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Strengthening of Nationally-Coordinated Blood Transfusion Services in South-East Asia

*Report of a Regional Consultation
Jakarta, Indonesia, 20-23 April 2004*

WHO Project: ICP BCT 001



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1. INTRODUCTION

Blood safety is one of the identified priority areas of WHO as well as of the SEAR High Level Task Force on Inter-country Collaboration. The WHO Global Strategy for Safe Blood focuses on a nationally-coordinated blood transfusion service with adequate government commitment and a national policy. In the SEA Region, four of the 11 countries have not formulated a national blood policy. In the remaining countries also a national blood policy is in varying phases of implementation. A nationally-coordinated blood service is functioning optimally only in Thailand. Similar services exist in Indonesia and Nepal but they need considerable strengthening. Sri Lanka is currently undertaking a major transformation of its blood transfusion service through a grant from the Japanese Bank of International Cooperation (JBIC) and technical support from WHO to develop a modern nationally-coordinated blood transfusion services (BTS).

An efficient blood transfusion service should be well organized, nationally-coordinated with policies and plans, and with an appropriate legal framework/regulations in place to cover its activities. The national coordination mechanism involves the development of policies, standards, regulations, assessment tools, technical support and restructuring, if needed, to optimally utilize the resources and run blood transfusion services on a modern and technically appropriate mandate. To address issues of advocacy, planning and implementation of national policies, plans for nationally-coordinated blood transfusion services and appropriate regulatory framework that have government commitment and support with sustainable infrastructures, a regional consultation on the subject was convened in Jakarta, Indonesia, from 20 to 23 April 2004.

Eighteen participants from all the Member Countries of the SEA Region, (Annex 1) attended this consultation. The detailed programme of the Consultation is placed as Annex 1. Four experts from Thailand, Egypt and Indonesia facilitated the workshop. Dr Guntor Bambang Hanurwono

(Indonesia) and Prof Chaivej Nuchprayoon (Thailand), were elected as the Co-chairpersons and Dr Yuyun Sudarmono (Indonesia) was elected Rapporteur.

2. OBJECTIVES

The following were the objectives of the Consultation:

- (1) To review the status of implementation of national blood transfusion services in the SEA Region and to identify constraints and possible solutions for implementation of nationally-coordinated blood transfusion services and their regulation;
- (2) To discuss the regional generic framework for implementation of nationally-coordinated blood transfusion services, and
- (3) To formulate a country-specific plan of action and follow-up mechanism for implementation of nationally-coordinated blood transfusion services.

3. INAUGURAL SESSION

Prof Dr Sujudi, Director, Blood Transfusion Programme, Indonesian Red Cross Society welcomed the participants and facilitators of the consultation. He was appreciative of WHO's initiative in bringing together programme managers from all the countries of the South-East Asia Region to share their experiences to move forward. Dr Guntor Bambang Hanurwono, Director, Basic Medical Sciences, Ministry of Health, Indonesia, also welcomed the participants and shared with them the problems of inadequacy, safety and quality of blood in Indonesia as well as efforts being made by the Indonesian Red Cross and the Government of Indonesia. He too was appreciative of WHO's efforts in organizing this consultation at Jakarta which, he said, would be gainful to all the countries of the Region.

Dr Bing Wibisono from the WHO Office, Indonesia read out the address of Dr Samlee Plianbangchang, WHO Regional Director for South-East Asia. Dr Samlee said that blood was universally recognized as the most precious element that sustains life. Blood is neither a commercial product nor can it be

synthesized artificially. However, its demand is bound to increase exponentially with increased access of people to health care services. The responsibility for ensuring its continuous supply therefore rested with health care providers who need to galvanize entire communities for regular and non-remunerated blood donations. Dr Samlee emphasized that safety of blood had assumed greater importance and relevance in developing countries where hepatitis B and hepatitis C were becoming diseases of great public health importance, and where HIV/AIDS was growing at an alarming pace. Currently, the countries of the South-East Asia Region were estimated to have six million carriers of HIV, 85 million of hepatitis B and 25 million of hepatitis C. Unfortunately, blood transfusion is an easy mode of transmission of HIV and viruses of hepatitis B and hepatitis C. Globally, 5-10% of HIV transmission was estimated to be through transfusion of blood. Only meticulous screening of blood with reliable kits and reagents can prevent such transmissions.

Dr Samlee informed that WHO had developed a global strategy for safe blood to improve access to, and ensure quality as well as safety of blood. The strategy focused on a nationally-coordinated blood transfusion service, supported with government commitment and a national policy. Dr Samlee assured WHO's continued support to Member countries for effective implementation of the Global Strategy on Blood Safety.

4. CONSULTATION

4.1 Review of Status

Global and regional perspectives

Dr Rajesh Bhatia, Short-Term Professional, WHO/SEARO, New Delhi presented the global scenario. He highlighted the disparities in the availability and safety of blood and quality systems between blood banks from countries with low HDI (as most countries in the SEA Region are) and high HDI (including most developed countries). Of the 80 million units of blood that is collected globally, 98% is screened for HIV and hepatitis B and 97.3% for hepatitis C. Most of the blood that is not screened is from countries with low HDI. He also emphasized the need to assure quality and improve collection of blood from voluntary non-remunerative blood donors.

Dr Bhatia elaborated upon the importance given to blood safety at the global and regional levels. Blood safety was the theme of World Health Day 2000 and this acted as an advocacy tool and stimulated developing countries to strengthen BTS. The countries of the SEA Region need 15 million units of blood, of which only 8 million is collected annually at present. Of this 62% is from voluntary non-remunerative donors. Apart from the shortage of blood in the SEA Region, the quality of screening for infectious markers was also a cause for concern. Though almost 100% of the blood collected is being screened for HIV and hepatitis B and the number of blood units that are being screened for hepatitis C is also increasing, the quality of testing remains questionable. He also briefed the participants about the various activities undertaken by WHO in strengthening quality. These included implementation of a quality management project of WHO which trained 126 blood bank staff as quality managers, 16 of whom have been provided access to an external quality assessment scheme through the Thai EQAS on blood group serology and transfusion transmissible infections (TTI). WHO is also providing technical support on quality issues through the Regional Quality Centre located at the National Blood Centre, Bangkok.

Current status of BTS in the SEA Region

The status of blood transfusion services in the SEA Region, based upon presentations made by the country representatives, is summarized in the Table below. Four countries have national blood policies whereas a nationally-coordinated BTS is functional in eight countries. There are 2830 blood banks operating in the Region and they collect 9.3 million units of blood annually. The cost of each unit of blood ranges from US\$ 5 to 23. Paid donors exist in Bangladesh and contribute 18% of the total collection of blood. Some donors (0.095%) with rare blood groups are provided support by families of recipients in Thailand.

Screening of blood for viral transfusion transmissible infections (TTI) is almost universal with the exception of hepatitis C. Prevalence rates for HIV, HBV and HCV in donors varies from 0-0.9 %, 1.42-7.0 % and 0.14 – 2.5 % respectively. The use of whole blood varies from 5% in Sri Lanka to 100% in Timor-Leste. National regulations for blood transfusion services are available in five countries.

Table 1: Status of blood transfusion services in the countries of the SEA Region

Country(No of blood banks)	BAN (98)	BHU (29)	KRD (12)	IND (1854)	INO (157)	MAV* (21)	MMR (363)	NEP (55)	SRL (64)	THA (159)	T-L (3)
Number of units collected per year	160,000	6,000	100,000	6 million	1,198,000	6,200	180,000	74,000	170,000	1.4 mil	1,400
Nationally-coordinated BTS	Partial	No	Yes	Yes	Yes	No	Yes	Yes	Yes	Yes	Yes
National Blood Policy	No	No	In process	Yes	In process	In process	In process	Yes	Yes	Yes	No
National BTS Committee	Yes	No	Yes	No	Yes	In process	In process	Yes	Yes	Yes	No
Cost/unit blood (\$)	10	ND	21.8	15	15	NA	10	10	5	15	NA
Adequate trained staff available	Yes	No	Yes	Yes	No	No	No	No	Yes	Partial	Yes
VNRD%	27	30	100	50	77	20	57	90	60	94.45	5
Replacement donors %	56	70	0	50	23	80	43	10	40	5.36	95
Paid donors%	18	0	0	0	0	0	0	0	0	0.095	0
Used as whole blood %	90	45	80	80	28	30	90	90	5	20	100
% screened for HIV	100	100	100	100	100	100	100	100	100	100	NA
% screened for HBV	100	100	100	100	100	100	85	100	100	100	NA
%screened for HCV	100	100	100	100	60	100	30	100	40	100	NA
Prevalence of HIV in donors	0.002	0	NA	0.50	0.092	0	0.6	0.4	0.0002	0.16	NA
Prevalence of HBV in donors	1.48	1.6	NA	1.4	2.0	0.8	7.0	1.2	0.03	1.51	NA
Prevalence of HCV in donors	0.14	0.15	NA	0.4	0.08	0.001	2.5	0.57	NA	0.32	NA
National Regulations for BTS	Partial	No	Yes	Yes	Yes	In process	Yes	No	No	Yes	No
National Regulatory Authority	Yes	No	Yes	Yes	Yes	No	Yes	No	Yes	Yes	No
Licensing requirements for BTS	No	No	No	Yes	Yes	No	Yes	Yes	No	No	Yes

BAN: Bangladesh, BHU:Bhutan; KRD: DPR Korea; IND:India; INO:Indonesia; MAV:Maldives; MMR:Myanmar; NEP:Nepal; SRL:Sri Lanka; THA:Thailand; T-L: Timor Leste NA: Not available; ND: Not done

4.2 Management of Nationally-coordinated Blood Transfusion Services

Three presentations were made by the National Programme Directors of Thailand (Dr Rachanee O Charoen), Sri Lanka (Dr Bindusara) and Egypt (Dr Faten Mohammed) regarding the genesis and essential components of a nationally-coordinated blood transfusion service. In all three countries, the commitment of top political and administrative management to modernization of nationally-coordinated blood transfusion services of the countries was highlighted which facilitated forward movement of the programme. The importance of consolidating testing of blood for TTI and blood group serology in centralized testing locations was emphasized. The advantages of such structural reforms include cost reduction because of high volumes, better quality assurance and reduction of workload on smaller blood banks. Sri Lanka and Egypt also availed of substantial international financial aid and technical support from WHO. Considerable importance was also accorded to the use of modern information technology in bar coding and data management.

Group Work 1

The participants discussed various facets of nationally-coordinated blood transfusion services which included the need for a national blood policy, initiation of its development, steps required to draft a national blood policy and get approval thereafter from the competent authority (Parliament) and various components which must be articulated in the national blood policy. They also deliberated upon the mechanism by which the policy could be converted into an efficient programme. The structure, functions and regulation of blood transfusion services were also discussed and a generic country-level framework developed. The following steps were suggested:

- (1) It is essential to get government intention and commitment through a national blood policy to facilitate standardization of the quality of blood services. Even countries with limited number of blood banks and small populations, viz Maldives, Bhutan and Timor Leste, should formulate national blood policies.
- (2) Blood transfusion services/experts or the users of blood should initiate the process of development of a policy.

- (3) Drafting of the policy may be undertaken in following sequence:
 - Establishment of a national committee/council with the concurrence of the Ministry of Health; it must comprise of all stakeholders;
 - Preparation of a draft policy.
 - Dissemination of the draft to professional bodies, academic institutes, general public etc .
 - Finalization of the draft by incorporation of appropriate suggestions and modifications
 - Approval by the Ministry of Health, Government and the Parliament
- (4) The components of the policy should pertain to:
 - Organization and management of blood transfusion service;
 - Donor recruitment and selection process, and
 - Blood collection, screening, processing, storage, distribution and utilization to optimize its quality, efficiency and cost recovery.
- (5) The responsibility for running nationally-coordinated blood transfusion services should rest with the government and if need be, this may be delegated to a non-profit organization with mutually agreed and clearly-defined terms and conditions.
- (6) Structural units should be in a pyramidal shape:
 - One central blood centre
 - Few regional blood centres
 - District blood centre/collection centres and hospital blood banks
- (7) Function of different structural units should be decided on the following lines:
 - Central
 - A reference centre for all BTS activities.
 - Setting of norms
 - Training of human resource

- Assessment of quality
 - Regional blood centre (testing centres)
 - Blood processing
 - District blood centre :
 - Blood collection, storage and distribution
 - Hospital blood bank :
 - Blood storage and rational use of blood
- (8) The government (FDA and/ or MOH) to regulate BTS by establishing:
- Good manufacturing practices
 - National standards for blood service.
 - Blood utilization norms
 - Adequate regulatory mechanism through an authorized competent structure
- (9) Funding for BTS:
- Mainly from the government.
 - Support by relevant stakeholders/funding donors may be sought
 - Cost recovery (non profit).

4.3 Development of National Blood Donor Programme

Prof Chaivej provided a historical background of the development of the blood donation programme in Thailand. The programme is run by the Thai Red Cross, with government support (policy and budget), organized in a network, through the National Blood Centre in Bangkok (1); Regional Blood Centres, I – XII (12) and Provincial Blood Centres, in each of the 75 provinces. The programme ensures that to secure adequate and safe blood from voluntary donations same standards are used throughout the country. Advertising and marketing of the concept and utility of blood donation are

extensively used to target population. He emphasized that it took Thailand over 20 years of consistent effort to eliminate paid blood donation.

Prof Chaivej suggested the establishment of a national committee for the recruitment and promotion of voluntary blood donors; Department of Public relation and donor recruitment, recruitment of volunteers and mobile blood collection teams to collect blood at donor's workplaces. He also suggested focusing on three groups of donors to augment safe blood supply. These are: unpaid general donors (rather than family or replacement donors); regular (repeat) donors (rather than first time) and female donors. Data collected in Thailand during the last few years have shown that repeat donors and females were safer donors. Extensive use of mass media and endorsement by national celebrities are helpful in attracting more donors.

Group Work

The participants deliberated on the generic step-wise approach in developing a national blood donation programme that any country can adapt to suit its needs. They identified the requirements of the structure of a blood donor programme within the nationally-coordinated blood transfusion services with adequate number of trained staff. A national advisory committee on blood donation with members from different walks of life shall provide technical inputs to the national programme. Modern marketing tools should be applied to enrol younger and safer blood donors, select them for blood donation through nationally-accepted standards and efforts initiated to retain and convert them as regular donors. The donors must be provided appropriate care before, during and after the donation to make it a pleasant experience for them. The social recognition of donors shall also give a boost to national efforts in increasing the number of donors. A confidential database need to be maintained, especially for donors with rare blood groups. A consensus with the top authorities and colleagues should be reached to manage the influx of a large number of unwanted donors during natural calamities.

4.4 Testing of Blood

Dr Rachanee O Chareon introduced technical and management issues to optimize the testing of blood. She relied heavily on the Thailand model where centralized or regionalized infectious markers testing of donated blood has

been initiated. There are 12 regional testing centres whereas 151 regional branches are in operation. This change has resulted in increased blood safety, reduction in manpower, human error and the cost of reagents. All these lead to reduction of unit cost/sample, reduction in the quantity of reagents used for positive control, negative control, internal positive control etc. The process also allows authorities to exert a bargaining power for the purchase of large volumes of material at lower prices, better after-sales service, and maintenance of equipment.

Dr Rachanee also emphasized on the local production of reagents to ensure continuous supply, indigenous availability and almost 50% reduction in cost as compared to those of commercially- available reagents. She discussed the criteria that may be considered for selecting technology, reagents and equipment. She highlighted the need for validation, calibration and monitoring of equipment to have their optimal utilization. Dr Rachanee described the use of bar-coded identification of specimen, computerization with customized software programme and automation to reduce transcription error, reduce human error and reduce manpower. She also suggested that technology and equipment should be regularly updated and modernization should be a continuous process.

Group Work

The participants identified various factors in the Region that warrant greater attention to screening of blood for TTI. These include: high prevalence of transfusion transmissible infections, lack of consolidation in testing and standardization of the functional components of BTS, poor technical skills/low expertise, poor quality of cheap kits due to insufficient funds, and inadequate government support/commitment. They suggested that under the nationally-coordinated blood transfusion services a comprehensive analysis of the current situation should be done followed by the formation of a Task Force. The Task Force should bring about amendments in national policies or plans (if needed) to ensure a re-organization/restructuring of the blood transfusion services into one National Blood Centre and selected appropriate regional centres depending on the geographical situation of the country where testing of blood on the pattern of Egypt, Sri Lanka and Thailand can take place. In addition, the programme should identify the roles of each level of centre and staff, undertake capacity building of all categories of staff, develop testing strategies with appropriate technology, and apply quality systems. These efforts must be complemented with appropriate national donor programme

and strategy for appropriate clinical use of blood. These activities are expected to augment the availability of safe blood, reduce transmission of TTIs, reduce burden of health care, while increasing cost-effectiveness and credibility of BTS.

4.5 Integration of Quality in Nationally-Coordinated Blood Transfusion Services

Dr Rajesh Bhatia (SEARO) gave an overview of the concept and utility of quality and its implementation in a systematic way. Five key elements of a quality system comprising organizational management, standards, training, documentation and assessment were introduced. Various tools for internal and external assessment of the quality system, including quality audit and external quality assessment scheme (EQAS) and internal quality assessment scheme (IQAS) were also discussed. Documentation is an important element of any quality system. Dr Bhatia discussed the definition of documents, their types, utility and classification by ISO. Standard operating procedures (SOP) were critical sub-elements of the quality system and are essential to ensure that every procedure is undertaken in a standardized way and consistent results generated.

Assessment of quality system is undertaken with the help of a variety of tools. Dr Bhatia gave an overview of various methods and tools for the assessment of quality and their utility in monitoring and evaluation of quality system. Quality can be assessed through on-site inspection (audit) or by sending material of known but undisclosed characteristics for testing by blood banks by a designated institute (external quality assessment scheme). Dr Bhatia also elaborated upon the activities undertaken by WHO in the recent past to implement a Quality Management Project for BTS, a regional external quality assessment scheme for TTI and blood group serology as well as establishment of a regional quality centre to provide continuous support to all the blood banks in the Region.

Group Work

The participants agreed on the need to integrate quality into the nationally-coordinated BTS. They suggested following steps to achieve this:

- Develop quality policy
- Develop a quality plan

- Create a quality department
- Appoint a quality manager
- Develop skills and knowledge of all staff members on various facets of quality
- Develop an action plan for integration of quality system
- Train all staff members in concepts and practices of quality
- Adopt national standards for quality
- Institute a system of documentation
- Undertake assessment through regular audit and participation in external quality assessment scheme.

4.6 Clinical Interface

Dr Yuyun M. Sudarmono discussed the importance of an active interface between the supplier of blood (blood centres) and users in hospitals. A two-way continuous communication between suppliers and users is a prerequisite. She showed various forms that need to be filled for requisitioning blood from blood centres in Indonesia. Dr Yuyun highlighted the need to improve clinical use of blood by assuring the quality of the blood product, establishment of blood banks in hospitals, developing guidelines for blood requisition and usage. She said that the situation could improve with the constitution of hospital blood transfusion committee to ensure rational use of blood and overseeing the same. Orientation of clinicians, availability of quality components, preservation of potency of products while in transit and appropriate documentation were other areas that needed strengthening in the countries. She advocated greater use of WHO publications on clinical use of blood by clinicians.

Group Work

The participants suggested that national guidelines should be drafted to maximize utilization of the available blood and components and minimizing unnecessary transfusions. The use of blood components need to be promoted by augmenting awareness of the prescribers and standardization of component therapy practices. National guidelines should include information on components, patient identification and records, transport and storage,

information on administration of blood, mechanism of haemovigilance, indications and contra-indications for use of blood and blood products. Capacity building of physicians is essential. The use of whole blood should be discouraged and facilities for special services such as leuco-reduction, irradiation and washed red cells initiated at national centres. The participants also felt the need to strengthen documentation at users-end and to develop standardized forms for the same. A mechanism of haemovigilance either through sentinel surveillance or across the country should be constituted. Major adverse reactions must be investigated.

4.7 Development of Plan of Action and a Follow up Mechanism

Dr Rajesh Bhatia briefed the participants on the need for planning and the method of developing of an action plan with specific activities. Various parameters that need to be considered and included in the action plan were: activity, type of activity, time-frame, person designated to undertake the same and resources required to accomplish the activity. The participants developed country-specific action plans in group works and presented them at a plenary session. Several issues that need to be considered by the participants in strengthening nationally-coordinated BTS in their own settings were thoroughly discussed in a plenary session.

5. RECOMMENDATIONS

For Member countries

- (1) All Member countries should formulate a national blood policy and implement it in all the blood banks through a nationally-coordinated blood transfusion service and allocation of adequate resources.
- (2) Member countries should constitute a national blood transfusion committee to manage the national programme.
- (3) Member countries should, as far as possible, initiate regionalization of testing centres on the pattern of Egypt and Sri Lanka to enhance safety and cost-efficiency of testing of blood.
- (4) Member countries should develop a national blood programme to augment voluntary donors with focus on increasing the number of regular donors.

- (5) Member countries should integrate quality in all aspects of blood transfusion services by formulating a quality policy, and plan and implement it to strengthen the quality system.
- (6) Member countries should strengthen interface between the supplier of blood and its users and develop national guidelines and assure appropriate use of blood.

For WHO

- (1) WHO should continue to provide advocacy and technical support to all Member Countries through intercountry capacity building activities in the field of promotion of VNRD, regulation of blood services, implementation of quality system and preparation of components.
- (2) WHO should provide technical support for country-specific activities to strengthen nationally-coordinated BTS.
- (3) WHO should widely disseminate all its publications related to blood safety.
- (4) WHO should assure continuous technical support to Member countries in the implementation of the quality system.
- (5) WHO should develop guidelines for the establishment of component production units in developing countries.
- (6) WHO should organize periodic meetings of national programme managers to review the progress made and develop strategies to improve blood transfusion services.

6. CONCLUDING SESSION

The concluding session was chaired by Dr Sujudi. He thanked the organizers and facilitators for making the consultation a success and hoped that the participants would be able to translate the knowledge gained in strengthening quality assurance practices in their own settings. Dr Rajesh Bhatia assured WHO's continued support in this area. He also thanked the local organizers for their excellent support for the conduct of this consultation.

Annex 1
PROGRAMME

Tuesday, 20 April 2004

0900 hrs	Registration Inauguration RD's address Objectives Introduction of participants Election of chair and rapporteur	
1030 hrs	WHO global strategies for blood safety - Regional status	Dr Rajesh Bhatia
1100 hrs	Country presentations 15 minutes each including discussion	
1330 hrs	Country presentations contd	
1500 hrs	Reorganization of BTS in Egypt	Dr Faten
1545 hrs	Organization and management of National BTS	Dr Rachanee
1615 hrs	Experience in Sri Lanka with revamping of BTS	Dr Bindusara
1645 hrs	Briefing for Group work 1 <i>Formulation of national blood policy and plan</i> <ul style="list-style-type: none">• Structure of nationally-coordinated BTS• Functions of various organs of nationally-coordinated BTS• Regulation of national BTS• Costing and cost recovery• Requirements and development of human resource	

Wednesday, 21 April 2004

0900 hrs **Group Work 1**

Presentation of group work :

1330 hrs Establishing a voluntary non-remunerative blood donor programme and experience in Thailand Dr Chaivez

1415 hrs **Group Work 2 and presentation**

National Blood Donor Programme

Structure of programme

Functions of programme

Donor education and motivation

Donor recruitment

Donor selection

Donor retention

Thursday, 22 April 2004

0900 hrs Testing and processing of blood: policy and strategic planning and Thai experience Dr Rachanee

0945 hrs **Group Work 3 and presentation**

Testing and processing of blood

- Selection and quality of test kits for screening and reagents for immunohaematology
- HIV/viral hepatitis testing strategies
- Technology and equipment
- Guidelines for national agencies
- Appropriate strategies and test methods
- Storage and transport methods
- Biosafety & disposal of wastes

1330 hrs Quality system in BTS Dr Rajesh Bhatia

1415 hrs	Group Work 4 and presentation <i>Integration of quality system in BTS</i> Organizational management Standards Documentation Training Assessment	
1645 hrs	Development of Plan of Action	Dr Rajesh Bhatia

Friday, 23 April 2004

0900 hrs	Clinical interface and experience in Indonesia	Director, PMI
1000 hrs	Group Work 5 and presentation <i>Clinical interface</i> <ul style="list-style-type: none">• National guidelines• Monitoring of adverse reactions• Awareness of prescribers• Availability of components• Regulations of components	
1330 hrs	Major constraints and draft recommendations	
1430 hrs	Presentation and discussion of model plan of action	
1530 hrs	The way forward	
1630 hrs	Conclusion and finalization of recommendations	
1700 hrs	Closure	

Annex 2

LIST OF PARTICIPANTS

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