship Date	Expenditures
BBIC					
Odessa Oblast Hospital	Overhead projector/training	24795	1 unit	Sep-95	693.74
	Surgical gloves-Ansell	96-0031	16,000 pairs	Apr-96	9,275.70
	Surgical gowns, XL-Fisher	96-0032	6 cases	May-96	801.54
	Surgical gowns, XL-Fisher	96-0032	4 packs	May-96	20.56
	Shoecovers-Fisher	96-0032	20 cases	May-96	933.40
	Caps, surgeon string tie-Fisher	96-0032	2 cases	May-96	291.70
	Caps, Kleengard Lg-Fisher	96-0032	10 cases	May-96	411.40
	Facemask earloops-Fisher	96-0032	9 cases	May-96	509.13
	Facemask earloops-Fisher	96-0032	2 packs	May-96	18.85
	Safeguard eyewear-Fisher	96-0032	450 each	May-96	2,344.50
	Scrub shirt, unisex Bl, Md-Fisher	96-0032	200 each	May-96	1,014.00
	Scrub shirt, unisex Jd, L-Fisher	96-0032	300 each	May-96	1,521.00
	Scrub shirt, unisex My,S-Fisher	96-0032	150 each	May-96	760.50
	Scrub shirt, unisex My,XL-Fisher	96-0032	100 each	May-96	507.00
	Scrub pants, unisex My, S-Fisher	96-0032	150 each	May-96	889.50
	Scrub pants, unisex My, M-Fisher	96-0032	200 each	May-96	1,186.00
	Scrub pants, unisex My, L-Fisher	96-0032	300 each	May-96	1,779.00
	Scrub pants, unisex My, XL-Fisher	96-0032	100 each	May-96	593.00
	Alconox detergent-Fisher	96-0032	1 case	May-96	86.65
	Face mask, Non-GL-Fisher	96-0032	2 cases	May-96	152.86
	Auto drop system-Fisher	96-0032	1 case	May-96	179.68
	Container, sharps-Fisher	96-0032	48 each	May-96	108.48
	Bacdown detergent-Fisher	96-0032	3 each	May-96	75.99
	Glove unlined, M-Fisher	96-0032	3 cases	May-96	216.00
	Glove unlined, M-Fisher	96-0032	6 packs	May-96	36.00
	Surgical gloves-VWR	96-0033	2,000 pairs	Apr-96	973.00
	Towels-HW Baker Linen Co.	7696	7 dozen	Apr-96	114.76
	Exam gloves-Aladan	96-0028	40,000 pairs	Apr-96	3,147.62
	Surgical gloves-Ansell	96-0064	63,200 pairs	Apr-96	19,425.35
	Utility gloves-Fisher	96-0063	576 pairs	May-96	288.00
	Total Odessa Oblast Hospital				48,354.91

Ukraine Humanitarian Health Assistance Activity
Commodities/Freight and Printed Materials

December 30, 1997

Commodity	Item/Supplier	PATH P.O. Number	Quantity	Ship Date	Expenditures
Lviv Railway Hospital	Glove samples-Various vendors			Feb-96	58.00
	Surgical & ortho gloves-Ansell	96-0015	20,000 pairs	Mar-96	7,702.00
	Exam gloves-Aladan	96-0014	40,000 pairs	Mar-96	3,040.00
	Utility gloves-VWR	5096	432 pairs	Mar-96	562.29
	Surgical gloves-Ansell	96-0059	168,000 pairs	Sep-96	5,228.88
	Exam gloves-Aladan	96-0062	129,000 pairs	Sep-96	9,804.00
	Safety goggles-3M donation		140 units	Apr-96	-
	Rubberized material	96-0109	1,600 meters	Nov-96	3,430.00
	Gauze fabric	96-0108	6,460 meters	Nov-96	2,172.00
	Fabric samples/thread	24796	113 meters & 50 cases	Sep-96	509.00
	Total Lviv Railway Hospital				32,506.17
Other BBIC Hospitals	Surgical gloves-Ansell	96-0068	471,200 pairs	Sep-96 & Oct-96	140,964.46
	Exam gloves-Aladan	96-0061	228,000 pairs	Sep-96 & Oct-96	17,726.00
	Utility gloves-Fisher	96-0072	5,184 pairs	Sep-96 & Oct-96	1,935.36
	Utility gloves-Fisher	96-0073	16,704 pairs	Sep-96 & Oct-96	6,774.18
	Utility gloves-Fisher	96-0065	900 units	Sep-96 & Oct-96	4,194.00
	Goggles-Fisher	96-0070	2,900 units	Sep-96 & Oct-96	13,514.00
	Surgical gloves-Ansell	97-0022	136,400 pairs	Apr-97	40,602.00
	Exam gloves-Aladan	97-0024	66,000 pairs	Apr-97	5,016.00
	Utility gloves-Fisher	97-0025	6,336 pairs	Apr-97	2,937.00
	Goggles-Fisher	97-0023	1,100 units	Apr-97	4,779.00
	Total Other BBIC Hospitals				238,442.00
TMA Sewing Workshop	Sewing machines & sergers-Juki	96-0108	6 units	Dec-96	27,994.00
	Irons & steam generator-Sussmann	96-0109	3 units	Dec-96	5,167.00
	Sewing & button machines-Juki	97-0100	2 units	Nov-97	4,237.00
	Ironing/steam tables-Theobold	97-0106	3 units	Nov-97	2,756.54
	Fabric-Monitor	97-0101	8,000 meters	Nov-97	9,374.00
	Fabric-Pang Rim	97-0107	1,000 meters	Nov-97	4,000.00
	Fabric-Avondale	97-0108	1,274 meters	Nov-97	4,130.00
	Fabric/notions-various vendors			Aug-97 & Sept-97	1,216.00
	Total Sewing Workshop				58,874.54

Ukraine Humanitarian Health Assistance Activity
Commodities/Freight and Printed Materials

December 30, 1997

Commodity	Item/Supplier	PATH P.O. Number	Quantity	Ship Date	Expenditures
Freight/Labels	Freight/Warehousing outside Ukraine				26,781.00
	In-country freight				9,350.00
	Labels				1,486.00
Office Equipment	PATH Ukraine computer equipment				1,091.00
Total BBIC					**$ 416,885.62**
Educational Materials	Monographs - printing	97-0029	5,000 copies	Mar-97	3,921.59
		97-0083	3,000 copies	Sep-97	2,664.41
	Brochures - printing	97-0016	10,000 copies	Mar-97	1,414.62
		97-0077	5,000 copies	Sep-97	941.11
	Brochures - 3-color production	97-0014		Mar-97	351.00
	Posters - printing	97-0009	10,000 copies	Mar-97	6,250.00
	Posters - 4-color production	97-0014			1,568.90
	Slide Sets	97-0013	160 sets	Mar-97	5,777.44
	Total Educational Materials				$ 22,889.07

Ukraine Humanitarian Health Assistance Activity
Commodities/Freight and Printed Materials

December 30, 1997

Commodity	Item/Supplier	PATH P.O. Number	Quantity	Ship Date		Expenditures
DIABETES IN CHILDREN						
Insulin/Supplies	Human insulin - Lilly	95-0007	95,500 vials	Feb-95 & Mar-95 Jul-95 & Nov-95		1,131,211.00
	Urine ketone test strips-Miles	95-0006	349,200 units	Aug-95		54,203.00
	Glucose strips-Chronimed	95-0001	34,020 boxes	Aug-95		412,150.00
	Insulin syringes-Terumo	95-0003	160,000 units	Jul-95		10,880.00
	Lancets-Can-Am Care	95-0002	17,472 boxes	Jul-95		79,606.00
	Insulin syringes-Terumo	96-0001	208,000 units	Feb-96		14,144.00
Misc. Supplies	Refrigerators-Nord/Ukraine	95-0050	27 units	Apr-95		5,035.00
	Labels and temperature monitors					5,292.00
	Transfer forms - printing	95-0149 & 8795	2 lots	Apr 95 & Nov 95		4,581.00
Freight	In-country distribution					16,776.46
Freight/insurance	Misc.					2,815.00
Office Equipment	PATH Ukraine computer equipment		1 lot			306.97
Total Diabetes					**$**	**1,737,000.43**
Grand Total Commodities/Freight					**$**	**9,537,317.56**
Educational Materials	Diabetes Care Manuals - printing	96-0071	6,000 copies	Aug-96	$	18,852.00
Grand Total Educational Materials					**$**	**41,741.07**

Notes:
$136 added to BBIC in-country freight to match projected MER total for commod. of $9537317

Attachment 2

Ukraine Humanitarian Health Assistance Activity Diphtheria Component Publications and Materials Produced

Item	Date Produced	Date Sent to USAID
Implementation Plan for Diphtheria Component	July 1994	July 1994
Assessment of Diphtheria Diagnostics Needs in Ukraine	Oct 1994	Oct 1994
Training Curriculum - Qualitative Research and the Design and Development of IEC Materials and Media Campaigns (in Ukrainian)	May 1995	not sent
Three TV Spots on adult immunization for social mobilization campaigns, October 1995 (in Ukrainian)	Oct 1995	not sent
Benefits and Effects of Using Electronic Temperature Recorders with Vaccines and Other Temperature Sensitive Products During Transportation and Storage, WHO/EPI TECHNET.96/WP.2	Feb 1996	not sent
Report of WHO/MOH Joint Assessment Meeting on Diphtheria, March 11-13, 1996	Mar 1996	April 1996
Assessment of Kharkiv Vaccine Production Facility	April 1996	April 1996
Two TV Spots on adult immunization for social mobilization campaigns, May 1996 (in Ukrainian)	May 1996	not sent
Two posters on adult immunization for social mobilization campaigns, May 1996 (in Ukrainian)	May 1996	not sent
One leaflet on adult immunization for social mobilization campaigns, May 1996 (in Ukrainian)	May 1996	not sent
One fact sheet and one press release on adult immunization for social mobilization campaigns, May 1996 (in Ukrainian)	May 1996	not sent
Newspaper articles, immunization notices, banners for social mobilization campaigns produced under subcontracts, May 1996 (in Ukrainian)	May 1996	not sent
NCIH International Health Conference Presentation, Washington, D.C., June 9-13, 1996, Cash-Control Evaluation of an Adult Immunization Program in Ukraine	June 1996	Aug 1996
Letter to the Editor - Ukraine's Diphtheria Campaign, The Lancet, Vol. 348, Nov. 2, 1996	Nov 1996	Feb 1997
Seminar on Use of PCR in the Diagnosis of Diphtheria and Typing of Corynebacteria, June 1997	July 1997	July 1997
Compendium of training and reference materials on vaccine procurement and quality assurance, July 1997 (in Russian)	July 1997	not sent
Seminar on Vaccine Procurement and Quality Assurance in Ukraine, July 1997	Sept 1997	Sept 1997
Case-Control Evaluation of An Adult Immunization Program in Ukraine (submitted to Journal of Infectious Diseases)	Sept 1997	Dec 1997

Ukraine Humanitarian Health Assistance Activity
Bloodborne Infection Control Component
Publications and Materials Produced

Item	Date Produced	Date Sent to USAID
Implementation Plan for Bloodborne Infection Control Component	Aug 1994	Aug 1994
Collaborative Blood Exposure (COBEX) Study Methodology (in Ukrainian)	July 1995	Dec 1997
Occupational Blood Contacts and Exposure Among Operating Room Personnel, Odessa Oblast Hospital	Dec 1995	Dec 1997
Occupational Blood Contacts and Exposure Among Delivery Room Personnel, Odessa Oblast Hospital	Dec 1995	Dec 1997
Lviv Accident Report Project	Dec 1995	Dec 1997
Market Feasibility Study on Local Production of Surgical Barrier Clothing and Business Plan, Lviv Institute of Management	Jan 1996	not sent
Lviv "Do-It-Yourself" Operating Room Study Results	Apr 1996	Dec 1997
Poster - Protect Yourself and Protect Your Patients (in Ukrainian and Russian)	Jan 1997	June 1997
Brochure - What You Need to Know about Bloodborne Diseases (in Ukrainian and Russian)	Jan 1997	June 1997
Slide Lecture (45 minute and 2 Hours) and Slides - Preventing Occupational Bloodborne Infections Among Health Care Workers (in Ukrainian and Russian)	Feb 1997	June 1997
Technical Monograph - Preventing Occupational Blood Exposure Among Health Care Workers (in Ukrainian and Russian)	Feb 1997	June 1997
Management of Post-Exposure Prophylaxis (in Russian)	Mar 1997	not sent
Glove Use Study, Lviv Railway Hospital	Nov 1997	Dec 1997

Ukraine Humanitarian Health Assistance Activity
Diabetes Component
Publications and Materials Produced

Item	Date Produced	Date Sent to USAID
Implementation Plan for Diabetes Component	Oct 1994	Oct 1994
An Instructional Aid on Insulin Dependent Diabetes Mellitus (in Ukrainian)	Aug 1996	Dec 1997
Report of Diabetes Care Conference held in Kyiv, September 1996, and Assessment of the Needs of Children with Diabetes in Ukraine	Nov 1996	Nov 1996
Practice Guidelines for Treatment of Children with Type I Diabetes (submitted to Ministry of Health in Russian)	Nov 1996	Dec 1996

Attachment 3

USAID/PATH Diphtheria Assistance Program in Ukraine

I. Introduction and Executive Summary

Diphtheria has long been recognized as endemic to the Ukraine region. Beginning in the 1960s, following the introduction by the Soviet Union of childhood immunizations with Diphtheria, Tetanus, and Pertussis (DTP) vaccine combined with adolescent and adult booster doses of DT and Td vaccine, the number of diphtheria cases in Ukraine decreased sharply, dropping by the late 1970s to fewer than 1 case per 1,000,000 population. Transmission was never completely interrupted, however, and isolated outbreaks continued to occur throughout the 1970s and 1980s, primarily among children, and the disease maintained a low-level endemicy in several regions of the country. In the mid 1980s, following several years of decline in the public health infrastructure, there began a resurgence of diphtheria in the Soviet Union, primarily in the major urban centers of western Russia. This Russian epidemic, which reached a peak incidence in 1995 of more than 50 cases per 100,000 population, differed from previous ones in that it primarily affected adults (Europe appears to have been experiencing a gradual demographic shift in risk towards older ages for more than 50 years, but the strength of the increased risk among adults for this new epidemic was unprecedented.) By 1991, the first year of its independence from the USSR, epidemic diphtheria had returned to Ukraine, where sharp increases in incidence were recorded in the cities of Kyiv, Lviv, and Odessa. By 1993, the epidemic had spread to more than 50 percent of the oblasts in the country, and by 1995 virtually the entire country was affected (See Figure 1). As in Russia, over 80 percent of these cases were diagnosed in adults 16-59 years of age.

In June 1994, in response to a Ukrainian request for assistance, USAID, with PATH (Program for Appropriate Technology in Health) as its executing agency, initiated a program to provide the Government of Ukraine (GOU) with 22 million doses of Td and technical assistance for adult immunization. The initial Ukrainian immunization strategy was to vaccinate "high risk" groups in oblasts where incidence was highest. However, in early 1995, following an international meeting in Kyiv, the Ukrainian Ministry of Health (MOH), upon the recommendation of WHO, CDC, and PATH, adopted a strategy of providing all adults, 16-59 years of age, with a single dose of Td, to be administered during 10-day mass immunization campaigns. In addition to these single mass campaign doses, additional second and third booster doses were to be given to 30-49 year olds at one month and 6-12 months following the initial campaign dose. The decision to include these second and third doses was based upon CDC field studies which found that a significant proportion of adults in this older age group, particularly those over 40, did not develop a sufficient protective immune response to a single dose of Td. All second and third doses were intended to come from Ukrainian-procured vaccine stores (i.e., not donor-supplied humanitarian vaccine). Adoption of this universal mass immunization strategy marked the first time since the 1976 swine flu immunization program in the United States (U.S.) that a national government attempted to immunize its entire adult population against an epidemic threat.

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The expansion of the target population to all adults significantly increased the Ukrainian need for additional vaccine and technical assistance. Consequently, in August 1995 the cooperative agreement with PATH was amended to provide for 10 million additional doses of vaccine and expanded technical assistance, primarily in the areas of program monitoring, management, and impact evaluation. A technical advisory group (TAG) of physicians and epidemiologists was formed within PATH to handle this function.

Despite the fact that the TAG enjoyed an exceptional relationship of cooperation and collaboration with the MOH, problems with accurately assessing vaccine distribution, consumption, coverage, and wastage persisted throughout the PATH program. There were several factors that contributed to these information problems. Principal among them were:

- a lack of preparation and capacity at the local level for accurately tracking and accounting for vaccine;
- target population definitions, vaccination schedules, campaign strategies, eligibility, and contraindication criteria all changed several times over the course of the program, in what sometimes must have appeared to oblast officials to be arbitrary fiat and indecision among international experts;
- apparent confusion regarding statistical definitions, and considerable non-standardization of reports and statistics between oblasts.

The situation was made all the more difficult to correct because economic realities, including nonpayment of health workers, had resulted in an evolving decentralization of the national public health system with management authority increasingly located away from Kyiv in the oblasts. Despite this, Ukraine, with material and technical support from the international community, achieved a remarkable public health accomplishment in 1995 and 1996. PATH estimates that, using the official definition of three doses of Td, over 80 percent of the adult population was completely immunized during that period. Disease incidence, while still unacceptably high, began to drop only after the mass campaign strategy was implemented, and never approached the levels seen in neighboring Russia. As diphtheria continues its decline, the epidemic appears to be coming under control.

This background document describes the history of the Ukrainian epidemic; the USAID/PATH program; key strengths and weaknesses of the immunization program, as seen from the perspective of the PATH TAG; the program's impact on the epidemic; recommendations for future actions; and the lessons learned by PATH during this ambitious international effort.

II. Description of Epidemic

Incidence. The spread of the epidemic of diphtheria from Russia into Ukraine was first recognized in 1991 in the major urban areas of Kyiv, Lviv, and Odessa, in the center, west, and south of the country, respectively. Following a brief decline during the first half of 1994, a second epidemic wave hit the country in late 1994 and 1995, peaking in the

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fourth quarter of 1995 with an annualized crude incidence of approximately 15 cases per 100,000 population. This second epidemic surge was initially confined to the southern Black Sea regions of the Autonomous Republic of Crimea, Mikolaivska, Odeska, Khersonska, and Zaporizhska oblasts, and the City of Kyiv; but by mid 1995 it had spread in a sweeping arc from the southwest of the country across the east and north through the industrial and coal mining regions of Dnipropetrovska, Donetska, Luganska, Kharkivska, and Sumska oblasts. Incidence began dropping in late 1995, following (though not necessarily as a result of) the introduction of mass immunization campaigns, and by December 1996, crude incidence was the lowest it had been in two and a half years (Graph 1). The last quarter of 1996 saw the lowest fourth quarter incidence in four years (Graph 2). The incidence pattern shown in Graph 2 also reflects the marked seasonality of the disease, with sharp increases during the fourth quarter of each year, particularly during the peak epidemic years of 1994 and 1995.

Another distinctive feature of the Ukrainian epidemic was the sharp age and sex-specific differences in risk and severity of disease. Historically, diphtheria has been a disease of children and adolescents. In Ukraine, as previously noted, over 80 percent of the cases were among adults over 15 years old, and as the epidemic progressed, two narrowly defined age groups, adolescents 16-19 years old, and adults 40-49 years old shared the highest incidence rates (Graph 3). Graph 3, which combines data for 1993 through 1996, also shows this second distinctive feature of the epidemic, the marked difference in sex-specific risk of disease. While disease incidence was roughly equally distributed between males and females below the age of 10 years, there was a sharp increase in cases among female relative to male adolescents. By the age of 25, cases among women were almost twice as common as among men, a differential that remained into old age.

There are several possible explanations for this age and sex pattern of disease, and all may have played a role. The increase in risk among adolescents may be due to increased social activity among this age group, with concomitant increases in high-risk behavior and exposure to *C. diphtherae*. There is also the possibility that this age group represents a cohort of inadequately immunized children who received reduced diphtheria toxoid or missed vaccinations altogether during the late 1970s. Ukrainian health officials indicate that during that period it was not uncommon for children to receive adult Td or DPT with a reduced diphtheria component as part or all of their primary series of immunizations. The sharp increase in risk noted among the older 40-49 year age group may be due, paradoxically, to the success of earlier Soviet immunization programs, as this cohort would have been too old to have received primary immunization protection, but would have been less likely to have acquired immunity through natural exposure as subsequent immunization coverage reduced circulation of toxogenic *C. diphtherea* to very low levels.

The sex differential in risk also has competing explanations. Case-control studies conducted by PATH in Ukraine and CDC research in Russia suggest that exposure to infected children may be a major source of transmission among adults. The roughly equal sex distribution of cases through early adolescence shown in Graph 3, followed by a widening gap of increasing incidence among women is consistent with a model in which

women, as primary care-givers for children, would have greater exposure opportunities than would men. However, it is also consistent with an explanation that men beyond the age of 20 could be expected to have greater immunization coverage due to past military service. Finally, this difference in risk may be due to occupational differences in which women more frequently work in service industries such as sales, education, and health care, which involve greater exposure to the public.

Mortality. Between 1993 and 1996 there were 519 deaths attributed to diphtheria, reflecting an overall case-fatality ratio, i.e., the proportion of cases resulting in death, of 3.6 percent. As the epidemic increased during this period, so too did case fatality, from 2.6 percent in 1993 to 4.0 percent in 1995 - a statistically significant increase of over 50 percent (X^2 trend $p < .005$) - before dropping slightly in 1996 to 3.6 percent.

In contrast to incidence, which was highest among women, adolescents, and adults 40-49 years of age, deaths from diphtheria were concentrated among children under 10 years and adults, particularly men, over 35 years. Graph 4 superimposes these two patterns, showing the strong bimodal age distribution of diphtheria deaths and the overrepresentation of nonfatal cases relative to fatal cases among those aged 10-35 years. As implied by the graph, case-fatality ratios were highest among the very young and adults over 40 (Table 1). Moreover, age-specific case-fatality ratios changed for cases over 40 years old over the course of the epidemic. While stable for most age groups, between 1993 and 1996 the risk that a case would be fatal increased by as much as 175 percent among those over 40 years old. This is particularly disturbing as this was also the period in which overall incidence for these age groups saw sharp increases in absolute risk as well as risk relative to other ages. In contrast to overall incidence, the case-fatality ratio was higher for males in every age group except the very youngest. This sex difference in case fatality was greatest for adults over 30 years old, and among the oldest cases, death resulted almost twice as often for men than for women (Graph 5).

There was also a sharp difference among case-fatality rates for cases in urban versus rural areas. The cases in the latter areas were, overall, more than two times more likely to result in death than were cases from urban areas (CFR 6.2% v. 2.8%) and for cases among 16-29 year olds, the age group with the lowest overall case-fatality ratio, case fatality was nevertheless over six times higher among rural cases (3.4% v. 0.5%). This excess severity in outcome among rural cases may be due to reduced access to adequate treatment, or it could be a result of case detection, in which only the more severe cases in rural areas were likely to seek treatment , or it could be a combination of the two.

III. The Ukrainian Response and the USAID/PATH Program

Mass Campaign Strategy. Prior to 1993, the GOU's immunization strategy was targeted to children, and while immunization plans were developed to vaccinate all children in the country, implementation was not strictly monitored and coverage was not computed. In 1993, the GOU began an aggressive campaign to immunize adults belonging to certain "high risk" groups - primarily those in service industries (teachers, students, health care

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workers, civil service workers, transport, and restaurant workers). In April 1994, following an appeal from the Ukrainian government for assistance in providing sufficient vaccine for this effort, USAID awarded a cooperative agreement to PATH to procure and deliver to Ukraine 22 million doses of Td vaccine. The first doses were shipped in July 1994, and were distributed by the MOH and used in accordance with this "targeted risk group" strategy.

By early 1995 it was evident that the selective "target group" immunization strategy was not arresting the epidemic. Consequently, in February 1995, at an international conference called by the GOU and WHO, organized by PATH and the MOH, and attended by advisors from the MOH, PATH, WHO, CDC, IFRC, UNICEF, and USAID, Ukraine adopted an ambitious mass-immunization strategy in which all adults between the ages of 16 and 59 years were to receive at least one dose of Td vaccine, and those between 30 and 49 were to receive additional doses. The additional doses for this latter age group followed recommendations by WHO and CDC, and were indicated by research by CDC which suggested that a significant proportion of this population may have been inadequately primed to respond to a single booster dose of reduced diphtheria toxoid.[1] The strategy called for the initial first doses to be administered during intensive 10-day campaigns, organized in sets of oblasts, during which all adults, regardless of past vaccination history, were to be given a single dose of Td. Subsequent doses were to be administered at one month and after 6-12 months.

Coverage. The first campaigns were organized and carried out in April, 1995 in four oblasts (Odeska, Khersonska, Zaporizhska, Mikolaivska) the Republic of Crimea, and the cities of Kyiv and Sevastopol.[2] Over the next 18 months, campaigns were conducted in all 27 oblasts and administrative regions of the country. However, not all campaigns were strictly coordinated centrally from Kyiv, and it was clear that a considerable proportion of PATH-procured vaccine was not being used in accordance with the agreed upon one-dose mass campaign strategy, but was distributed to oblasts and used during non-campaign periods, for routine immunizations, and for second and third follow-up doses. Because of this, and the general lack of information regarding the PATH vaccine distribution,

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[1] In fact, the original policy was three-tiered, with 16-29 and 50-59 year olds receiving a single dose, 30-39 two doses, and 40-49 three doses. This age-specific schedule was later changed to provide three doses to the 30-39 year age group and, finally, rejected to reflect the de facto policy of the oblasts, who followed a single schedule in which all adults 16 years and over were to receive three doses. In fact, there is a body of opinion among Ukraine public health officials that the original CDC research was flawed when it suggested that the younger age groups would respond adequately to a single dose of Td. Nevertheless, the evolving dosage schedule led to some confusion in the field, the central MOH, and PATH with regard to computing and interpreting coverage statistics and proved to be a major obstacle in PATH's attempt to define, much less monitor vaccine consumption and wastage.

[2] The first mass campaigns met with mixed results. Subsequent coverage surveys conducted by CDC estimated adult coverage during the campaign in the City of Kyiv to have been 55 percent, while coverage exceeded 90 percent in the rural population of Zaporizka. A population-based case-control study (using health center records) conducted in urban and rural areas of Zaporizka nine months later measured coverage among controls to be greater than 70 percent for at least one dose in the prior 5 years. This same study estimated the efficacy of 2 or more doses administered during the campaign to be 92 percent.

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consumption, and coverage, PATH established a Technical Advisory Group (TAG) of physicians and epidemiologists to provide assistance to the GOU and USAID in monitoring and accounting for the consumption of humanitarian vaccine and evaluating campaign processes and outcomes. The PATH TAG made its first assessment trip to Ukraine in September 1995, and by November 1995 had recommended to the MOH revised forms and reporting procedures to be used by the oblasts for monitoring and evaluation of immunization activities. These recommendations were accepted, and in December 1995 the Ministry of Health directed the oblasts to provide monthly information on vaccination coverage as well as vaccine distribution and consumption. These new reporting requirements became effective in January 1996, and form the basis for subsequent PATH estimates of vaccine consumption and coverage.

Monthly totals provided by the oblasts estimate that in 1996 alone, over 70 percent of the total adult population between 16 and 59 years of age received, at least, a third dose of Td vaccine. This percentage refers only to coverage achieved during 1996, and the numerator does not include adults who were fully immunized in 1995 (although the denominator does). It is therefore, only a measure of vaccination activity, and not of actual population coverage. Interpretation of this percentage to arrive at a coverage estimate is problematic because some 1996 campaigns were conducted in oblasts which had previously implemented intensified adult immunization efforts. Consequently, many of the adults included in this 70 percent coverage estimate had already completed a three-dose schedule, and were given an additional fourth dose as part of the campaign. The figure also does not include those adults who completed their immunizations within a year prior to the campaigns and were generally exempt from additional campaign doses. PATH has carefully examined oblast reports for 1996, along with retrospective vaccination numbers provided by oblasts for 1995 (before system-wide, standardized, reporting was initiated), and estimates that approximately 85 percent of the adult population were immunized, using the official Ukrainian definition of three Td doses within a year, during that two-year mass-immunization period. This estimate is approximately 10 percent less than that contained in official MOH statistical reports, but adjusts for obvious and likely instances of mathematical errors and double counting, as well as information obtained in discussions with oblast health officials regarding redundant injections given to already fully immunized individuals.

One measure of increasing coverage is, paradoxically, the proportion of cases who had been fully or partially immunized. The proportion of cases who received two or more doses in the two years prior to onset of disease has increased almost seven fold since 1993, from a 3.4 percent to 23.2 percent. Graph 6 shows that this increase is due to an overall sharp decrease in cases, beginning in later 1995, while the absolute number of partially and fully immunized cases has remained relatively constant, or increased only slightly. This is consistent with expected vaccine efficacy, which is less than 100 percent.

However, it is clear from analysis of the most recent case data that the force of morbidity that has allowed diphtheria to persist among both the immunized and nonimmunized populations is fueled by the excess risk among the shrinking pool of nonimmunized and

incompletely immunized adults. Looking only at data from 1995 and 1996, years during which the mass campaign strategy was carried out, for all ages above 15 years, i.e., the age group targeted for mass immunization, the large majority of cases continues to come from among the nonimmunized and partially immunized population (Graph 7). These populations provide the pool of circulating toxogenic *C. diphtherae* which allows the epidemic to continue, albeit at decreasing levels over time. This graph is also important in that it suggests that following three doses of Td vaccine, the age-specific differences in risk noted for adolescents and adults 40-49 years of age disappears.

Impact. In the description of the epidemic above it is clear that the diphtheria epidemic is abating in Ukraine. In all but one oblast, disease incidence was lower in 1996 than it had been in 1995; and for many oblasts, particularly those that were hardest hit by the epidemic in 1995, 1996 incidence was lower than it had been in 1993 (Table 2). This decrease is consistent across all age groups (Graph 8) and accelerated as 1996 progressed. That is, the yearly aggregate incidence statistics mask the observation that change in the rate of decrease has been largely exponential over time, approximating a mirror image of the exponential rate of increase witnessed between June 1994 and June 1995 (Graph 9). Incomplete data for 1997 confirm that these decreases continue.

It is, of course, impossible to determine with certainty whether the decreases seen since late 1995 are a result of the Ukrainian immunization program, or whether they reflect a natural epidemic curve associated with infectious disease outbreaks. However, these observations regarding these decreases give strong support that the immunization program has been effective:

- incidence in Ukraine never approached the levels seen in neighboring Russia, although there is no apparent demographic or prior immunologic history to explain why Ukraine's experience should have been different;
- incidence began to decrease within six months of the initiation of the mass campaigns;
- the rate of decrease has been greatest in those oblasts where mass campaigns had been conducted.

Moreover, a case-control study conducted by PATH in 1996 estimated that disease risk was decreased by over 70 percent for individuals who had received three or more recent doses of vaccine; and it is clear from government statistics and coverage surveys that since the initiation of mass campaigns the Spring of 1995, with the infusion of 32 million doses under the PATH program, 23 million doses provided by the IFRC, and an unknown but substantial quantity of Ukrainian-procured Russian and European vaccine, adult coverage with three or more doses of vaccine has seen a rapid increase and is now over 80 percent.

Ukrainian public health vigilance will require that intensified EPI coverage, rigorous adult immunization programs, and rapid case investigations with prophylactic measures for contacts, will need to be faced for years to come. But the current evidence justifies optimism that diphtheria is coming under control in the country, and that the massive public health response mounted by the Ukrainian MOH is in large part responsible.

IV. Lessons Learned

Despite the fact that the TAG enjoyed an exceptional relationship of cooperation and collaboration with the MOH, problems with accurately assessing vaccine distribution, consumption, coverage, and wastage persisted throughout the PATH program. There were several factors that contributed to these information problems. Principal among them was

- a lack of preparation and capacity at the local level for accurately tracking and accounting for vaccine;
- target population definitions, vaccination schedules, campaign strategies, eligibility, and contraindication criteria all changed several times over the course of the program, in what sometimes must have appeared to oblast officials to be arbitrary fiat and expert indecision;
- apparent confusion regarding statistical definitions, and considerable non-standardization of reports and statistics between oblasts.

Responsibility for the first of two of these factors, which are largely implementation errors rather than weaknesses in the health system, must be shared by the MOH, PATH, and USAID. Because of the urgency with which the program was launched, insufficient time was spent in organizing, briefing, and assisting oblasts with program goals and strategies. Following the adoption of the universal mass campaign strategy, this lack of up-front planning for adequate systems of monitoring and evaluation became a problem that, almost by definition, could not be adequately corrected. It is clear that PATH, USAID, the international community, and no doubt the Ukrainian MOH themselves underestimated the readiness of the existing public health structure to be able to do what it was being asked to accomplish.

In a retrospective effort to impose a monitoring and evaluation reporting system on the oblasts after the program had been in place, reporting forms were designed and protocols established in a collaborative process between PATH and the central MOH. However, there was little opportunity to prepare the oblasts for these reporting changes, nor was there a system of incentives (or disincentives) in place to ensure compliance. Furthermore, the oblasts, already having had no input into the decisions regarding reporting requirements, were also not given adequate feedback or benefits regarding the information they generated. Consequently, compliance, particularly in the first months of the new system, was poor and the numbers often incomplete or inaccurate.

In addition to inadequate logistical and strategic preparation, there was an unanticipated resistance from certain powerful quarters within the Ukrainian medical community to acceptance of Western vaccine, which is formulated at a lower potency than Russian vaccine. These opponents of the program also rejected, in principle, the strategy of mass immunization, and some questioned the effectiveness of immunizations at all - voicing an

apparently deep-seated distrust of vaccinations which shared by a small but significant proportion of the population[3].

The situation was made all the more difficult to correct because economic realities, including nonpayment of health workers, had resulted in an evolving decentralization of the national public health system with management authority increasingly located away from Kyiv in the oblasts.

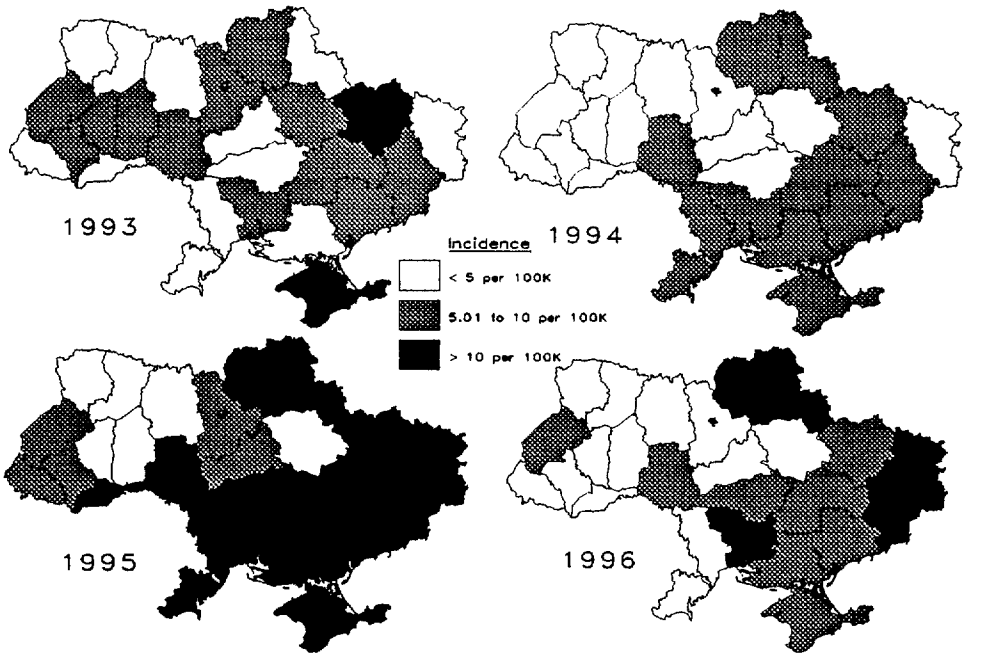
In fairness to all partners, the Ukraine mass immunization program was virtually unique in the history of public health interventions, so recognition of many of the obstacles, which now seem to have been plainly inevitable, benefit from the clarity of hindsight. Furthermore, the PATH/USAID humanitarian assistance program was initially designed as a donation of commodities, and only expanded in scope to include significant technical assistance after the first year of the project. The scope and level of effort that was ultimately invested in the program had not been part of the original project vision. Many of the management information problems identified in the course of the PATH program are now being targeted for additional assistance by the U.S. government, as evidenced by the newly initiated health management information system program currently being developed by USAID, BASICS, PATH, and CDC.

As noted above, the Ukrainian effort of universal adult immunization against diphtheria was the first time since the 1976 swine flu immunization program in the U.S., and only the second time in history, that such a national strategy has been adopted; and it is the only time universal immunization has been adopted to arrest an epidemic already in progress. Results have been mixed. All the available evidence suggests that the Ukrainian efforts, with the assistance of the international community, are producing, albeit qualified, success. But the persistence of diphtheria in the country also points to the poor cost-efficiency of adult immunization as a means of protecting against outbreaks of disease. The current epidemic started among children, who had been left vulnerable due to inadequate childhood immunizations, and then quickly spread to inadequately protected adults. The cost of prevention, through strengthening and enforcing a universal program of immunization of infants and children, is far less than that of arresting an epidemic once it reaches the general population.

[3] This undercurrent of public distrust of vaccinations is also widespread in Russia, and may be common to all the states of the former Soviet Union.

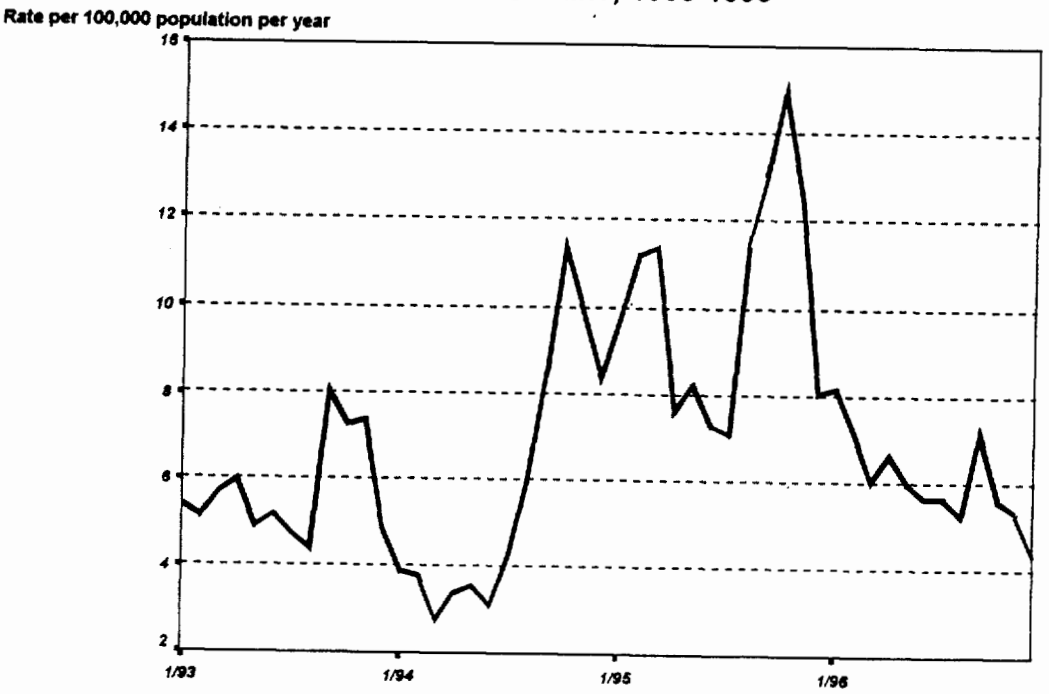
TABLES, FIGURES, AND GRAPHS

FIGURE 1
Diphtheria Epidemic, Ukraine 1993-1996



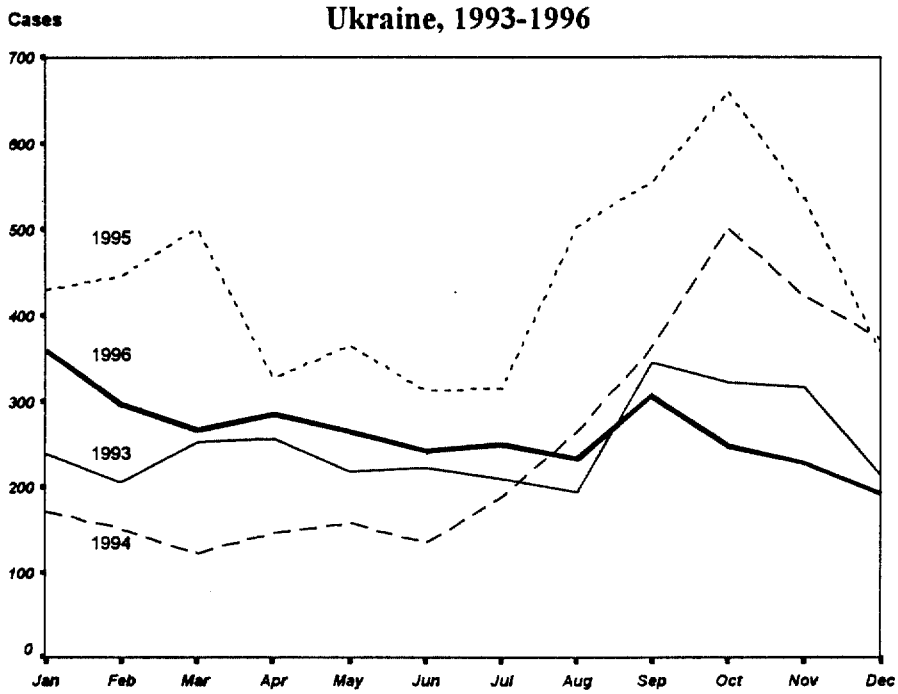
GRAPH 1

Diphtheria Incidence
Ukraine, 1993-1996



GRAPH 2

Diphtheria Incidence
Ukraine, 1993-1996



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GRAPH 3
Age and Sex Distribution of Diphtheria Cases
Ukraine, 1993-1996

GRAPH 4

Diphtheria Cases and Deaths
Ukraine, 1993-1996

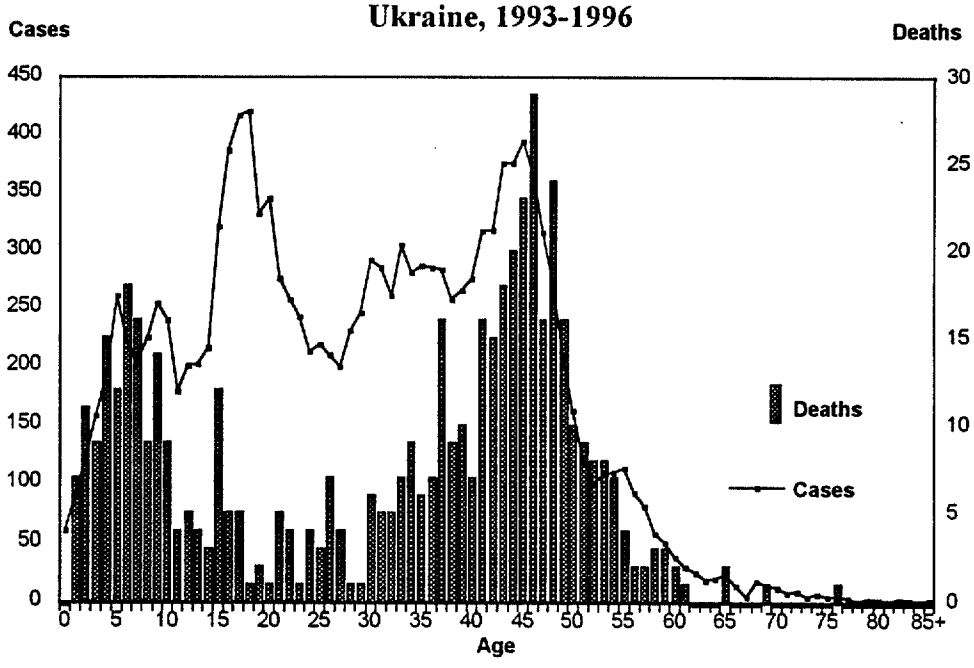


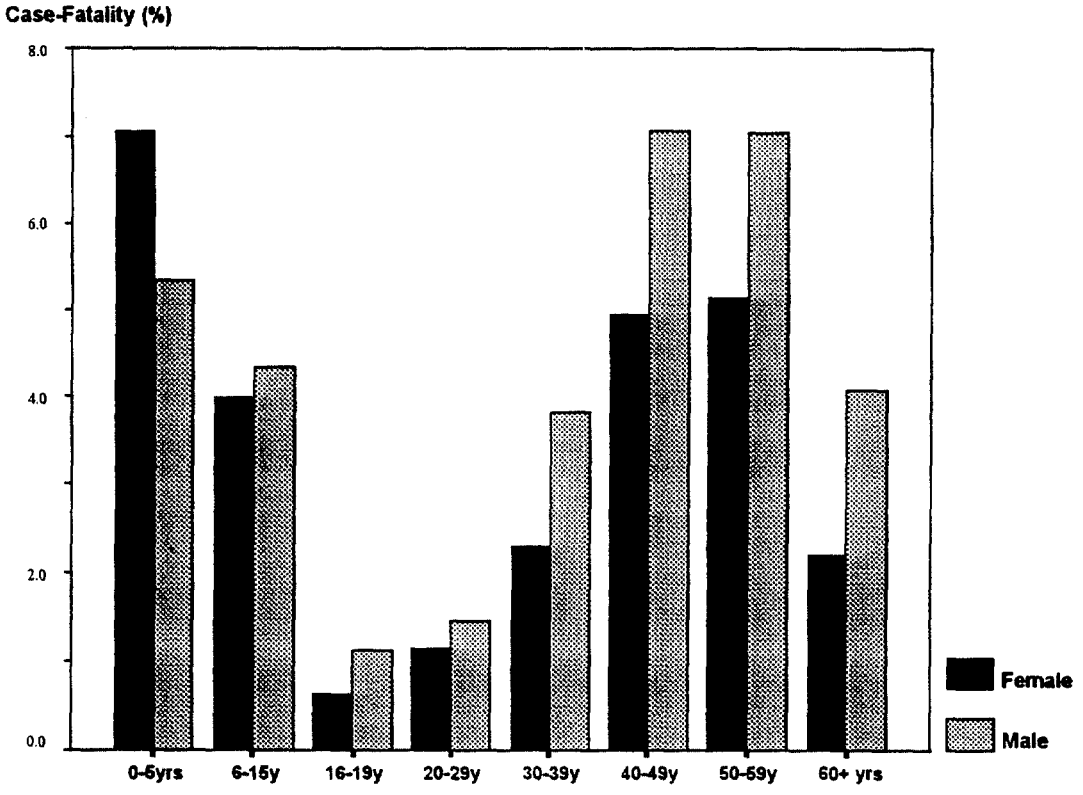
TABLE 1

Age Specific Diphtheria Case-Fatality Rates
Ukraine, by Year, 1993-1996

	0-5yrs	6-15y	16-19y	20-29y	30-39y	40-49y	50-59y	60+ yrs	Overall
1993	6.28%	3.74%	.29%	1.07%	2.24%	3.80%	2.76%	1.96%	2.61%
1994	5.82%	3.85%	1.08%	1.76%	3.29%	5.30%	7.43%	2.56%	3.78%
1995	5.50%	4.88%	.74%	1.33%	2.99%	6.75%	5.90%	.00%	4.03%
1996	7.26%	3.47%	1.27%	.92%	2.88%	5.88%	5.38%	5.43%	3.60%
Overall	6.11%	4.15%	.83%	1.27%	2.85%	5.72%	5.62%	2.53%	3.59%

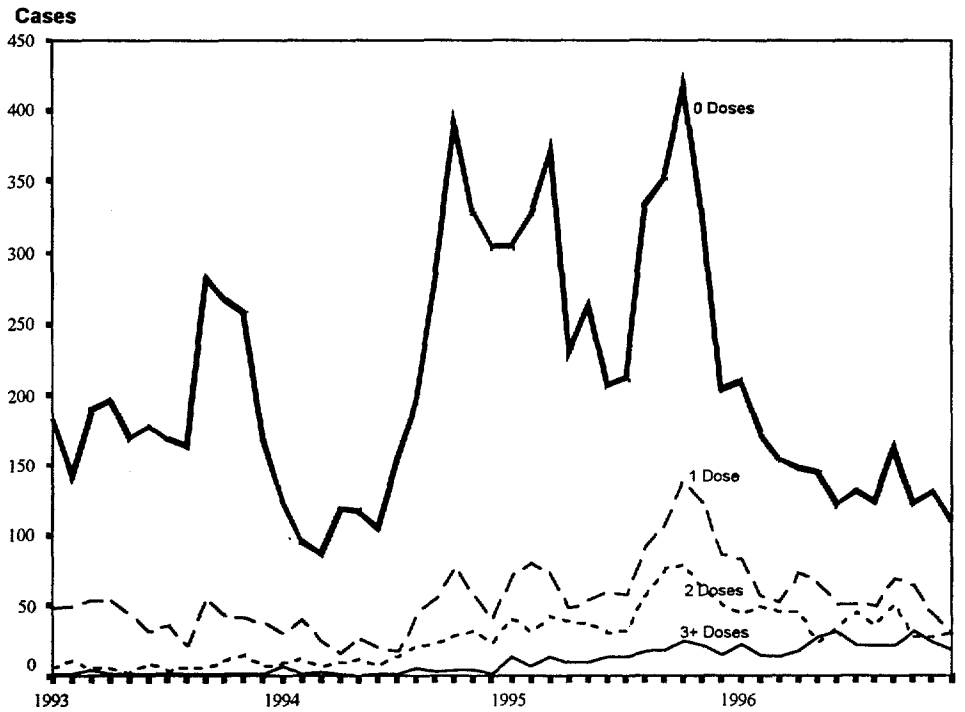
GRAPH 5

Age-Specific Diphtheria Case-Fatality Rates by Sex, Ukraine 1993-1996



GRAPH 6

Immunization History Among Diphtheria Cases
Cases by Number of Td Doses Received in Previous 2 Years
Ukraine, 1993-1996



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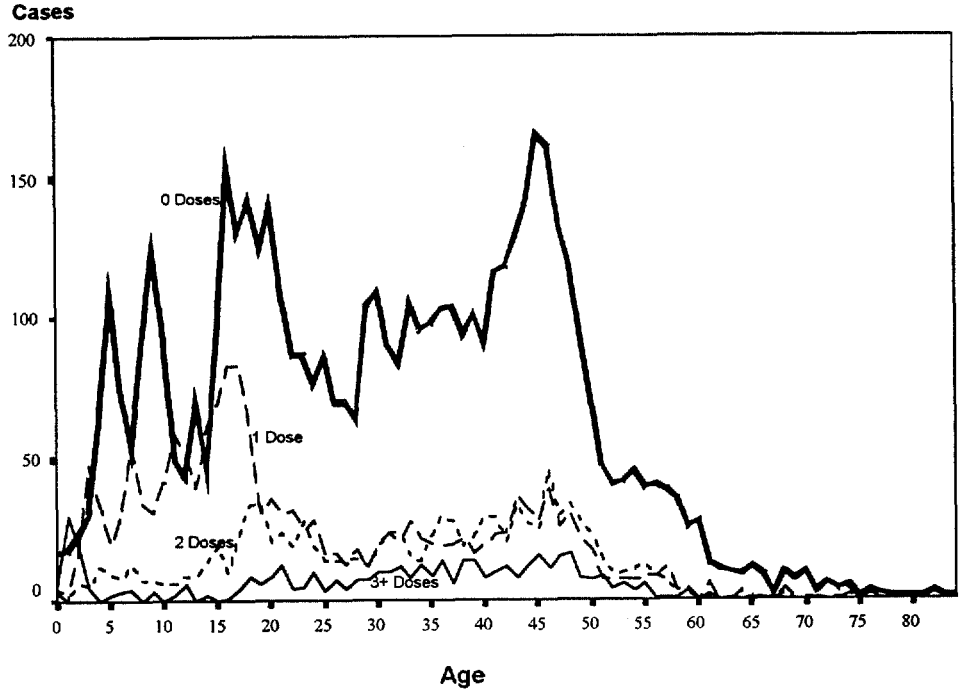
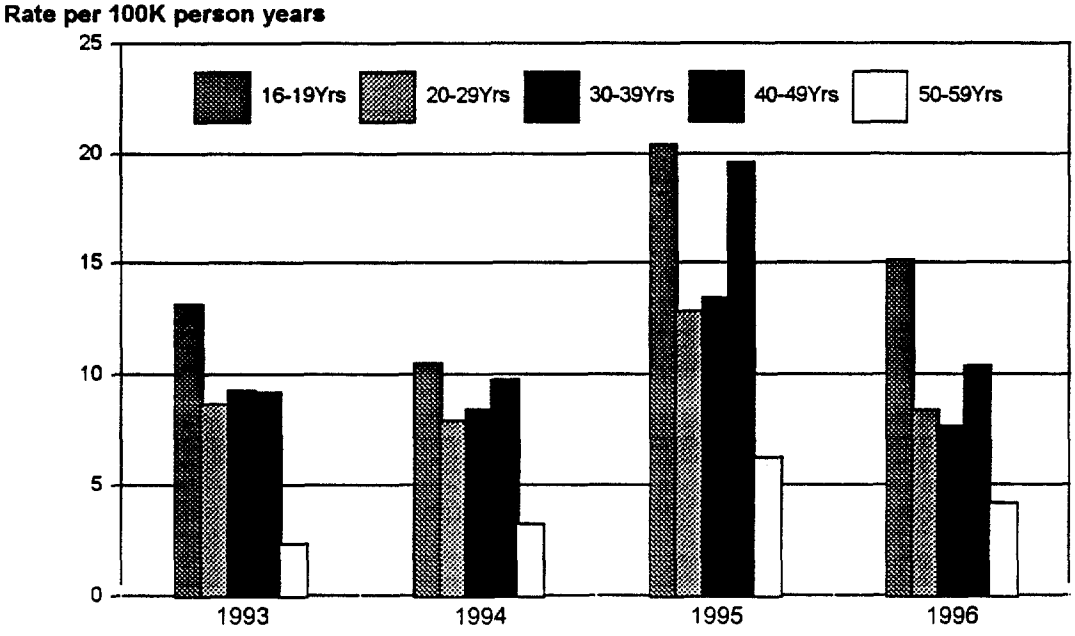
GRAPH 7

Immunization History Among Diphtheria Cases by Age
Cases by Age and Number of Td Doses Received in Previous 2 Years
Ukraine, 1995-1996



GRAPH 8

Diphtheria Incidence by Age and Year
Ukraine 1993-1996



GRAPH 9

Percent Change in Diphtheria Incidence
Ukraine 1994-1996

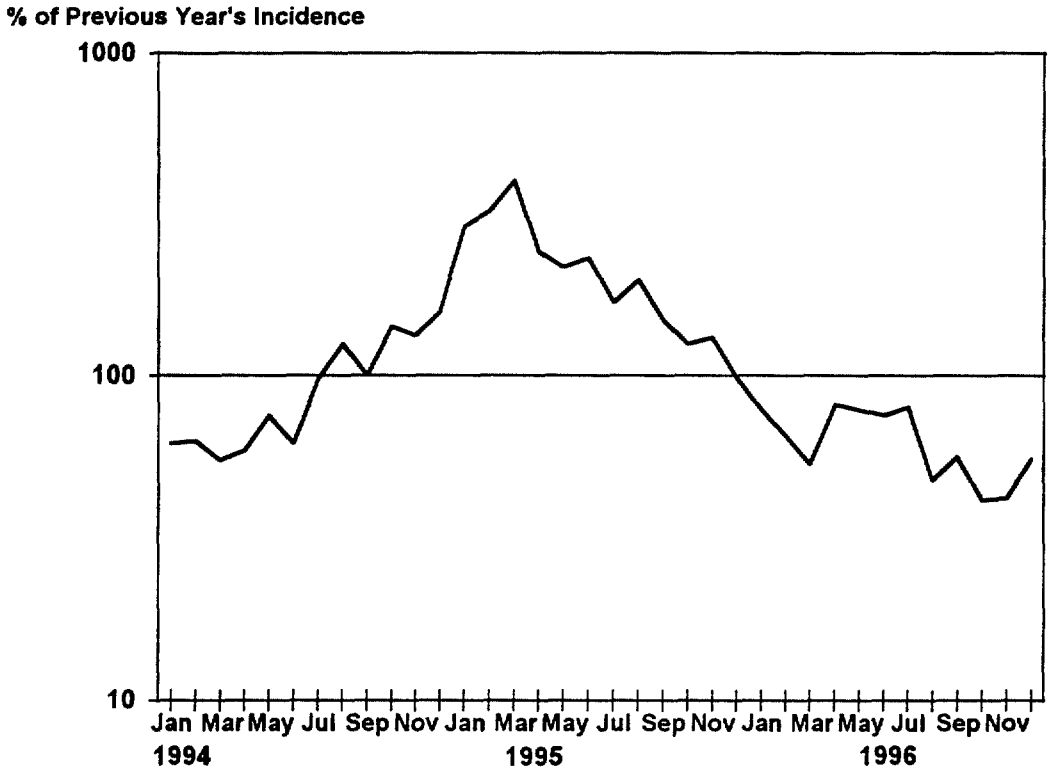


TABLE 2

Diphtheria Cases Among Adults, 16-59 Years
Ukraine, 1993-1996
Oblasts with Controlled Campaigns Using USAID/PATH Vaccine:

	OBLAST	1993	1994	1995	1996	% Change 94-95	% Change 95-96	% Change 93-96
*	Mikolaivska	55	92	241	87	161.96	-63.90	58.18
*	Sevastopol	41	143	97	36	-32.17	-62.89	-12.20
*	Kherson	25	75	170	68	126.67	-60.00	172.00
*	Crimea	211	159	219	89	37.74	-59.36	-57.82
**	Dnipropetrovsk	112	125	257	121	105.60	-52.92	8.04
*	Odessa	71	162	180	87	11.11	-51.67	22.54
**	Kharkiv	278	117	287	167	145.30	-41.81	-39.93
**	Donetsk	151	252	464	303	84.13	-34.70	100.66
*	Zaporizhska	163	149	182	129	22.15	-29.12	-20.86
*	Kiev City	483	349	670	508	91.98	-24.18	5.18
**	Lugansk	17	58	164	164	182.76	0.00	864.71
	TOTAL	1607	1681	2931	1759	74.36	-39.99	9.46
All other oblasts:								
	Chernivetsk	9	12	58	6	383.33	-89.66	-33.33
	Zakarpatsk	20	16	51	9	218.75	-82.35	-55.00
	Ivan-Frankivsk	60	23	75	26	226.09	-65.33	-56.67
	Rivninsk	24	21	27	10	28.57	-62.96	-58.33
	Volinsk	8	15	17	8	13.33	-52.94	0.00
	Ternopil	43	35	34	18	-2.86	-47.06	-58.14
	Vinnitsk	54	77	118	64	53.25	-45.76	18.52
	Kirovograd	17	34	103	58	202.94	-43.69	241.18
	Cherkask	30	27	62	36	129.63	-41.94	20.00
	Kievska	61	32	46	28	43.75	-39.13	-54.10
	Khmelnitsk	124	28	32	20	14.29	-37.50	-83.87
	Chernigivsk	57	49	112	72	128.57	-35.71	26.32
	Poltavsk	62	41	45	29	9.76	-35.56	-53.23
	Zhitomyr	17	24	36	31	50.00	-13.89	82.35
	Sumska	12	53	145	133	173.58	-8.28	1008.33
	Lviv	123	71	126	124	77.46	-1.59	0.81
	TOTAL	721	558	1087	672	94.80	-38.18	-6.80
TOTAL All Oblasts		2328	2239	4018	2431	79.46	-39.50	4.42

* April/May 1995 Campaign

** June/July 1996 Campaign

Attachment 4

Case-Control Evaluation of an Adult Immunization Program in Ukraine

Vivien Tsu, Ph.D.
Dmitri Tyshchenko, M.D.

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PATH

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In 1991 the incidence of diphtheria in Ukraine began to rise sharply after decades of very low levels of disease. Mirroring a similar resurgence of diphtheria in neighboring Russia, the epidemic in Ukraine peaked in 1995 with more than 5,000 cases, 80 percent of whom were adults between the ages of 16 and 59. In June 1994 the United States Agency for International Development (USAID) initiated a cooperative program, executed by the Program for Appropriate Technology in Health (PATH), to respond to a request from the Government of Ukraine (GOU) for assistance in meeting the need for massive supplies of adult diphtheria toxoid. In 1993 and 1994 the Ukraine government had intensified its own efforts to immunize the adult population, but with no apparent effect on disease incidence. In the first quarter of 1995, after discussions at an international meeting in Kyiv attended by Ukrainian experts and representatives of the World Health Organization (WHO), the U.S. Centers for Disease Control and Prevention (CDC), USAID and PATH, the GOU adopted the consensus recommendation for a mass immunization campaign strategy. In April 1995 four southern oblasts, or provinces, the Republic of Crimea, and two cities undertook mass adult campaigns. In the Fall of 1995, when the usual seasonal increase in diphtheria cases was beginning again, several more oblasts launched their own campaigns.

Although case surveillance was good, vaccine coverage data were incomplete and estimates varied widely between and even within oblasts, making it difficult to determine what effect, if any, the campaigns were having. In addition, the use of Western vaccine instead of the more familiar Russian vaccine raised concerns about vaccine efficacy among Ukrainian health workers. The persistence of the adult diphtheria epidemic, in a population previously thought to be well immunized, raised questions about the number of doses needed to re-establish immunity among different age groups. There were also questions about the relationship between the adult epidemic and the epidemic among children.

Serologic studies carried out by the Ukrainian Ministry of Health (MOH) in collaboration with CDC (Hardy et al, 1996) had demonstrated that the Western vaccine was as efficacious as the Russian vaccine and that most adult groups needed only one booster dose (although 30-49 years olds would benefit from 1 or 2 additional doses). However, some Ukrainian scientists still had reservations about the study findings so the MOH decided to use 3 doses for all adults (although only 1 dose was to come from humanitarian assistance sources).

To address some of these questions PATH, in collaboration with the MOH, undertook a matched case-control study. Since factors such as age, potential exposure to other cases, and number and timing of vaccine doses were known to affect risk, a multivariate analysis was undertaken in order to disentangle the various factors.

Materials and Methods

The study was carried out in three locations. One was in the urban area of Lviv, a region which was not part of the organized campaigns of the first half of 1995. The second and third were in the urban and rural areas respectively of Zaporizhzhya city and Melitopol raion (or district), both in the southeast oblast of Zaporizhzhya. Melitopol had been the earliest focal

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point of the epidemic in the Zaporizhska oblast. Sixty cases and two matched controls for each case were identified in each site. Both cases and controls were between the ages of 16 and 59 at the index date (the date the case's diagnosis was made).

Cases

Cases were identified from polyclinic records and were diagnosed, with laboratory confirmation, between January and December 1995; in Melitopol, where the epidemic started earlier and numbers were smaller, the eligibility was extended back to July 1994. All consecutive eligible cases were enrolled at each eligible polyclinic until the study quota (60) was reached. The enrolled cases represent more than 75% of all eligible cases in each location.

Controls

Controls were adults who had not had diphtheria (prior to the index date) according to their polyclinic records. They were selected from the polyclinic where the case was listed, using the register of all residents in the designated catchment area for that polyclinic (based on a semi-annual household census). Two controls were drawn randomly, one each from the household just above and just below the case in the register. This usually means the controls lived in either the same or an adjacent building as the case.

Data collection and analysis

Age, sex, vaccination history, date of diagnosis, and clinical course for the cases were taken from the case's medical record at the polyclinic; household size and composition for cases were taken from the polyclinic register. Age, sex, household size and composition, and vaccination history for controls were taken from the polyclinic registers. When the polyclinic register identified a control as being under the care of an employer-based clinic, the vaccination history was checked by telephone with the polyclinic holding the records. Vaccine source was noted as "USAID" when indicated as such on the record; if not so indicated, it was recorded as "other". All data were collected by local MOH staff in February 1996. A sample of 5% of controls in each of the three sites was contacted within the next two months by telephone or in person to verify the data in the polyclinic register. Nearly 85% of the items checked were in complete agreement with the records, while the remaining variances were generally minor. Vaccinations occurring less than seven days before and at any time after the index date for cases and controls were excluded from the analysis since they cannot have been expected to have offered any protection within the time period under consideration.

Data were entered into the computer using Epi Info 5.0, and descriptive statistics were carried out using SPSS-PC. Conditional multiple logistic regression (for matched analysis) using the EGRET software package was carried out to identify independent risk factors and control for confounding variables. Relative risks approximated by the odds ratios were estimated by the method of maximum likelihood, and 95% confidence intervals (CI) were based on the standard error of the coefficient estimate and the normal approximation. Age was categorized into 10-year groups except for 16-19 year olds; age-group, number of children in the household and doses were factored for the analysis, while household size was entered in the model as a continuous variable.

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Results

Table 1 shows the characteristics of the study participants in terms of age, sex, and household size and composition. Cases were much more likely than controls to be 16-19 or 40-49 years old. National case data show a similar distribution of age. However, national age distribution figures for the general population suggest that younger adults were substantially underrepresented among the controls (16-19 year- olds should have been about 9.5% of the control group and 20-29 year-olds about 25%). Overall, both groups were nearly 40% male, 60% female, with the proportion of women increasing with age as it does in the general population. However, women were significantly over-represented among controls in the 40-49 year old age group, while there was a very marked over-representation of women cases in the 50-59 year age group (Table 2). A higher proportion of cases (13 vs. 7%) came from the largest households and from medium-sized households (43 vs. 28%). Similarly, cases were more likely to come from households with either young or school-age children.

Cases were much less likely than controls to have been vaccinated (Table 3) in the year preceding the onset of disease (the index date for controls),and were somewhat less likely to have had at least one dose since January 1990. However, cases were twice as likely to have a record of being vaccinated before 1990. Among those who were vaccinated after January 1990, cases were more than twice as likely to have had their most recent and next most recent dose of vaccine before 1994 and were about seven times as likely to have had their most recent dose before 1992 (although numbers are small). There is very little difference between vaccinated cases and controls as to whether vaccine they received in 1994 or 1995 came from USAID-funded supplies or other European or Russian sources.

As seen on Table 4, there were differences in vaccination coverage in the three study sites (based on the rates among the controls), with Lviv having much lower rates of recent vaccination than Zaporizhzhya and Melitopol (which participated in the April 1995 mass campaign while Lviv's campaign occurred late in 1995). The differences are much less when considering the level of coverage with 2 or more doses in the year preceding the index date, although Lviv is still lower than the others. On the other hand, Lviv had much higher rates of vaccination reported before 1990 while Melitopol had no controls with such a history, suggesting either lower rates of vaccination before 1990 or weaker record-keeping. Since the epidemic (and active vaccination efforts) started in 1993 in Melitopol, it is not surprising that the proportion of vaccinated people whose most recent dose was in 1994 or 1995 is somewhat lower there than in the other two sites. As to the source of vaccine received in general (based on controls), Melitopol was much more likely to have used vaccine provided by USAID funds.

Using conditional multiple logistic regression to control for variations in age, sex and household size and composition, cases were five times as likely as controls to have had no vaccine in the year preceding the onset of disease (Table 5). This implies an efficacy of 80% for at least one dose of vaccine in the year preceding the index date. In looking at the effect of vaccination in the 3-5 years earlier than the year preceding the index date, it is difficult to

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disentangle the effects since so many people were immunized in the most recent year. The apparent threefold risk associated with lack of vaccination since 1992 drops to 1.0 when it is adjusted for prior-year-vaccination, suggesting that the protective effect of vaccine given since 1992 is largely or entirely due to very recent vaccinations (i.e., those received in the year preceding the index date). There is a clear dose relationship for doses given in the year preceding the index date, with vaccine efficacy of nearly 70% for a single dose and above 90% for those receiving 2 or 3 doses in the most recent year. The dose relationship is less clear when considering all doses given since January 1992, especially for the third dose (more of which occurred in the earlier part of the period).

Using the logistic regression model and adjusting for vaccination history in the year immediately preceding the index dates, it was possible to identify several risk factors for adult diphtheria infection independent of vaccination (Table 6). Using the 50-59 year olds (who had the lowest disease risk) as the reference group, 16-19 year olds had a very high relative risk with 40-49 year olds having the next highest risk levels. Contrary to the trends seen in national case data showing women with much higher incidence, these data show only a slightly elevated risk for women once they are adjusted for age, vaccination history and household size and composition. However, given the small numbers in each age group and the skewed sex distribution in the upper two age categories, it was not possible to disentangle the potential effects of selection bias on the gender-related risk. The total number of people living in the household is associated with a modest increase in risk that rises to more than twofold with four people or more. In addition, there is a modest, not quite significant increase in risk associated with having one or two children under five years or one school-age child in the household. With two or more school-age children in the household, the risk is significant and more than twofold.

Discussion

The level of efficacy for diphtheria vaccine shown in this study (70-90%, depending on the number and recency of doses) is consistent with the vaccine efficacy and adult seroconversion levels reported elsewhere (Galazka and Robertson, 1996; Jones et al, 1985). Since the vaccine is not 100% effective, it is not surprising that some cases were infected despite vaccination. It is interesting to note that vaccinated cases were much more likely than vaccinated controls to have received their vaccine prior to the introduction of mass campaigns and Western vaccines in 1994. Since immunization efforts prior to the campaigns were directed at groups considered to be at higher risk of infection because of occupational exposures (a factor not measurable in the data sources available in this study), the association with earlier vaccination may be a result of confounding (by occupational exposure).

For the period when both Western and Russian vaccines were in use (1994 forward), the data show equivalent experience between cases and controls with regard to USAID-supplied vaccine versus other sources. Polyclinic records, however, were not reliable in distinguishing between other donated Western vaccines and Russian vaccines purchased by oblasts. The lower level of efficacy of doses prior to 1994 may be due just to waning immunity over time.

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This would support the finding that vaccine-induced immunity may not last nearly as long as had been previously assumed (Galazka and Robertson, 1996).

The recommendation that only people aged 30-49 years might need more than one dose, based on the CDC/GOU serostudy cited earlier, was not borne out by these data. Even when the data were adjusted for age, the protective benefit of a second dose was statistically significant. When interaction terms of age and dose were entered in the logistic regression model, they were not suggestive of any substantial effect ($p>0.4$). Among the controls, 16-19 year olds had the highest rate of recent vaccination (73% vs. 49-58% in other groups) but the lowest rate of multiple doses (9% vs. 25-31% in other groups). Among the cases, there was little difference in recent vaccination rates among the different age groups (28% vs. 28-40%). The effect of multiple doses, generally, is difficult to interpret without knowing whether and when a primary series was given. Controls were half as likely as cases to have any record of vaccination prior to 1990, but this may be due to more effort being made to ascertain the full immunization history of cases.

The extremely elevated risks for 16-19 year olds may have to be explained by several factors. This age group was significantly underrepresented among the controls, perhaps because they are more mobile (as students or young workers) and are less likely to register with the local polyclinic or to be identified during the household census. As noted earlier, they were also less likely to have more than one dose of vaccine in recent years. Members of this age group may have missed scheduled childhood booster doses during the 1980s and early 1990s when childhood vaccination coverage rates dropped below 50% in Ukraine (Galazka et al, 1995). A larger study with better data on childhood vaccination history (kept at the pediatric clinics and often not transferred when adolescents switch to adult services at age 16) will be needed to clarify why this age group has experienced such elevated rates of diphtheria infection.

National incidence data (Mercer et al 1997) and other studies (Galazka and Robertson, 1995) have suggested that women may be at greater risk than men. Two explanations given are that women may have more exposure through their roles as caregiver to children and ill family members, and men are more likely to receive vaccine boosters during military service. In the univariate analysis in this study, women in various age groups had increased disease risks ranging from 1.1-4.0, except for women aged 40-49 who had a lower risk than men. While the apparent increased risk for women was reduced to a modest, non-significant elevation once age, recent vaccination history, household size and exposure to children were controlled for, thereby lending weight to the suggested explanations, it is not possible to rule out other gender-related factors given the potentially biased age distribution.

Since many Western countries have low levels of protective immunity against diphtheria among adults, similar to Ukraine, it has been suggested that this epidemic took hold in Ukraine and Russia because of the drop in childhood vaccination levels during the 1980s and early 1990s (Galazka and Robertson, 1995). Because many diphtheria infections are subclinical or are not identified as diphtheria, it was not possible to measure adult exposure to infected children directly in this study. However, the increased risk associated with the presence of children in the household (especially school-age children, who would have been

eligible for their primary DTP series in the 1980s when coverage levels in Ukraine dropped below 50%) lends weight to this hypothesis. While one might have expected infants and toddlers to be moe efficient in spreading respiratory infections, it is notable that the risk was actually higher for the older children. This stronger association is not likely to be explained by greater exposure at school, since even toddlers attend public daycare facilities in high numbers in Ukraine.

There are certain limitations in the study which suggest the need for caution in interpreting its findings. The data on vaccine history prior to 1990 were incomplete, possibly unreliable (given some anecdotal reports of falsified immunization records during the 1980s), and quite variable across the three study sites. The number of people with three doses of vaccine in recent years was small, so dose relationships were unstable. The high level of participation in the recent campaigns made it difficult to distinguish possible protective effects of earlier doses. Also, it was not possible to distinguish with certainty the origins of the various vaccines in use in 1994-1995, thus preventing a definitive answer to questions about the effectiveness of vaccines of different strengths.

Conclusions

Given the limitations listed above, it is clear that recent vaccination with one or more doses of diphtheria toxoid (whether Russian or Western) is highly protective among adults. Two doses provide substantially more protection than one, regardless of age. Recent vaccine provides greater protection in an epidemic than vaccine given several years earlier, although vaccination given within 3-4 years before the epidemic provides some protective effect.

Separate from recent vaccination, several other characteristics appear to be independent risk factors, although the mechanisms for them are not yet fully understood. Older adolescents (16-19 years old) and people 30-49 years appear to be at higher risk, as compared to 20-29 and 50-59 year olds. Any elevated risk experienced by women may be explained by the age, recent vaccination history, and household exposure to children. All adults (men and women) experience increased risk of disease when living with school-age children and, to a lesser extent, younger children. This last point indicates the importance of ensuring that children receive appropriate boosters, as well as a primary series.

These findings suggest that MOH officials, health workers and international donor and health agencies can feel reassured that the massive efforts to vaccinate the adult population in Ukraine were responsible for substantial disease reduction and the saving of many lives.

Table 1. Selected Demographic Characteristics

	Cases - % (n=180)	Controls - % (n=360)
Age (years)		
16-19	13.9	3.1
20-29	15.6	18.9
30-39	29.4	29.2
40-49	32.2	24.4
50-59	8.9	24.4
Sex: (male)	37.2	37.8
Household Size		
1-3	43.9	64.4
4-5	43.3	28.3
6+	12.8	7.2
Children <5 years	18.9	10.3
Children 5-15 years	43.9	26.7

Table 2. Proportion of Women in Each Group, by Age

	Cases - %	Controls - %
Age (years)		
16-19	56.0	54.5
20-29	64.3	57.4
30-39	66.0	60.0
40-49	55.2	68.2
50-59	87.5	63.6
Total	62.8	62.2

Table 3. Timing and Source of Vaccines Used

	Cases Number (%)	Controls Number (%)
Any vaccine in year prior to index date	57 (31.7)	194 (53.9)
Any vaccine since 1990	97 (53.9)	227 (63.1)
Any vaccine before 1990	36 (21.6)	30 (9.8)
Among those vaccinated post-1989:		
Most recent dose before 1994	32 (33.0)	33 (13.7)
Next most recent dose before 1994	34 (54.8)	29 (19.3)
Most recent dose before 1992	15 (15.5)	5 (2.2)
Among those vaccinated post-1993[1]:		
USAID vaccine as most recent dose	32 (49.2)	92 (47.9)
USAID vaccine as next most recent dose	11 (39.3)	50 (41.7)

[1] USAID-funded vaccine was first supplied September 1994.
Other vaccines post-1993 were European or Russian.

Table 4 - Differences in Vaccine Use by Site

	Lviv	Melitopol	Zaporizhzhya
% of controls with any vaccine in year prior to index date	36.7	60.8	64.2
% of controls with 2+ doses in year prior to index date	21.7	30.0	34.2
% of controls with any vaccine recorded before 1990	26.1	0.0	6.4
% of vaccinated controls whose most recent dose was in 1994 or 1995	86.8	75.6	94.3
Among those vaccinated post-1993:			
% of controls with USAID vaccine as most recent dose	32.6	63.1	44.4
% of controls with USAID vaccine as next most recent dose	18.8	73.0	33.3

Table 5. Protective Effect of Vaccination in Recent Year

	Relative Risk [1]	95% C.I.[2]	Vaccine Efficacy [3]
No vaccine since January 1992: without adjustment for any prior-year vaccination	3.0	1.8, 5.1	66.7
with adjustment	1.0	0.46, 2.0	0.0
Doses in year preceding index date:			
0 vs 1	3.2	1.7, 6.3	68.8%
0 vs 2	12.5	5.0, 33.3	92.0%
0 vs 3	14.3	1.9, 100.0	93.0%
Doses since January 1992:			
0 vs 1	2.9	1.5, 5.9	65.5%
0 vs 2	3.9	2.0, 7.5	74.4%
0 vs 3	2.6	1.2, 5.6	61.5%

[1] Adjusted for age, sex, household size and composition.
[2] Confidence Interval
[3] Calculated as $\frac{RR-1}{RR}$

Table 6. Other Risk Factors for Adult Diphtheria Infection

	Relative Risk[1]	95% C.I.
Age: (vs. 50-59)		
16-19	22.4	7.0, 71.7
20-29	1.9	0.79, 4.6
30-39	2.7	1.2, 6.1
40-49	4.1	1.9, 9.0
Sex: (for women)	1.2	0.75, 1.9
Total Household:		1.0, 1.6
(with each additional person)	1.3	
Children aged 0-4 years:		
(1 or 2 vs 0)	1.9	0.94, 3.9
Children aged 5-15 years:		
1 vs 0	1.8	0.98, 3.4
2-4 vs 0	2.6	1.2, 5.7

[1] Adjusted for vaccine received in year preceding index date, and age, sex, household size, and children (as appropriate).

References

Galazka AM, Robertson SE. (1996) Immunization against diphtheria with special emphasis on immunization of adults. *Vaccine,* 14: 845-57.

Galazka AM, Robertson SE, Oblapenko GP. (1995) Resurgence of diphtheria. *European Journal of Epidemiology.* 11:95-105.

Hardy IRB, Dittmann S, Sutter RW. (1996) Current situation and control strategies for resurgence of diphtheria in newly independent states of the former Soviet Union. *Lancet,* 347:1739-44.

Jones EE, Kim-Farley RJ, Algunaid M, et al. (1985) A possible foodborne outbreak in Hodeida, Yemen Arab Republic. *Bulletin of the World Health Organization,* 63: 287-93.

Mercer D et al . (1997?) JID supplement.

Attachment 5

Information, Education, Communication (IEC) Activities in Ukraine

Social Mobilization Campaign Efforts in Ukraine

In March 1995, during initial meetings to determine PATH's strategy for assisting the Ministry of Health (MOH) in social mobilization campaign efforts, PATH was informed that it must work directly with Dr. Valery Movchaniuk, chief physician of the Republican Health Centers. The Health Centers had the responsibility within the MOH system for conducting all social mobilization campaigns related to health issues. PATH reviewed the MOH's overall plan for the social mobilization campaign and made comments and suggestions regarding target audiences and messages. The document entitled "Plan of Action To Be Taken During the Diphtheria Immunization Campaign in Ukraine" was issued to all Health Centers at the end of March.

Because of the lack of a modern conceptual framework for designing mass media campaigns, PATH worked in collaboration with Dr. Movchaniuk to provide training seminars for chief physicians representing Health Centers in key oblasts affected by diphtheria. The process of conducting these four regional seminars in Kherson, Kharkiv, Uzhhorod, and Ternopil required the design and development of a 300-page training curriculum, "Qualitative Research and the Design and Development of IEC Materials and Media Campaigns." The curriculum, including handouts and training aids, was translated into Ukrainian and thoroughly pretested. This curriculum was also provided to the USAID-funded BASICS Project for translation into Russian and use in other NIS countries affected by diphtheria. A core of four master trainers, selected among chief physicians from the Health Centers, were trained to conduct the training. They received hands-on training and conducted the fourth regional seminar themselves with PATH's IEC specialist observing their work.

The overall purpose of the regional seminars was to build the IEC capacity of the chief physicians responsible for conducting diphtheria social mobilization campaigns at the oblast, raion, and city level. The regional IEC seminars provided chief physicians in the four regions of Ukraine their only training in modern social mobilization campaign skills. Seventy-five physician health educators were trained. While other IEC activities were completed as part of the Humanitarian Assistance Project (five TV spots and raion-level broadcasting schedules, two posters, one leaflet, press releases, and a diphtheria fact sheet), the IEC seminars were developed specifically to ensure sustainability of IEC capacity within the MOH.

Aside from the regional IEC seminars, PATH provided limited financial assistance to Dr. Movchaniuk's Center to support the Health Centers' social mobilization campaign activities during 1995. The funds were to support production and broadcast of TV and radio spots, newspaper ads, metro announcements, bus and metro posters, and production and distribution of leaflets and posters. Unfortunately, Dr. Movchaniuk did not apply the funds as he had proposed to and no additional funds were provided directly to support his activities.

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To ensure the effectiveness of the media campaign activities, in spring 1995 PATH utilized data from a survey conducted by the U.S. Centers for Disease Control (CDC) to design the key messages of the first set of TV spots. PATH contracted with SOCIS, a Ukrainian-based Gallup-affiliated social marketing organization, to conduct focus groups in various areas of Ukraine to pretest the rough cuts of the TV spots before they were finalized. To pretest the second set of TV spots, posters, and leaflets developed in spring 1996, PATH contracted with Ukrainian Social Marketing (USM) for similar work.

Separate from the regional seminars with chief physicians of the Health Centers and other social mobilization campaign activities, PATH produced five TV spots for broadcast during diphtheria campaigns in various oblasts of Ukraine. The first three were developed in October 1995 and the final two in May 1996. The TV spots were directed to target audiences of youth between 15 and 19 years of age, and women 40 to 59 years of age. The key messages included: the need for adults to be immunized; the safety and quality of the vaccine and immunization supplies; the seriousness of the disease; and the mode of transmission. PATH contracted with the Center For Media Initiatives who subcontracted with oblast and raion-level TV stations to broadcast the TV spots at specific hours most popular with the target audiences. Receipts listing the actual broadcast times and days were provided to PATH from the TV stations.

During the summer campaign of 1996, PATH provided funds directly to several organizations to support social mobilization efforts. In an effort to complement the activities of the social mobilization campaign conducted by the MOH, PATH contacted Counterpart, a USAID-funded NGO that works to strengthen Ukrainian NGOs. With assistance from Counterpart, NGOs in all oblasts in which the immunization campaign was to occur were contacted. Unfortunately, the only NGO to respond was the Donetsk Oblast Council for Struggle for Sobriety and Health. PATH funded this NGO to distribute and post leaflets and posters throughout the city, especially in areas where the hard-to-reach populations resided. PATH also provided a small amount of funds to the Donetsk Health Center to cover expenses of distributing posters and flyers throughout the city. Reports from the Donetsk Health Center confirmed that the TV spots had been broadcast and posters and flyers were posted in key areas of the city.

In Luhansk, funds were provided to the Luhansk Health Center to subsidize newspaper articles and notices, to distribute posters and flyers, and to conduct a survey about the effectiveness of the mass immunization campaign. A survey was conducted with 925 people in June and July 1996 by Dr. Gavrushenko, chief physician of the Luhansk Health Center. The source of information for almost 40 percent of the people surveyed were from TV spots broadcast during the campaign. Forty-eight percent were informed by posters and leaflets.

Additionally, PATH provided a small amount of funds to the Dniepeprotrovsk Health Center to make cloth banners to promote the diphtheria campaign. The Health Center conducted a survey to determine how people going for diphtheria immunization at their polyclinic had heard of the campaign. During that time, Mr. Jean Roy, an epidemiologist from the CDC working in Dniepeprotrovsk, observed PATH-produced TV spots during broadcast and saw

cloth banners and posters (funded by PATH) displayed in the city during the campaign. In addition to the TV spots in the cities of Dniepeprotrovsk and Donetsk, press conferences were organized with representatives of PATH, the CDC, and the local SES to encourage adults to be immunized.

Descriptions of the IEC Materials Produced

The themes of the first three TV spots produced for the October 1995 campaign included people of authority stating that there was a diphtheria epidemic in Ukraine and that it was important that adults be immunized with the safe, effective vaccine. The authority figures included Deputy Minister of Health Dr. Viktor Marievsky, a polyclinic doctor, and a famous Ukrainian TV journalist. In the last two TV spots produced for the May 1996 campaign, one focused on women 40 to 49 years of age, and the second on youth 16 to 19 years of age, stating that these population groups should be immunized immediately against diphtheria with free, effective vaccine.

Separate from the TV spots, PATH produced two posters and one leaflet, a fact sheet, and a press release promoting the need for adults to be immunized. The themes of the posters were:

1) Diphtheria is a dangerous disease transmitted by air. It can be prevented through immunization with effective, free, anti-diphtheria vaccine;
2) Diphtheria is not only a child's disease. By protecting yourself, you protect your whole family. Get immunized against diphtheria immediately. The key message in the leaflet stated that regardless of how busy you are, find the time to immunize you and your family against diphtheria. The fact sheet and press releases provided information on the incidence of diphtheria in Ukraine; stated that it was an unusual epidemic because it affected older youth and adults more than children; and stated that there was quality, free, anti-diphtheria vaccine available through MOH polyclinics.

Attachment 6

ASSESSMENT KIT FOR MONITORING BLOOD EXPOSURES IN OPERATING ROOMS

OBJECTIVES. Monitoring occupational blood exposures accomplishes several objectives:

1. Provides information about frequency and epidemiological characteristics of blood exposures.
2. Identifies potentially effective prevention strategies from the results of monitoring. Predictable patterns for exposures provide the blueprint for prevention.

Surgical and delivery room personnel are known to be at high risk for acquiring infections caused by bloodborne pathogens: Hepatitis B and C, and HIV have all been transmitted through occupational blood contact in these departments. Transmission of an infective dose of virus is most likely to result from a parenteral contact, especially a puncture with a used hollow needle, but infection has resulted from mucous membrane and nonintact skin exposures also. Transmission from intact skin contacts is possible but unusual, and transmission from aerosols has been the subject of speculation, but has never been demonstrated. Therefore, efforts should be focused first on preventing punctures and mucous membrane exposures.

There are several reasons for preventing occupational blood exposures among personnel. Besides the unfortunate effects of the diseases on the infected individuals and their families, the risk for such occurrences has a negative effect on co-workers and prospective employees. Additionally, patients have acquired bloodborne diseases from exposures that resulted from occupational punctures of health care workers, especially in operative settings. Reducing the frequency of occupational exposures has potential benefits for society, for the health of personnel and patients, and for recruitment and retention of highly trained, specialized personnel.

COLLABORATIVE OPERATIVE BLOOD EXPOSURE STUDIES. The purpose of the Collaborative Operative Blood Exposure (COBEX) studies is to prevent blood exposures in these high risk departments. This blood exposure assessment kit is based on the COBEX forms and methods, adapted so that surgery personnel can measure the important characteristics of blood exposures in their own work settings so that preventive strategies can be based on the experience of individual facilities.

The definitions, forms and methods were developed during the Collaborative Operative Blood Exposure (COBEX) study in the US , Ukraine and Taiwan. In the studies that were conducted in those countries, blood exposure patterns from the individual hospital operating rooms were quite different from each other; this means that prevention methods are more likely to be successful if they reflect the case mix and practices of individual facilities. Prevention strategies based on the experience of each department may also be less expensive since they can be tailored for that facility.

CONFIDENTIALITY. The first step in preventing occupational transmission of bloodborne pathogens is knowing the true incidence and characteristics of blood exposures in your own facility. Some facilities already require that personnel complete an exposure report whenever they have skin, mucous membrane or parenteral contact with blood. Often personnel do not comply with the reporting requirements for a variety of reasons, but they are more willing to provide information if:

1. Complete confidentiality and anonymity can be assured, and
2. A neutral person (not the exposed person or the supervisor) completes the actual report.

One study of three hospitals found that reporting improved by as much as 25 times when the COBEX study methods were used compared to having exposed personnel complete their own reports. Complete, accurate information makes it more likely that accurate, efficient prevention methods will be identified. The COBEX report does not replace the other reporting methods used by departments participating in the study. However, it should be stressed with the staff that their cooperation with the COBEX reporting is essential, and that no repercussions will result.

PREPARATION. The purpose of monitoring is to identify the practices and products that should be changed in order to reduce risk for exposure. Change is always a difficult process, but careful preparation will make it less difficult. In the COBEX studies, the operating rooms that were most comfortable with the monitoring and change processes did several things:

1. Established a blood exposure prevention committee to direct the changes that result from the monitoring process. (This could also be a subcommittee of an existing committee.) They involved surgeons by presenting the plan at a surgical committee meeting, and had one interested surgeon appointed to the blood exposure prevention committee. They included administration and purchasing departments by having an interested person appointed from each department. They also included an employee representative. The committee should report results to a high ranking hospital committee. The monitoring process should be directed by an interested individual; in the COBEX study hospitals, the Coordinator was often the OR director or nurse educator.

2. Prioritized changes. It is essential to focus on the most important risks first, especially if they appear to be potentially preventable. Sometimes the cost of products is an issue; consider the overall costs of the exposures and determine what proportion may be prevented by the new products, or how the products might be used most economically. Introducing many changes all at once makes people nervous; it is usually better to make a few important changes first and gradually incorporate other changes.

3. Determined the best time to begin the monitoring process. The process should not begin until the reporting structure and blood exposure prevention committee are established, and until every bit of necessary information such as the number of cases on a surgical service is available.

INSTRUCTIONS: STEP BY STEP

1. Obtain necessary approvals and support.

2. Study the data recording form and the summary tables in the assessment kit. The report form contains the information necessary for each exposure report. Information from the report forms will be tabulated on worksheets to compose the final summary forms. Make as many copies of the report form as needed to evaluate contacts and exposures in your facility. Analysis of less than 50 exposures may be meaningless, but more than 100 exposures will become unwieldy for manual analysis. (Computerized data storage and analysis is more efficient for larger studies.) Construct forms for summarizing the information from the data form. Make extra copies of all the forms so that you can keep a clean set for future use. You may want to modify the forms for your specific situation.

3. Select either a specific period of time, such as three months, or a specific number of surgical cases for the monitoring process; this will be the study period. It is important that the cases be consecutive, and that the study methods be used consistently during the study period. Be sure the necessary information about surgical services is available from the operating room records. For example, when Table 1 is constructed, you will need to know how many general surgery cases were performed during the study period and how many exposures occurred in order to calculate exposure rates.

4. Train the data recorders. The COBEX study recorders have been circulating or delivery nurses who were trained to ask at the end of every case, "Did anyone have a blood exposure?" This is the signal for surgeons and personnel to check their skin, and to remember the events during the case. The nurse also asks, "Did you have an exposure?" any time during the case when personnel act as if a contact might have occurred--for example, needing glasses cleaned, flinching as if from a puncture, or asking for fresh gloves are indications that an exposure might have occurred. When recorders turn in their report forms, the Coordinator should check them promptly for completeness.

5. Tabulate the report form information onto the proper worksheet. To avoid errors from interruptions, go to a quiet place. It will take approximately 2-4 hours to enter the information from 100 reports on worksheets and to calculate the rates. It will be faster and more accurate for two persons to tabulate. Make small tally marks in the appropriate place on each worksheet. Check the totals frequently to detect errors so that you can correct them early.

6. Transfer the final numbers from the worksheets to the corresponding Summary Table. Calculate percentages for each total; for example, if there were 14 exposures during 230 general surgical cases performed during the study period, the exposure rate would be 6%. Circle or highlight the areas that signal greater frequency of exposures, especially for punctures since they are more likely to result in transmission. Identify the surgical services

with greater risk, the times of day, rates for emergency procedures, the role of duration of the procedures, and the devices associated with exposures. Highlight the important areas on the Job Classification/ Exposure table that shows the types of exposures, activities and anatomic locations of exposures by each job classification of personnel.

7. Review the results with personnel. Conduct a meeting with personnel (physicians, nurses and others) from the department that participated in the study. Report the results and clarify any questions about the data or the activities associated with the exposures. Often personnel can identify practices that may influence risk. For example, they may describe safer ways of passing suture needles or other sharp objects; simply announcing "Passing a sharp" may reduce risk.

8. Plan the prevention strategies. Prevention methods for these high risk events will become more apparent as you examine the pattern of these highlighted areas. For example, on the spreadsheet, "surgeons-puncture-suturing-fingers" could have risk reduction focused on protecting the fingers with double gloves or gloves with cotton liner gloves, using blunt suture needles, or changing technique by avoiding finger guided suture placement. "Circulator-intact skin-spatter-arms" could be reduced by having circulators wear clothing with long sleeves. "Anesthesia personnel-mucous membrane-power equipment" could be reduced by having personnel wear protective eyewear or face shields when drills or other power equipment are being used. "Surgeon-intact skin-strikethrough-body" is a clue that more fluid resistant gowns or plastic aprons under the surgical gowns are necessary.

For the items that had more exposures than anticipated, identify potential prevention methods for each item, and whenever prevention seems practical.

9. Use the summary tables to accompany a written report. The report should describe the undesirable effects of occupational transmission, the potential cost of transmission, and the cost of the prevention strategies.

CONCLUSION. In a follow-up study in the US, three of the original COBEX study hospitals measured blood contacts and exposures after they had reviewed the results of their first monitoring process; they selected prevention strategies and implemented them, then monitored the frequency of blood contacts and exposures again. All three had significant reductions in the frequency of blood contacts in their operating room personnel. Your operating room can reduce the frequency of blood exposures also.

BLOOD EXPOSURE REPORT FORM

Complete a separate form for each blood exposure. Circle the number of only one correct answer. See reverse for additional instructions and definitions.

Date of surgery_____

1. Report number_____
(leave number blank)

2. Type of case
1. burn
2. eye
3. general surgery
4. gynecology
5. multiservice trauma
6. neurosurgical
7. obstetric
8. oral maxillofacial/ENT
9. organ transplant
10. orthopedic
11. thoracic/cardiac
12. urology
13. other_____

0. Unknown

3. Time of day
1. Weekday 7AM-7PM
2. Weekday 7PM-7AM
3. Weekend 7AM-7PM
4. Weekend 7PM-7AM

4. Emergency case
1. no
2. yes

5. Length of surgery
_____hours
_____minutes

6. Job classification
1. surgeon, assistant surgeon, resident
2. scrub assistant
3. circulator
4. anesthesia personnel
5. student nurse
6. medical student
7. other_____

7. Type of exposure
1. puncture with blood exposure
2. mucous membrane
3. nonintact skin
4. intact skin

8. Activity at the time of blood contact
1. incising
2. suturing
3. passing instrument
4. receiving passed instrument
5. suction/suction-irrigation
6. changing suction
7. injecting
8. IV manipulation
9. sharps manipulation
10. glove leak, tear
11. power equipment (saw, drill)
12. strikethrough clothing
13. spatter from surgical activity
14. blood in improper location
15. other _____

9. Device causing injury
1. hollow needle
2. solid (suture) needle
3. scalpel
4. wire
5. saw
6. Bovie (electrocautery)
7. staple
8. bone spike
9. other_____
10. no device associated

10. Location of blood exposure
1. fingers
2. hand, not fingers
3. facial mucous membranes
4. face, not mucous membrane
5. neck
6. arm(s)
7. body, trunk
8. legs, feet
9. other_____

11. Is it likely that the patient was exposed to blood from the punctured personnel?
1. No
2. yes

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DEFINITIONS AND INSTRUCTIONS FOR COLLABORATIVE OPERATIVE BLOOD EXPOSURE (COBEX) STUDY

Definition of blood exposure: Puncture with used needle or other used sharp OR visible blood on mucous membranes or nonintact skin.
Blood contact: Visible blood on intact skin.
Blood on clothing, eyeglasses, mask or other articles is not a blood contact or exposure.

Instructions: At the end of each case the designated data recorder asks, "Did anyone have a blood contact or exposure?" Personnel examine their skin and respond to the data recorder. During a case, the data recorder asks, "Did you have an exposure?" at any time personnel behave as if an exposure might have occurred: needing glasses cleaned, flinching as if from a puncture, etc. A separate data form should be used for each separate exposure event. Only one answer can be coded for each question.

1. **Report number:** Leave blank at the time of data collection; fill in sequential numbers at the time of tabulation.
2. **Case type:** Select the most important procedure, or the case type associated with exposure or blood contact. Specify "other".
3. **Time of day:** select the time when the procedure began.
4. **Emergency:** select "yes" only for emergencies, not routine unscheduled cases.
5. **Length of surgery:** Record duration from the time the patient entered. Collapse data into reasonable groups for analysis.
6. **Job class:** choose the best answer based on the individual's classification. Specify "other.
7. **Exposure type:** Choose the one best answer. Punctures with used sharps outrank all others. Nonintact skin exposure outranks mucous membrane and intact skin. Mucous membrane exposures outrank intact skin contacts.
8. **Activity:** read the list carefully before selecting the one best answer. Note that:

- "Passing instrument" and "receiving passed instrument" are coded differently.
- Strikethrough means visible blood penetrated through the clothing onto the skin.
- IV manipulation means all intravascular devices, venous and arterial.
- Manipulating sharps means any sharp tool or object unless specifically identified elsewhere.
- Blood in improper location means blood where it could not have been anticipated.

Specify "other.

9. **Device:** Read the list before selecting the one best answer. Specify "other". "Wire" means all pins and wires.
10. **Location:** If more than one location had blood contact or exposure, choose the most important site, remembering the ranking order: punctures, nonintact skin, mucous membranes, intact skin.
11. **Patient exposure to blood of punctured personnel:** Did the punctured health care worker likely bleed in contact with patient tissue? Did the sharp that punctured the health care worker subsequently have contact with patient tissue? (This could happen with indwelling pins and wires, suture needles, and bone spikes.)

Table 1. Case types and types of exposures.

Type of Exposure or Contact

Case Type	Puncture	Mucous membrane	Nonintact skin	Intact skin	Total contacts	Number of cases (%)
1. Burn						
2. Eye						
3. General surgery						
4. Gynecology						
5. Multiservice trauma						
6. Neurosurgery						
7. Obstetric						
8. Oral maxil-lofacial/ENT						
9. Organ transplant						
10. Orthopedic						
11. Thoracic/ cardiac						
12. Urology						
13. Other (specify)						
TOTAL						

Table 2. Exposures and Time of Day.

Contacts and Exposures

Time of Day	**Number**	**%**	**TOTAL**
Weekday 7AM-7PM			
Weekday 7PM-7AM			
Weekend 7AM-7PM			
Weekend 7PM-7AM			
TOTAL			

Table 3. Emergency Cases.

Emergency case	Number	%	Total
Yes			
No			
Total			

Table 4. Length of surgical procedures that resulted in blood contacts and exposures

Length of surgery	Number	%	Total
<30 minutes			
0.5-1.5 hours			
1.5-2.5 hours			
2.5-3.5 hours			
3.5-4.5 hours			
>4.5 hours			
Total			

Table 5. Devices associated with blood contacts and exposures.

Device	Number	%	Total
Hollow needle			
Solid (suture) needle			
Scalpel			
Wire, pins			
Power equipment: saw			
Bovie			
Staple			
Bone spike			
Other (Specify)			
Total			

Table 6. Patients exposed to blood of punctured personnel.

Patient exposure likely?	Number	%	Total
No			
Yes			
Total			

Table 7. Summary of job classification, type of exposure, activity at the time of exposure, and anatomic location of exposures.

	SURGEON/ ASSISTANT/ RESIDENTS	SCRUB	CIRCU-LATOR	ANESTHESIA PERSONNEL	STUDENT/ OTHER/ UNKNOWN	**TOTAL**
TYPE OF EXPOSURE						
1 Puncture						
2 Mucous Membrane						
3 Nonintact Skin						
4 Intact Skin						
TOTAL						
ACTIVITY AT EXPOSURE						
1 Incising						
2 Suturing						
3,4 Passing/ Receiving						
5,6 Suction-ing/Irrigating						
7 Injecting						
8 IV Manipu-lation						
9 Sharps Man-ipulation						
10Glove Leak						
11Power Equipment						
12Strike-through						
13Spatter						
14Improper Blood						
15Other/ Unknown						
TOTAL						

	SURGEON/ ASSISTANT/ RESIDENT	SCRUB	CIRCULA-TOR	ANESTHESIA PERSONNEL	STUDENT, OTHER, UNKNOWN	TOTAL
LOCATION OF EXPOSURE						
1 Finger						
2 Hand						
3 Mucous Membrane						
4,5. Face, Neck						
6. Arm						
7 Body						
8 Legs, Feet						
9,0 Other/ Unknown						
TOTAL						

COBEX Summary Form

Job Classification	TYPE OF EXPOSURE					ACTIVITY AT EXPOSURE														LOCATION OF EXPOSURE								
	Puncture	Mucous Membrane	Nonintact Skin	Intact Skin	Total	Incising	Suturing	Passing/Receiving	Suctioning/Irrigating	Injecting	IV Manipulation	Sharps Manipulation	Glove Leak	Power Equipment	Strikethrough	Spatter	Improper Blood	Other/Unknown	Total	Finger	Hand	Mucous Membrane	Face, Neck	Arm	Body	Legs, Feet	Other/Unknown	Total
	1	2	3	4		1	2	3, 4	5, 6	7	8	9	10	11	12	13	14	15		1	2	3	4, 5	6	7	8	9, 0	
Surgeon/ Assistant/ Residents																												
Scrub																												
Circulator																												
Anesthesia																												
Student/ Other/ Unknown																												
TOTAL																												

Attachment 7

ASSESSMENT KIT FOR MONITORING OCCUPATIONAL BLOOD EXPOSURES

OBJECTIVES. The objectives for this occupational blood exposure monitoring kit are:

1. To provide information about infectious agents transmitted by blood.

2. To provide tools for measuring the frequency and epidemiological characteristics of blood exposures in a health care setting, and for interpreting the results.

3. To describe how to develop effective prevention strategies based on the results of monitoring.

Health care workers are known to be at high risk for acquiring infections caused by bloodborne pathogens: Hepatitis B and C, and HIV have all been transmitted through operating room contacts with infectious blood. Transmission of an infective dose of virus is most likely to result from a parenteral contact, especially a puncture with a used hollow needle, but infection has resulted from mucous membrane and nonintact skin exposures also. Transmission from intact skin contacts is possible but unusual, and transmission from aerosols has been the subject of speculation, but has never been demonstrated.

There are several reasons for preventing occupational blood exposures among operating room personnel. Besides the unfortunate effects of the diseases on the infected individuals and their families, the risk for such occurrences has a negative effect on co-workers and prospective employees. Additionally, patients have acquired bloodborne diseases from exposures that resulted from occupational punctures of health care workers, especially in operative settings. Reducing the frequency of occupational exposures has potential benefits for society, for the health of personnel and patients, and recruitment and retention of health care workers.

The definitions, forms and methods were developed during the Collaborative Operative Blood Exposure (COBEX) studies in the US and in Taiwan. In the studies that were conducted in those countries, blood exposure patterns from the individual hospitals were quite different from each other; this means that prevention methods are more likely to be successful if they reflect the case mix and practices at individual facilities. Prevention strategies based on the experience of each operating room may also be less expensive since they can be tailored for that facility.

CONFIDENTIALITY. The first step in preventing occupational transmission of bloodborne pathogens is knowing the true incidence and characteristics of blood exposures in your own facility. Some facilities already require that personnel complete an exposure report whenever they have skin, mucous membrane or parenteral contact with blood. Often personnel do not comply with the reporting requirements for a variety of reasons, but they are more willing to provide information if complete confidentiality and anonymity can be assured. Complete, accurate information makes it more likely that efficient prevention methods will be identified. Personnel should be assured that their cooperation with the reporting is essential, and that no repercussions will result.

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PREPARATION. The purpose of monitoring is to identify the practices and products that should be changed in order to reduce risk for exposure. Change is always a difficult process, but careful preparation will make it less difficult. In the previous studies, hospitals that were most successful with the monitoring and change processes did several things:

1. **Established a blood exposure prevention committee to direct the changes that result from the monitoring process.** (This could also be a subcommittee of an existing committee.) They involved physicians, surgeons, nurses, laboratory personnel and other personnel who had frequent contact with blood. They included administrative representatives. The committee should report results to a high ranking hospital committee. The monitoring process should be directed by an interested individual; in the previous study hospitals, the Coordinator was often the OR director or nurse educator.

2. **Prioritized changes.** It is essential to focus on the most important risks first, especially if they appear to be potentially preventable. Sometimes the cost of products is an issue; consider the overall costs of the exposures and determine what proportion may be prevented by the new products, or how the products might be used most economically. Introducing many changes all at once makes people nervous; it is usually better to make a few important changes first and gradually incorporate other changes.

3. **Determined the best time to begin the monitoring process.** The process should not begin until the reporting structure and blood exposure prevention committee are established, and until every bit of necessary information such as the number of cases on a surgical service is available.

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Report form for Occupational Blood Contacts and Exposures

Report number _____

Instructions: This form is to be completed anonymously each time physicians, nurses, laboratory personnel, and all other health care workers have blood exposures (punctures or blood in contact with mucous membranes or broken skin) or blood contact with intact skin.
Please answer each question by circling the number of the best answer. If no answer is correct, please write an explanation. Avoid choosing "unknown" as an answer.

Date _____

1. Type of exposure. 1=puncture with used sharp item. 2=blood in contact with mucous membrane of mouth, nose or eyes. 3=blood in contact with nonintact skin. 4=blood in contact with intact skin.

2. Name of your department.

_____

3. Location where the accident happened. 1=ward 2=intensive care 3=operating room 4=emergency department 5=laboratory 6=delivery room 7=Xray 8=procedure/bandage rooms 9=clinic 10=dental
11=other_____ 0=unknown.

4. Type of personnel. 1=nursing 2=physician 3=laboratorian 4=student 5=support service 6=cleaner 7=technician
8=other_____ 0=unknown.

5. Type of device associated with the accident. 1=hollow needle 2=solid needle (suture needle or stylet) 3=non-needle sharp item such as a lancet 4=glass item 5=no device was being used
6=other_____ 0=unknown.

6. Type of activity you were doing at the time of the accident. 1=giving an intramuscular or subcutaneous injection 2=starting an IV infusion 3=injecting fluid into a port in the IV tubing 4=drawing blood IV 5=finger or heel stick to obtain blood 6=recapping a needle 7=suction or irrigation 8=cleaning the room 9=disassembling sharp items 10=washing used items 11=dental procedures 12=other
_____ 0=unknown.

7. When did the accident happen? 1=during the activity--when the item was being used for its intended purpose 2=after the item had been used but before it had been disposed of 3=during the process of putting the item into a disposal container 4=after disposal.

8. Where did the blood contact or exposure occur? 1=fingers 2=hand 3=facial mucous membranes 4=face, not mucous membranes 5=neck 6=arm(s) 7=body 8=legs/feet
9=other_____

9. Was the patient likely to have been exposed to blood from a punctured health care worker? 1=no 2=yes.

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INSTRUCTIONS FOR REPORTING OCCUPATIONAL BLOOD CONTACTS AND EXPOSURES

Definition of blood exposure: Puncture with used needle or other used sharp OR visible blood on mucous membranes or nonintact skin.
Blood contact: Visible blood on intact skin. (Blood on clothing, eyeglasses, mask or other articles is not a blood contact or exposure.)

Instructions: A separate data form should be used for each separate exposure event. Only one answer can be coded for each question.

A. **Report number:** Leave blank at the time of data collection; fill in sequential numbers at the time of tabulation.

1. **Type of exposure or contact** Choose the one best answer. Punctures with used sharps outrank all others. Nonintact skin exposure outranks mucous membrane and intact skin. Mucous membrane exposures outrank intact skin contacts.

2. **Name of department where the accident happened.** Write in the exact name, for example, Therapy Department 1.

3. **Type of location.** Write specific type if not included in the list.

4. **Type of personnel (job classification).** Write in exact job classification if not included in the list.

5. **Type of device associated with the accident.**

6. **Type of activity at the time of the accident.** Read the list carefully before choosing an answer that describes the activity you were doing, not the activity the device is used for. Specify "other.

7. **When refers to timing, not time of the day.**

8. **Where did the blood contact occur?** Select the best answer. If more than one location had blood contact or exposure, choose the most important site, remembering the ranking order: punctures, nonintact skin, mucous membranes, intact skin.

9. **Patient exposure to blood of punctured personnel:** Did the punctured health care worker likely bleed in contact with patient tissue? Did the sharp that punctured the health care worker subsequently have contact with patient tissue? (This could happen with indwelling pins and wires, suture needles, and bone spikes.)

INSTRUCTIONS: STEP BY STEP

1. Obtain necessary approvals and support.

2. Study the forms in the assessment kit. The report form contains the information necessary for each exposure report. Information from the report forms will be tabulated on the worksheets to compose the final summary forms. Make copies of the forms and save a complete set of forms for future copies. Analysis of less than 50 exposures may be meaningless, but more than 100 exposures will become unwieldy for manual analysis. (Computerized data storage and analysis is more efficient for larger studies.) You may want to modify the forms for your specific situation.

3. Select either a specific period of time, such as three months, or a specific number of exposures for the monitoring process; this will be the study period. It is important that the study methods be used consistently during the study period.

4. Tabulate the report form information onto the proper worksheet. To avoid errors from interruptions, go to a quiet place. It will take approximately 2-4 hours to enter the information from 100 reports on worksheets and to calculate the rates. It will be faster and more accurate for two persons to tabulate. Make small tally marks in the appropriate place on each worksheet. Check the totals frequently to detect errors so that you can correct them early.

5. Calculate percentages for exposures when this is possible. For example, if the number of personnel in a department is known, a crude rate would be the number of exposures divided by the number of persons at risk. Another potentially useful rate would be the number of exposures divided by the number of work days in the department. Circle or highlight the areas that signal greater frequency of exposures, especially for punctures since they are more likely to result in transmission. Identify the departments, locations, and the devices associated with exposures. Highlight the important areas on the Job Classification/ Exposure table that shows the types of exposures, activities and anatomic locations of exposures by each job classification of personnel.

7. Review the results with personnel. Conduct a meeting with personnel (physicians, nurses and others) from departments that participated in the study. Report the results and clarify any questions about the data or the activities associated with the exposures. Often personnel can identify practices that may influence risk. For example, safer ways of passing suture needles or other sharp objects, or simply announcing "Passing a sharp" may reduce risk.

8. Plan the prevention strategies. Prevention methods for high risk events will become more apparent as you examine the pattern of these highlighted areas, particularly for job classification, exposure type, activity, and anatomic location. For example, on the tally sheet, "surgeons-puncture-suturing-fingers" could have risk reduction focused on protecting the fingers with double gloves or gloves with cotton liner gloves, using blunt suture needles, or changing technique by avoiding finger guided suture placement. "Cleaner-puncture-cleaning-hands" could be reduced by having cleaners wear heavy gloves or requiring personnel to not put sharp objects like uncapped syringes in the trash.

For the items that had more exposures than anticipated, identify potential prevention methods for each item, and whenever prevention seems practical.

9. Use the summary tables to accompany a written report. The report should describe the undesirable effects of occupational transmission, the potential cost of transmission, and the cost of the prevention strategies.

CONCLUSION. In a follow-up study in the US, three of the original COBEX study hospitals measured blood contacts and exposures after they had reviewed the results of their first monitoring process; they selected prevention strategies and implemented them, then monitored the frequency of blood contacts and exposures again. All three hospitals found that their interventions had resulted in significant reductions in the frequency of blood contacts in the operating room.

Table 1. Departments where exposures occurred and types of exposures.

Type of Exposure or Contact

Department (write in)	Puncture	Mucous membrane	Nonintact skin	Intact skin	Total contacts	% With contact
1.						
2.						
3.						
4.						
5.						
6.						
7.						
8.						
9.						
10.						
11.						
12.						
13. Other 14.						
TOTAL						

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Table 2. Activity at the time of exposure and timing of exposures in the performance of the activity.

Timing of Exposure	During use	After use, before disposal	During disposal	After disposal	Total
Activity					
Give injection					
Start IV infusion					
Draw blood IV					
Finger/ heel stick					
Recap used needle					
Suction/ irrigation					
Clean room					
Disassemble sharps					
Wash used items					
Dental procedure					
Other					
Unknown					
Total					

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Table 3. Patients exposed to blood of punctured personnel.

Patient exposure likely?	Number of cases	% Punctures with patient exposure
No		
Yes		
Total		

Table 4. Summary of job classification, type of exposure, activity at the time of exposure, and anatomic location of exposures.

JOB CLASS	NURSING	PHYSICIAN	LAB	SUPPORT/ TECHNICAL	CLEANER	STUDENT/ OTHER/UNK	TOTAL
TYPE EXPOSURE							
1 Puncture							
2 Mucous Membrane							
3 Nonintact Skin							
4 Intact Skin							
TOTAL							
ACTIVITY							
1 Give injection							
2 Start IV infusion							
3 Inject IV line							
4 Draw blood IV							
5 Finger/ heel stick							
6 Recap used needle							
7 Suction/ Irrigation							
8 Clean room							
9 Disassemble sharps							
10 Wash used items							
11 Dental procedure							
12 Other/ Unknown							
TOTAL							
Location							
1 Finger							
2 Hand							
3 Mucous Membrane							
4,5 Face/ Mask							
6,7 Arm/ Body							
8 Legs/ Feet							
Total							

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Table 5 Types of devices and activities associated with occupational blood exposures.

Type of Device	Hollow needle	Solid needle	Non-needle sharp	Glass item	No device used	Other	Total
Activity							
Give injection							
Start IV infusion							
Inject IV line							
Draw blood IV							
Finger/heel stick							
Recap used needle							
Suction/ Irrigation							
Clean room, area							
Disassemble sharps							
Wash used items							
Dental procedure							
Other							
Unknown							
Total							

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Attachment 8

Occupational Blood Contacts and Exposures Among Operating Room Personnel, Odessa Oblast Hospital, 1995

Occupational blood contacts and exposures increase risk for hepatitis B, hepatitis C and human immunodeficiency virus (HIV) infection. Percutaneous injuries have the highest risk of transmitting infection, but bloodborne pathogens have been transmitted by contact with skin (especially nonintact skin) or mucous membranes. Surgical team members have been among those personnel at highest risk for occupationally-acquired diseases transmitted by blood.

Additionally, patients have acquired infections as a result of exposure to blood of infected, punctured health care workers. These exposures are most likely to occur when personnel are punctured when their hands are in contact with patient tissue, for example, during suturing. The potential for blood exposures is influenced by personnel practices related to manipulating sharp tools, to availability and use of protective barriers including gloves, eyewear and protective clothing, and to the surgical case mix. Risk for exposure can be reduced most efficiently when prevention strategies address the factors associated with exposures in a specific hospital. This project had several purposes:

1. To identify epidemiologic factors associated with occupational blood exposures at Odessa Oblast Hospital in Ukraine. Important epidemiologic factors included job

classifications at greater risk, types of cases, activities and devices which increased risk, and anatomic locations that could be protected by changes in practices and barrier precautions.

2. To estimate the frequency for blood contacts and exposures in hospitals with centralized operating rooms similar to OOH in case mix and practices.

3. To develop prevention strategies that could be broadly applied in Ukraine.

4. To evaluate definitions and methods that would facilitate analysis of blood exposures in individual facilities and subsequent prevention strategies.

Methods and Materials

A survey tool was developed and introduced to administrative and clinical personnel in the surgical department at Odessa Oblast Hospital, a X bed acute care facility. The surgery department contains X operating rooms staffed by X physicians and X nurses. Personnel were oriented to the purpose, definitions and methods for the study by clinical administrators accompanied by personnel from Program for Appropriate Technology in Health (PATH). PATH has a cooperative agreement with USAID to provide humanitarian assistance in control of occupationally-associated bloodborne infections.

Definitions. The definitions used by the Collaborative Operative Blood Exposure (COBEX) study were used. [15] Cutaneous contact was defined as visible blood on the skin of personnel. Exposure was defined as

visible blood on nonintact skin or mucous membranes of personnel, or when a puncture or laceration with a used sharp item occurred.

Data collection and analysis. The case report form was translated into Russian, the language preferred by the Odessa Hospital personnel. Site coordinators and PATH personnel trained the operating room nurses, reviewed their reports for completeness, and translated the completed forms into English. The data were entered and analyzed on Epi-Info, version 6.2.

At the end of each surgical procedure, the appointed nurse asked, "Did anyone have a blood exposure?" During the procedure itself, if an obstetric team member gave any indication that an exposure had occurred such as flinching or needing glasses cleaned, the nurse asked, "Did you have a blood exposure?" For each contact and exposure, data were recorded on the case type, time of day, case status (scheduled or emergent), length of procedure rounded to the nearest hour, job classification of the exposed individual, activity at the time of contact, associated devices, anatomic location of the contact and whether the patient was exposed to blood of a punctured health care worker. Report forms were completed by the operating room nurse, not by the individuals who sustained the exposures.

Report forms contained no information which would identify either the patient or personnel involved; the data were anonymous and the information, including results, was confidential. Information was not

collected about persons who did not have blood contact during a case in which blood contact occurred; thus, there was no control group.

Results

Types of procedures and blood contacts. The sample included 98 blood contacts and exposures among 2300 surgical cases (4.3%): 55 (56%) were cutaneous contacts with apparently intact skin, 1 (1%) was a contact with nonintact skin, 7 (7%) involved blood contact with mucous membranes, and 35 (36%) were punctures. The rate for punctures was 1.5%. The surgical services and the type of contact are shown in **Table 1.** High risk procedures occurred on Thoracic (12.4%), Vascular/Microsurgery (11.7%), and Urology (7.2%) services. Punctures were more common on the thoracic and urologic surgical services. The frequency of blood contacts and exposures is considerably lower than that reported elsewhere [5,7,8,14,14A,15]; the low rate may reflect the influence of case mix (types and complexity of cases), procedures of shorter duration, or underreporting.

Emergency. Forty nine (50.5%) of the surgical procedures that resulted in blood contacts or exposures occurred during the 364 emergency cases. The rate for contacts and exposures was 13% for emergency cases, 2.5% for non-emergency. Punctures occurred during 23/1936 (1.2%) of the non-emergent and 12/364 (3.3%) of the emergency cases.

Job classification. Physicians sustained 77 (78%) of the 98 punctures and 16 (16%) were among nurses. The types of contacts and job classifications are shown in **Table 2.**

Activities and devices associated with blood contact. Suturing, passing and receiving instruments, and glove leaks were high risk activities. Strikethrough of blood to the skin of the personnel occurred only 3 times, suggesting that the gown materials were relatively effective. Spatter to personnel was only reported twice. **Table 3** shows the activities and devices associated with punctures.

Job classification and anatomic location of the blood contact. Fingers (51) and hands (24) were the location for 77% of contacts and facial mucous membranes (8) for 8%. All of the locations and job classifications are described in **Table 4.**

Duration of surgical procedures. Most of the surgical procedures that resulted in blood exposures were relatively short: 69 of 97 were 2.5 hours or less. There was a clear tendency for punctures to increase with duration: rates ranged from a low of 1.3% for cases of 30 minutes or less to a high of 15.8% for cases longer than 4 hours, and the relationship was linear.

Patient exposure to blood of punctured personnel. Four of 35 punctures (11%) were reported to have resulted in a patient exposure. The range in other operating room studies is 9-29%.[7,8,15] Two occurred while suturing, one each while incising and while manipulating other sharp instruments.

Discussion

The risk for transmission of bloodborne pathogens is greatest from punctures with blood-filled hollow needles, a situation which occurred rarely in this study. Most of the punctures were from suture needles which carry much lower risk. The trend for punctures in the Odessa operating rooms (36%) was greater than that reported in the aggregated data from nine US hospital operating rooms (13%) [15] and from three Taiwan operating rooms (19%).[8]

Surgeons had the highest frequency of blood contacts in this study; this is consistent with studies in the surgical literature that demonstrated that surgeons were the job classification at highest risk.[14,15] The surgical nurses had considerably fewer punctures and other exposures than reported elsewhere.

It is evident that transmission risks for HIV, HBV, and HCV due to occupational blood exposures depend on the unique demographic profile of patients receiving care in a specific hospital and on the practices of caregivers. Prevention strategies should first consider the predictable activities, personnel and anatomic locations of exposures that are known to present higher risk for transmission: punctures, mucous membrane and nonintact skin contacts. Facility-specific surveillance of occupational exposures an essential component of a prevention program; it is not possible to identify the epidemiology of risk or assess the impact of prevention strategies without such surveillance.[12,15]

In this study, management of suture needles, and passing and receiving instruments are practices that require change. Previous investigators have suggested that surgeons avoid finger guided suture placement,[1] use specially manufactured blunt suture needles,[2] and use "no-touch" techniques for passing loaded suture needle holders. Staples may have a better safety profile than sutures for closing the skin.

Changes in practices can not eliminate entirely risks due to inadvertent blood contact. Barrier precautions and use of devices that are modified for safety can significantly reduce blood contacts. [11,16]

Personnel in this study site should wear double gloves more frequently for emergencies, longer cases and for those in which wear on the gloves will be greater because of the presence of sharp wire or bone fragments. In one study, hand contact with blood was 72% lower among surgeons who double gloved. [14A] Cleaners should wear utility gloves when they are clearing linen and trash from the rooms after surgical procedures. While gloves do not prevent punctures, they do reduce risk for transmission of bloodborne pathogens by cleaning blood off the outside of the penetrating needle thus decreasing the inoculum.[9]

Strikethrough of blood to the skin of caregivers only occurred in 3 instances; the attire of these personnel is unknown, and they may have not worn cover gowns.

Mucous membrane exposures numbered 7 and were associated with spatter from the procedure. These exposures are often predictable and can

usually be prevented by masks that cover the nose and mouth combined with protective eyewear. These items should be worn by all personnel who are within spatter distance during a case.

All prevention strategies involve cost, as do all occupational blood exposures and infections; these costs vary in response to local conditions. One investigator identified the average cost for an occupational needlestick as $260 US dollars.[11] This included costs for the necessary lab tests, time off work, and a model figure for prophylaxis.

A recent analysis compared risk from a needlestick from a patient with symptomatic HIV infection to similar needlestick from a patient with e-antigen-positive hepatitis B and found the HIV-associated needlestick to present lower risk for morbidity and mortality.[17] The author explained the results by the fact that, although HIV is associated with higher morbidity and mortality rates, HBV infection is about 40 times more likely than HIV to occur after percutaneous exposure and the morbidity of HBV is of longer duration.

Persons with chronic infection are the reservoir for the bloodborne pathogens; sexually active, infected health care workers may be responsible for considerable subsequent infections among their sexual partners; children borne to infected mothers are likely to become infected, and even the patients of infected health care workers may become infected during exposure-prone procedures.

Additionally, loss of a HCW to occupationally-associated illness or death results in the loss of costs spent on their training plus loss of their productivity. Thus, the direct expense of a prevention program aimed at the high risk accidents based on facility-specific surveillance may be well justified. A targeted approach has been recommended for operating rooms and the methods could be applied in any surgical setting. [5]

References

1. Bell DM, Martone WJ, Culver DH. Risk of endemic HIV and hepatitis B transmission to patients during invasive procedures. (Abstract MD-59) Seventh International Conference on AIDS, Florence, Italy, 1991.

2. Davis MS. Blunt-tipped suture needles. Infect Control Hosp Epidemiol 1994;15:224-5.

3. Denes AE, Smith JL, Maynard JE, Doto IL, Berquist KR, Finkel AJ. Hepatitis B infection in physicians: Results of a nationwide seroepidemiologic study. JAMA 1978;239:210-12.

4. Dienstag JL and Ryan DM. Occupational exposure to hepatitis B virus in hospital personnel: infection or immunization. Am J Epidemiol 1982;115:26-39.

5. Gerberding JL. Procedure-specific infection control for preventing intraoperative blood exposures. Am J Infect Contr 1993;21:364-7.

6. Ippolito, G, Puro V, DeCarli G. The risk of occupational human immunodeficiency virus infection in health care workers: Italian multi-center study. Arch Int Med 1993;153:1451-58.

7. Lynch P and White MC. Perioperative blood contact and exposures: A comparison of incident reports and focused studies. Am J Infec Contr 1993;21:357-63.

8. Lynch P, Wang H, White MC. Surgical blood exposures in Taiwan and the US: frequency and prevention. Taiwan Nursing Journal (in press).

9. Mast ST, Woolwine JD, Gerberding JL. Efficacy of gloves in reducing blood volumes transferred during simulated needlestick injury. J Infect Dis 1993;168:1589-92.

10. Mitsui T, Iwano K, Masuko K, et al. Hepatitis C virus infection in medical personnel after needlestick accident. Hepatology 1992;16:1109-14.

11. Orenstein RO, Reynolds L, Karabaic M, Lamb A, Markowitz SM, Wong ES. Do protective devices prevent needlestick among health care workers? Am J Infect Control 1995;23:344-51.

12. Petrosillo N, Puro V, Jagger J, Ippolito G, and the Italian Multicenter Study on Nosocomial and Occupational Risk of Infections in Dialysis. The risks of occupational exposure and infection by human immunodeficiency virus, hepatitis B virus, and hepatitis C virus in the dialysis setting. Am J Infect Control 1995;23:273-77.

13. Puro V, Petrosillo N, Ippolito G, and the Italian Study Group on Occupational Risk of HIV and Other Bloodborne Infections. Risk of hepatitis C seroconversion after occupational exposures in health care workers. Am J Infect Control 1995;23:273-77.

14. Tokars JI, Bell DM, Culver DH, Marcus R, Mendelson MH, Sloan EP, Farber BF, Fligner D, Chamberland ME, McKibben PS, Martone WJ. Percutaneous injuries during surgical procedures. JAMA 1992;267:2899-904.

14A. Tokars JI, Culver DH, Mendelson MH, Sloan EP, Farber BF, Fligner DJ, Chamberland ME, Marcus R, McKibben PS, Bell DM. Skin and mucous membrane contacts with blood during surgical procedures: Risk and prevention. Infect Control Hospital Epidemiology 1995;16:703-711.

15. White MC and Lynch P. Blood contact and exposures in operating room personnel: A multi-center study. Am J Infection Control, 1993;21:243-48.

16. Wong ES, Stotka JL, Chinchilli VM, Williams DS, Stuart CG, Markowitz SM. Are universal precautions effective in reducing the number of occupational exposures among health care workers? J Am Med Ass 1991;265:1123-8.

17. Zuckerman AJ. Occupational exposure to hepatitis B virus and human immunodeficiency virus: A comparative risk analysis. Am J Infect Control 1995;23:286-9.

Table 1. Distribution of 98 occupational blood contacts and exposures among operating room personnel by service and type of contact during 2300 surgical cases at Odessa Oblast Hospital, 1995.

	Type of Blood Contact				
Surgical Service(cases)	Puncture	Mucous Membrane	Nonintact Skin	Intact Skin	Total(%)
Burn (0)					
Eye (191)	0	0	0	0	0(0)
General surgery (645)	6	0	0	24	30(4.7)
Gynecology (95)	2	0	0	3	5(5.3)
Trauma/ortho (136)	1	0	0	2	3(2.2)
Neurosurgery (0)					
Gastrointestinal (341)	6	2	0	16	24(7.0)
Oral maxillofacial (378)	0	0	0	1	1(0.3)
Organ transplant (0)					
Thoracic/cardiac (149)	7	1	1	3	12(12.4)
Urology (152)	7	2	0	2	11(7.2)
Vascular/Micro (103)	6	2	0	4	12(11.7)
Total (2300)	35	7	1	55	98(4.3)

No blood contacts or exposures were reported from burn, ophthalmologic, or neurologic surgery.

Table 2. Job classification and types of blood contacts among operating room personnel at Odessa Oblast Hospital, 1995. N=98

	Type of Blood Contact				
Job Classification	Puncture	Mucous Membrane	Nonintact Skin	Intact Skin	Total
Physician	27	6	0	44	77
Surgery nurse	7	1	1	7	16
Anesthetist	1	0	0	2	3
Student	0	0	0	0	0
Cleaner	0	0	0	2	2
Total	35	7	1	55	98

Table 3. Activities and medical devices associated with 35 occupational puncture injuries among operating room personnel at Odessa Oblast Hospital, 1995.

	Types of Devices						
Activity	Hollow Needle	Suture Needle	Scalpel	Electro-Cautery	Other	Unknown	Total
Incising	0	0	2	1	0	0	3
Suturing	0	14	0	0	0	0	14
Passing instrument	0	3	1	0	3	0	7
Receiving instrument	0	1	0	0	1	0	2
Injecting	1	0	0	0	0	0	1
Manipulating instrument	0	0	0	0	1	0	1
Glove leak	0	0	0	0	0	1	1
Power equip.	0	0	0	2	1	0	3
Other	0	1	0	0	1	0	2
Total	1	20	3	3	7	1	35

Table 4. Anatomic location and job classification for 97 occupational blood contacts and exposures among operating room personnel at Odessa Oblast Hospital, 1995. N=97*

	Job Classification					
Location	Surgeons	Nurses	Anesthetists	Students	Cleaners	Total
Fingers	42	7	2	0	0	51
Hands	20	3	0	0	1	24
Facial mucous membranes	6	2	0	0	0	8
Face	5	0	0	0	0	5
Neck	0	0	0	0	0	0
Arm	1	1	0	0	1	3
Body	1	1	0	0	0	2
Legs, feet	1	1	0	0	0	2
Unknown	1	1	0	0	0	2
Total	77	16	2	0	2	97

*One location was not specified.

Duration of surgical procedures for 2300 cases.

Duration and # Blood Contacts

Service	.5	1	1.5	2	2.5	3	3.5	4	>4	Total
Trauma/orth	28	28	20	31	9	13	2	3	2	136
ENT	85	118	63	58	26	13	13	2		378
GenSur	191	222	78	93	25	18	8	7	3	645
Vasc/micro	5	38	39	34	18	14	5	7	4	164
GI	6	55	79	53	48	18	15	9	4	287
Gyn	3	17	23	29	8	9	1	3	2	95
Uro	16	25	30	39	17	18	3	4		152
Thor	3	18	19	34	20	35	13	7		149
Micro	3	17	11	7		4		3	4	49
Procto	11	33	10							54
Ophth	32	108	34	10	4	3				191
Total	**383**	**679**	**406**	**388**	**175**	**145**	**60**	**45**	**19**	**2300**
	5	40		24		20		5	3	97
	1.3%	5.9		6.2		13.8		11.1	15.8	xxx

Emergency=364
Non-emergent=1936

Attachment 9

Occupational Blood Contacts and Exposures Among Delivery Room Personnel, Odessa Oblast Hospital, 1995

Introduction

Occupational blood exposures increase risk for hepatitis B, hepatitis C and human immunodeficiency virus(HIV) infection among health care workers. Surgical team members have been identified being among those personnel at highest risk for occupationally-acquired diseases transmitted by blood. [3,4,6] Numerous studies in many countries have documented transmission of bloodborne pathogens in various care settings.[13,14] Few studies have evaluated occupational blood exposure and prevention strategies among obstetric personnel who may also be at extremely high risk. Additionally, patients have acquired infections with bloodborne pathogens as a result of exposure to blood of infected, punctured health care workers. [1] These exposures are most likely to occur when personnel are punctured when their hands are in contact with patient tissue, for example, during suturing.

The potential for blood exposures is influenced by hospital practices related to manipulating sharp tools, to availability and use of protective barriers including gloves, eyewear and protective clothing. Risk for exposure can be reduced most efficiently when prevention strategies address the factors

associated with exposures in a specific hospital. This project had several purposes:

1. To identify epidemiologic factors associated with occupational blood exposures at Odessa Oblast Hospital in Ukraine. Important epidemiologic factors included job classifications at greater risk, types of cases, activities and devices which increased risk, and anatomic locations that could be protected by changes in practices and barrier precautions.
2. To estimate the frequency for blood contacts and exposures in hospitals similar to OOH in case mix and practices.
3. To develop prevention strategies that could be broadly applied in Ukraine.
4. To evaluate definitions and methods that would facilitate analysis of blood exposures in individual facilities and subsequent prevention strategies.

Methods and Materials

A survey tool was developed and introduced to administrative and clinical personnel in the Obstetrics Department at Odessa Oblast Hospital, a X bed acute care facility. The obstetrics department contains X delivery rooms staffed by X physicians and X nurses. Personnel were oriented to the purpose, definitions and methods for the study by clinical administrators accompanied by personnel from Program for

Appropriate Technology in Health (PATH). PATH has a cooperative agreement with USAID to provide humanitarian assistance in control of occupationally-associated bloodborne infections.

Definitions. The definitions used by the Collaborative Operative Blood Exposure (COBEX) study were used. [15] *Cutaneous contact* was defined as visible blood on the skin of personnel. *Exposure* was defined as visible blood on nonintact skin or mucous membranes of personnel, or when a puncture or laceration with a used sharp item occurred.

Data collection and analysis. The case report form was translated into Russian, the language preferred by the Odessa Hospital personnel. Site coordinators and PATH personnel trained the delivery nurses, reviewed their reports for completeness, and translated the completed forms into English. The data were entered and analyzed on Epi-Info, version 6.2.

At the end of each obstetric procedure, the appointed nurse asked, "Did anyone have a blood exposure?" During the procedure itself, if an obstetric team member gave any indication that an exposure had occurred such as flinching or needing glasses cleaned, the nurse asked, "Did you have a blood exposure?" For each contact and exposure, data were recorded on the case type, time of day, case status (scheduled or emergent), length of procedure rounded to the nearest hour,

job classification of the exposed individual, activity at the time of contact, associated devices, anatomic location of the contact and whether the patient was exposed to blood of a punctured health care worker. Report forms were completed by the delivery room nurse, not by the individuals who sustained the exposures.

Report forms contained no information which would identify either the patient or personnel involved; the data were anonymous and the information, including results, was confidential. Information was not collected about persons who did not have blood contact during a case in which blood contact occurred; thus, there was no control group.

Results

Types of procedures and blood contacts. The sample included 183 blood contacts and exposures: 120 (66%) were cutaneous contacts with apparently intact skin, 6 (3%) were contacts with nonintact skin, 19 (10%) involved blood contact with mucous membranes, and 38 (21%) were punctures. Vaginal deliveries and C-sections accounted for 80 (44%) and 75 (41%) of the total. The remaining 28 cases included abortions, tubal ligations and other procedures. Exposures occurred at a rate of 41/100 vaginal delivery cases and 37/100 C-sections.

None of the puncture exposures during vaginal deliveries occurred during an emergency procedure but 14/16 punctures that occurred during C-sections involved emergency procedures.

Job classification. Physicians sustained 18 (47%) of the punctures and 19 (50%) were among nurses. The types of contacts and job classifications are shown in **Table 1.**

Activities and devices associated with blood contact. Table 2 shows the activities and devices associated with blood contact and exposures. Most (74%) of the blood contacts did not involve a medical device, but of those that did, 39/47 (83%) were with suture needles. Suturing, spatter from the procedure, and glove leaks were high risk activities. Strikethrough of blood to the skin of the personnel occurred 11 times, suggesting that the gown materials were relatively effective.

Job classification and anatomic location of the blood contact. Fingers and hands were the location of contact for 65% of contacts and facial mucous membranes for 12%. Approximately 22% of the contacts and exposures could be prevented by improved facial protection that covered the skin and mucous membranes. All of the locations and job classifications are described in **Table 3.**

Patient exposure to blood of punctured personnel. Only one (.5%) puncture was reported to have resulted in a patient exposure. This is far below the 9-29% [7,8,15] rate reported for punctures in operating room studies, and may reflect underreporting since many of the punctures in this study occurred while suturing.

Discussion

The risk for transmission of bloodborne pathogens is greatest from punctures with blood-filled hollow needles, a situation which occurred rarely in this study. Most of the punctures were from suture needles which carry much lower risk. The trend for punctures in the Odessa delivery room was greater than that reported in the aggregated data from nine US hospital operating rooms (13%) [15] and from three Taiwan operating rooms (19). [8]

Obstetricians had the highest frequency of blood contacts in this study; this is consistent with studies in the surgical literature that demonstrated that surgeons were the job classification at highest risk. [14,15]

It is evident that transmission risks for HIV, HBV, and HCV due to occupational blood exposures depend on the unique demographic profile of patients receiving care and on the practices of caregivers. Prevention strategies should first consider the predictable activities, personnel and anatomic

locations of exposures that are known to present higher risk for transmission: punctures, mucous membrane and nonintact skin contacts. Facility-specific surveillance of occupational exposures an essential component of a prevention program; it is not possible to identify the epidemiology of risk or assess the impact of prevention strategies without such surveillance. [12,15]

In this study, management of suture needles, and passing and receiving instruments are practices that require change. Previous investigators have suggested avoiding finger guided suture placement,[1] using specially manufactured blunt suture needles,[2] and using "no-touch" techniques for passing loaded suture needle holders.

Changes in practices can not eliminate entirely risks due to inadvertent blood contact. Barrier precautions and use of devices that are modified for safety can significantly reduce blood contacts. [11,16]

Personnel in this study site should wear gloves more frequently for IV manipulations and IV injections. Double gloves may be necessary considering that glove leaks and tears were recorded for 26/136 instances (19%) in which no device was being used at the time of blood contact. Cleaners should wear utility gloves when they are clearing linen and trash from the delivery rooms after obstetrical procedures. While

gloves do not prevent punctures, they do reduce risk for transmission of bloodborne pathogens by cleaning blood off the outside of the penetrating needle and decreasing the inoculum.[9]

Strikethrough of blood to the skin of caregivers only occurred in 11/136 instances in which no device was being used; the attire of these personnel is unknown, and they may have not worn cover gowns. Either better quality gowns or plastic aprons under the existing gowns are indicated.

Mucous membrane exposures numbered 21 and were associated with spatter from the procedure. These exposures are often predictable and can usually be prevented by masks that cover the nose and mouth combined with protective eyewear. These items should be worn by all personnel who are within spatter distance during a case.

All prevention strategies involve cost, as do all occupational blood exposures and infections; these costs vary in response to local conditions. One investigator identified tha average cost for an occupational needlestick as $260 US dollars. [11] A recent analysis compared risk from a needlestick from a patient with symptomatic HIV infection to similar needlestick from a patient with e-antigen-positive hepatitis B and found the HIV-associated needlestick to present lower risk for morbidity and mortality. [17] The author explained the results

by the fact that, although HIV is associated with higher morbidity and mortality rates, HBV infection is about 40 times more likely than HIV to occur after percutaneous exposure and the morbidity of HBV is of longer duration.

Persons with chronic infection are the reservoir for the virus; sexually active, infected health care workers may be responsible for considerable subsequent infections among their sexual partners, children, and even patients if they perform exposure-prone procedures.

Additionally, loss of a HCW to occupationally-associated illness or death results in the loss of costs spent on their training plus loss of their productivity. Thus, the direct expense of a prevention program aimed at the high risk accidents based on facility-specific surveillance may be well justified. A targeted approach has been recommended for operating rooms and the methods could be applied in obstetric as well as surgical settings. [5]

References

1. Bell DM, Martone WJ, Culver DH. Risk of endemic HIV and hepatitis B transmission to patients during invasive procedures. (Abstract MD-59) Seventh International Conference on AIDS, Florence, Italy, 1991.

2. Davis MS. Blunt-tipped suture needles. Infect Control Hosp Epidemiol 1994;15:224-5.

3. Denes AE, Smith JL, Maynard JE, Doto IL, Berquist KR, Finkel AJ. Hepatitis B infection in physicians: Results of a nationwide seroepidemiologic study. JAMA 1978;239:210-12.

4. Dienstag JL and Ryan DM. Occupational exposure to hepatitis B virus in hospital personnel: infection or immunization. Am J Epidemiol 1982;115:26-39.

5. Gerberding JL. Procedure-specific infection control for preventing intraoperative blood exposures. Am J Infect Contr 1993;21:364-7.

6. Ippolito, G, Puro V, DeCarli G. The risk of occupational human immunodeficiency virus infection in health care workers: Italian multi-center study. Arch Int Med 1993;153:1451-58.

7. Lynch P and White MC. Perioperative blood contact and exposures: A comparison of incident reports and focused studies. Am J Infec Contr 1993;21:357-63.

8. Lynch P, Wang H, White MC. Surgical blood exposures in Taiwan and the US: frequency and prevention. Taiwan Nursing Journal (in press).

9. Mast ST, Woolwine JD, Gerberding JL. Efficacy of gloves in reducing blood volumes transferred during simulated needlestick injury. J Infect Dis 1993;168:1589-92.

10. Mitsui T, Iwano K, Masuko K, et al. Hepatitis C virus infection in medical personnel after needlestick accident. Hepatology 1992;16:1109-14.

11. Orenstein RO, Reynolds L, Karabaic M, Lamb A, Markowitz SM, Wong ES. Do protective devices prevent needlestick among health care workers? Am J Infect Control 1995;23:344-51.

12. Petrosillo N, Puro V, Jagger J, Ippolito G, and the Italian Multicenter Study on Nosocomial and Occupational Risk of Infections in Dialysis. The risks of occupational exposure and infection by human immunodeficiency virus, hepatitis B virus, and hepatitis C virus in the dialysis setting. Am J Infect Control 1995;23:273-77.

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13. Puro V, Petrosillo N, Ippolito G, and the Italian Study Group on Occupational Risk of HIV and Other Bloodborne Infections. Risk of hepatitis C seroconversion after occupational exposures in health care workers. Am J Infect Control 1995;23:273-77.

14. Tokars JI, Bell DM, Culver DH, Marcus R, Mendelson MH, Sloan EP, Farber BF, Fligner D, Chamberland ME, McKibben PS, Martone WJ. Percutaneous injuries during surgical procedures. JAMA 1992;267:2899-904.

15. White MC and Lynch P. Blood contact and exposures in operating room personnel: A multi-center study. Am J Infection Control, 1993;21:243-48.

16. Wong ES, Stotka JL, Chinchilli VM, Williams DS, Stuart CG, Markowitz SM. Are universal precautions effective in reducing the number of occupational exposures among health care workers? J Am Med Ass 1991;265:1123-8.

17. Zuckerman AJ. Occupational exposure to hepatitis B virus and human immunodeficiency virus: A comparative risk analysis. Am J Infect Control 1995;23:286-9.

Table 1. Job classification and types of blood contacts among delivery room personnel at Odessa Oblast Hospital, 1995. N=183

	Type of Blood Contact				
Job Classification	Puncture	Mucous Membrane	Nonintact Skin	Intact Skin	TOTAL
Physician	18	8	1	52	79
Obstetric nurse	14	6	2	25	47
Surgery nurse	5	4	1	9	19
Anesthesia personnel	0	1	2	16	19
Student nurse	0	0	0	1	1
Other (Cleaners)	1	0	0	17	18
TOTAL	38	19	6	120	183

Table 2. Activities and devices associated with 182 occupational blood contacts among delivery room personnel at Odessa Oblast Hospital, 1995

	Types of Devices					
Activities	Hollow needle	Solid needle	Coker forcep	Other	No Device	TOTAL
Incising	0	0	0	1	0	1
Suturing	0	30	0	0	1	31
Passing instruments	0	3	0	0	0	3
Receiving instr.	0	6	1	1	0	8
Injecting	1	0	0	0	0	1
IV manipulation	0	0	0	2	12	14
Glove leak	0	0	0	0	26	26
Strikethrough	0	0	0	0	11	11
Spatter to skin	0	0	0	2	72	74
Blood-improper locat.	0	0	0	0	10	10
IV injection	0	0	0	0	4	4
TOTAL	1	39	1	6	136	183

Table 3. Anatomic location and job classification for 182* occupational blood contacts among delivery room personnel at Odessa Oblast Hospital, 1995

Anatomic Location	Job Classification						
	MD	Obstet nurse	Surg. nurse	Anesthesia personnel	Student nurse	Other Cleaner	TOTAL
Fingers	31	18	6	6	1	3	65
Hands	24	13	1	6	0	10	54
Muc. membrane	9	6	5	1	0	0	21
Face	4	4	3	0	0	0	11
Neck	3	2	2	1	0	0	8
Arm	4	3	0	0	0	1	8
Body (Trunk)	2	1	0	2	0	0	5
Feet/legs	2	0	2	1	0	4	9
Other	0	0	0	1	0	0	1
TOTAL	79	47	19	18	1	18	182

*One report was incomplete.

Attachment 10

Summary

Lviv Accident Report Project

Purpose.

Occupational blood exposure increases risk for hepatitis B, C and HIV infection among health care workers. Risk for exposure can be reduced most efficiently when prevention strategies target the specific factors associated with exposures. This project had several purposes:

To identify epidemiologic factors associated with occupational blood exposures,
estimate the frequency for blood contacts and exposures in similar hospitals,
develop prevention strategies based on the data, and
determine whether a set of forms and instructions could be developed that would facilitate self-reporting of blood exposures, and subsequent prevention strategies.

Methods.

A survey tool was developed and introduced to administrators at Lviv Railway Hospital. Personnel were oriented to the purpose, definitions and methods for the study by clinical administrators using teaching materials developed by PATH. *Blood exposure* was defined as puncture with a used sharp item, mucous membrane or nonintact skin contact with blood. *Blood contact* was defined as blood in contact with

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apparently intact skin or any exposure. During the month of October, 1995, personnel who sustained any type of occupational blood contact were instructed to complete anonymously a report describing the accident. Data were tabulated and analyzed using Epi-Info version 6.2.

Results.

Types of contacts and exposures. There were 274 reports describing 26 punctures (9%), 2 mucous membrane exposures (1%), and 246 intact skin contacts with blood (90%). The greatest risk for disease transmission is associated with punctures, less risk with mucous membrane and nonintact skin exposures, and least with intact skin contact.

Job classification. Nurses, physicians and laboratory staff had 94% of the blood contacts and are the best target for prevention strategies. **Table 1** shows the job classifications of persons who had blood contact and exposures. Nurses sustained 20/26 punctures.

Location. Blood contacts and exposures appear to be widely dispersed around the hospital and polyclinics, with concentration in the wards (85), procedure and bandage rooms (54), dental areas (49) and Lab/X-Ray (39). **Table 2** shows the departments and locations where blood contacts and exposures occurred.

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Departments. Personnel from some departments appear to be at considerably higher risk for blood contact than others. For punctures, 6 occurred in Therapy Unit I, 3 in Resuscitation, 2 each in the Endocrinology clinic and Therapy unit II; the rest were scattered. For all blood contacts and exposures, 60 (22%) involved personnel from Therapy Unit I, 39 (14%) were from the laboratory, 32 (12%) were from the pediatric dental clinic, and 24 (9%) were from the ENT department.

Devices associated with blood contact and exposures. Punctures with hollow needles filled with blood carry the greatest risk for disease transmission; blood filled needles are common after phlebotomy and after removing needles used for IV infusions. **Table 3** shows the devices and activities. Hollow needlesticks accounted for 19/26 punctures.

Activity at time of the exposure. Activities associated with increased risk were phlebotomy and other blood drawing (72), IV starts and IV port injections (55) dental extractions (49) and other, unspecified activities (60). **Table 4** shows activities and locations associated with blood contact and exposure.

Timing of the exposure is important information for prevention: it is difficult to prevent punctures that occur during the course of the activity, but easier to prevent those that occur after use and before disposal, during

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disposal or after disposal. (This question was flawed in some way and many people were unable to select an answer from the choices that were given.) Approximately half of the blood contacts and exposures occurred during the activities, leaving about half that could be prevented by safe recapping techniques, and improved methods and containers for disposal.

Patient exposures to blood of punctured personnel. Two punctures were considered to have possibly resulted in the patient being exposed to blood from a punctured health care worker: one IV injection and one unspecified activity.

Conclusions.

It is efficient and economical to prioritize prevention strategies using epidemiological paramenters. In Lviv Railway Hospital and the associated polyclinics, there are clearly defined high risk job classes, activities, departments and locations.

First, glove use should be increased for activities that involve sharp tools or invasive procedures, or predictable bloody fluid such as occurs in the dental clinics. While gloves do not prevent punctures, they do reduce the amount of blood that penetrates from a puncture significantly by cleaning off the exterior of penetrating devices. Utility, examination and surgical gloves should be available.

Second, education/training programs could be targeted efficiently for physicians, nursing and laboratory personnel, since they have highest incidence of blood contacts and exposures. They should be taught how to recap needles using a 1-handed technique and when to glove. Personnel may underestimate the risk for transmission of bloodborne pathogens and the seriousness of infection for themselves and subsequently to others.

Third, a combination of barriers and device modification may be appropriate for IV-related activities.

Fourth, better disposal methods for sharps may reduce post-use injuries and blood contact. Sharps containers should be fairly rigid and be readily accessible.

Last, the personnel seemed to be able to use this method of describing the epidemiology of blood contacts and exposures fairly well. Similar methods may be effective for other Ukrainian hospitals.

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Table 1. Jobclass and type of exposure Lviv Railway Hospital and associated polyclinics, 1995. (N=274)

	Type of exposure			
Jobclass	Punct	Mucous Membrane	Intact Skin	Total
Nursing	20	1	141	162
MD	2	0	68	70
Laboratory	2	0	25	27
Support	0	1	4	5
Other/unk	0	0	4	4
Cleaner	2	0	4	6
TOTAL	26	2	246	274

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Table 2. Department and location of occupational blood contacts and exposures, 1995. (N=274)

	Location								
Department	Ward	ICU	OR	Lab	Obst	Other/ Unk	Dental	Procedure Room	Total
Clin. Surg*	1	0	7	0	0	0	0	0	8
Ped. Clinic	0	0	0	0	0	13	0	6	19
Ped. Dentist	2	0	0	0	0	0	30	0	32
Laboratory	0	0	1	38	0	0	0	0	39
Therapy I	52	0	0	1	0	1	0	6	60
Therapy II	1	0	0	0	0	0	0	7	8
ENT	5	0	2	0	0	4	0	13	24
Ophthalmol	0	0	0	0	0	0	0	3	3
Surg Unit I	2	0	0	0	0	0	0	5	7
Gastroenterol	0	0	0	0	0	0	0	1	1
Dentist	0	0	0	0	0	0	19	0	19
Other	12	1	1	0	0	5	0	11	[illegible]
Surg Dep.3	6	0	0	0	0	6	0	2	[illegible]
Gynecology	1	0	0	0	2	2	0	0	[illegible]
Intensiv Care	3	0	0	0	0	2	0	0	5
TOTAL	85	1	11	39	2	33	49	54	274

*Polyclinic surgery room

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Table 3. Activities and devices associated with blood contact and exposure, 1995. (N=272)*

	Devices					
Activity	Hollow Needle	Solid Needle	Other Sharp	No Device	Other/ Unk	Total
Injection	5	0	0	0	1	6
IV Start	34	0	0	1	1	36
IV Port Inj	19	0	0	0	0	19
Blood Draw	19	0	14	11	28	72
Suturing	1	4	0	0	0	5
Recapping	3	0	0	0	0	3
Cleaning	4	0	1	6	1	12
Disassembly	4	0	2	1	4	11
Other/Unknown	2	0	10	30	17	59
Dental	0	0	5	0	44	49
TOTAL	91	4	32	49	96	272

*Activities or devices were not recorded for 2 reports.

Table 4. Activities and locations associated with blood contact, Lviv Railway Hospital and polyclinics, 1995. (N=273)*

	Location								
Activity	Ward	ICU	OR	Lab/ XRay	Obst	Other/ Unk	Dent	Procedure Room	Total
Injection	2	0	0	0	0	0	0	4	6
IV start	25	0	0	0	0	2	0	9	36
IV port	6	1	0	0	0	1	0	11	19
Blood draw	39	0	1	8	0	14	0	10	72
Suturing	0	0	1	0	0	4	0	0	5
Recapping	0	0	0	0	0	1	0	2	3
Cleaning	3	0	3	1	0	2	0	3	12
Disassembly	1	0	4	0	0	3	0	3	11
Other/unk	9	0	2	29	2	6	0	12	60
Dental	0	0	0	0	0	0	49	0	49
TOTAL	85	1	11	38	2	33	49	54	273

*Activity was not recorded for one report.

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Attachment 11

Lviv "Do It Yourself" Operating Room Study Results

Case Type and Blood Exposure Types:

Out of 102 blood exposure case studies:

79 (77.5%)- intact skin blood contacts
10 (9.8%) - non intact skin blood contacts
6 (5.9%) - blood on mucous membranes
7 (6.9%) - punctures

The high prevalence of intact skin blood exposures is explained by the lack of surgical gloves. Therefore, the HCWs, mainly from the ophthalmology and ENT departments, were working without wearing gloves.

As to case types, 102 blood exposures are broken down as follows:

Ophthalmology - 39 (38.2%)
General surgery - 37 (36.3%)
ENT - 20 (19.6%)
Gynecology - 5 (4.4%)

Blood exposure incidence for general surgeries is 14.5 per 100; for gynecological cases - 3.6. For 24 ophthalmologic surgeries performed, 39 blood exposures occurred (incidence is 102.5 per 100). For ENT surgeries, there were 20 blood exposures (incidence is 91 per 100). The likelihood of bloodborne pathogen transmission is the highest in these two departments.

Job Category:

Sixty six (64.7%) blood exposures occurred among surgeons and surgery assistants, 29 cases (28.4%) blood contacts were among scrub nurses and only 7 cases (6.9%) were among anesthesiology personnel.

The likelihood of a patient being exposed to a HCWs blood was registered only once. This low incidence probably represents underreporting.

Activity and Device:

Majority of blood contacts occurred while passing (29 cases - 28.4%) and receiving sharp instruments (20 cases - 19.6%), which suggests careless performance of these procedures and /or improper protection of the hands: no gloves were worn.

A lot of blood exposures occurred with no device involved (50 cases - 49%). Puncture exposures were the lowest category (7 cases - 6.9%).

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Discussion:

Securing a sufficient supply of quality gloves and barrier clothing would be the most significant risk reduction factor. In addition, practices in surgical instrument transfer need to be improved.

Table 1:

Activities Associated with Exposures LRH OR

Activity	Number of Cases	%
Incising	11	10.8
Suturing	12	11.8
Passing instruments	29	28.4
Receiving instruments	20	19.6
IV manipulations	5	4.9
Sharps	1	0.9
Glove leak	4	3.9
Spatter	7	6.9
Improper blood	1	0.9
IV infections	9	8.8
Other	3	2.9

Table 2:

Devices Associated with Blood Exposure LRH OR

Device	Number of cases	%
Hollow needle	11	10.8
Solid needle	18	17.6
Scalpel	8	7.8
Other	12	11.8
No device	50	49
Unknown	3	2.9

Table 3:

Location of Blood Exposure LRH OR

Location	Number	%
Fingers	56	54.9
Hand	35	34.3
Face, mucous membrane	5	4.9
Face, not mucous membrane	2	2
Neck	1	0.9
Arm	3	2.9

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Attachment 12

Analysis of Komsomolsky Raion Hospital, Kherson, Delivery Room
COBEX Study Results

October 21, 1996

Dear Rosh and Katya,

I have looked at the data from the Kherson hospital. The proportion of blood exposures during surgeries reported in published literature varies greatly. Certainly some of the variation is due to whether the study design was direct observation by dedicated personnel (range 20-50%), or reporting by a third person such as the COBEX hospitals where the range was 6-32%; the mean for the COBEX study hospitals was 10.2% for any blood contact and 1.6% for punctures.

The reported rate for the Ukrainian hospital was 2.9%. A rate this low is hard to believe. It is far below the results from very well-equipped hospitals with abundant barrier materials and vigorous blood exposure prevention programs. It is also much lower than our direct observation of the Odessa C-section (100%) and the surgery in Lviv. As far as I know, no OR has reported such low rates for occupational blood exposures.

Accuracy is important for the participants so that they can correctly identify the nature of their own blood exposures and develop effective prevention strategies. Accuracy is also very important for us: we need to know whether changes in practices can reduce blood exposure frequency in the absence of abundant barrier materials.

How shall we approach this problem?

Pat

Pat

Pat Lynch, R.N.
PATH BBIC Consultant

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Table 4-2. Occupational blood exposures among personnel during surgical procedures reported by six operating room studies in US hospitals.

Investigator	Hospital type (s)	Number of cases in study	Any blood exposure: % of cases	Punctures only: % of cases
Gerberding	1 University	1307	6	1.3
Popejoy	1 University	684	28	3
Panlilio	1 University	206	30	4.9
Tokars	2 University 2 Community	1382	N/A	6.9
Lynch	1 University	1291	4	1.6
White	2 University 7 Community	8502	10.2	1.6

Occupational blood exposures among health care workers of the delivery room and the operating room of the delivery and labor department; operating rooms of the traumatology department and operational suite; Komsomolsky raion hospital, Kherson, 1996

Special reasearch personnel was designated to perform the study, the scope of their responsibilies included: keeping track of the blood or body substancies exposure cases - after deliveries and operations surgical teams were interviewed and the report forms specified were completed.

Results for operating suite and :
Out of 235 surgeries performed: 7 blood exposure cases occurred (61% - intact skin exposures, 6% - nonintact, 5% - mucous membrane exposures);
The riskiest are the gynecological operations - 34% of the blood exposure cases, 25% - during orthopedic operations and 25% - general surgeries.
48% of the blood exposures occurred while urgent operations were performed, 3% - during planed operations;
52% blood exposures - among physicians; 27% - nurses.
Blood exposure related types of activities - surgical needles, non-disposable scalpels made of poor-quality metal, while performing orthopedic procedures.
Anatomic location - 40% fingers, 35% - hands, 10%-body, 7%- face mucous membrane.

Delivery room and operating room of the delivery and labor department:
- for the July-September 1996 period: 277 deliveries registered were accompanied with blood and body substances exposures (24% - intact skin and 4% - nonintact skin contacts);
- out of 63 punctures - 49% occurred among obstetricians and 44% - among gynecologists;
- exposure related activities - suturing with solid needle use (12%); while passing instruments (11%) and IV manipulations. 50% of exposures occurred while performing emergency operations.
location of exposure: 36% - fingers; 20% - hands; 19% - body.

Prevention measures: analysis of the research results and the work conducted had a positive effect in motivating the HCWs to change their behavior in respect of occupational blood exposures. Nurses were more responsible in applying preventive measures while doctors took them less serious.

Punctures and cuts were more frequent among nurses and cleaning personnel while washing non-disposable soiled medical instruments (needles, non-disposable blades, glass syringes). Hand skin blood exposures were in the majority cases experienced by surgeons-orthopedists while performing urgent operations - with bones or due to poor quality metal blades are made of (the later are not good after 2-3 times of pre-sterilization cleaning).
Lack of barrier body covering clothing leads to blood exposures due to blood spatters in the delivery or operational rooms. Eyes mucous membrane exposures occur while no gaugles are worn.

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Conclusions:

1. It seems relevant to develop specific preventive measures for each of the OR depending on the character of the OR and on the basis of the results of the preliminary study related to blood exposures in the OR under consideration.
2. Medical instruments selection should depend on the character of the procedures performed in the specific OR.
3. It is critical to supply OR with disposable instruments in the amounts needed.
4. All the personnel working with blood or any other body substances should be provided with the appropriate protective clothing.

Suggestions:

Develop database re. occupational blood born infections incidence among HCWs in Ukraine and inform medical personnel on the status hereof.
It seems critical for the health care workers to exchange any information and experiences with respect to the results of prevention strategies implementation at different levels of the bloodborn infection incidence monitoring.
Specialized conferences will be extremely helpful in rasing the level of the HCWs awarance on the issues above.

Attachment 13

Operating Room COBEX Report from Kherson Oblast Hospital

The protection of medical personnel from bloodborne infection is an urgent problem. Yet the questions of assessment and control of blood exposures remain a subject for study. With the help of the COBEX questionnaire methodology the types and locations of blood exposure were detected toward the goal of implementing additional means of protection.

We studied 479 operations carried out over a two-month period in 1997 in the operating suite of Kherson Oblast Hospital.

In 35 cases blood exposure questionnaires were completed. General surgical and traumatological operations had the most frequent incidence of blood exposure (3.34% and 1.9%, respectively). By type of blood exposure, 91.4 percent of punctures and intact skin blood exposures occurred during the interval from 7 am to 3:30 pm, in the period of greatest surgical activity.

Contacts occurred in operations with a duration from greater than 30 minutes to two and a half hours.

In 52% of the recordings of devices associated with exposure, the category "other" was marked. This category included poor quality of gloves, tears, the presence of microdefects, and failed latex. In 25% of cases the cause of injury was a surgical needle; in 8.7%, surgical wire.

Patient exposure to blood of the health care worker could not be excluded in 85% of cases.

Conclusions:

For protection against blood contacts, it is necessary to raise the level of sanitary and hygienic measures at all stages of medical care from the admission department to hospital discharge. It also involves a high level of professionalism and modern equipment.

A second group of measures involves the reliability of barrier materials such as gloves, shoe covers and operative dressing, processing of instruments and dressing before sterilization, and the lengthening of glove sleeves or the use of gowns with double sleeves.

(Another measure would be) the routine testing of surgical workers for HBs antigen and HIV.

During the course of this survey, the number of blood contacts dropped by a factor of two from January to February, owing to the emergence of the care and attention of the surgical teams.

V. M. Bitchenko
Head Nurse of the Operating Suite of Kherson Oblast Hospital

Attachment 14

Conclusion: Strategy for Blood Exposure Prevention in the Microvascular Operating Room of the Ukrainian Institute of Clinical and Experimental Surgery

Analysis of medical workers by staff categories revealed a significant increase in blood contacts among two groups, the surgeons and the surgical nurses. These medical workers may receive injuries during the passing of surgical instruments. That is why explanatory lectures on prevention must become a high priority, the primary aim of which is to persuade surgeons and nurses that visual control is necessary when instruments are passed.

It is important to pay attention to methodological issues as well. For example, whether suture placement at the beginning of the operation and suture closure of the operative incision shouldn't be considered separately from the overall surgical operation. Above all, abrupt changes in the pace of the operation are inadvisable. On the contrary, short pauses between phases of the operation may instill confidence in the medical workers of a good result when the operation is finished: "everything went per routine."

The surgeons should focus attention on the inadequate use of forceps during suture placement and on the need to exchange the needle for a different size, depending on the thickness of the tissue being sutured.

Certainly, these medical workers first of all should be equipped with double surgical gloves.

It is also important for the surgeons to use barrier clothing such as safety goggles and aprons that will permit a reduction in the rate of blood exposures, as has been proven experimentally.

Since the major part of operations at the Institute are scheduled surgeries, it would be useful to conduct the survey during the winter or spring months because fewer surgical operations are conducted in summer.

Dr. L.S. Tkachuk

Chief of the Specialized Emergency Surgical Department of
the Institute of Clinical and Experimental Surgery of
the Academy of Medical Sciences of Ukraine

COBEX Worksheet

Table 1. Case types and types of exposures.

Case Type	Total Cases	Type of Exposure: Puncture	Mucous Membrane	Nonintact Skin	Intact Skin	Total Exposures
General Surgery	18	1	2			3
Thoracic	13	4			2	6
Orthopedic						
Neurosurgery						
Gynecology						
OMF/ENT						
Gastroenterology	237	12	4	1	34	51
Burn						
Trauma Multiserv.						
Organ Transplant	12		2		1	3
Other	14	1	1		2	4
Vascular	139	7	2	2	20	31
Ophthalmology						
Unknown						
Total	433	25	11	3	59	98

COBEX Worksheet

Table 2. Exposures and time of day. **Table 3.** Emergency Cases. **Table 4.** Length of surgical procedures.

Table 2. Exposures and time of day.

Time of Day	N	%	Total
Weekday 7 am - 3 pm	90	91.8	
Weekday 3 pm - 11 pm	8	8.2	
Weekday 11 pm - 7 am			
Weekend 7 am - 3 pm			
Weekend 3 pm - 11 pm			
Weekend 11 pm - 7 am			
Total		100	

Table 3. Emergency cases.

Emergency Case	N	%	Total
Yes	10	10.3	
No	88	89.7	
Total		100	

Table 4. Length of surgical procedures.

Length of Surgery	N	%	Total
0 = < 30 minutes			
1 = 1/2 - 1.5 hours	20	20.2	
2 = 1.5 - 2.5 hours	27	27.5	
3 = 2.5 - 3.5 hours	19	19.4	
4 = 3.5 - 4.5 hours	14	14.2	
5 = 4.5 - 5.5 hours	9	9.1	
6 = 5.5 - 6.5 hours	9	9.1	
Total	98	99.6	

COBEX Tally Sheet

Job Classification	TYPE OF EXPOSURE					ACTIVITY AT EXPOSURE														LOCATION OF EXPOSURE								
	Puncture	Mucous Membrane	Nonintact Skin	Intact Skin	Total	Incising	Suturing	Passing/Receiving	Suctioning/Irrigating	Injecting	IV Manipulation	Sharps Manipulation	Glove Leak	Power Equipment	Strikethrough	Spatter	Improper Blood	Other/Unknown	Total	Finger	Hand	Mucous Membrane	Face, Neck	Arm	Body	Legs, Feet	Other/Unknown	Total
	1	2	3	4		1	2	3, 4	5, 6	7	8	9	10	11	12	13	14	15		1	2	3	4, 5	6	7	8	9, 0	
Surgeon/ Assistant/ Residents	22 1	9		35		2	12 1	8	2				8		16	14				24 1	13	9	6	3	6	1		
Scrub	5		3	11				5			2		3			7				5	5		3		3	1		
Circulator																												
Anesthesia				15						3	12										12							
Student/ Other/ Unknown				1									1								1							
TOTAL																												

COBEX Worksheet

Table 5. Devices associated with exposures,
Table 6. Patient exposure to blood of *punctured* health care worker,

Table 5. Devices associated with exposures.

Devices	N	%	Total
Hollow Needle	2	6.5	
Solid Needle	24	77.4	
Scalpel	3	9.6	
Wire			
Saw			
Bovie			
Staple			
Bone			
Other	2	6.45	
None			
Unknown			
Total	31	99.95	

Table 6. Patient exposure to blood of *punctured* health care worker.

Patient Exposure Likely?	N	N of Punctures	%	Total
Yes	2	2	6.5	2
No	29	29	93.5	29
Total	31	31	100	31

Attachment 15

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Odessa Oblast Clinical Hospital
Bloodborne Infection Risk Reduction Strategy

1. Teach the operating and surgical nurses to work carefully with the sharp instruments, including the passing of instruments to the surgeon and taking them back.
2. Instruct young doctors and interns on safe technique for debridement under emergency conditions.
3. Make the appropriate choice of surgical needle when suturing.
4. If the length of surgery is anticipated to go over two hours, wear double gloves.
5. According to the type of operation, use protective masks and appropriate eye protection.
6. Wear waterproof gowns and shoe covers if you expect heavy bleeding during the operation.
7. Use long-sleeved gloves in the delivery suite.

Attachment 16

MEETING IN KYIV, DECEMBER 1996
STRATEGIES FOR PREVENTING OCCUPATIONAL BLOOD EXPOSURES

HEPATITIS B ANTIBODY IN US AND UKRAINIAN HEALTH CARE WORKERS

- US range: community baseline of 1-5% to ±30%; varies by job class, HBV infection in community, and case mix of patients including types and amounts of surgery.
- Few published studies in Ukraine, but rates in the south of the country are higher than in the north, and rates in general are higher than in Western Europe and US.

INCIDENCE OF OCCUPATIONAL BLOOD CONTACTS AND EXPOSURES IN SURGERY: US COBEX STUDY

Range among hospitals:

- Community hospitals: 4-18/100 cases.
- University hospitals: 22-31/100 cases
- 3 hospitals reduced rates significantly after monitoring, using individualized strategies based on their own data

BARRIER PRECAUTIONS

1. Gloves: protect skin, reduce amount of blood that penetrates from punctures
2. Eyewear and masks: protect facial mucous membranes from spatter of bloody fluid
3. Fluid-resistant gowns, aprons, leg covers: protect from soak-through

SHARPS MANAGEMENT

Hollow needles

1. Recap 1-handed
2. Used needles recapped or cleaned up by the person who used them
3. Single use needles
4. Blood tube transfers using tube holder
5. Point-of-use disposal containers for needles and syringes

Solid needles

1. Place in foam "pincushion" when finished if needle will be reprocessed
2. Lancets in disposal containers
3. Automatic lancet devices cleaned with each use
4. Cover tips of sharp pins and wires

SURGICAL TECHNIQUE

Incising:

1. Pass scalpel safely: Use neutral zone, basin, or announce "Sharp coming"
2. Control spurting during incision
3. Cautery tip

Suturing:

1. Avoid finger-guided suture placement, especially in closed spaces
2. Use blunt suture needles
3. Use staples to close
4. Remove suture needle before tying knot

Attachment 17

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Status of Hospitals Participating in COBEX Studies

November 18, 1997

Hospital	Type of Study*	Phase I**	Phase II**
1. Crimea (Simferopol')	OR	+	–
2. Kherson oblast hospital	OR/DR	+	+
3. Kherson city hospital Suvorovskiy	ACC	+	+
4. Kherson city hospital Komsomolski	OR	+	+
5. Mykolaiv oblast hospital	OR	+	–
6. Kirovohrad oblast hospital	OR	--	–
7. Sevastopol' oblast hospital #1	OR/ACC	+	+
8. Zaporizhia oblast hospital	OR	?	–
9. Cherkasy oblast hospital	OR	?	–
10. Kyiv central hospital of Min. Int.Affs.	OR/DR	+	+
11. Chernihiv oblast hospital	OR	+	–
12. Luhans'k oblast hospital	OR/DR	+	+
13. Kharkiv oblast hospital	OR/DR	+	+
14. Poltava oblast hospital	OR	+	–
15. Donets'k oblast hospital (Ilyicha avenue)	OR	+	+
16. Donets'k oblast hospital (Lenin avenue)		?	-
17. Sumy oblast hospital	OR/DR	+	+
18. Dnipropetrovs'k oblast hospital	OR/DR	+	–
19. Vynnytsia oblast hospital	OR	+	–
20. Rivne oblast hospital	ACC	+	+
21. Ivano-Frankivs'k oblast hospital		+	–
22. Chernivtsi oblast hospital	ACC	+	+
23. Volyns'ka oblast hospital		+	–
24. Zhytomyr oblast hospital	OR	+	–
25. Khmel'nytskyi oblast hospital		–	–
26. Ternopil' oblast hospital		+	–
27. L'viv oblast hospital	OR	–	–
28. Zakarpats'ka oblast hospital	ACC	+	+
29. L'viv maternity center	DR	+	–
30. Institute of clinical surgery (Shalimov)	OR	+	+
31. Institute of orthopedy	OR	+	+
32. Kyiv oblast hospital		–	–
33. Kyiv city hospital of emergency care	ACC	–	–
34. Odesa oblast hospital	OR/DR	+	+
35. L'viv railway hospital	OR/ACC	+	+

* OR = Operating Room; DR = Delivery Room; ACC = Occupational Accident Self-Report.
** + = Done or underway; ? = Status unknown; – = Not yet started.

Attachment 18

Appropriate Use of Gloves to Reduce Bloodborne Infection Risk Among Hospital Personnel in Ukraine

Vivien Tsu, Ph.D.
Katerina Gamazina, M.D.

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PATH

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I. Introduction

This study was designed to assess the impact of introducing purpose-specific gloves on glove usage and failure rates among hospital workers at the Lviv Railway Hospital (LRH) in Lviv, Ukraine. In addition, the study will help in estimating future glove commodity needs for the LRH and perhaps other Ukrainian hospitals.

At the start of the study in 1996, LRH was a 700-bed facility staffed by 300 doctors, 420 nurses, and 780 service employees. Approximately 13,500 sterile procedures were performed in 1994. The LRH's primary focus is on elective surgery or planned procedures and tertiary care. Trauma cases account for only about 1.4 percent of sterile procedures. Each service in the hospital has its own operating room. Since the start of the study there have been significant cutbacks in staff; it is not yet clear what the impact on the number of procedures and patients served has been or will be.

Prior to the study, the hospital relied heavily on sterile surgical gloves donated from various sources. Some patients also supplied gloves, although no information exists regarding the numbers of gloves supplied by patients. The LRH used and retired about 13,590 pairs of latex gloves per year, although the actual total annual need for sterile, clean (non-sterile), and utility (heavy-duty) gloves was estimated to be over 165,000 pairs. LRH staff used sterile surgical gloves or reprocessed surgical gloves for all applications, including clinical examination, surgical care, laboratory and pharmacy work, and utility purposes (housekeeping, laundry, and glass washing).

Sterile gloves are expensive, are not necessary for many aspects of routine patient care, and are too fragile for housekeeping tasks. Typically, new sterile gloves were used for surgery, then reprocessed and passed on to the remaining services where they were repeatedly reprocessed until no longer functional, a usage pattern common in many countries with limited resources. Utility workers generally received gloves that were in their last stages of effectiveness. Glove shortages were common and led to non-use, re-use, and extended use that may increase the risk of exposure to bloodborne pathogens due to glove failure. Finally, such patterns of use may not be cost-effective. Glove failure rates were not known.

The overall goal of this USAID-funded project was to reduce the risk of infection among hospital workers by reducing personnel contact with blood and moist body substances (thereby reducing potential exposure to bloodborne pathogens) through the use of purpose-specific gloves. By replacing the former sterile and reprocessed gloves with purpose-specific gloves, it was hypothesized that glove failure rates would decrease, leading to decreased infection risk for hospital personnel. The project also aimed to increase overall glove usage among hospital personnel. Data collected during the study were to be used to design a strategy for meeting actual glove needs at the LRH.

II. Study Objectives

The study had two main objectives:

A. To measure the impact of using purpose-specific gloves instead of sterile or reprocessed gloves on glove failure rates in the local setting.
B. To determine actual glove use rates by type of glove and application when supply constraints do not exist.

III. Materials and Methods

A. Site and Participants

The study took place at the Lviv Railway Hospital (LRH) in Ukraine. Health workers (doctors, nurses, and cleaners) in all departments of the hospital were asked to complete a variety of data collection forms if they had any reason to need gloves for any part of their work.

B. Baseline and Intervention Phases

The study was divided into a baseline phase of four weeks (March 1996) and an intervention phase of approximately three months (June to September 1996). During the baseline phase, hospital staff used their existing glove supplies and followed their usual practices with regard to reprocessing and re-use of gloves. During the intervention period, 36,800 pairs of sterile surgical gloves, 169,000 pairs of clean exam gloves, and 2,592 pairs of utility gloves were provided to the hospital by PATH. Contrary to their usual practices, staff were asked not to reprocess surgical gloves during the intervention phase or to wash, disinfect, and re-use exam gloves at the end of the day (although such disinfection and re-use in the course of a day was permitted).

C. Data Collection

Data were collected using a variety of instruments during both the baseline and intervention phases.

1. Employee Survey

This survey was completed by doctors, nurses, and cleaners once at the beginning of the baseline period and again at the end of the intervention period. Respondents were asked about the type of gloves they used, the types of procedures for which they used gloves, any problems they had with their gloves, and how they rated the quality and performance of their gloves. In the final survey they were asked to compare the new gloves with the ones used before the study.

2. Weekly Glove Use/Failure Form (example in Appendix 1)

In both baseline and intervention phases, employees using gloves (or needing gloves) were asked to keep a tally of the number of gloves they used, the number

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of times they reused the gloves, any glove failures they experienced, and the number of times they needed gloves but did not have them.

3. Supervisors' Inventory Log

   The head nurses of each department kept a record of the number of gloves they received from the hospital pharmacy and the number they distributed to staff in their department. This inventory was intended to serve as a check on the completeness of reporting of glove use by employees.

4. Supervisors' Periodic Consumption Report

   For two one-week periods in each phase, the head nurse in each department listed the most common four procedures requiring gloves in her department and estimated the number of gloves required during the week for each of those procedures.

5. Pharmacy Supply Inventory

   The hospital pharmacy, which was responsible for dispensing gloves to each department, kept an inventory of the numbers of glove pairs of each type distributed during the baseline and intervention phases.

D. Training and Supervision

Training in how to complete the data collection forms was provided to department chief doctors and chief nurses by the head of the hospital's epidemiology department at the beginning of the baseline period. Refresher training and review of minor modifications of study data forms was given at the beginning of the study period. A review of preliminary data after the first few weeks of each period revealed confusion on the part of a few staff, to whom extra training and clarification were provided.

E. Data Processing and Analysis

Data were entered into Epi Info 6.0 files or Quattro Pro spreadsheets (for the inventory logs) by bilingual English/Ukrainian personnel. Forms were reviewed by one of the authors (Dr. Katya Gamazina, a physician with experience in hospital infection control and the professional responsibilities of various hospital personnel) whenever inconsistencies were identified during data entry or analysis. In all cases, the number of gloves refers to pairs.

Staff were divided into eight types (relating to their work responsibilities and differential exposure to bloodborne pathogens). "Doctors" include all non-surgeon physicians. "Nurses" include general ward nurses, junior nurses, lab technician nurses, and others without special blood exposure risk. "IV nurses" include those who do intravenous injections and other "manipulations" as their primary job. "OR nurses" assist in operating rooms and prepare kits of sterile instruments. "Surgical nurses" are responsible for surgical dressings and other wound care, while "midwives" conduct most normal deliveries. "Cleaners" are auxiliary personnel who do a variety of general patient services and housekeeping tasks. Categories relating to expected risk of

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exposure to infectious materials ("high", "medium", "low" risk) were also developed by Dr. Gamazina based on responsibilities and department; all staff were assigned to a single risk category.

Similarly, the procedures named in the Supervisors' Periodic Consumption Report were grouped into 38 categories and were rated (by Dr. Gamazina) as needing sterile, clean or utility gloves (depending on local regulations and the nature of the task).

IV. Results

A. Description of Study Participants

In the one-month baseline phase about 175 employees completed 708 weekly Glove Use Forms, while in the three-month intervention phase approximately 300 employees filled out 3,535 weekly Glove Use Forms. The distribution of types of staff was similar in the two phases (Figure 1) except that more general nurses and cleaners participated in the intervention phase. Because information was not available on the total number of employees who ought to be using gloves, it is not possible to determine what proportion of eligible employees using gloves actually participated fully. In the baseline phase 14 departments recorded weekly glove use data, while in the intervention phase 18 departments did (Figure 2). Among those completing weekly Glove Use Forms, they were approximately evenly distributed in the three exposure risk categories in the baseline phase, while in the intervention phase more low-risk employees were included (Figure 3).

The distribution of staff participating in the Employee Survey was similar (Figure 4) to those filling out weekly forms except that no midwives completed the post-intervention survey and fewer cleaners completed the survey generally. Substantially fewer surgeons completed the post-intervention survey than did the baseline version. It was not possible to determine how much of the drop-off was due to staff reductions or vacations.

B. Glove Usage and Projected Needs

Table 1 shows various aspects of use for the different glove types, as well as the number of person-weeks of reported use among actual users of each type. The total number of gloves reported as taken fresh and used are shown for each phase. To account for the different time periods in the two phases, the average number of gloves taken per person-week was calculated; it shows a dramatic shift from predominant use of sterile gloves (new and reprocessed) in the baseline period to clean gloves in the intervention period. The number of utility gloves taken could not be determined precisely because the number of gloves on hand at the beginning and end of the baseline period and the number still functional at the end of the intervention period could not be obtained. Since gloves are often used for multiple procedures (such as lab analyses or giving injections), sometimes with just a rinse of disinfectant in between, the total number of uses was also recorded. Dramatic rises in clean and utility glove use in the intervention period reflect the serious unmet need for these gloves in the baseline period. Again, calculating average number of uses per reported person-week confirms the shift from sterile to clean glove use once clean gloves

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became available. Utility glove uses were reported by each shift rather than by individual tasks.

Unlike the baseline phase when all types of staff used at least some sterile gloves and only surgical nurses used more than one clean glove per person-week (data not shown), in the intervention phase the distribution by staff type changed substantially (Figure 5). In the intervention period, surgeons, OR nurses, and midwives were the main users of sterile gloves while all staff used clean gloves. Cleaners were by far the predominant users of utility gloves. The distribution of glove use per person-week by department in the intervention phase (Figure 6) reflects differences in the types of procedures and patient load in each department and may also reflect differential glove use practices.

Estimates of the leading types of procedures requiring gloves and their estimated numbers (Supervisors' Periodic Consumption Report) were provided by 14 departments in the baseline phase and 18 departments in the intervention phase (although in the intervention phase 14 provided no information on utility glove use and 8 made no estimates for sterile glove use). Although these represent only estimates, they show the same trend seen in the weekly glove use reported by staff — that is, a drop in sterile glove use (from 8,575 for a two-week baseline period to 5,056 during the intervention period) and a significant rise in clean glove use (from 1,872 to 26,660).

With regard to the appropriateness of the gloves used (according to the supervisors' report), the vast majority conformed to practice recommendations with only a few instances of disagreement between procedure and correct glove type. Occasionally in the baseline period and almost uniformly in the intervention period, clean gloves were used for intravenous manipulations although official regulations call for sterile gloves. Similarly, clean rather than sterile gloves were used in three departments for blood transfusions and in one department for finger-stick blood draws. In four instances, each in a different department, clean gloves were used for procedures that normally require sterile gloves (sterile puncture, subclavicular catheterization, vaginal or urological examination, ultraviolet blood treatment). The remaining discrepancies involved use of clean gloves where utility gloves would suffice. For example, four departments in the baseline period and ten in the intervention period used clean exam gloves rather than utility gloves to disinfect instruments or to use disinfectant. Similarly, six departments used clean gloves when doing general patient care tasks better done with utility gloves. In the Laboratory and Recovery departments sterile gloves were used in the baseline period for procedures needing only clean gloves, but this was not the case in the intervention period when a sufficient supply of clean gloves was available.

In the baseline period (but not in the intervention period), staff frequently reported that gloves were needed but not available (Figure 7). Staff whose jobs put them at high risk of blood exposure reported on average more than 45 instances per person-week when needed sterile gloves were unavailable and about 70 instances when utility gloves were unavailable. Staff in the medium risk category had even higher rates of glove unavailability where sterile and clean gloves were concerned, suggesting that some prioritization was going on to meet the needs of high risk staff first.

There are two possible approaches to making projections of likely future needs for gloves of each type for this hospital. Taking the actual number of gloves used during the three-month intervention period, multiplying by four (for an annual rate), and adding a correction factor of 20 percent for the slow-down associated with the summer months would provide a minimum annual number for surgical and clean gloves as follows – surgical - 17,520 pairs and clean - 113,885 pairs. It is not possible to estimate the durability of the utility gloves since most of them appear to have still been functioning at the end of the study (very few additional ones had been requested from the pharmacy). This type of estimate is useful only if the participation of eligible staff was nearly complete and if the activity and staff levels remain at that level (neither of which appears to be the case in this situation). Such an estimate is also of little use to hospitals with different staff and activity configurations.

An alternative approach is to estimate a rate of use per week for different categories of personnel, thus allowing any facility to estimate its glove needs based on its own staffing (although staff activity levels might still vary widely depending on patient load). The levels identified in this study can serve as a starting point, with modifications based on any existing facility-specific glove usage information. The basic formulae given below for sterile and clean gloves are based on weekly rates (to be multiplied by 52 to get annual rates).

Sterile: 2x(non-surgeon physicians) + 5x(surgeons) + 7x(OR nurses) + 5x(midwives)

Clean: 10x(non-surgeon physicians) + 6x(surgeons) + 9x(nurses) + 14x(IV nurses) +5x(OR nurses) + 12x(surgical nurses) + 5x(midwives) + 1x(cleaners)

Using these formulae and two different staffing estimates (one based on those who completed the survey and one based on an early 1996 list of staff who usually need gloves), an upper and lower level estimate of glove need can be calculated. For sterile gloves the range of estimated need is 16,016-18,564 pairs per year, while for clean gloves the range is 77,116-301,080 pairs per year. The breadth of the range for clean gloves is due to the difference in the number of nurses in the two staffing estimates; the range could be narrowed by using more precise staffing information. It is reassuring to see that estimates based on weekly averages are generally consistent with the estimates based on the intervention period plus a 20 percent "summer slow-down" correction (given above).

To estimate the number of utility gloves, it appears that about one new pair among five was replaced during the three-month intervention period, although it is not clear whether this was due to loss or to wear. There is no way to know whether this rate of replacement continued after the study ended, although it is known that of 10 pair of utility gloves given to the hospital in the year prior to the study at least four pair were still in use a year later. It seems reasonable to estimate two to three pair of utility gloves per year for each cleaner as a starting point, to be adjusted in light of subsequent experience. Given the early 1996 staff level of 290 cleaners, this would entail 580-870 pair per year.

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C. Glove Failure Rates

Visible glove leaks and tears occurred frequently in the baseline period, ranging from 6.7 per 100 uses among reprocessed sterile surgical gloves to 39.4 per 100 uses among washed and disinfected clean gloves (Figure 8). Failure rates dropped off dramatically with the new gloves provided in the intervention period, below 3 per 100 uses for sterile and clean gloves and just 3 per 10,000 shifts for utility gloves. Operating room nurses experienced the highest failure rates with sterile gloves in both baseline and intervention periods, with cleaners also experiencing high failure rates in the baseline period (Figure 9). The high failure rates with clean gloves reported by doctors were based on a very small sample, but surgeons, IV nurses and cleaners also had high rates (Figure 10). More than 98 percent of utility glove use and failures were reported by cleaners (data not shown).

In both the baseline and intervention periods, the highest rates of sterile glove failure were among those staff with the highest risk of exposure to bloodborne infection, although in the intervention period the rates dropped to one-quarter of what they had been in the baseline period (Figure 11). Staff with high exposure risk also had the highest clean glove failure rates in the baseline period, but these rates dropped off uniformly for staff in all risk categories in the intervention period (Figure 12).

Failure rates varied widely by department, as did general use rates. In the baseline period, Recovery, Urology, Obstetrics and Gynecology all reported failure rates above 30 percent for new sterile surgical gloves, while ENT, Urology, and Surgery departments reported failure rates above 40 percent for reprocessed sterile gloves (data not shown). Of the six departments reporting use of clean gloves in the baseline period, failure rates varied from 9.5 to 54.3 percent for new clean exam gloves and from 12.3 to 100 percent for washed and disinfected gloves. Of the seven departments reporting utility glove use in the baseline period, failure rates varied from 5.8 to 100 percent. Of the ten departments reporting sterile glove use in the intervention period, failure rates varied from 0 to 25.9 percent (Gynecology). All departments reported clean glove use in the intervention phase, and failure rates varied from 0.5 to 18.3 percent (Recovery).

D. Types of Visible Failures

The distribution of glove failure types in the baseline period varied somewhat among the different types of gloves, although pre-existing tears discovered before putting the gloves on were least common for all types (Figure 13). New sterile gloves were most likely to tear in conjunction with using sharp instruments, while new clean exam gloves and utility gloves were more likely to tear during use but without sharps present. Among staff in the high and medium exposure risk groups, more than 40 percent of sterile glove failures occurred in conjunction with sharps -- a situation which puts these staff at extremely high risk of infection (Figure 14). The pattern was very similar for failures with clean gloves (not shown).

E. Staff Perception and Satisfaction

Staff were asked to rate glove performance with regard to the tasks they performed with them, both in the baseline period and at the end of the intervention period. New

sterile surgical gloves were generally rated as functioning well in the baseline period; however, reprocessed sterile surgical gloves, washed and disinfected clean gloves, and utility gloves were rated as failing "often" or "mostly" for 90 percent or more of the tasks done with them (Table 2). Ratings with regard to the new gloves provided in the intervention period went up slightly for sterile gloves and substantially for clean and utility gloves.

Staff were also asked to directly compare the prior gloves with the new ones for several characteristics. The sterile gloves and utility gloves provided in the intervention period were unanimously rated as "better" in fit, durability, availability, protection, compatibility with the task, and overall quality. For clean gloves, 96 percent or more rated the intervention gloves "better" on all characteristics, while the remaining staff rated them "the same" except one person who rated them "worse" for durability and overall quality.

When asked to name what feature(s) they liked best about the new gloves, "quality" and "protectiveness" were most often mentioned for all three glove types. "Availability", "elasticity" and "comfort" were the next most common features named for sterile and clean gloves, while "durability" was the next most valued feature for utility gloves. The only negative feature mentioned was "short length" mentioned by six people with regard to clean exam gloves.

Nearly two-thirds of baseline survey respondents reported that they sometimes did not use gloves when they ought to. Of those reporting non-use, the most commonly cited reasons were that new gloves were not always available and that available gloves did not fit well (Table 3). More than half of respondents also mentioned that the poor quality and unsuitability of the available gloves to the tasks being done were important factors.

F. Measures of Study Validity

It is difficult to measure the completeness of participation in the study since only those staff who need to use gloves were asked to complete any forms and it is not possible to identify the exact number of eligible staff; in addition, the number of staff changed (declined) during the course of the study and part of the intervention phase occurred during August (the prime vacation month). A few departments participated in one but not both phases of the study, but all the major departments where glove use is significant were represented and there is little reason to think that glove use or failure patterns would have differed substantially in the non-participating departments.

There was good agreement between the major data collection instruments with regard to the shift in the intervention period from sterile to clean gloves for many procedures. For example, the survey data regarding which types of gloves staff generally report using confirmed a drop in sterile glove use and sharp rises in clean and utility glove use (Table 4), as seen in the Weekly Glove Use Forms, the Supervisors forms and the inventory data.

Inventory systems at pharmacy and department levels, designed to confirm the number of gloves distributed, were not reported consistently, particularly in the baseline period. During the intervention period, the numbers of surgical and clean gloves

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reported in the department inventories correspond well with the number of gloves reported as used on the individual weekly forms. The pharmacy records show that gloves were distributed to several departments that did not complete any study forms. Problems in tracking utility gloves have been described above. Gloves were also collected after use in disposal boxes (with the intention of providing a further check on reported use), but it was not possible to get the actual numbers of gloves in these boxes counted given the constraints on staff time.

V. Discussion

This study clearly documents the high level of risk incurred by health workers in a medical setting when gloves of adequate quality were not available. While HIV was not perceived as much of a risk at the time the study was conducted (rates are now rising rapidly), there was already a good appreciation of the risks of hepatitis B infection. Annual tests of medical staff for hepatitis B surface antigen are routine in Ukraine, and the hospital had also recently undertaken a study of blood exposures based on anonymous self-reports. This study demonstrated that in approximately ten weeks 274 blood exposures were reported, most of which involved intact skin contact (i.e., where gloves would make a difference). Most of the contacts were reported by nurses, doctors, and lab workers, with IV injections and drawing of blood most frequently identified as high risk activities (Doan, personal communication 1997).

The high rates of glove failures in the baseline period are consistent with other studies that have shown that gloves that are washed and reprocessed are six times as likely to leak as new gloves (Adams et al, 1992). On the other hand, it has been demonstrated that it is better to use gloves with leaks than to use no gloves at all (Olsen et al, 1993).

There are very few published studies on glove use in resource-poor settings, but others have identified failure to recognize the need for gloves as a more significant problem than lack of supply. For example, in a recent study undertaken in a teaching hospital in Nigeria (Adegboye et al, 1997) 36 percent of staff not using gloves when they ought to reported they did not believe gloves to be necessary for the particular tasks involved. Only 21 percent reported lack of supplies as the cause of their non-use. In Lviv, non-availability was by far the most important reason for non-use, evident both in survey responses and in the surge in use once gloves became available. Staff also generally demonstrated a good understanding of the type of gloves various procedures required.

Data on actual health worker infection rates related to non-use of gloves were not available (nor was information on patient iatrogenic infection rates), so a cost-benefit ratio for purchasing additional gloves could not be calculated. Using international procurement prices plus 15 percent for shipping and handling and the glove need estimates calculated above, the cost of a one-year supply of gloves has been estimated at about US$13,000-34,000. Given the high-risk status of workers and the rapidly rising rate of HIV as well as hepatitis B, prevention of just one or two cases of HIV or hepatitis B would easily offset the cost of a year's supply of gloves, based on time lost to work and whatever treatment costs might be incurred.

While the study was intended primarily as a practical demonstration of the value of purpose-specific gloves and of the magnitude of the problem faced by the hospital at the start of the study, it has some limitations as to its generalizability to the overall hospital

and to its ability to generate estimates of future glove needs. Since the staff levels were changing and it was not possible to determine whether participation in the study was systematically biased in any particular direction, it is possible that those who had poor experiences with glove failures or inadequate supplies were more motivated to participate. If this occurred, the glove failure rates might be over-estimated. Since the major glove-using departments were well-represented in the study, though, the extent of this possible bias seems small. On the other hand, since only defects perceptible to the users were reported as failures and no objective tests of glove integrity were undertaken, the failure rates represent a minimum and may be under-estimated if many defects went unnoticed. Since it was left to individuals to define the circumstances when they believed gloves were needed, it is possible that non-use due to non-recognition of the need was under-estimated. However, on the survey questions regarding which tasks were done using which types of gloves, answers were generally in line with existing recommendations.

The study was not able to produce a solid estimate of future glove needs for a variety of reasons. During the course of the study, major changes in the hospital's staffing and activity levels were initiated. Further analysis of these changes (and stabilization of the situation) must occur before the relevance of the glove use levels during the study period can be tested and refined. In addition, the extent of non-participation by certain departments must be assessed. Using the staff-based estimating procedure described above might overcome some of these problems. Finally, the study was not long enough nor was the recording system adequately designed to capture the level or duration of use of utility gloves. Experience over time will give a better idea of how long they last and how many are needed.

VI. Conclusions

The original situation at the LRH (and perhaps at other hospitals in Ukraine) represented one of great unmet need, both in quantity and quality, for an essential tool for good medical care—a situation that put health workers (and possibly patients) at considerable risk for occupationally-acquired or nosocomial infections. Such infections could have serious consequences not only for the individual health of hospital staff and patients but also for the hospital's economic well-being in terms of employee time lost due to illness. When offered the choice, hospital workers not only willingly use gloves but they have a good grasp of the value of using gloves appropriate to the particular tasks. There was no hesitation in giving up the use of sterile gloves once clean gloves became available.

As expected, the new sterile and clean gloves provided were significantly less likely to leak than the reprocessed gloves previously being used. They were also generally reported to fit better and to be more comfortable. While the hospital saved the gloves used during the study and has expressed its intention to reprocess them for future re-use, it is hoped that such re-use will be limited to just a few cycles to avoid a return to the high failure rates seen in the baseline period and that sterile gloves in particular will not be re-sterilized repeatedly (given the extra stress high-temperature processing causes latex gloves).

Although finding the funds to purchase adequate supplies of gloves is a major challenge in these resource-constrained times in Ukraine, shifting to less expensive clean and utility gloves and reducing hazardous blood exposures associated with glove failure and non-use should result in a net economic and health benefit.

References:

Adams D, Bagg J, Limaye M, et al. (1992) A clinical evaluation of glove washing and reuse in a dental practice. *Journal of Hospital Infection* 20: 153-162.

Adegboye AA, Roy PK, Emeka C. (1997) Glove utilization and reasons for poor compliance by health care workers in a Nigerian teaching hospital. *Tropical Doctor* 27: 93-97.

Doan, R. Personal communication, October 1997.

Olsen RJ, Lynch P, Coyle MB, et al. (1993). Examination gloves as barriers to hand contamination in clinical practice. *Journal of the American Medical Association* 270: 350-353.

Week of: ___/___/___

Employee assignment: _____

LVIV GLOVE STUDY-BASELINE

Employee's Weekly Report

Type of Glove	# Used	# Discarded	# Failed	Description of failure*	# Procedures without gloves†
New sterile surgical				a. Pre-existing puncture or tear _____ b. Tear while putting on _____ c. Puncture with sharps during use _____ d. Tear without sharps during use _____	
Reprocessed sterile surgical				a. Pre-existing puncture or tear _____ b. Tear while putting on _____ c. Puncture with sharps during use _____ d. Tear without sharps during use _____	
New clean exam				a. Pre-existing puncture or tear _____ b. Tear while putting on _____ c. Puncture with sharps during use _____ d. Tear without sharps during use _____	
Reprocessed clean exam				a. Pre-existing puncture or tear _____ b. Tear while putting on _____ c. Puncture with sharps during use _____ d. Tear without sharps during use _____	
New, heavy-duty utility				a. Pre-existing puncture or tear _____ b. Tear while putting on _____ c. Puncture with sharps during use _____ d. Tear without sharps during use _____	

***For each failure, describe how and when failure occurred on reverse side.**
†Number of procedures for which gloves were needed but not available.

Weekly Glove Use/Failure Form

Appendix 1

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Figure 1. Positions of Participants Completing Weekly Glove Use Forms

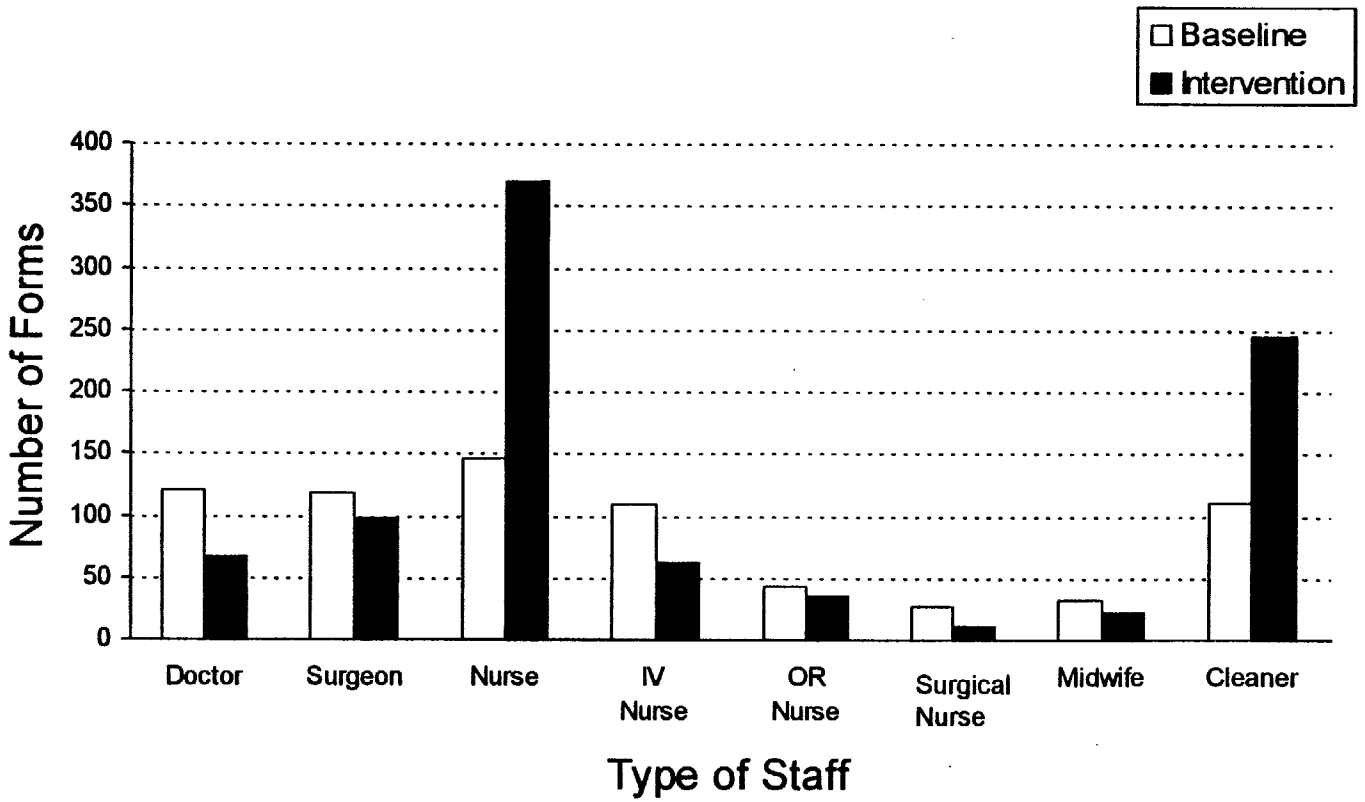


Figure 2. Departments of Participants Completing Weekly Glove Use Forms

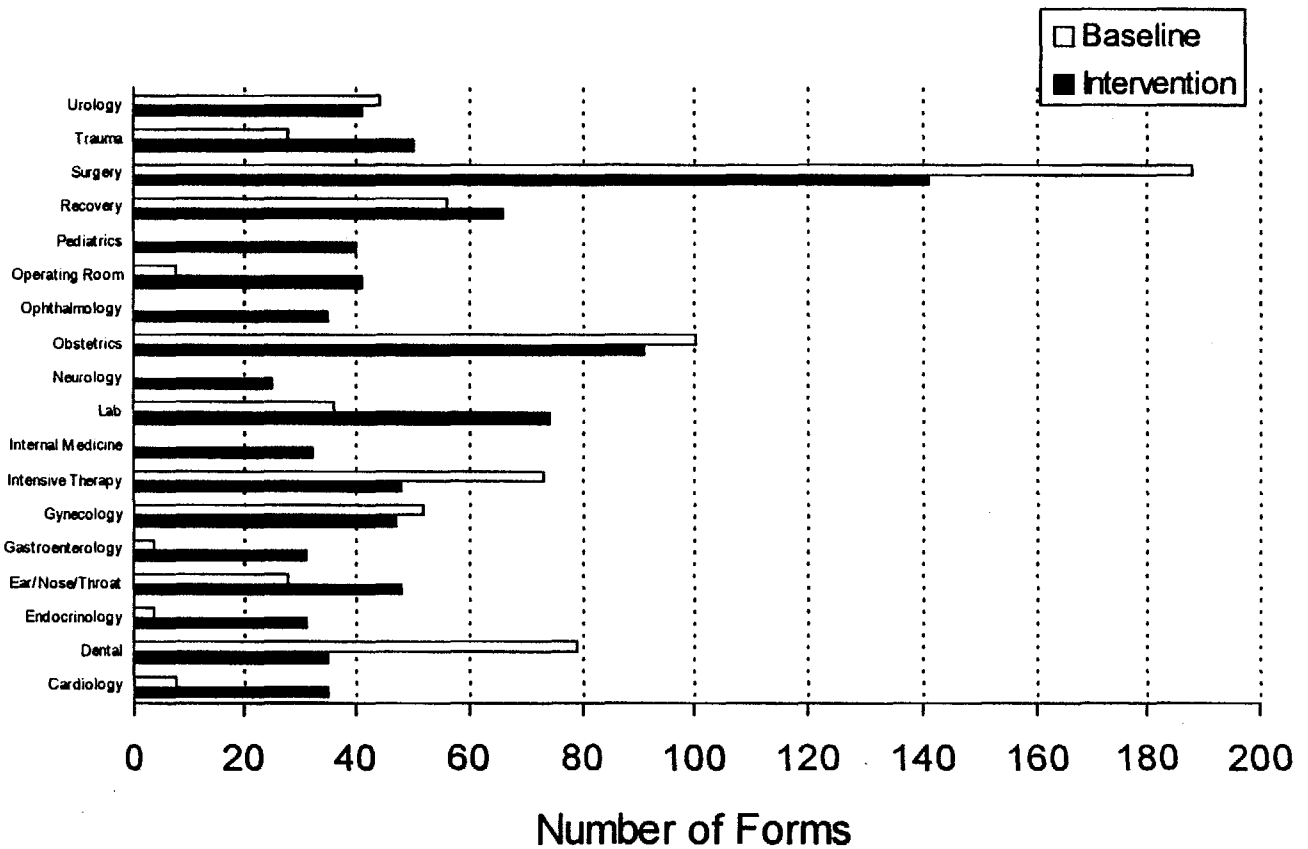


Figure 3. Risk Status of Participants Completing Weekly Glove Use Forms

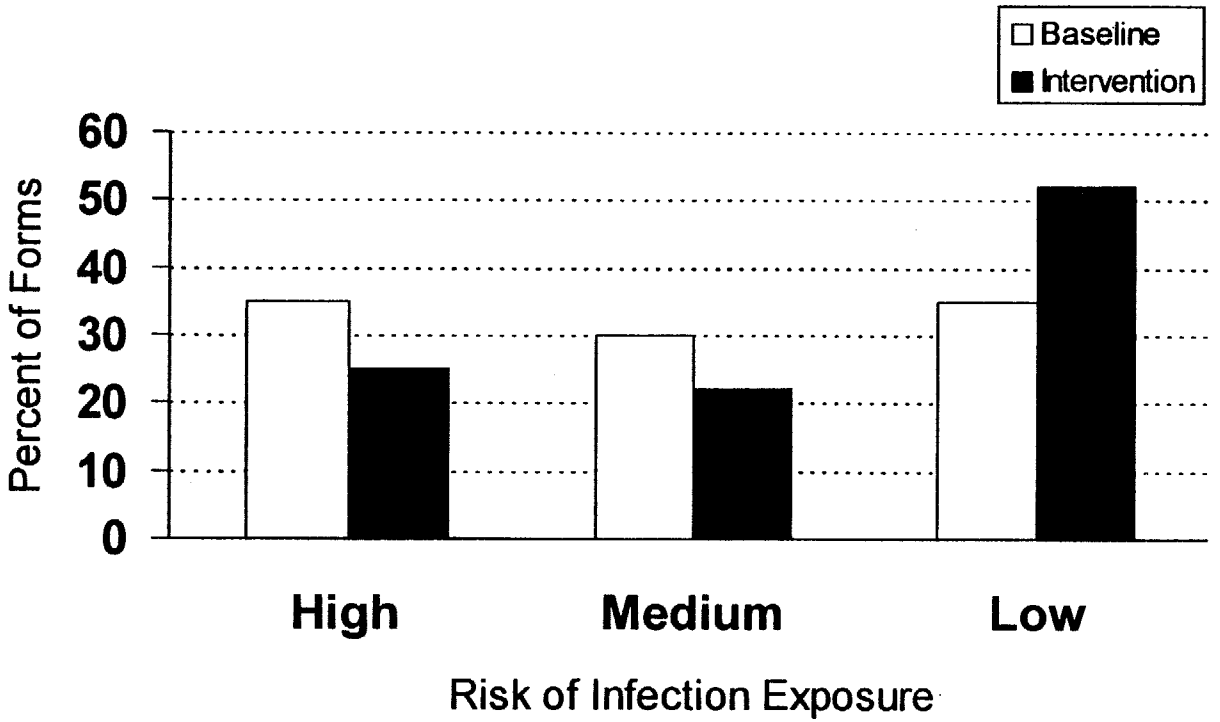


Figure 4. Positions of Participants in Employee Survey

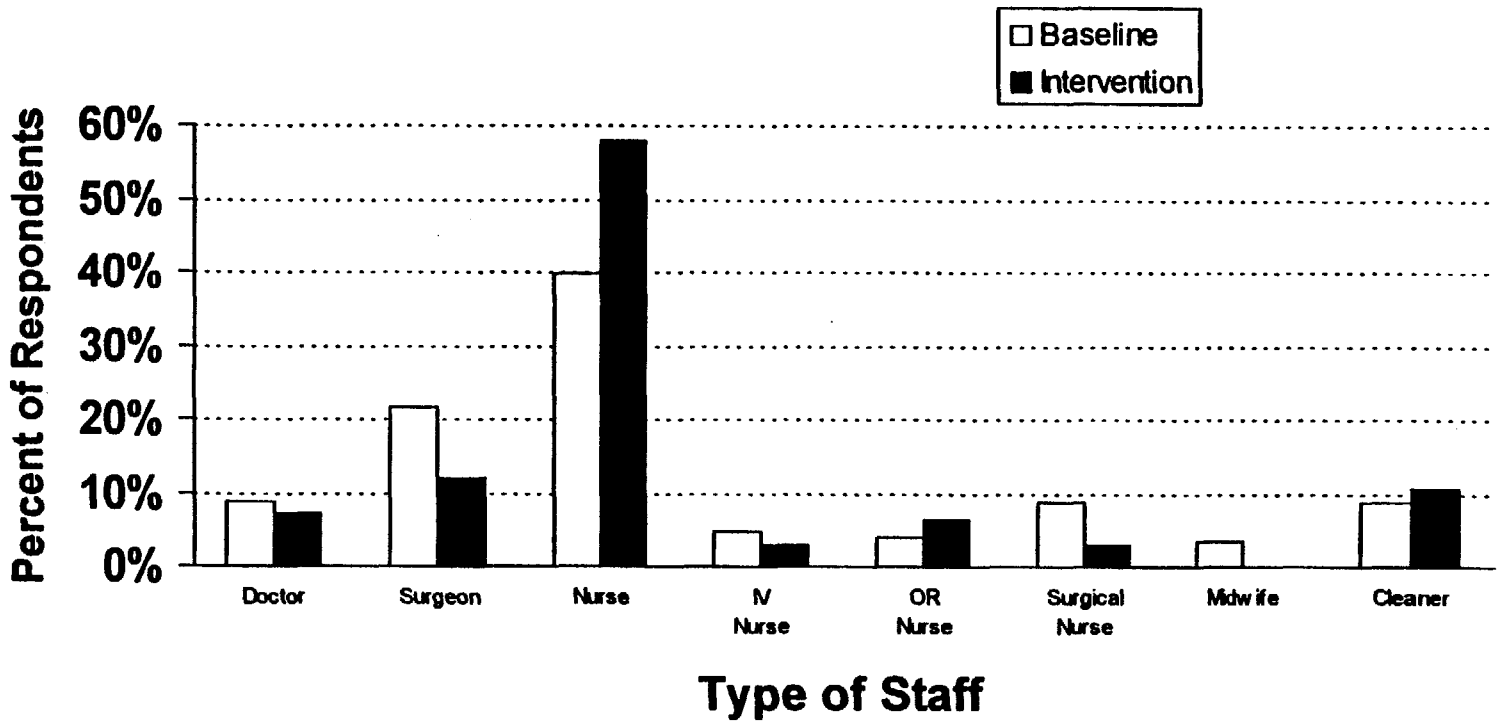


Figure 5. Average Number of Glove Uses in Intervention Period by Staff Type (per person-week)

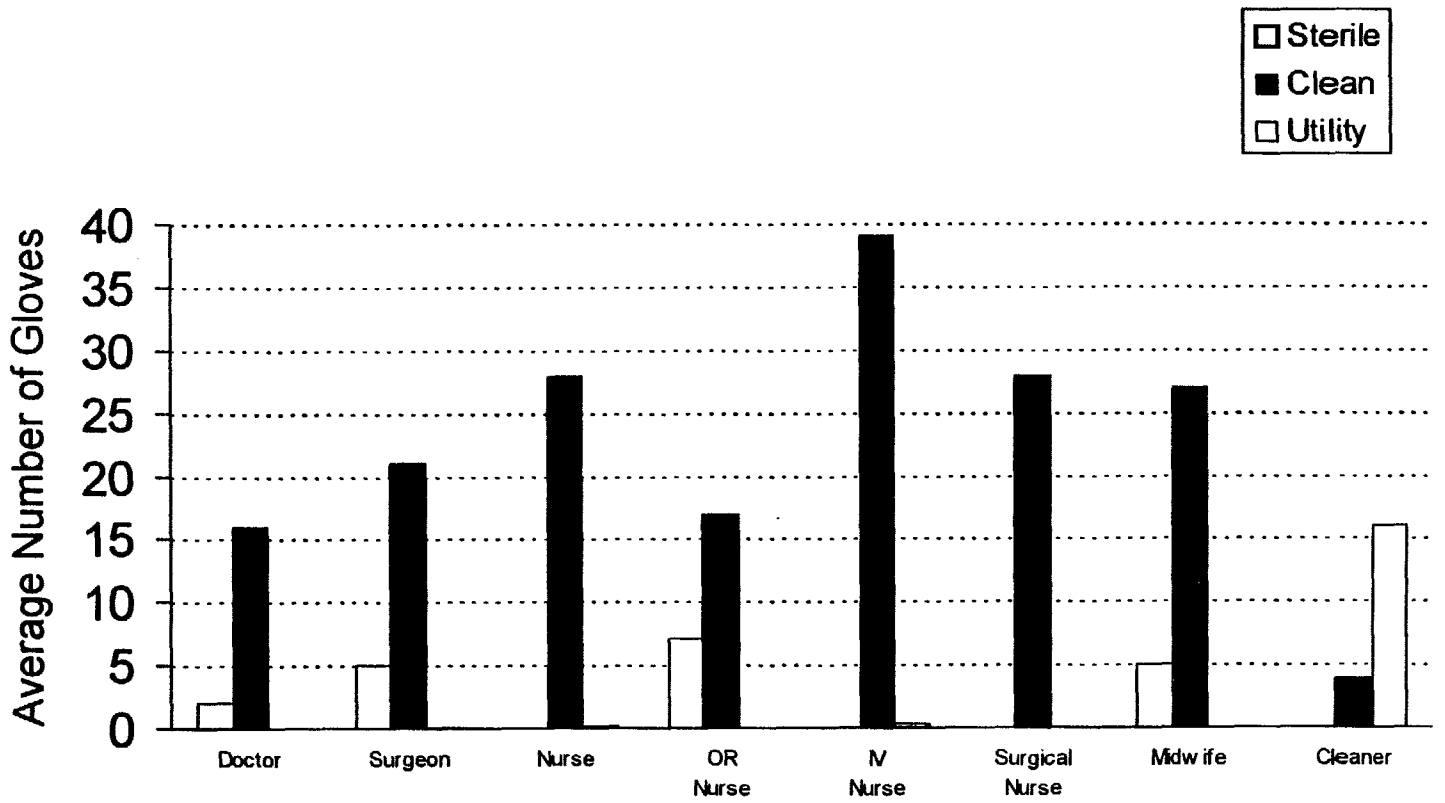


Figure 6. Average Number of Glove Uses in Intervention Period by Department (per person-week among actual users)

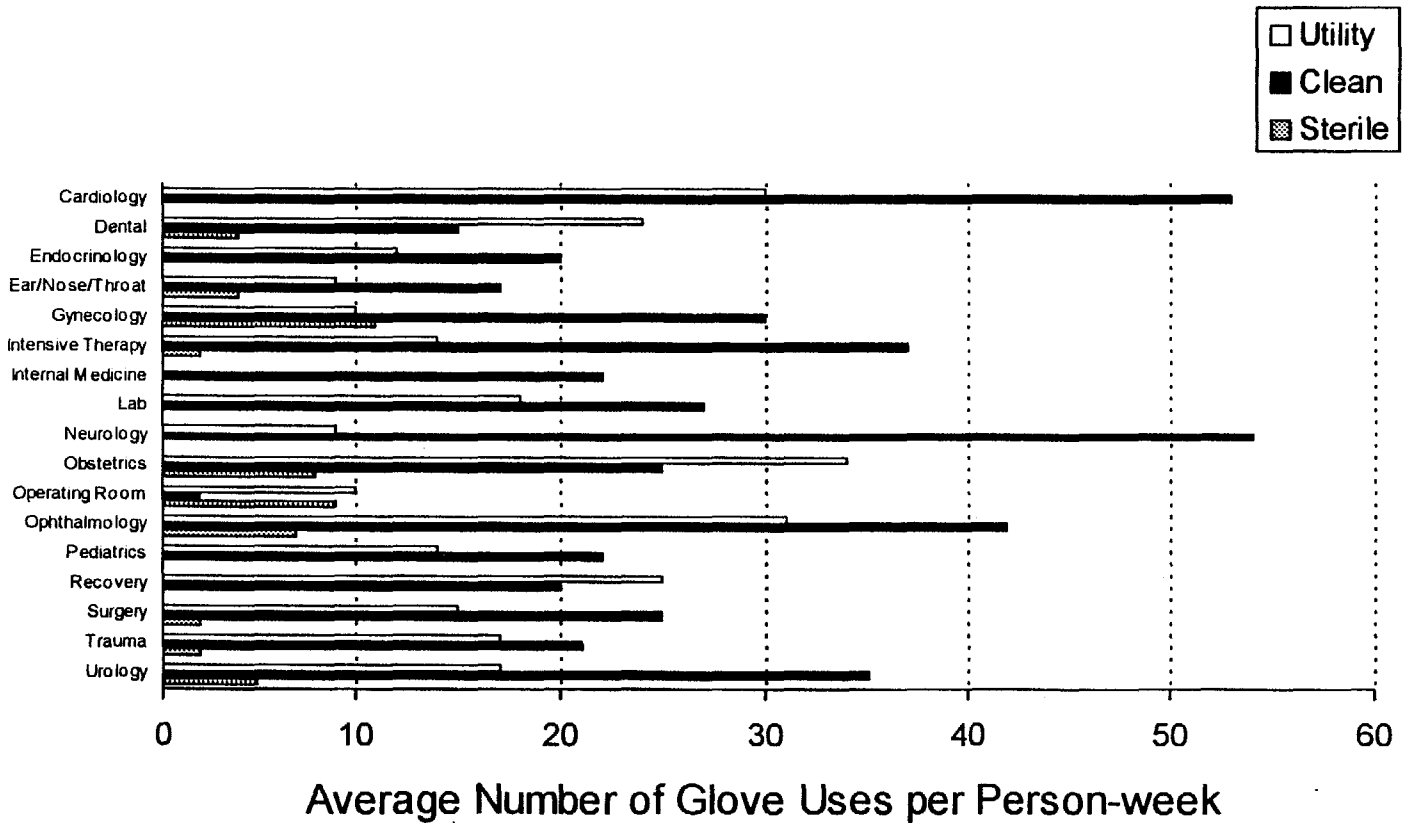


Figure 7. Average Number of Times Gloves Were Needed but Unavailable per Person-Week (Baseline Period)

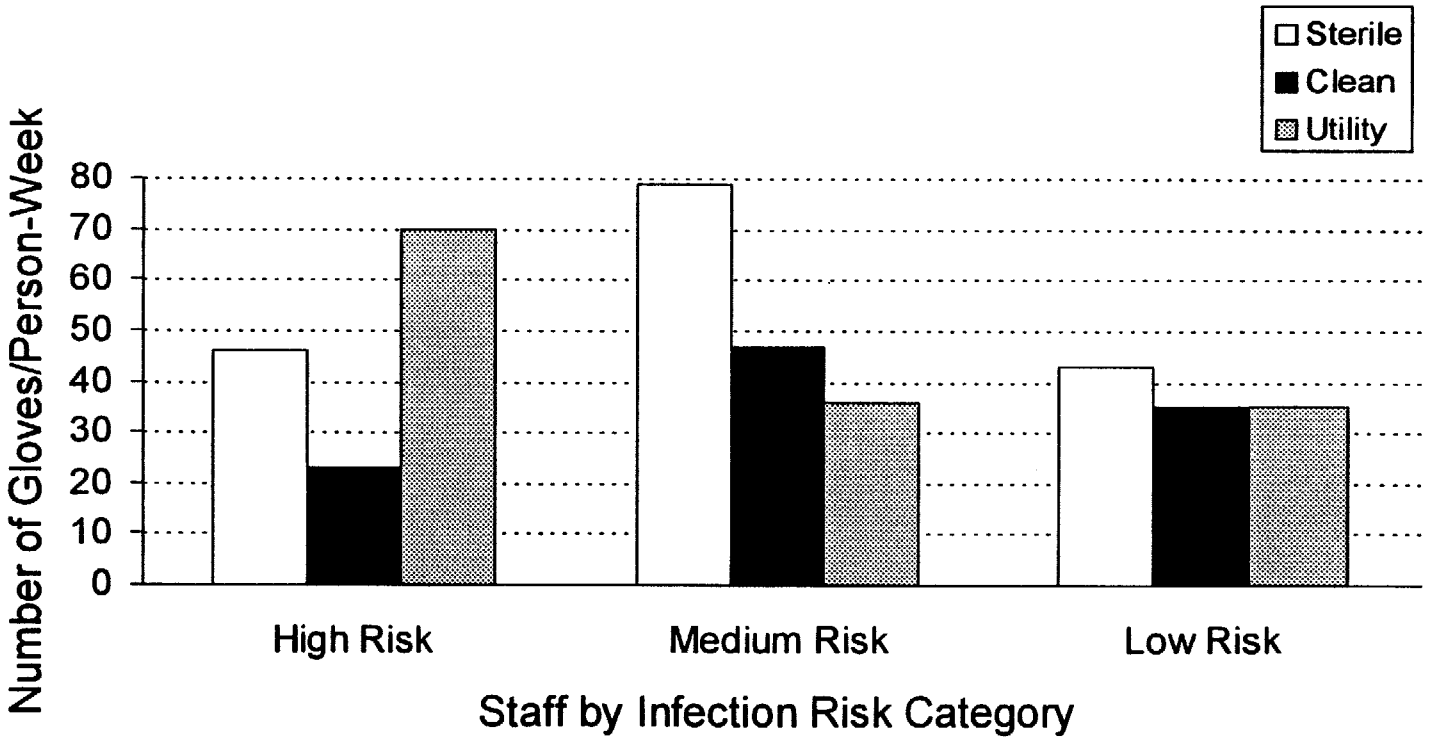
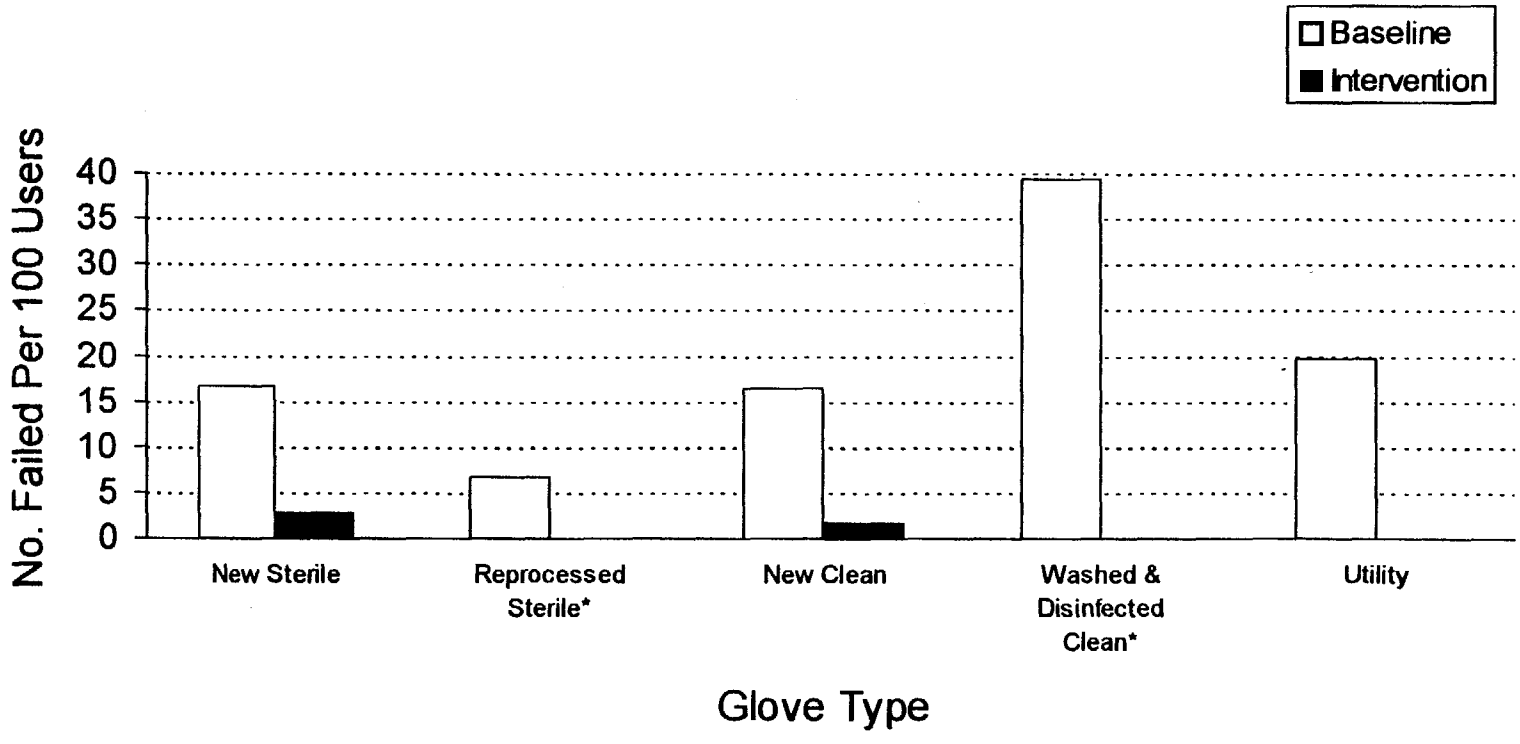
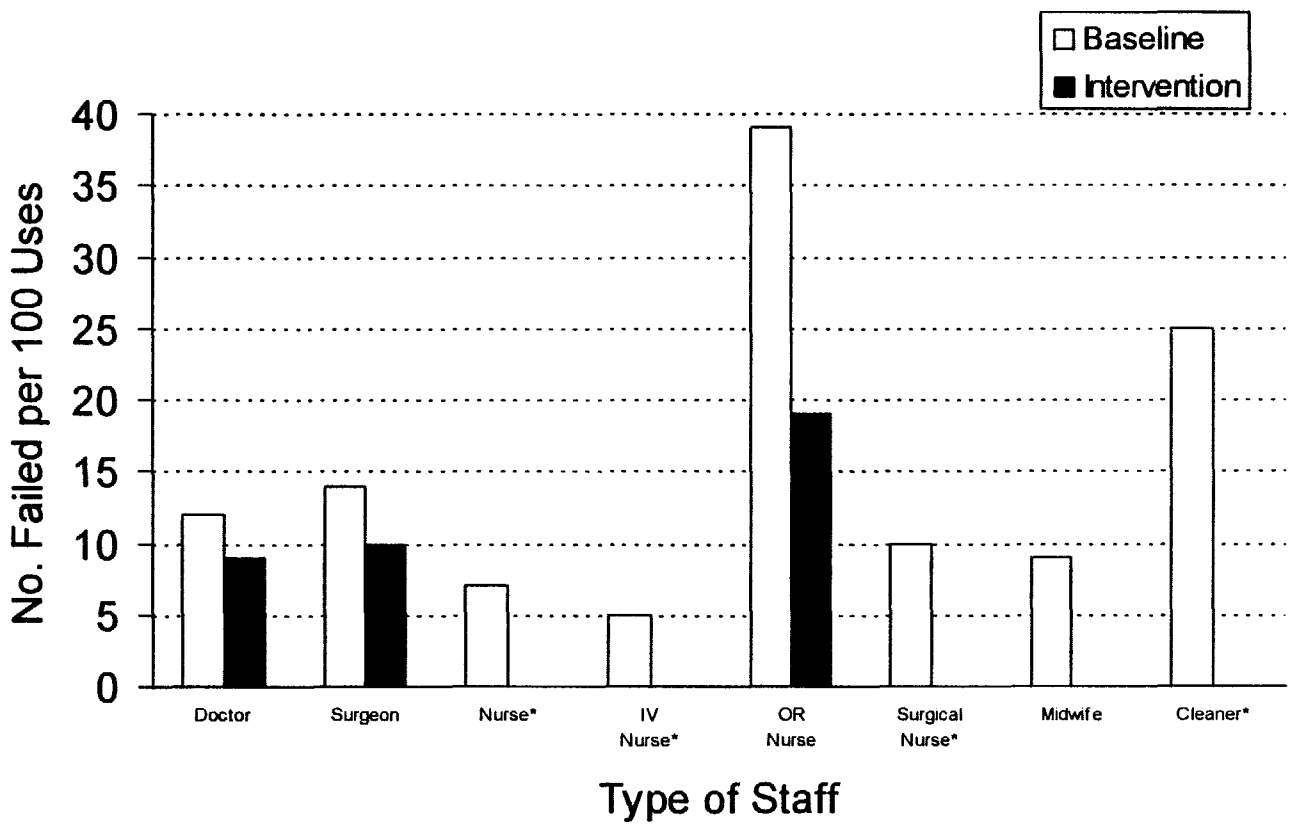


Figure 8. Overall Glove Failure Rates



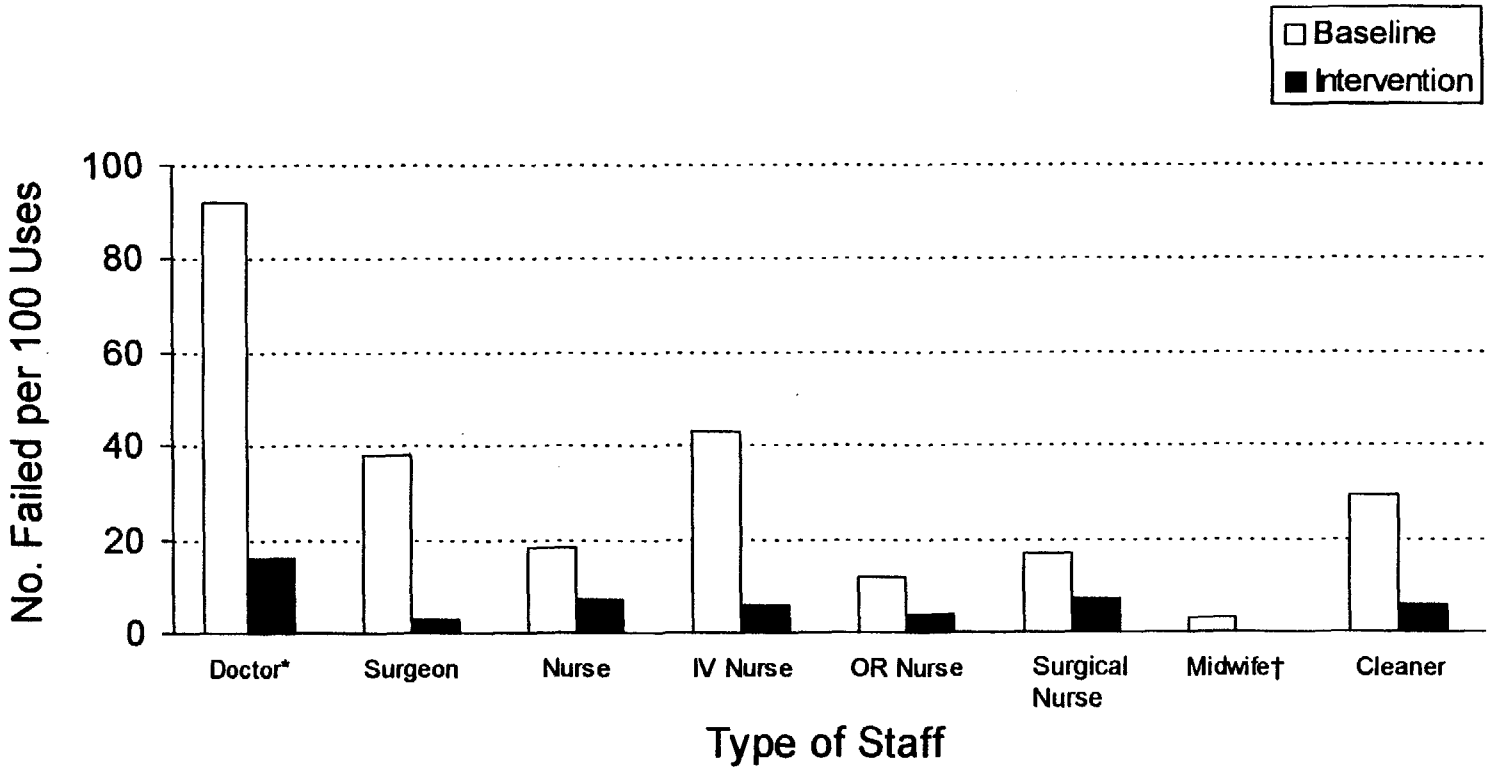
* Not used in Intervention Period

Figure 9. Sterile Glove Failure Rates Among Different Types of Staff



* Sterile gloves not used in Intervention period

Figure 10. Clean Glove Failure Rates among Different Types of Staff



* Based on 2 doctors and 12 washed and disinfected gloves

† Clean gloves not used in Baseline Period

Figure 11. Sterile Glove Failure Rates among Staff with Different Risk of Infection Exposure

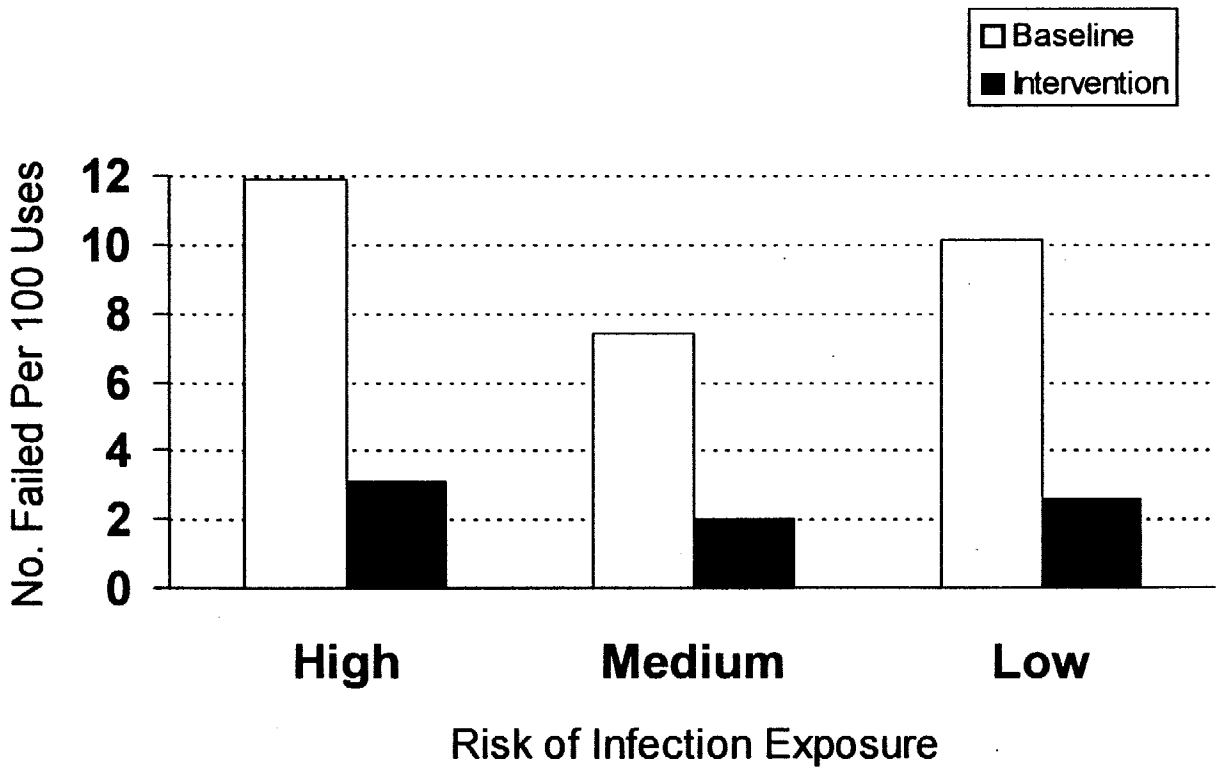


Figure 12. Clean Glove Failure Rates among Staff with Different Risk of Infection Exposure

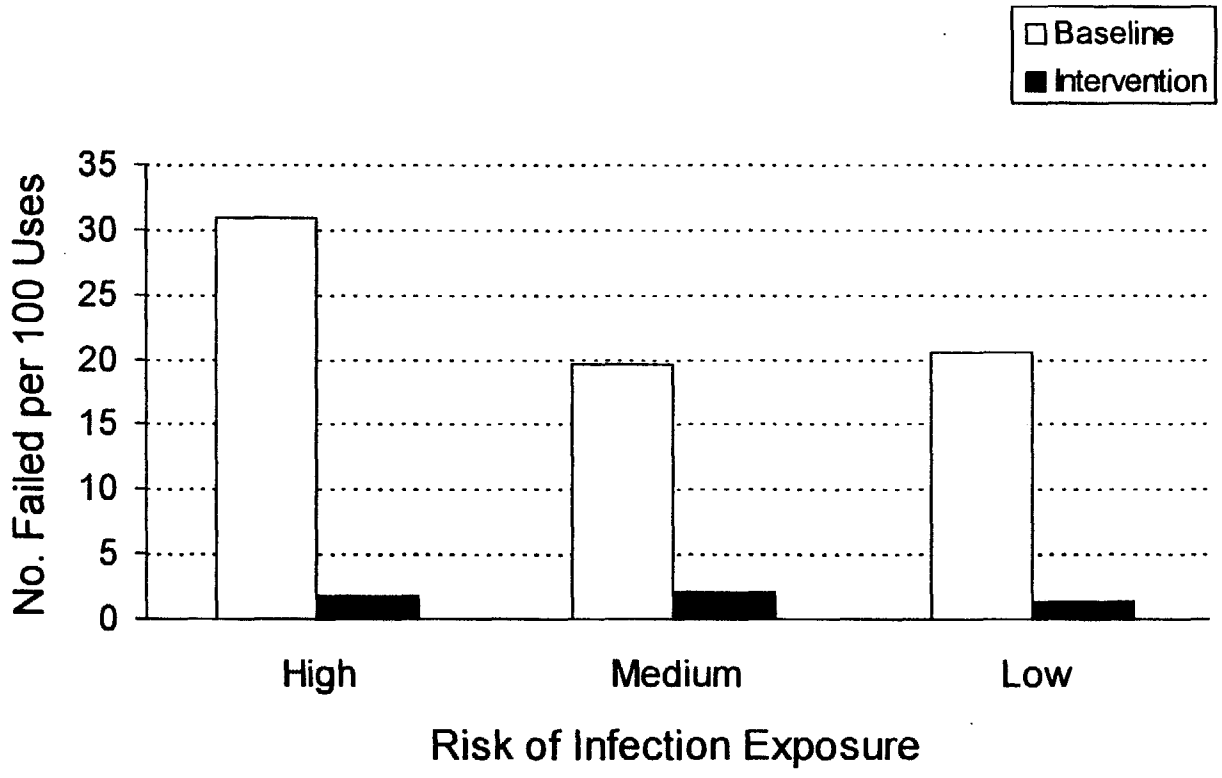


Figure 13. Types of Glove Failures (Baseline Period)

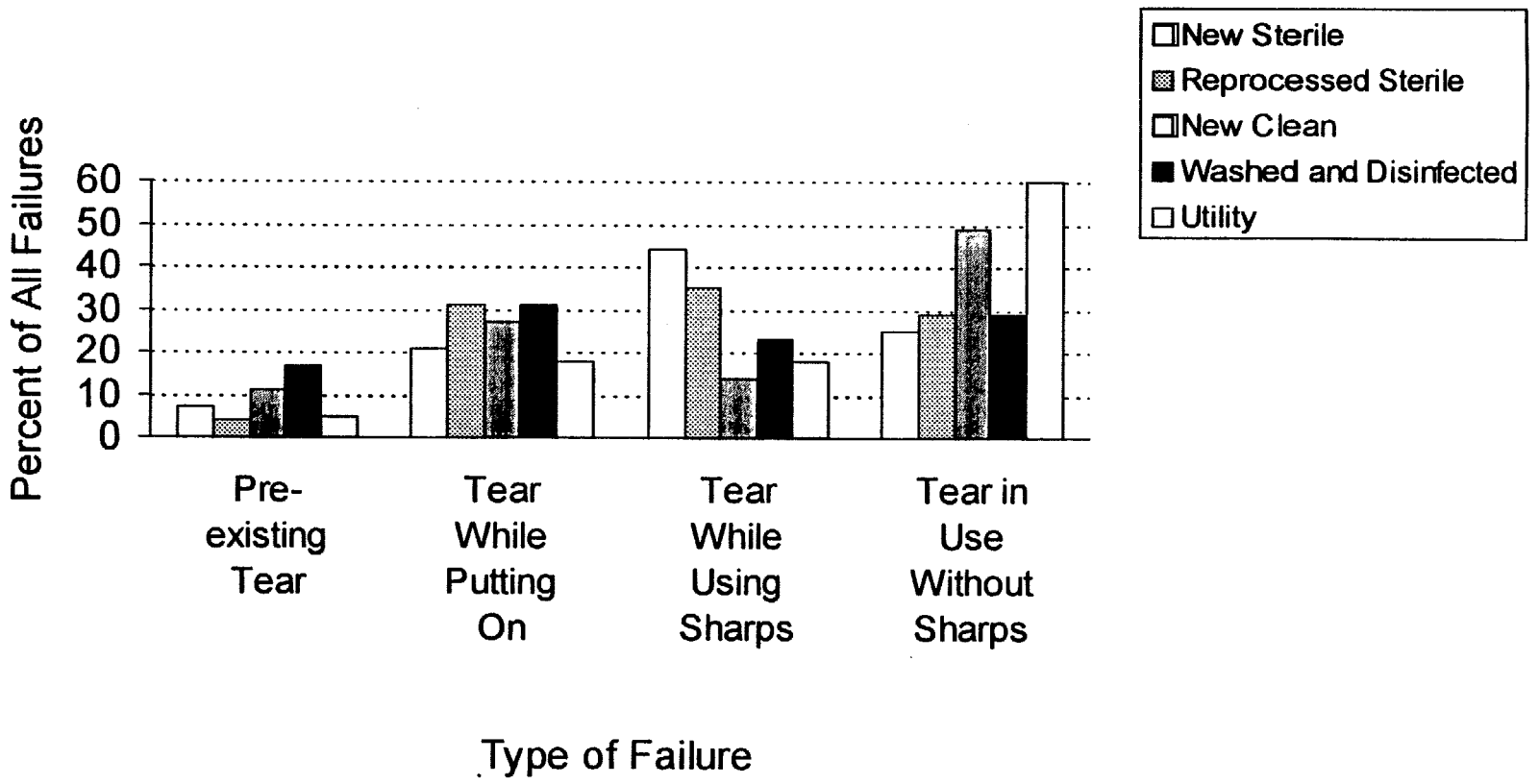


Figure 14. Types of Glove Failures Among Sterile Glove Users in Different Exposure Risk Groups

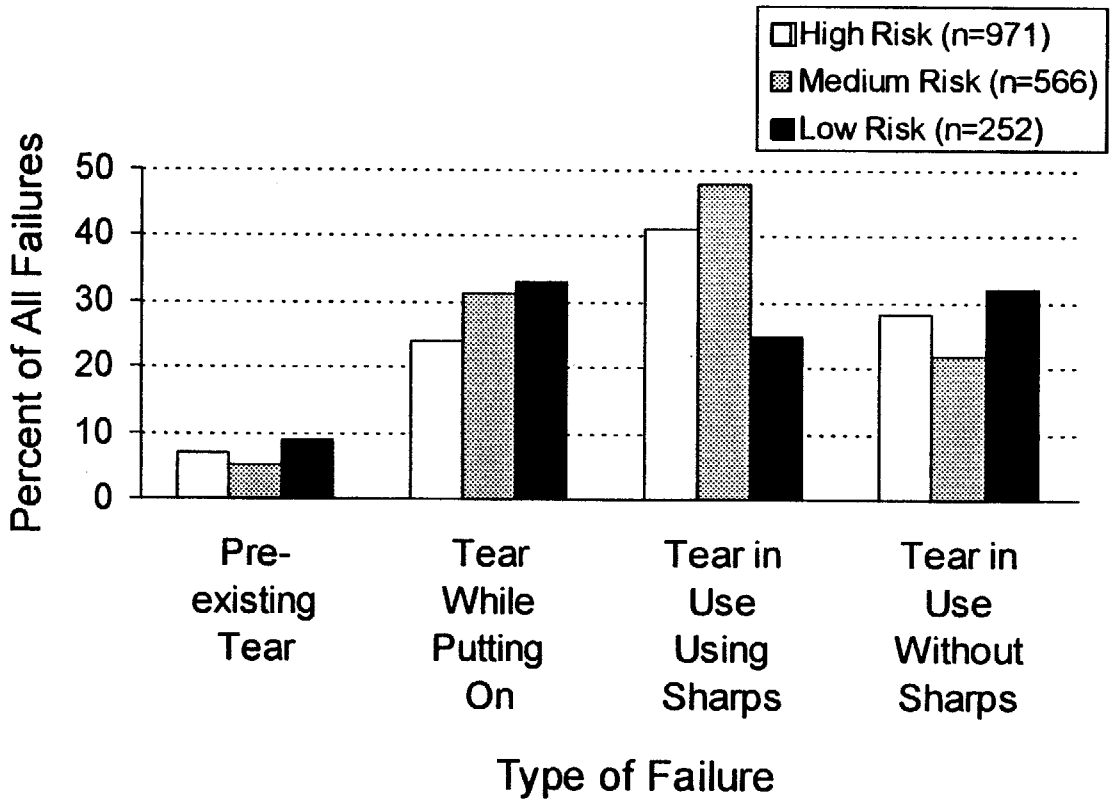


Table 1. Use of Gloves Before and During Intervention

	All Sterile	All Clean	Utility[1]
Number of person-weeks of glove use reported[2]			
Baseline (1 month)	542	155	82
Intervention (3 months)	675	2,658	637
Number of gloves used (taken fresh)			
Baseline	3,169	528	--
Intervention	3,650	23,726	--
Average number of gloves used (per person-week)			
Baseline	5.8	3.4	--
Intervention	5.4	8.9	--
Number of occasions when gloves were used (fresh or re-used)			
Baseline	17,351	1,706	1,229
Intervention	3,650	71,010	15,315
Average number of occasions when gloves were used (per person-week)			
Baseline	32.0	11.0	15.0
Intervention	5.4	26.7	24.0

[1] Exact numbers of gloves available at beginning of baseline and still functional at end of intervention could not be obtained to calculate number "consumed."
[2] Among actual users.

Table 2. Ratings of Glove Performance for Various Uses by Survey Respondents

	Functions Well Always (%)	Functions Well Mostly (%)	Fails Often (%)	Fails Mostly (%)	Incompatible with Task (%)
Pre-intervention					
New sterile surgical	787 (95.0)	41 (5.0)	--	--	--
Reprocessed sterile surgical	2 (0.7)	25 (8.3)	163 (54.2)	111 (36.9)	--
New clean exam	83 (62.9)	48 (36.4)	1 (0.7)	--	--
Washed, disinfected	2 (0.9)	3 (1.4)	108 (49.1)	104 (47.3)	3 (1.4)
Utility	0	2 (8.7)	21 (91.3)	--	--
Post-intervention					
Sterile surgical	231 (97.1)	7 (2.9)	--	--	--
Clean exam	234 (79.3)	58 (19.7)	3 (1.0)	--	--
Utility	127 (97.7)	3 (2.3)	--	--	--

Table 3. Reasons Given for Not Being Able to Use Gloves Even Though Indicated (Pre-intervention)

	Number (%)*	
New gloves not available	106	(98.1)
Reprocessed gloves not available	84	(77.8)
Available gloves do not fit well	89	(82.4)
Available gloves in poor condition	59	(54.6)
Available gloves not suited to task	60	(55.6)
Personal preference not to wear gloves	0	(0)

* More than one answer could be checked.

Table 4. Reported Use of Glove Types Pre- and Post-Intervention

	Baseline (%)		Post-Intervention (%)	
New Sterile Surgical	120	(70.2)	36	(25.7)
Reprocessed Sterile	135	(78.9)	0	
New Clean Exam	61	(35.7)	100	(71.4)
Washed & Disinfected	88	(51.5)	0	
Utility	7	(4.1)	38	(27.1)

Attachment 19

Total Insulin and Syringe Distribution

INSULIN:

Kiev Institute of Endocrinology	1,569
Kirovograd (7/1/96)	400
Ivano-Frankivsk (2/95)	1,309
Sumy (2/95)	798
Total vials:	4,076

Total vials of confirmed distributed insulin	93,911
Total vials of shipped insulin	95,500
Percentage confirmed distributed	98.34%
Percentage presumed lost	1.66%

SYRINGES:

Total syringes confirmed distributed to oblasts	549,638
Lilly donation	191,000
Terumo P.O. 95-0003	160,000
Terumo P.O. 96-0001	208,000

Total of shipped syringes	559,000
Percentage confirmed distributed	98.33%
Percentage presumed lost	1.67%

RECEIPT
of insulin and concomitant supplies confirmed by oblasts

№ OH	Oblast/ City	First Distribution								
		NPH insulin vials			R insulin vials			Syringes		
		Received	Distributed	In stock	Received	Distributed	In stock	Received	Distributed	In stock
1	Vinnitskaya	148	148	0	133	133	0	1300	1300	0
2	Volynskaya	356	356	0	192	30	162	1738	1738	0
3	Luganskaya	1266	1266	0	682	682	0	6200	6200	0
4	Dnepropetrovskaya	1081	1081	0	582	582	0	5280	5280	0
5	Donetskaya	441	441	0	238	238	0	2156	2156	0
6	Zhitomirskaya	410	410	0	221	221	0	2100	2100	0
7	Zakarpatskaya	270	270	0	146	146	0	1320	1320	0
8	Zaporozhskaya	676	676	0	344	344	0	3300	3300	0
9	Ivano-Frankovskaya	716	716	0	386	386	0	3200	3200	0
10	Kievskaya	631	631	0	340	340	0	3100	3100	0
11	Kirovogradskaya	550	550	0	300	300	0	2840	2840	0
12	Krymskaya	923	923	0	497	497	0	4600	4600	0
13	Lvovskaya	946	946	0	509	509	0	4620	4620	0
14	Nikolayevskaya	509	509	0	274	274	0	2500	2500	0
15	Odesskaya	324	324	0	175	175	0	1600	1560	40
16	Poltavskaya	559	559	0	301	301	0	2728	2728	0
17	Rovenskaya	401	401	0	210	210	0	1924	1924	0
18	Sumskaya	509	509	0	289	289	0	3200	3200	0
19	Ternopolskaya	475	475	0	255	255	0	2400	2400	0
20	Kharkovskaya	565	565	0	1050	1050	0	5200	5200	0
21	Khersonskaya	261	261	0	141	141	0	1300	1300	0
22	Khmelnitskaya	527	527	0	284	284	0	2600	2600	0
23	Cherkasskaya	477	477	0	257	257	0	2400	2400	0
24	Chernovitskaya	365	365	0	196	196	0	1800	1800	0
25	Chernigovskaya	378	378	0	203	203	0	1836	1836	0
26	Kiev City	1270	1270	0	684	684	0	6300	6300	0
27	Sevastopol City	185	185	0	99	99	0	1000	1000	0
	TOTALS	15219	15219	0	8968	8806	162	78542	78502	40

RECEIPT
of insulin and concomitant supplies confirmed by oblasts

MOH	Oblast/ City	Second Distribution								
		NPH insulin vials			R insulin vials			Syringes		
		Received	Distributed	In stock	Received	Distributed	In stock	Received	Distributed	In stock
1	Vinnitskaya	752	752	0	405	405	0	2700	2700	0
2	Volynskaya	356	349	7	192	121	71	9700	9100	600
3	Luganskaya	1099	1099	0	592	592	0	5400	5400	0
4	Dnepropetrovskaya	1297	191	1106	699	465	234	6300	2409	3891
5	Donetskaya	929	929	0	1116	1116	0	3400	3400	0
6	Zhitomirskaya	230	230	0	124	124	0	5400	5400	0
7	Zakarpatskaya	270	270	0	196	196	0	1300	1300	0
8	Zaporozhskaya	676	608	68	364	338	26	3300	3080	220
9	Ivano-Frankovskay	716	716	0	386	386	0	3200	3200	0
10	Kievskaya	833	768	65	449	384	65	4100	4100	0
11	Kirovogradskaya	577	577	0	310	310	0	2816	2816	0
12	Krymskaya	931	931	0	486	486	0	4500	4500	0
13	Lvovskaya	757	757	0	407	407	0	3700	3700	0
14	Mikolayevskaya	509	509	0	274	274	0	2500	2500	0
15	Odesskaya	324	248	76	175	172	3	1600	1475	125
16	Poltavskaya	559	559	0	301	301	0	2700	2700	0
17	Rovenskaya	302	302	0	163	163	0	1500	1500	0
18	Sumskaya	500	500	0	319	319	0	2400	2400	0
19	Ternopolskaya	554	514	40	298	262	36	2700	2320	380
20	Kharkovskaya	1050	1050	0	565	565	0	5100	5100	0
21	Khersonskaya	266	266	0	143	143	0	1298	1298	0
22	Khmelnitskaya	527	527	0	287	287	0	2800	2800	0
23	Cherkasskaya	477	477	0	257	257	0	2332	2332	0
24	Chernovitskaya	365	365	0	196	196	0	1800	1800	0
25	Chernigovskaya	419	273	146	226	197	29	2000	1640	360
26	Kiev City	1333	1333	0	718	718	0	6500	6500	0
27	Sevastopol City	185	185	0	99	99	0	902	902	0
	TOTALS	16793	15285	1508	9747	9283	464	91748	86172	5576

RECEIPT
of insulin and concomitant supplies confirmed by oblasts

№ OH	Oblast/ City	Third Distribution								
		NPH insulin vials			R insulin vials			Syringes		
		Received	Distributed	In stock	Received	Distributed	In stock	Received	Distributed	In stock
1	Vinnitskaya	1064	465	599	510	408	102	13100	6100	7000
2	Volynskaya	847	603	244	393	219	174	8800	6170	2630
3	Lugantskaya	1501	1400	101	745	700	45	22200	12000	10200
4	Dnepropetrovskaya	1532	0	1532	825	0	825	32100	0	32100
5	Donetskaya	1116	1085	31	501	441	60	36000	34930	1070
6	Zhitomirskaya	396	396	0	231	231	0	10800	10800	0
7	Zakarpatskaya	354	167	187	317	42	275	7400	3720	3680
8	Zaporozhskaya	0			0			0		
9	Ivano-Frankovskaya	1028	966	62	400	367	33	12500	12210	290
10	Kievskaya	1312	1026	286	590	442	148	16300	12588	3712
11	Kirovogradskaya	847	419	428	393	170	223	8800	4200	4600
12	Krymskaya	1656	1060	796	721	721	0	21350	11250	10100
13	Lvovskaya	1887	483	1404	738	283	455	22000	3205	18795
14	Nikolayevskaya	829	63	766	320	249	71	9400	231	9169
15	Odesskaya	1032	642	390	493	321	172	12000	4921	7079
16	Poltavskaya	900	585	315	461	252	209	11400	8050	3350
17	Rovenskaya	776	608	158	350	304	46	7200	6180	1020
18	Sumskaya	1066	592	474	561	444	117	7400	5800	1600
19	Ternopolskaya	971	498	473	473	261	212	11900	3690	8210
20	Kharkovskaya	1663	248	1415	806	541	265	24500	4850	19650
21	Khersonskaya	1239	453	786	585	256	329	9098	8413	685
22	Khmelnitskaya	626	0	626	337	0	337	13500	0	13500
23	Cherkasskaya	956	167	789	452	198	254	8800	960	7840
24	Chernovitskaya	288	205	83	155	127	38	6600	4065	2535
25	Chernigovskaya	541	253	288	291	154	137	11100	5380	5720
26	Kiev City	1646	632	1014	869	549	320	30400	13750	16650
27	Sevastopol City	194	96	98	104	88	16	4700	2950	1750
	TOTALS	26467	13112	13345	12621	7768	4863	379348	186413	192935

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RECEIPT
of insulin and concomitant supplies confirmed by oblasts

MOH	Oblast/ City	Total Distribution								
		NPH insulin vials			R insulin vials			Syringes		
		Received	Distributed	In stock	Received	Distributed	In stock	Received	Distributed	In stock
1	Vinnitskaya	1964	1365	599	1048	946	102	17100	10100	7000
2	Volynskaya	1559	1308	251	777	370	407	20236	17006	3230
3	Luganskaya	3866	3765	101	2019	1974	45	33800	23600	10200
4	Dnepropetskaya	3910	1272	2638	2106	1047	1059	43680	7689	35991
5	Donetskaya	2486	2455	31	1855	1795	60	41556	40486	1070
6	Zhitomirskaya	1036	1036	0	576	576	0	18300	18300	0
7	Zakarpatskaya	894	707	187	659	384	275	10020	6340	3680
8	Zaporozhskaya	1352	1284	68	708	682	26	6600	6380	220
9	Ivano-Frankovskay	2460	2398	62	1172	1139	33	18900	18610	290
10	Kievskaya	2776	2425	351	1379	1166	213	23500	19788	3712
11	Kirovogradskaya	1974	1546	428	1003	780	223	14456	9856	4600
12	Krymskaya	3710	2914	796	1704	1704	0	30450	20350	10100
13	Lvovskaya	3590	2186	1404	1654	1199	455	30320	11525	18795
14	Nikolayevskaya	1847	1061	786	868	797	71	14400	5231	9169
15	Odesskaya	1680	1214	466	843	668	175	15200	7956	7244
16	Poltavskaya	2018	1703	315	1063	854	209	16828	13478	3350
17	Rovenskaya	1470	1311	158	723	677	46	10624	9604	1020
18	Sumskaya	2075	1601	474	1169	1052	117	13000	11400	1600
19	Ternopolskaya	2000	1487	513	1026	778	248	17000	8410	8590
20	Kharkovskaya	3276	1863	1415	2421	2156	265	34800	15150	19650
21	Khersonskaya	1766	980	786	869	540	329	11696	11011	685
22	Khmelnitskaya	1680	1054	626	908	571	337	18700	5200	13500
23	Cherkasskaya	1910	1121	789	966	712	254	13532	5692	7840
24	Chernovitskaya	1018	935	83	547	519	38	10200	7665	2535
25	Chernigovskaya	1338	904	434	720	554	166	14938	8858	6080
26	Kiev City	4249	3235	1014	2271	1951	320	43200	26550	16650
27	Sevastopol City	564	466	98	302	286	16	6602	4852	1750
	TOTALS	58479	43616	14863	31356	25877	5489	549638	351087	198551

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Attachment 20

Results of Telephone Survey to Parents of Diabetic Children

Survey interviewers should give brief background of project and purpose of the interview. The following questions are to be asked to the parent/guardian of a child (under age 18) with diabetes:

Name of patient: _____

Name of parent/guardian: _____

Address (including Oblast): _____

_____ Phone number _____

1. How did you first hear of the PATH Diabetes Project? _____

2. I would like to ask you a few questions about the insulin provided by the project:
   a) What date(s) did you receive insulin from the project? (month/year) ____ ____ ____ ____ ____
   b) Did you receive a transfer form with the insulin "Registry of Transfer from the Raion to the Patient"? 71 (100%) Yes
   c) Was more than half of the year's supply given to you at once? 61 (85.9%) No 10 (14.1%) Yes
   d) If no, was it provided in small portions on regular dates? _____ No _____ Yes
   e) Have you used up the insulin provided by the project? 26 (36.6%) No 45 (63.4%) Yes
3. Did you experience any problems with getting the PATH insulin? 67 (94.4%) No 4 (5.6%) Yes
   (What? Could not receive on time)
4. Did you experience any problems using the PATH insulin? 69 (97.2%) No 2 (2.8%) Yes
   (What? Insulin was not appropriate for child's organism)
5. Did you receive adequate quantities of needles and syringes? 1 (1.4%) No 70 (98.6%) Yes
6. Did you get the glucose strips and the ketone strips? _____ No 71 (100%) Yes
7. Did you use them as needed? 9 (12.7%) No 62 (87.3%) Yes
8. a) Have you received the Travis manual? 35 (49.3%) No 36 (50.7%) Yes
   b) Has your child read parts of it? 6 (16.7%) No 30 (83.3%) Yes
   c) Have you read it? 3(8.3%) No 33 (91.7%) Yes
9. Did your doctor use the Travis manual in teaching you about diabetes? 4 (11.1%) No 32 (88.9%) Yes
   If yes, how: Talk-explanation
10. Would you say the Travis manual was (0) not very helpful, (3 [8.3%]) somewhat helpful, or (33 [91.7%]) very helpful to you?
11. Would you say overall that the Travis manual was (0) not very easy to understand, (6 [16.7%]) somewhat easy, or (30 [83.3%]) very easy to understand?
12. Would you say overall that the Travis manual was (0) not very easy for your child to understand, (6 [16.7%]) somewhat easy, or (24 [66.6%]) very easy?
13. What is the age of your child? ____ years

"We would like some information about how your child is doing, and about your experiences with diabetes. The information will be confidential and will be released only anonymously to organizations which may in the future assist children with diabetes in Ukraine. May I ask you a few more questions?" If yes, then ask the following questions. If no, thank the participant for their time.

14. How is the health of your child currently? Good 62 (87.3%)
    Not good 9 (12.7%)

15. Has he/she been hospitalized during the past year? If so, why? Yes 30 (42.3%)

    Reason - observation and tests related to diabetes.

16. Has your child had insulin reactions (hypoglycemia) in the past year? Hyperglycemia with ketoacidosis?

    Yes 28 (39.4%)

17. Has your child had other health problems this past year? If yes, please describe:

    Yes 34 (47.9%)

18. Were these problems related to diabetes? Yes 21 (29.6%)

19. Overall, how has the insulin provided by the PATH Diabetes Project affected your child's health?

    Positively 66 (93%)

20. What are the major problems with getting sufficient insulin for your child? (If more than one, number by importance, e.g., "1" = most important, "2" next, etc.)

    2 Cost 14 (19.7%) 3 Transportation to source of insulin 5 (7%)

    1 Availability 29 (40.8%) _ Changing needs for potency of insulin

    _ Other (what? 27 (38%) did not have problems)

21. Is insulin (14 [19.7%]) usually difficult to obtain, (29 [40.8%]) occasionally difficult, or (28 [39.4%]) generally easily available when you try to obtain it in your area?

22. a) What do you pay for insulin for your child currently? (Try to specify cost per vial of what type and size)

    Do not buy 31 (43.7%)

    Buy 40 (56.3%) - from 8 to 41 hryvna per bottle

    b) What kind of insulin does your child ordinarily use? (Brand, country of origin if known.)

    In general, Actrapid (Novo Nordisk, Denmark)

23. Has your family been in contact in the past year with organizations that are involved in diabetes? What are their names?

    Yes 6 (8.5%)

24. In your view, what are the most critical needs for families such as yours which have a child with diabetes?

    a) Means of self-monitoring of blood sugar at home (test-strips, reading devices)

    b) Regular yearly health improvement (sanatoria, health camps)

    c) Regular supply of good quality insulin

    d) Provision of necessary medication as a benefit

    e) Regular supply of special diet product for children with diabetes and, also, special sweets

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f) Timely payment of children pension (37 hryvna)

g) Improvement of service provided by endocrinologists, especially in rural areas

h) Improvement of social protection of children with diabetes

i) Special physical education programs at school for children with diabetes

Thank the participant for their time and assistance.

*Date of interview:*_____

*Interviewer:*_____

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Attachment 21

Travis Manual Distribution

Insulin Manual Distribution
10/18/96 FINAL

	No. of Children 1996 3rd Distribution	No. of Cases required	No. of Cases Proposed	No. of manuals proposed	No. of extra manuals	Percentage extra manuals	Total weight of cases/kg	Total cu. meter of cases
Vinnitskaya	136	8.00	10	170	34	25.0%	116	0.2
Volynskaya	88	5.18	7	119	31	35.2%	81.2	0.14
Luganskaya	233	13.71	17	289	56	24.0%	197.2	0.34
Dnepropetskaya	340	20.00	24	408	68	20.0%	278.4	0.48
Donetskaya	386	22.71	28	476	90	23.3%	324.8	0.56
Zhitomirskaya	51	3.00	4	68	17	33.3%	46.4	0.08
Zakjarpatskaya	73	4.29	6	102	29	39.7%	69.6	0.12
Zaporozhkaya	164	9.65	12	204	40	24.4%	139.2	0.24
Ivano-Frankovskaya	128	7.53	10	170	42	32.8%	116	0.2
Kievskaya	169	9.94	13	221	52	30.8%	150.8	0.26
Kirovogradskaya	88	5.18	7	119	31	35.2%	81.2	0.14
Krymskaya	223	13.12	16	272	49	22.0%	185.6	0.32
Lvovskaya	230	13.53	17	289	59	25.7%	197.2	0.34
Nikolayevskaya	95	5.59	7	119	24	25.3%	81.2	0.14
Odesskaya	129	7.59	10	170	41	31.8%	116	0.2
Poltavskaya	116	6.82	9	153	37	31.9%	104.4	0.18
Rovenskaya	70	4.12	6	102	32	45.7%	69.6	0.12
Sumskaya	123	7.24	9	153	30	24.4%	104.4	0.18
Ternopolskaya	121	7.12	9	153	32	26.4%	104.4	0.18
Kharkovskaya	258	15.18	19	323	65	25.2%	220.4	0.38
Khersonskaya	58	3.41	5	85	27	46.6%	58	0.1
Khmelnitskaya	139	8.18	11	187	48	34.5%	127.6	0.22
Cherkasskaya	112	6.59	9	153	41	36.6%	104.4	0.18
Chernovitskaya	64	3.76	5	85	21	32.8%	58	0.1
Chernigovskaya	120	7.06	10	170	50	41.7%	116	0.2
Kiev City	321	18.88	24	408	87	27.1%	278.4	0.48
Sevastopol City	43	2.53	4	68	25	58.1%	46.4	0.08
TOTAL	4078	239.88	308.00	5236	1158	28.4%	3572.8	6.16

	Manuals	Cases
Total manuals ordere	6018.00	354
less manuals at PATH Seattle	34.00	2
less manuals shipped air 8/96	102.00	6
Total manuals shipped ocean	5882.00	346
Less manuals for oblasts	5236.00	308
Available for third parties	646.00	38
• Nickberg	51.00	3
• KIEM	85.00	5
• Skrypka	340.00	20
• PATH Kiev	43.00	2.5
• Lilly	8.00	0.5
• Kiev Childrens Hosp	85.00	5
• Kharkiv Childrens Home	34.00	2
Total	646.00	38

Attachment 22

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Diphtheria

GOAL*: Terminate the diphtheria epidemic in Ukraine
Objective: 90% Immunization coverage of adult population by late 1996

(assumption: 90% immunization of adults will terminate the epidemic, provided that pediatric immunization is adequate)

PATH OBJECTIVES	PATH OUTCOMES	INDICATORS	ACHIEVEMENTS: May 1, 1994 - Dec. 30, 1997
A.1 Deliver USAID commitment in Td vaccine to Ukraine	• Remaining 8.2 million doses delivered by November 1995	• XX doses shipped	• 100% shipped, July 1994 - December 1995
	• Additional 10 million doses ordered and delivered according to mass campaign plan	• XX doses shipped	• 100% shipped, December 1995 - May 1996
A.2 Distribute vaccine according to plan	• Td vaccine stocks inventoried	• XX doses on hand at oblast level as of __ date	• Nine million doses in stocks at Obukhov, for mass campaigns in May - June 1996. By end of September 1996, 100% distributed.
	• Current Td distribution spot monitored	• XX doses on hand at raion level as of __ date (reference periodic reports)	• Information on vaccine stock at oblast and raions was spot monitored in September and November 1996.
A.3 Support efforts to maintain cold chain standards	• Integrity of cold chain assured during procurement and distribution through use of temperature monitors	• XX doses of vaccine within acceptable cold chain standards (2-8°C)	• All PATH/USAID shipments were safely delivered to Obukhov cold stores with cold chain integrity confirmed by electronic cold monitoring

* Shared goal - PATH, MOH, USAID, WHO, CDC, European Community, Canadian Government, Red Cross, other donors and PVOs

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PATH OBJECTIVES	PATH OUTCOMES	INDICATORS	ACHIEVEMENTS: May 1, 1994 - Dec. 30, 1997
	• Local MOH staff responsible for cold chain maintenance provided with training	• #s of oblasts and of attendees trained, # of oblasts represented by those attending	• Formal training provided August 1994. From project inception, 14 oblast central cold rooms visited and training provided.
	• Cold chain activity monitored at oblast level storage sites due to temperature recorders	• Minimum of 5 spot checks at oblast storage sites	• 100% complete; all oblasts monitoring cold room temperatures. At end of each month, records from 27 oblasts sent to Ukrvaccina.
		• 27 TTMs and software to support monitoring provided	• 28 cold monitor sets (TINY TTM) provided to Ukrvaccina in May 1995; all were distributed (to oblasts, Crimea, Kiev, and Sevastopol). MOH ordered these administrative units to submit monthly graphic reports. Compliance reportedly poor.
A.4 Monitor utilization of vaccine to determine compliance with agreed strategy	• Consumption of distributed vaccine monitored	• # of consumption reports received from oblasts	• 100% of oblasts reporting through MOH (approx. 2 month delay)
	• Consumption data evaluated; MOH advised of status, conclusions, and recommendations	• % of oblasts reporting consumption data	• All oblasts reporting distribution/consumption data
		• % completeness of available consumption data	• Information system in operation. Differences between PATH, Directive No. 408, and MOH reports were not entirely resolved. PATH has access to central MOH database.
A.5 Support social mobilization activities for diphtheria campaign	• EC and qualitative research concepts introduced to chief physicians of HECs responsible for local social mobilization activities	• 4 regional IEC conferences conducted	• 100% complete; final conference held in October 1996.

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PATH OBJECTIVES	PATH OUTCOMES	INDICATORS	ACHIEVEMENTS: May 1, 1994 - Dec. 30, 1997
	• 4 TV PSAs promoting adult immunization produced, pretested, and broadcasted	• 4 TV PSAs produced • TV PSAs broadcast in campaign oblasts	• 100% complete; 4 TV PSAs produced Jan. 1996. Two additional PSAs produced for May/June 1996 mass immunization campaigns. • TV PSAs broadcast January-February 1996 per broadcast reports. PSAs broadcast for May-June campaigns in 3 oblasts.
B.1 Promote standardized systems for laboratory diagnosis	• Current laboratory protocols and systems assessed • Report produced comparing current Ukrainian laboratory protocols with international standards and practices	• National lab protocols documented and analyzed • 2 assessment consultations made	• 100% complete • 100% complete
B.2 Support laboratory diagnosis through provision of diphtheria laboratory supplies	• Quantity requirements for laboratory supplies estabished based on consultations • Corresponding products ordered and delivered	• XX of XX total products delivered	• 100% of all lab supplies delivered; Hoyle medium and PZA kits delivered in 1995; final shipment of second Hoyle order was delivered in August 1996; supply of equipment to support a PCR lab shipped and lab workers trained June 1997.
C.1 Support patient management through provision of antitoxin for case treatment and antibiotics for prophylaxis of contact cases	• Antitoxin procured and delivered • Request for antibiotics policy submitted	• 350 of vials delivered • No response received from MOH for antibiotics distribution plan or policy	• 100% complete; 350 vials delivered September 1994 • Offer of prophylactic antibiotics withdrawn; funds reallocated to mass campaign effort

PATH OBJECTIVES	PATH OUTCOMES	INDICATORS	ACHIEVEMENTS: May 1, 1994 - Dec. 30, 1997
D.1 Strengthen surveillance systems	• Technical assistance by TAG collaborators provided to MOH on all aspects of disease surveillance through monthly consultations	• XX of working meetings with MOH	• Since Sept 95, 16 meetings held
	• Recommendations for changes in practices and policies submitted to MOH	• XX of site visits to oblast centers	• Since Sept 95, 10 oblasts visited
	• Standardized reporting system developed to document implementation of immunization strategy	• Forms and instructions developed	• 100% complete; Directive No.408 issued November 24, 1995
D.2 Determine impact of immunization strategy on epidemic	• Reports based on data from incidence surveys, coverage surveys, case control studies collected and analyzed	• XX surveys and studies conducted	• 100% complete; collaboration on CDC incidence survey in Odessa and coverage survey in Kyiv and Zaporozhya provided; case control study completed; preliminary results presented at March 1996 interagency meeting and final results at June 1996 NCIH meeting
	• Interagency meeting conducted with MOH	• XX of MOH and interagency meetings conducted/attended	• Major meetings conducted March 1995 (Pushcha Vodytsa) and March 1996 (Pushcha Ozernaya); participated in several IICC meetings.

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Bloodborne Infection Control (BBIC)

GOAL: Reduce exposure to bloodborne infections among health care worker s in Ukraine

PATH OBJECTIVES	PATH OUTCOMES	INDICATORS	ACHIEVEMENTS: May 1, 1994 - Dec. 30, 1997
A.1 Provide new data on blood exposures in two hospital demonstration sites	• Research tools and methods introduced for monitoring blood exposure among HCWs	• 4 studies undertaken	• 100% complete. Several studies analyzed and reports completed. Glove failure study finished.
		• 3 working meetings held to present findings	• 100% complete. Two regional conferences held in April 1996; national conference held in March 1997.
A.2 Improve HCW's training and education related to bloodborne infection control	• Multi-level educational materials developed	• 1 monograph, 1 brochure, 1 wall poster developed and disseminated	• 100% complete; production completed in March 1997. Additional printing scheduled for fall 1997.
	• Training materials developed	• 2 slide presentations developed	• 100% complete; production completed in March 1997.
B.1 Improve availability and access to barrier material supplies for bloodborne infection control	• Current local supply practices and access to barrier supplies determined and documented	• Baseline surveys conducted and reported	• 100% complete
	• Additional sources of barrier materials and supplies identified	• One report on supply options presented to two hospital demo sites	• 100% complete in Oct 1997. To LRH (Lviv) and OOCH (Odessa).
	• Feasibility of local production of barrier materials analyzed	• Two business plans for local production of barrier materials prepared	• 100% complete

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PATH OBJECTIVES	PATH OUTCOMES	INDICATORS	ACHIEVEMENTS: May 1, 1994 - Dec. 30, 1997
	• Methodology made available for determining and comparing the funds required by hospital demonstration sites for BBIC barrier supplies at several incremental levels of barrier use and various supply source options	• Report produced and presented to hospital demo sites	• 100% complete. Glove Failure Study Report released.
	• Workplace(s) for barrier clothing production equipped and operating	• Production site producing XX new or improved items and XX products sold	• 100% complete; Memorandum of Understanding signed with LRH by October 1996; equipment orders placed October 1996. New partner named in March 1997. Kyiv workshop installed. Model items produced. Workshop inaugurated September 1997.
B.2 Deliver USAID commitment in products in support of bloodborne infection control	• Items needed to support initial hospital-based production and comparative studies identified	• XX items shipped	• 100% complete; items delivered to Odessa and Lviv; sewing equipment delivered. Fabric has been ordered for delivery in December 1997.
	• Barrier material supplies procured and delivered to cooperating hospitals	• XX items shipped	• 100% complete; BBIC materials for more cooperating hospitals delivered to Ukraine. Shipment delivered July-October 1997.
C. Propose changes in bloodborne infection control policy and practice among HCWs	• Experience and supporting data compiled into final report with recommendations for other facilities interested in replicating the program	• Reports presented at 2 regional and 1 national summation conference	• Discussion and planning with cooperating hospitals and MOH ongoing. • 100% complete; results of studies discussed with MOH; two regional conferences held in April 1996 with study results presented; BBIC working meeting held in December 1996. National BBIC Conference held in March 1997. Recommendations from March conference communicated to MOH.

Diabetes in Children

GOAL: Enhance the health of all children in Ukraine with diabetes

	PATH OBJECTIVES	PATH OUTCOMES	INDICATORS	ACHIEVEMENTS: May 1, 1994 -Dec.30, 1997
A.1	Provide insulin and diabetes supplies to Ukraine	• One year's supply of insulin and related supplies delivered to children on PATH/MOH registry (approximately 4,000 children)	• XX doses shipped	• 100% complete
A.2	Distribute insulin and diabetes supplies directly to children's pediatric endocrinologist at oblast level to safeguard against loss or diversion	• Insulin and supplies loaded on contracted trucks and delivered by PATH or Ukrainian physicians; instructions on product use reinforced	• XX Ukrvaccina cargo manifests produced representing inland shipments	• 100% complete; 2 cargo manifests produced for first distribution to oblasts in July and second distribution in October-November 1995. Third and final distribution to eastern oblasts in April 1996 and western oblasts in May 1996.
		• Insulin and diabetes supply deliveries monitored	• Transfer forms collected, corresponding to doses/ products delivered to oblast, rayon, and patient level	• 100% complete
B.	Increase availability of information on diabetes to diabetic children and their parents	• Brochures on correct use of U-100 insulin distributed	• XX brochures distributed	• 100% complete
		• U.S. diabetes care manual adapted for Ukraine and distributed to families receiving USAID/PATH supplies	• 6,000 manuals printed and distributed	• 100% complete; presentation of manual to health care personnel given at September 1996 national conference. Distribution to all oblasts scheduled for Fall 1996.
		• Collaboration with Eli Lilly established regarding diabetic education and educational materials	• XX collaborative activities with Lilly undertaken	• Discussions held in September and December 1995. Visitation of Lilly/Ukraine office in September 1996.

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PATH OBJECTIVES	PATH OUTCOMES	INDICATORS	ACHIEVEMENTS: May 1, 1994 -Dec.30, 1997
C. Document status of ongoing needs of diabetic children for possible future intervention	• Current availability, quantities, and alternative sourcing of insulin and supplies surveyed	• Survey outcome report produced and disseminated to MOH	• 100% complete. Assessment Report written.
	• Feasibility of continued use of established independent distribution system assessed	• XX feasibility assessment report produced and disseminated to MOH	• 100% complete. Assessment Report written.
	• Other potential, non-USAID insulin donors identified	• XX donors identified	• 100% complete. Assessment Report written.

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