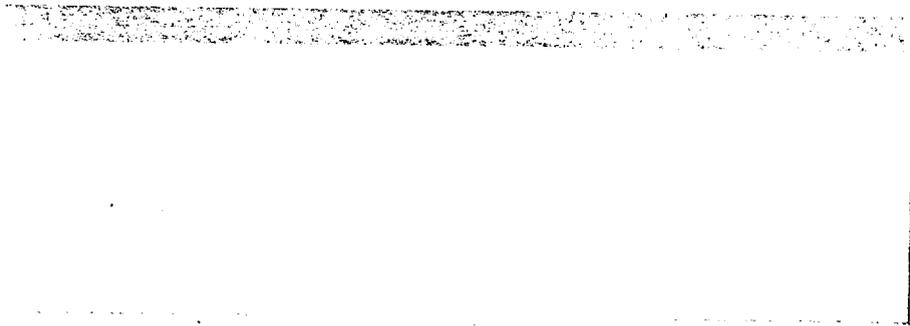


# TRIP REPORT



 **BASICS**

PD-ABN-373

**REVIEW OF THE UKRAINIAN DIPHTHERIA  
CONTROL EFFORTS AND WHO/MOH  
MEETING HELD AT  
PUSHCHA OZERNAYA, UKRAINE  
(March 11-13, 1996)**

Ukraine, March 7-17, 1996

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## ACRONYMS

BASICS	Basics Support for Institutionalizing Child Survival
CDC	Centers for Disease Control and Prevention
DTP	Diphtheria-Tetanus-Pertussis Vaccine
GMP	Good Manufacturing Practices
IFRC	International Federation of Red Cross and Red Crescent Societies
LF	Limit of Flocculation
MOH	Ministry of Health
PATH	Program for Appropriate Technology in Health
SOW	Scope of Work
Td	Tetanus-Diphtheria Toxoids (for adult use)
USAID	United States Agency for International Development
WHO	World Health Organization

## **EXECUTIVE SUMMARY**

The officials of WHO and MOH/Ukraine scheduled a joint assessment meeting on diphtheria to be held March 11-13 at Pushcha Ozernaya, a sanatorium retreat near Kiev. The author was invited by USAID (Kiev and Washington offices) and BASICS to participate as a consultant to the American team during, before and after the formal three-day meeting.

- 1) Prior to the meeting, the author met with the PATH representative to review their ongoing epidemiologic analysis of the diphtheria data supplied by MOH. There was also a meeting with USAID/Kiev staff to discuss the USAID position.
- 2) The three-day WHO/MOH meeting resulted in a general re-affirmation of the soundness of the current approvals to controlling epidemic diphtheria in Ukraine:
  - a) Continue mass immunization campaigns to vaccinate adult populations in the oblasts as supplies of the Td toxoid allow;
  - b) Continue to use the Western Td toxoid (2 Lf), as it has been found to be as effective as the Russian toxoid (5 Lf); and,
  - c) To assure maximum vaccine coverage, reduce the number of contraindications to immunization to a minimum.
- 3) As part of the diphtheria control program review, the author traveled with two PATH representatives to Kharkiv to assess the possibility of re-establishing a vaccine production facility. The situation seemed to be promising but requiring further financial and technical feasibility assessments.

## **PURPOSE OF VISIT**

The consultant's scope of work description included the following:

- 1) Travel to Ukraine to participate in the review of the Ukrainian diphtheria control strategy;
- 2) Represent the interests of USAID in defining the role that USAID and PATH should take in Ukraine to achieve the objective of controlling the current epidemic;
- 3) Meet with certain Ukrainian health officials to review the national strategy and make suggestions on its possible improvement;
- 4) Review the current data on the diphtheria epidemic and evaluate the performance of the strategies employed to control the epidemic;

- 5) Review the translation of reports by PATH staff to ascertain their accuracy;
- 6) Debrief with Mission officials on the performance of the program; and,
- 7) As needed, proceed to Kharkiv with PATH representatives to assess the possibility of re-establishing a vaccine production facility there.

## ACTIVITIES AND CONCLUSIONS

In accordance with the SOW, the author traveled to Kiev in advance of the scheduled WHO/MOH meeting to meet with USAID and PATH staff members. The meeting clarified the USAID position regarding the continuing role that USAID and PATH should take in assisting Ukraine in its efforts to control the epidemic of diphtheria. It was agreed that the WHO/MOH meeting should result in a general acceptance of the conclusions reached by USAID/CDC/PATH teams in assessing the WHO regional strategy:

- 1) Mass campaigns have been effective in significantly reducing the incidence of diphtheria in those oblasts where immunization of adults was practiced;
- 2) As evidenced by CDC studies, the Western-type vaccine supplied by USAID (2 Lf) has been as effective as the previously used Russian vaccine of a much higher Lf unit content (5 Lf); and,
- 3) It is essential to convince not only the MOH officials, but also the medical practitioners of Ukraine, that the list of unnecessary contraindications to immunization has been a part of the problem, and should be reduced to a minimum (the single contraindication of a serious previous reaction to the toxoid).

While at the PATH offices, the author reviewed the latest results of their epidemiological analyses of the oblast immunization data supplied by the MOH. The author also had the opportunity to help edit certain technical translations.

While attending the three-day meeting at Pushcha Ozernaya the author met formally and informally with a number of Ukrainian health officials. When indicated, the USAID/PATH position in continuing humanitarian assistance directed at control of the epidemic was clarified. The author also expressed my belief that a major disagreement between the MOH and certain influential Ukrainian infectious disease specialists is due to a failure to explain the reasons for the advice given by Western technical consultants to WHO/CDC/USAID/PATH. In the course of these discussions, it was agreed that -- should there be an opportunity to return to Ukraine in the next few weeks -- it could be useful to meet personally with the critics of the WHO/MOH strategy to discuss (in Russian) the background for the Western position.

Approximately 40 people participated in the joint assessment meeting. The Ukrainian side was represented by the MOH, the Kiev Institute of Epidemiology and Infectious Diseases, the health offices of several oblasts, and the civilian and military clinical infectious disease experts. The foreign participants represented the WHO, USAID, IFRC, CDC, and PATH.

During the first day, the MOH and the oblast representatives summarized the Ukrainian data, while PATH and CDC representatives presented the results of their epidemiological and seroconversion studies, respectively. Because of the concern with the Lf content of various vaccines, a WHO representative reviewed this issue in detail.

On the second day, the participants divided into two groups, reviewing the strategies employed in the adult immunization campaigns and in the ongoing programs of childhood immunizations.

On the last day, both groups presented their findings and conclusions. Dr. Roscius Doan of PATH recently summarized this so well that the author cannot do better than quote him with but a few modifications (Source: Roscius Doan, M.D., Memorandum, March 20, 1996: Ukraine Trip Report, February 26 - March 14, 1996):

- 1) CDC seroconversion studies show that both Russian 5 Lf and Western 2 Lf Td vaccines evoke adequate and comparable serological responses in Ukrainian adults at one month after a single injected dose.
- 2) The PATH analysis of the MOH database indicates that the mass immunization strategy in the southern oblasts has succeeded in producing a drop in the rate of growth of diphtheria incidence.
- 3) The PATH case-control study demonstrates that the vaccine is protective.
- 4) The Ukrainian database of children's cases reveals that the lack of primary vaccination is more frequently associated with a fatal outcome.
- 5) In the children's immunization subgroup, three studies, conducted at the Lviv Institute of Epidemiology, were presented to show that treatment of contact of cases with antibiotics reduced carrier rates by half and eliminated tox-positive forms of *C. diphtheriae*. There was support in the subgroup for the introduction of a policy in favor of the use of antibiotics for contact treatment.
- 6) Accordingly, Ukraine has renewed its commitment to a mass campaign strategy in the 20 remaining oblasts, covering all 15-59 year olds with one dose of Td, regardless of previous vaccine history. (Note this is now 15 to 59 year olds, not the previous 16 to 59 years old category.)

- 7) The MOH Order No. 14 of January 25, 1996, was communicated to the international participants in the children's immunization subgroup. It contains a revised immunization schedule and reduced list of contraindications governing immunization (seven in place of 14 - A.S., the author believes).

After the meeting at Pushcha Ozernaya, the author joined Drs. J. Maynard and D. Tishchenko of PATH in a visit to BIOLEK, a vaccine production facility in Kharkiv. Until 1988, this was the regional center for the production of diphtheria-, tetanus-, and pertussis-containing vaccines, as well as certain other biologics. They are now successfully producing small lots of diphtheria toxoid under nearly GMP conditions. It is likely that with a relatively limited amount of financial and technical assistance, the facility could resume routine vaccine production, and even satisfy the rigorous requirements of WHO-GMP standards. The Kharkiv visit was separately described in a report to PATH.

**APPENDICES**

**APPENDIX A**

**International Diphtheria  
Assessment Meeting,  
Kiev, Ukraine**

**11 - 13 March 1996**

**PROVISIONAL PROGRAMME**

**Monday, 11 March 1996**

- 9:30 - 10:00 Registration**
- 10:00 - 10:30 Opening ceremony:  
Dr. Marievskiy, Chief State Sanitary Doctor of Ukraine,  
First Deputy Minister of Health**
- WHO Representative**
- PATH Representative**
- 10:30 - 10:50 Overview of the dynamics of the diphtheria epidemic in  
Ukraine and the status of interventions -  
Dr. Dobroshtan, Chief Doctor Epidemiologist of MOH of  
Ukraine, 20 minutes**
- 10:50 - 11:10 Epidemiological efficacy of mass immunization in  
Ukraine and its peculiarity - Gladkaya O.A., Chief of  
Laboratory, Lviv Scientific Research Institute of  
Epidemiology and Hygiene, 20 minutes;**
- Organization and implementation of mass  
immunization in:**
- 11:10 - 11:20 Kievskaya oblast - Bulavka L.V., Deputy Chief  
Doctor of SES of the Kiev Oblast;**
- 11:20 - 11:30 Zaporozhskaya oblast - Volzhin Y.M., Chief of the  
Epidemiological Department of SES of the  
Zaporozhskaya Oblast;**
- 11:30 - 11:40 Nikolaevskaya oblast - Bonenko V.O., Chief of the  
Epidemiological Department of SES of the  
Nikolayevskaya Oblast.**
- 11:40 - 12:00 Coffee-break**
- 12:00 - 14:00 PATH speakers:  
Dr. David Mercer  
Dr. James Maynard  
Dr. Roscius Doan**

- Epidemiological assessment of diphtheria morbidity among adults;
- Efficiency research of immunization and other factors affecting risk by case-control-study method;
- Assessment of April mass immunization campaigns;
- PATH/USAID humanitarian vaccine distribution and consumption;

14:00 - 15:00 Lunch

15:00 - 17:00 CDC speakers:  
 Dr. Strebel  
 Dr. Ching  
 - Vaccine immunogenicity:

Td, made in Russia  
 (5 Lf), Kiev  
 Td, made in other  
 countries  
 (2 Lf), Odessa

- Mass immunization coverage - Zaporozhye, Kiev
- Clinicoepidemiological description of diphtheria pediatric cases.

**Tuesday, 12 March 1996**

10:00 - 10:30 General discussions

10:30 - 14:00 Work in groups, discussion of improvement of diphtheria epidemiological surveillance

14:00 - 15:00 Lunch

10:00 - 14:00 Continuation of work in groups, discussion of improvement of diphtheria epidemiological surveillance, working on reports for the Meeting Conclusions and Recommendations report draft.

**Wednesday, 13 March 1996**

10:00 - 10:30 General discussions

10:30 - 11:40 Discussion

11:40 - 12:00 Coffee-break

12:00 - 13:00 1st Working Group recommendations for the Meeting report draft, Dr. Shirobokov, group leader.  
 Discussion

13:00 - 14:00 2nd Working Group recommendations for the Meeting  
report draft, Dr. Scherbinskiy, group leader.  
Discussion

14:00 - 15:00 Lunch

15:00 - 17:00 General discussion

Final Discussion of the Meeting Conclusions and  
Recommendations

Closure of the Meeting.

**APPENDIX B**

**List  
of the International Diphtheria Assessment Meeting  
participants**

- |                  |   |
|------------------|---|
| Marievskiy V. F. | - Chief State Sanitary Doctor of Ukraine, First Deputy Minister of Health                             |
| Scherbinska A.M. | - Director of Kiev Scientific Research Institute of Epidemiology and Infectious Diseases              |
| Sinyak K.M.      | - Professor, Epidemiology sub-faculty, Kiev Institute for post-graduated doctors training             |
| Shirobokov V.P.  | - Chief of Microbiology sub-faculty of National Medical University                                    |
| Vozianova Z.I.   | - Chief of Infectious Diseases Department, National Medical University                                |
| Dobroshtan E.V.  | - Chief Doctor Epidemiologist of MOH of Ukraine   |
| Berezhnyi V.V.   | - Chief Doctor Pediatricist of MOH of Ukraine   |
| Kovalenko V.M.   | - Chief Doctor Therapist of MOH of Ukraine  |
| Kramarev C.O.    | - Chief Doctor Pediatric Infectionist of MOH of Ukraine   |
| Rudenko A.O.     | - Chief Doctor Infectionist of MOH of Ukraine   |
| Karina N.G.      | - Deputy Chief of the Mother and Child Care Department  |
| Loboda T.V.      | - Deputy Chief, Main Health Department for adults, MOH of Ukraine                                     |
| Gladka O.A.      | - Chief of Laboratory, Lviv Scientific Research Institute of Epidemiology and Hygiene                 |
| Chudna L.M.      | - Chief member of staff of Kiev Scientific Research Institute of Epidemiology and Infectious Diseases |
| Glushkevich T.G. | - Chief of Bacteriolaboratory, State Sanitary Epidemiological Surveillance Ukrainian Center           |
| Bulavka L.V.     | - Deputy Chief Doctor of SES of the Kiev Oblast   |
| Gorobets Y.F.    | - State Head Sanitary Doctor, Ministry of Defense of Ukraine  |
| Gorodetskiy M.M. | - Chief Doctor Infectionist, Ministry of Defense of Ukraine   |
| Volzhin Y.M.     | - Chief of the Epidemiological Department of SES of the Zaporozhskaya Oblast                          |
| Bonenko V.O.     | - Chief of the Epidemiological Department of SES of the Nikolayevskaya Oblast                         |