



ICBS' COUNTRY PROJECTS

The provision of support to developing countries continues to be governed by numerous factors that have to be considered prior to providing support. The following are among these factors:

- Availability of necessary funds for ICBS to initiate activities. [The number of countries to be considered and the nature of ICBS support to be provided to a developing country in order to assist in improving its blood safety program depend on the availability of funds. Many countries of the developing world in need of assistance are on the list of ICBS, subject to the availability of additional funds.] for the implementation of the Expanded ICBS Initiative.
- Government commitment to the improvement of its country's blood safety program.
- Presence of motivated and dedicated leadership in charge of blood safety programs.
- Government approval to sign Memoranda of Understanding indicating the country's commitment to ensure the sustainability of screening of all the blood units collected by the blood banks.
- Assessment of the blood transfusion service based on information collected from various sources and an ICBS team fact-finding visit as well as priority identification.
- Maximization of resources by complementing other existing support provided by other organizations, agencies or through bilateral agreements and coordination with the other providers.

ICBS has had and continues to have (with the exception of Viet Nam and Paraguay at the present time) activities in India, Viet Nam and Paraguay (and some of the other Latin American Countries), Pakistan, Indonesia, twelve African countries, the five countries of Central Asia (Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan) and Laos.

The assistance provided by ICBS to the afore-mentioned countries/regions includes one or more of the following:

- Assisting countries to achieve sustainable blood safety testing of all blood units collected by blood banks by:

- *Providing some of the less fortunate public blood banks with the requisite quantity of blood screening reagents for one year provided that the authorities in the respective Ministries of Health sign Memoranda of Understanding indicating their commitment to ensure the sustainability of screening of all the blood units collected by the blood banks. Part of the commitment indicated in the Memoranda of Understanding is that:*
 - a- during the second year of support by ICBS only 50% of the quantity of reagents of the first year will be provided by ICBS, and the Ministries of Health will purchase the remaining quantity;
 - b- during the third year the Ministries of Health will ensure covering 100% of the required screening reagents, using their own resources and improved mechanisms for purchasing blood-screening reagents for public sector blood banks
- Advising on purchase mechanisms of efficient reagents and
- Informing on the availability of affordable reagents of high quality.
- Assisting in the evaluation of blood safety kits available in the market to identify reagents at low cost and of good quality. This is facilitated by means of:
 - (i) training scientists from the few countries having national control authority laboratories in proper systems for the evaluation and licensing of reagents, as well as establishing their national panels
 - (ii) establishing ICBS Master Panels for HIV, HBV, and HCV
 - (iii) initially providing, as appropriate, national control authority laboratories with ICBS panels for HIV, HBV, and HCV and providing assistance to develop their own panels for continued use and
 - (iv) sponsoring an international center for the evaluation of blood-screening reagents to identify affordable screening reagents of high quality using the ICBS Master Panels.
- Playing an important role in training in specific areas, especially assisting in the training of blood safety laboratory testing techniques and conducting and sponsoring workshops to train trainers in the principles and practices of blood safety quality assurance.
- Helping, as appropriate, regions/countries to establish central confirmatory reference laboratories.

It is heartening and encouraging to note that significant progress has been achieved despite the factors that could limit success in certain developing countries such as political instability, lack of government commitment, insufficient funds allocated to blood transfusion services and the absence of dedicated and lack of committed leadership in charge of blood transfusion programs.

1. India

Introduction

During the period November 28 through December 8, 1999, an ICBS team visited India. The principal purpose of the visit was to prepare a proposal to offer technical and project assistance in implementing mandatory anti-HCV and improved HBsAg testing in India.

[HIV testing is provided by the National AIDS Control Organization (NACO) with the assistance of a loan from the World Bank.] The ICBS team systematically surveyed the state of blood screening in India by visiting various blood banks, diagnostic manufacturers and Government authorities responsible for the State and the National AIDS Control Organization (NACO), which is entrusted with the responsibility for blood transfusion safety in India. During this visit, the Indian Government mandated universal testing of transfused blood for HCV (which was practically applied during the first quarter of 2001). This decision offered ICBS the opportunity to use its expertise to expedite and enhance the quality and affordability of HCV (and HBV) testing throughout the public and non-profit sectors in India, using NACO as the distribution mechanism. NACO is already funded by the Government of India for the next five years to pay for the test reagents and hence ICBS funds would not have to be expended in India for this purpose.

Thus the initial ICBS plan to begin introduction of HCV testing in one test site to serve as a model was superseded by subsequent events. A revised plan evolved in consultation with senior local officials (of NACO) for a nationwide program. As the decision to introduce HCV testing had already been made, the need became clear for ICBS to assist NACO both in the QA of test performance and in the introduction of state based confirmatory laboratories. ICBS and the Indian Government signed the following Memoranda of Understanding to fulfill these tasks:

Three Memoranda of Understanding (MOUs) were signed between the Government of India and ICBS to: a) assist the National Control Authorities in the establishment of a viral sample panel to be used for test evaluation and test licensing approvals; b) assist regional laboratories in India to establish quality assurance programs for blood bank serological testing and c) assist in establishing a Central Reference Laboratory for confirmatory testing.

Implementation Progress:

ICBS provided the National Institute of Biologicals (NIB) with a panel of serum specimens containing HCV and controls. ICBS also trained a scientist in the laboratory of the Hepatitis Branch, Centers for Disease Control and Prevention (CDC), Atlanta, GA, U.S.A., and a Senior Molecular Biologist was supported and trained for three months at the Lindsley F. Kimball Research Institute (LFKRI), New York. Equipment for the Central Confirmatory NAT Testing Laboratory has been purchased with funds provided by ICBS.

ICBS in coordination with NIB, India fulfilled its commitment to conduct a workshop on Quality Assurance.

One of the three Memoranda of Understanding signed between ICBS and the Ministry of Health in India was addressed to assist India in establishing a Central Reference Laboratory for confirmatory testing. Due to leadership changes in the National Institute of Biologicals (NIB), New Delhi, during the year 2002, the Central Reference Laboratory for the confirmatory testing project and its

implementation slowed down and was not fulfilled within the anticipated time frame. After a field visit to the site by the Chairman and the Executive Director of ICBS in November 2003 when the situation was assessed and discussed with the Ministry of Health of India, ICBS received a letter from the Secretary of the Ministry of Health informing us that they instructed NIB to speed up the implementation and also send monthly reports to both the Ministry of Health and ICBS about progress achieved. Since then matters have started to move in the right direction though at a relatively slow pace.

2. Viet Nam

Introduction

Three Memoranda of Understanding were signed between the Government of Viet Nam and ICBS to: a) provide provincial blood banks for one year with HCV and HBV test-kits sufficient to screen blood units collected by provincial blood banks; b) establish and upgrade quality assurance in blood screening serology and c) provide support training for qualified scientist(s) from CENCOBI laboratories on techniques and practices needed to establish the national panel to be used for kits-evaluation.

Implementation Progress:

All ICBS commitments were fulfilled according to the MOUs signed between ICBS and the Government of Viet Nam.

The World Bank is implementing a ten-year program of 30 million dollars support with the Government of Vietnam to achieve improvements in the quality of hospital care provided, particularly in the poorer provinces. Now that the World Bank project is being implemented, ICBS will redirect its modest resources to supporting other developing countries in the region. ICBS expressed its willingness to collaborate with the Word Bank in implementing its project.

3. Laos

ICBS has over the course of 2004 extended its assistance to the Blood Transfusion Services in Laos. Blood screening reagents for HCV, HBV and Syphilis as well as necessary equipment (shakers and tension rollers) were supplied to the Laos Red Cross Blood Transfusion Services.

4. Latin American Countries

a) Paraguay

Two Memoranda of Understanding were signed between the Government of Paraguay and ICBS to: (a) provide the public blood banks of the national network of blood transfusion services with HCV test-kits needed during the first year and half the quantity

during the second year and (b) provide training in the principles and practices of quality assurance and laboratory testing techniques.

Implementation Progress:

All the commitments of ICBS were fulfilled

b) Other Latin American Countries

Since the launching of the First Initiative for Safe Blood in Latin America by the Pan American Health Organization (PAHO/WHO-AMRO) on February 27, 2001 and after PAHO received a grant of 4.9 Million US Dollars from the Bill and Melinda Gates Foundation for the purpose, ICBS redirected its limited resources to supporting other developing countries in other regions of the world. ICBS continued to collaborate with PAHO in all areas of blood safety, including participation in its workshops; and is co-sponsoring a training program together with PAHO (WHO-AMRO) and the Government of Spain to train 32 trainers from 19 Latin American countries in blood safety and quality assurance. ICBS's role and its cooperation were acknowledged several times by PAHO in several official meetings and workshops of PAHO.

The close cooperation and collaboration between PAHO and ICBS in supporting training activities and the introduction of screening for HCV of blood collected by the blood banks in countries of South and Central America has resulted in the marked increase of screening for HCV, of blood units collected by the blood banks in Latin American and Caribbean countries. Eleven (of 19) Latin American countries and eight (of 22) Caribbean countries are now testing all blood units collected by public blood banks for HCV. Other countries are partially testing blood units collected and are striving to routinely screen more blood units.

5. African countries

Introduction

For the purpose of assessing the situation and identifying the priorities and needs of first phase African countries, an ICBS organization meeting with the Directors of Blood Transfusion Services in six countries in West Africa was held in Abidjan, Ivory Coast on January 5, 2001. The meeting was attended by the WHO-AFRO Regional Adviser for health, laboratory and blood safety services.

In an effort to coordinate ICBS's activities to serve both the WHO-Regional Office for Africa and ICBS's goals in the area of blood safety, ICBS and WHO/AFRO agreed to closely collaborate and coordinate their blood safety activities. ICBS signed MOUs with the governments of 12 African countries.

Implementation Progress:

Assistance and reagents have been provided, and continued to be provided during the last year by ICBS to the following countries: Benin, Burundi, Burkina Faso, Cape Verde, Congo, Ghana, Guinea, Liberia, Mali, Niger, Senegal, and Togo.

Arrangements are being made to provide assistance and reagents, subject to availability of funds, to other African countries as well.

ICBS co-sponsored and participated in WHO/AFRO meetings and workshops on blood safety, quality assurance and total quality management.

The National Blood Transfusion Center of Cote D'Ivoire in its capacity as an ICBS Collaborating Center supported ICBS's activities by:

- *Contributing to the efforts of ICBS aimed at improving quality assurance and installing quality systems in African blood transfusion centers and blood banks.*
- *Training of personnel at blood transfusion centers and blood banks in African countries, especially the French speaking African countries, in quality assurance principles and applications, including help to set up their own national quality assurance programs in a broader sense.*
- *Playing the role of a Reference Center for blood transfusion centers in the West African Region.*

An attempt was made to demonstrate the importance of continuing efforts to introduce HCV screening of all blood units collected in all countries based on some data and information from Africa. From available data received from 10 African countries which reported having tested 140,511 blood units per year for HCV antibody, 4,065 blood units were discarded because they tested positive to HCV-antibody. The percentage is 2.89% (which is close to the WHO estimated prevalence for HCV worldwide i.e. 3%). Based on the reports and information from 36 African countries, it is reported that a total of 1,119,577 blood units were collected by the 36 countries. Ten of these countries test blood units for HCV, 17 do not test at all and 9 perform partial testing. The discarded blood in these countries ranged from 1 & 2 % to 32 % varying from one country to another. Out of the 1,119,577 blood units collected in the 36 countries, 564,553 units were not tested for HCV antibodies. There were 16,937 recipients, of whom the number of recipients not reacting positively to HCV prior to the transfusion would have been 16,429 recipients. Based on the fact that 70% to 80% will develop infection with HCV as a result of receiving the infected blood units; in the 36 countries there would be at least 11,500 to 13,143 newly infected HCV persons per year, as result of receiving HCV. This clearly demonstrates the importance of continuing the efforts to introduce HCV screening of all blood units collected in all countries

6. Indonesia

A Memorandum of Understanding was signed between the Government of Indonesia and ICBS to: (a) establish a provincial demonstration model at the Bandung Blood

Transfusion Center and to secure a quality service capable of teaching and training at other similar blood centers in Indonesia; (b) help in establishing a blood safety quality management system at the central level; and (c) assist and advise the Reagents Manufacturing Laboratory in Mataram to establish a quality management system in their place of manufacture in order to bring the facility in line with international manufacturing standards.

The Situation and Implementation Progress:

There are 157 blood transfusion centers in Indonesia, 60% of them are located on the island of Java. The annual blood collection is 1.1 – 1.2 million units of which about 77 – 85% come from voluntary non-remunerated blood donors. The blood units collected at the blood banks (fixed sites) represent 55% while the remaining 45% is collected by Mobile Units. Of the 157 blood transfusion centers, only 22 blood centers have facilities to prepare the blood component. However since these 22 blood centers collect the majority of blood units, 72% of blood units collected is separated into blood component. Blood units are screened for syphilis, HBV, HCV and HIV.

Both the Government and the Indonesian Red Cross are working to improve blood transfusion services. On a regulatory level the Ministry of Health is updating the Government Regulations and policy on Blood Transfusion. The draft of the new regulations has been submitted to the authorities for approval before it can become effective. The National Agency of Drug and Food Control of the Republic of Indonesia has also finalized and submitted to the authorities for approval a draft of Good Manufacturing Practices for Human blood and blood products. For its part the Indonesian Red Cross continues, despite many constraints, to make an effort to strengthen the Blood Transfusion Centers at central, provincial and district levels. Emphasis is put on improving the quality of services and training.

Progress at Bandung Blood Transfusion Unit

- *Implementation started with an initial audit and training took place from May 06 to May 12, 2002.*

The staff was also introduced to a timely phased plan of action. Meanwhile the Director of the Bandung Blood Center and her staff started taking practical steps towards improving the working conditions at the Blood Center including the abandoning of pooling in the testing for HCV antibodies using the ELISA technique, improving blood sample handling and transportation, improving hygienic conditions and waste disposal and working on the development of SOPs.

- *The new organizational structure of the Bandung Blood Transfusion Unit (BTU) has been established. A Supervisor has been appointed for each laboratory.*
- *The BTU has been authorized to manage its own budget and financial affairs.*
- *The number of mobile units was increased in order to make available a 3 – 5 day stock of blood.*
- *Software for the Blood Bank Management System has been installed and is being used.*

- *Standard operating procedures on blood donor selection, blood collection, blood screening for transfusion transmitted infections (TTIs), blood storage, blood component preparation and cross matching have been developed.*
- *All blood testing for TTIs are performed individually without pooling. EIA testing increased from 50 % to 90-100 %; 0-10 %. The use of rapid test decreased and now represents zero to 10%.*
- *Hygienic conditions and waste disposal were improved in all sections of the blood center. Infectious waste is separated from non infectious waste.*
- *Work sheets/assay sheets and a record of laboratory process were developed and are being used.*
- *The laboratory space was extended and facilities improved.*
- *A quality officer has been appointed.*
- *ICBS has provided external quality assurance panels for all of Indonesia's blood banks, to evaluate the sensitivity and specificity of testing for TTIs. Of 147 participating Indonesian Red Cross Blood Transfusion Units (IRC BTUs), the results were correct from 128 BTUs (87%) for HBsAg testing, 70 BTUs (48%) for anti-HCV testing and from 130 BTUs (88%) for anti-HIV testing.*
- *In response to the unsatisfactory results of the EQAS, corrective action was taken wherever needed. The corrective action included retraining of personnel, improving equipment maintenance, using EIA testing techniques rather than using rapid test-kits, and advising on centralization of blood screening. The corrective measures undertaken to improve the services and the quality led to an almost one hundred percent increase in the blood service cost in the country.*
- *Regular joint meetings between the blood center staff and users from hospitals were introduced. These meetings are being held every three months to review the situation and discuss ways for improvement.*

7. Pakistan

A Memorandum of Understanding was signed between the Federal Government of Pakistan/National Institute of Health (NIH) and ICBS to: (a) assist the Federal Government of Pakistan/NIH in the phased establishment of a National Reference Center for the Blood Transfusion Services; (b) apply viral screening assays of optimal sensitivity and specificity to be uniformly applied throughout the country and (c) implement the principles of Quality Assurance/GLP in all aspects of transfusion practice.

Implementation Progress:

A plan of Action, based on the MOU was developed. The following steps of the Action Plan have been implemented:

The Project Director has been appointed by NIH.

Space and laboratory premises within NIH have been allocated.

The center/laboratory has been officially designated by the Ministry of Health as a National Reference Center for Blood Transfusion Services. The National Reference Center for Blood Transfusion Services, established and upgraded with the help of ICBS, has been notified.

The laboratory is being upgraded by the NIH at present (about 60% completed)

Two Fellows were trained (training started in October 2003), in the ICBS Collaborating Centers in Berlin and Langen in Germany, and in Groningen in the Netherlands.

They were trained as planned in virology (genomic amplification techniques, genotyping, constructing and utilizing serological panels, conventional techniques) and Quality Assurance/GLP, with particular reference to virology testing.

Essential equipment, as per the MOU, has been purchased by ICBS.

The equipment has been received and installed by the National Institute of Health in Islamabad, Pakistan.

The Government of Pakistan has also accomplished the following:

- 1. Legislation has been passed on compulsory screening for all transfusion-transmitted infection ((HIV, HBV, HCV, Malaria and Syphilis) and maintenance of essential standards by the blood banks in all the provinces. Funds have been committed for the purchase of Hepatitis C test-kits to fulfill one of the government commitments of the MOU signed with ICBS. One federal office and four provincial offices of the Blood Transfusion Services will monitor the implementation of the legislation.*
- 2. The National Blood Transfusion Committee (NBTC) has been established under the Chairmanship of the Federal Health Minister with its secretariat at the NIH. The ICBS has representation in the NBTC as an NGO along with the WHO and the Red Crescent.*
- 3. The National Strategic Plan, and the policy and framework (for 2003-2007) have been developed in broad consultations with all the stakeholders including public and private sectors, Army Transfusion Service, Academia and international development agencies. The NBTC and the Federal Government have formally approved the National Blood Policy and the Strategic Framework for the Blood Transfusion Services for the period 2003-2008.*
- 4. WHO/MoH have approved the Work plan titled 'Blood Safety' 2004-2005 through the Joint Program Review Mission (JPRM) at a cost of US \$ 62,685. Under this project the following amounts have been committed for the National Reference Centre and the Secretariat of the National Blood Transfusion Committee:*
 - a- US \$ 5000- Communication and logistic support to the National Reference Centre for Blood Transfusion Centre (NRCBTS) [the proposal against the allocated amount was submitted in April 2004 to WHO/MoH for laboratory benches, fixtures, conference table & chairs for workshops, air conditioners]*
 - b- US \$ 5000- for Communication and logistic support for the secretariat of National Blood Transfusion Committee (NBTC)*
 - c- US \$ 7000- Supplies and equipment for the headquarters of BTS (bio-hazard safety cabinet etc).*
 - d- Additional items will be provided under the WHO project towards Health Laboratory Support*

8. Central Asia

Introduction

a) Establishment of a model training demonstration project at the Bishkek Blood Transfusion Center for quality blood service for all countries of Central Asia (CAR).

After the blood safety situation in Central Asia was assessed, a Memorandum of Understanding was signed between the Government of Kyrgyzstan and ICBS in February 2002. The purpose of the MOU was to establish a model training demonstration project at the Bishkek Blood Transfusion Center for quality blood service for all countries of Central Asia (CAR) and possibly for other countries of the former Soviet Union. This demonstration center is intended to serve as a model of good laboratory practice in virology screening and as an illustration of the principles of Quality Assurance/GLP and their application. ICBS has been working in close collaboration with the Republican Centers for Viral Hepatitis in the five countries of Central Asia and CDC/CAR who are expected to come forward with their contributions as well. The objectives of the project are to:

1. Install a quality management system at the training model facility
2. Enlist the support of the Central Blood Transfusion Services in CAR
3. Establish a laboratory safety program.

Implementation Progress:

A Plan of Action was jointly developed with the Blood Transfusion Center in Bishkek. The first phase focused on:

Using internationally recognized guidelines for the principles of Quality Assurance/GLP and their application.

Advising on standards and procedures for operations in a stepwise fashion.

Developing a training program for trainers and carrying out training to meet the required standards.

Establishing a laboratory safety program by advising on safety policy and safety standards and implementing the policy.

ICBS's first step in this direction was to enable the Bishkek Blood Center Laboratory to be qualified to host such training courses. This meant that ICBS had to assist in putting in place essential elements of quality systems and ensuring that the appropriate facilities were available before inviting participants from countries of Central Asia for training. The Director of the Bishkek Blood Transfusion Center took important steps to organize the blood bank as a future regional training center for blood safety staff from countries of Central Asia. A consultant (Professor Dr. Karl-Otto Habermehl) visited the Bishkek Blood Center to assess the conditions and conduct a training workshop covering different aspects of

quality systems. He also inspected and assessed the facility and gave recommendations for improvement.

b) Collaboration between WHO-EURO and ICBS

The Blood Safety and Diagnostic Support, WHO-EURO and ICBS agreed to start their collaboration by jointly conducting a workshop on the laboratory component of quality management/systems applied to blood safety (including the principles of Quality Assurance/GLP).

Implementation Progress:

During the last year of funding, several activities took place in the model-training center for quality blood service for all countries of Central Asia (Kazakhstan, Kyrgyzstan, Tajikistan, Turkmenistan and Uzbekistan) located at the Bishkek Blood Transfusion Center, Kyrgyzstan. The activities addressed putting in place essential elements of quality systems and good laboratory practice in virology screening as an illustration of the principles of quality assurance/GLP, total quality management and their application. ICBS, in collaboration with WHO-EURO, conducted other training workshops in Bishkek for participants from the five countries of Central Asia. The first workshop was on Quality Management and took place in Bishkek in June 16-28, 2003 while the second workshop was on Quality Assurance of HIV and Hepatitis Testing and was held also in Bishkek from March 24 to 26, 2004. A third workshop on Quality Assurance and Biosafety in the Laboratory was held in Almaty, Kazakhstan from May 31 to June 02, 2004

c) Creation of a Joint Program by the CDC/CAR and ICBS to improve blood safety in countries of Central Asia.

In concert with the goals of the International Consortium for Blood Safety (ICBS), the Office of Health and Population-USAID Regional Office for Central Asia (USAID/CAR) and its partner CDC/CAR (which is working on infectious disease surveillance prevention and control in Central Asia); and in line with the dedication of the three above mentioned parties to assist the Ministries of Health in the countries of Central Asia to improve their blood transfusion services (BTS), CDC/CAR and ICBS agreed to establish a partnership and jointly execute and implement activities aimed at improving the blood safety situation in Central Asia.

Implementation Progress:

- *The Directors of four selected sites in Uzbekistan (2 sites), Turkmenistan and Kyrgyzstan as well as have the project coordinator at the CDC branch of Central Asia visited the blood bank in Amman, Jordan on a study tour.*
- *Dr. Janiet Niquir Merza visited the four sites in Uzbekistan, Turkmenistan and Kyrgyzstan for the period from June 26 to July 6, 2003. She advised on*

necessary activities to improve the situation and formulated a plan of action and recommendation for this purpose.

- *ICBS in collaboration with CDC/CAR, started conducting a series of training workshops on blood safety (six in total); the first workshop was conducted in Bishkek, Kyrgyzstan from 16 to 19 March 2004. The other 5 workshops will be conducted in July and August 2004 starting with two workshops in Uzbekistan to be followed by one workshop each in Tajikistan, Turkmenistan and Kazakhstan.*

9. Moldova

ICBS sponsored the training of a doctor from Chisinau, Moldova to be trained for two months in the preparation of panels from March to May 2004 at the National Reference Laboratory in Tashkent, Uzbekistan (which also happens to be an ICBS Collaborating Center) under the guidance and supervision of Professor Erkin Musabaev, Director of the National Reference Laboratory, in Tashkent.

Implementation Progress:

The National Reference Laboratory in Tashkent reported that the training was successful and a report detailing the various aspects of the training was also submitted by the trainee on completion of training.