REPORT

WORKSHOP ON IMPROVING ACCESS TO ESSENTIAL MEDICINES AND STRENGTHENING VACCINE SECURITY FOR PACIFIC ISLAND COUNTRIES

Nadi, Fiji
25-27 November 2003

Manila, Philippines
April 2004
REPORT
WORKSHOP ON IMPROVING ACCESS TO ESSENTIAL MEDICINES
AND STRENGTHENING VACCINE SECURITY FOR
PACIFIC ISLAND COUNTRIES

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The views expressed in this report are those of the participants on the Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries and do not necessarily reflect the policy of the World Health Organization.

This report has been prepared by the World Health Organization Regional Office for the Western Pacific for governments of Member States in the Region and for those who participated in the Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries, which was held in Suva, Fiji from 25-27 November 2003.
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Keywords

Drugs, Essential / Vaccines / Pacific islands
SUMMARY

The workshop on improving access to essential medicines and strengthening vaccine security for Pacific Island Countries (PIC) took place in Nadi, Fiji, from 25 to 27 November 2003. Close to 50 persons, 30 from medicines and vaccines management in government health services in 19 Pacific island countries, 10 observers, two temporary advisors, one consultant and a secretariat of six persons participated in the workshop. The secretariat had representatives from three departments in the Western Pacific Regional Office, Pharmaceuticals, Expanded Programme on Immunization and Health Systems Development plus the WHO Fiji country office. The objectives of the workshop were:

1. to discuss the draft “Regional strategy for Improving Access to Essential Medicines in the Western Pacific Region of the World Health Organization (2004-2009)”, emphasizing elements of particular relevance to Pacific island countries;

2. to discuss opportunities to strengthen country level vaccine management systems through the WHO Vaccine Management Training Network;

3. to identify problems, exchange experiences and explore possible actions to improve access to essential medicines and vaccines, including selection, estimation, use, pricing, financing and maintaining reliable supply systems and cold chain management; and

4. to prepare a plan for collaborative activities for Pacific island countries (PIC) with the aim to improve access to essential medicines and strengthen vaccine security.

The programme consisted of presentations and exchanges of experiences and discussions in plenary on: global, regional and country access to essential medicines and vaccines; examples of inter-country collaboration; human resource development; WTO/TRIPS and access to medicines; financing essential medicines and vaccines; improving financial planning for medicines supply; management and problems in supplies in the Pacific; rational drug use and quality assurance of medicines and vaccines; Pacific prospective of current vaccine situation and vaccine security; vaccine management (effective vaccine stores management initiative, cold chain certification and policy and management); and vaccine arrival reporting (simple tests to check vaccine quality, description of the UNICEF vaccine arrival report). Participants also undertook group work and individual work in an exercise to complete a Vaccine Arrival Report VAR. At the end of the workshop they split into two groups, one on essential medicines and one on vaccines, and selected and prepared a plan for priority collaborative activities, from a long list of recommendations to improve access to essential medicines and vaccines in PIC.

Priority recommendations to improve access to essential medicines include: explore setting up a PIC e-drug network for information exchange; explore the feasibility of cooperation on regional contracting under pooled procurement; align various initiatives in pharmacy education and training and exchange information on training needs; develop a common approach to supplier and product registration towards harmonization in quality assurance and identify suitable laboratories for quality testing. Priority vaccine recommendations concerned the need to use Vaccine Improvement Initiative (VII) and mechanism in procurement; the need for updating the Cold Chain Management, perform CC inventories and look for funding; and the start of an information exchange on successes, issues and problems in vaccine management.
1. INTRODUCTION

A Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries (PICs) was held in Nadi, Fiji from 25 to 27 November 2003.

1.1 Background information

As recommended by the ministers of health in the Rarotonga Agreement (1997) and the Palau Action Statement (1999), support has been provided to Pacific island countries for drug supply management, rational drug use, quality assurance and information exchange on issues related to medicines. Although progress has been made in the area of pharmaceuticals in the Pacific, problems related to access to essential medicines, including antiretrovirals of affordable price and assured quality, still remain.

With the potential global shortage of vaccines recommended by the Expanded Programme on Immunization (EPI), the vaccine security (uninterrupted sustainable supply of quality affordable vaccines, to the point of the administration of the child) of many Pacific countries is also uncertain.

Based on the WHO framework for improving access to essential medicines, the “Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region of the World Health Organization (2004–2009)”, and opportunities to strengthen vaccine management systems through the WHO Vaccine Management Training Network, it was decided to hold this workshop to discuss feasible options and collaboration between countries to improve access to essential medicines and strengthen vaccine security.

A collaborative plan of action, one of the outcomes of the workshop, will be presented to the governments concerned for their consideration, endorsement and action.

1.2 Objectives

The objectives of the workshop were:

(1) to discuss the draft “Regional Strategy for Improving Access to Essential Medicines in the Western Pacific Region of the World Health Organization (2004-2009)”, emphasizing elements of particular relevance to Pacific island countries;

(2) to discuss opportunities to strengthen country-level vaccine management systems through the WHO Vaccine Management Training Network;

(3) to identify problems, exchange experiences and explore possible actions to improve access to essential medicines and vaccines, including selection, estimation, use, pricing, financing and maintaining reliable supply systems and cold chain management; and

(4) to prepare a plan for collaborative activities for Pacific island countries with the aim to improve access to essential medicines and strengthen vaccine security.
1.3 Participants

Close to 50 persons took part in this workshop on the combined topics of improving access to essential medicines and strengthening vaccine security in the Pacific island countries. The participants were: 30 persons involved in medicines and vaccines management in government health services in 19 Pacific island countries, 10 observers, two temporary advisers, one consultant and a secretariat of six WHO officials from the departments of Pharmaceuticals, Expanded Programme on Immunization, Health Systems Development and the WHO Fiji country office (Annex 1).

1.4 Organization and content of workshop

The programme (Annexes 2 and 3) consisted of presentations and exchanges of experiences and discussions in plenary on: global, regional and country access to essential medicines and vaccines; examples of intercountry collaboration; human resource development; the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) and access to medicines; financing essential medicines and vaccines; improving financial planning for medicines supply; management and problems in supplies in the Pacific; rational drug use and quality assurance of medicines and vaccines; Pacific prospective of current vaccine situation and vaccine security; vaccine management (effective vaccine stores management initiative, cold chain certification and policy and management); and vaccine arrival reporting (simple tests to check vaccine quality, description of the vaccine arrival report of the United Nations Children's Fund [UNICEF]).

Participants also undertook group work in the form of a practical exercise to complete a Vaccine Arrival Report (VAR). At the end of the workshop they split into two groups, one on essential medicines and one on vaccines, to review the draft recommendations and propose feasible strategies for a few priority collaborative activities to improve access to essential medicines and vaccines.

1.5 Opening ceremony

The Regional Adviser in Pharmaceuticals in the WHO Western Pacific Regional Office welcomed the participants. He announced that this meeting was going to cover many topics, and that it was replacing a previously planned meeting on just procurement collaboration. The fact that essential medicines and vaccines were now going to be discussed together, in the same workshop, was very important. It was foreseen that this workshop would lead to future closer collaboration between the two programmes and between PICs with their unique characteristics. Following the welcoming address, the Permanent Secretary of Fiji, Mr Luke Rokovada, officially opened the workshop. He expressed the same hope for active PIC collaboration, at least through participation in the Fiji joint pharmaceutical bulk procurement scheme. The workshop was briefly introduced to the development and work of this scheme, its new facilities, the country’s essential medicines work, Fiji’s vaccine security programme and policy framework.

A message from the WHO Western Pacific Regional Director touched on all the agenda items to be discussed. Improving access to good quality essential medicines and vaccines and their appropriate use have become priorities of the Western Pacific Region over the years. Vaccine security (the uninterrupted sustainable supply of quality affordable vaccines to the point of administration to the child) is increasingly uncertain in many PICs. Regional strategies had been developed to overcome these increasingly complex problems, caused by multiple factors. The workshop was convened to discuss feasible options for collaborative activities to improve access to essential medicines and vaccines.
1.6 Appointment of Chairperson, Vice-Chairperson and Rapporteur

The workshop elected Mr Peter Zink from Fiji and Ms Ariane Kienene from Kiribati as Chairperson and Vice-Chairperson, respectively, and Mr Ray Skinner of Solomon Islands as Rapporteur. The participants received PowerPoint presentations and other background documents in hard copy (Annex 4).

1.7 WHO Representative message

The Fiji WHO Representative, who had been out of the country on the opening day, joined the workshop. He spoke of the importance of improving access to essential medicines and vaccines. He informed briefly about other priority topics discussed at the recent meeting of WHO Representatives in Geneva, for example: the new WHO Director-General’s emphasis on country support; the “reintroduction” and pursuit of the primary health care concept born in the 1978 Alma Ata Conference; the “3 x 5” concept. He, like other speakers, encouraged participants to explore feasible options for collaborative activities in the Pacific and assured WHO commitment to assist in this.

2. PROCEEDINGS

2.1 Global, regional and country access to essential medicines and vaccines

2.1.1 Global perspectives on access to essential medicines: introductory overview

The essential medicines concept and national medicines policy were introduced in 1975. In 1977, a WHO expert committee produced the first essential medicines list (EML), which has been regularly updated since then. In the 1980s, WHO and countries started to develop programmes, which surged and broadened in the mid-1990s onward when new challenges arose with HIV/AIDS, tuberculosis (TB), malaria, TRIPS, etc. Among achievements to date are: more than 100 countries with national medicines policies, more than 156 countries with EMLs, and more than 130 countries with national treatment guidelines and formularies. Price information services have been introduced, collaborative work on pre-qualification of suppliers is ongoing, and generic medicines competition is encouraged in many countries. In spite of these achievements, roughly two billion people or one-third of the world’s population still lack regular access to essential medicines. A huge unfinished agenda remains to improve access to essential medicines.

WHO’s global policy for improving access is its Medicines Strategy, approved by the World Health Assembly in 2001 (WHA 54.11), reaffirmed in the commitment on ensuring accessibility to medicines in 2002 (WHA 55.14) – and in resolution WHA56.27 on intellectual property rights, innovation and public health, May 2003. Four strategic objectives have been agreed upon to improve global access: (1) promote rational selection and use; (2) increase quality and safety; (3) improve access; and (4) provide support for development and implementation of national medicines policies. Access depends on four factors: (1) rational selection and use; (2) affordable prices; (3) sustainable financing; and (4) reliable health systems.

Global procedures and tools to improve access include: revised procedures for WHO model EML; a first WHO Formulary in 2002 and updated clinical guidelines; WHO medicines bookshelf and a handbook on access to HIV/AIDS-related treatment; information on pre-
qualification of innovator and generic suppliers and studies of quality of medicines to improve quality and safety of medicines. Recently published are also prices of selected medicines and a new draft methodology to measure medicine prices. A network for monitoring impact of globalization and TRIPS has been established and options and mechanisms for drug financing, good procurement practices, inventory control, drug management and human resources development are regularly disseminated.

The consultant ended by saying that access to essential medicines is now on the world social, economic and political agendas. It has been discussed at the Millennium Summit of world leaders, at the Economic and Social Council (ECOSOC), at the UN Commission on Human Rights and at numerous WTO meetings. A Global Fund to Fight AIDS, Tuberculosis and Malaria has been set up, industry negotiations have intensified, and other foundations and funds are active in improving access to medicines, in particular, HIV/AIDS medicines. WHO essential medicines department has also increased collaboration with nongovernmental organizations (NGOs) and others.

2.1.2 Regional strategy for improving access to essential medicines in the Western Pacific Region

The WHO Western Pacific Regional Adviser in Pharmaceuticals stated that lack of access to essential medicines remains a major problem in the Region, in spite of improvements and increases in essential medicines programmes during the last 25 years – and in spite of existing policies, relevant tools and guidelines. The Region needs a focused and intensified effort – a practical strategy to provide guidance to countries and to WHO in consolidating efforts to improve access. In response to the request from Member States during the 53rd Regional Committee Meeting (RCM) in Kyoto, Japan in September 2002, a draft strategy was developed. A wide consultation process with experts and Member States, including a special expert meeting (Penang, July 2003), had taken place to review and revise the draft, before it was presented to the 54th RCM in Manila in September 2003. The RCM felt, however, that part of the strategy on trade globalization and the TRIPS Agreement needed further consultation and recommended that a small working group meet to review this and a few other issues. The working group meeting is planned for early 2004.

The Regional Adviser outlined the general framework of the strategy, which corresponds to the four global factors to improve access to medicines, i.e. rational selection, affordable prices, sustainable financing, and reliable health and supply systems. The strategy framework and contents, pictorially presented at the workshop as a jigsaw puzzle with parts fitting into each other, was clearly understood:

Example: “Rational selection” includes: avoiding spending on drugs of no or limited therapeutic interest; reducing number of drugs to improve rational prescription and use; and reducing transaction and storage facilities. “Affordable prices” could also be achieved by choosing one or several options, such as: striving for “best prices” through negotiations and competition; introducing generic policies; applying TRIPS safeguards; and reducing or abolishing duties, taxes and mark-ups.

The scope of the regional strategy covers eight relevant areas: rational selection; rational use; affordable prices; sustainable financing; supply and management system; quality; trade globalization and the TRIPS Agreement; and monitoring and evaluation. In each area, issues and challenges are presented before the strategies, which are followed by Member States’ and WHO’s actions.
Example: One of the issues and challenges under "rational use" is lack of a comprehensive package of interventions to improve rational use. The proposed strategy to address this is for Member States to develop and implement such a package for providers and consumers, combining educational, managerial and regulatory interventions, and for WHO to support the formulation, implementation and evaluation of such a rational drug use strategy.

In the discussions that followed the presentation of the regional draft strategy above, some participants asked for more elaborations on the TRIPS Agreement and its implications since they were not at all familiar with this. Explanations were deferred to the specific agenda item on this issue, discussed below under 2.4. Regarding questions on "how to implement the strategy", the Regional Adviser replied that guidelines would be prepared. Once the strategy was approved, joint country/regional work plans would also be developed. Collaborative PIC action plans in major technical areas of essential medicines would also follow.

2.1.3 Regional vaccine situation and supply, in particular that of the Pacific

A WHO resolution that "urges Members States to use measles elimination and hepatitis B strategies to strengthen EPI and other public health programmes" was recalled.

The vaccine situation today shows unique characteristics. There is a diverging vaccine market causing concern primarily in low and middle-income countries but also in high-income countries. There is a shift in production to newer and more expensive vaccines and shortages of traditional EPI vaccines. Countries need to ensure "vaccine security", i.e. "the uninterrupted and sustainable supply of vaccines of assured quality". Accurate orders and time to increase production are required globally. The two speakers under this agenda item stressed that countries must strive for strong vaccine management systems (estimation, procurement, cold chain, wastage), for securing medium to long-term financing, and for strengthening the national regulatory agency in vaccine producing countries (now also more in developing countries) in order to supply the global market.

Example: The presenter clearly illustrated the changing global vaccine situation by showing vaccine supply profiles (availability versus demand) for measles, diphtheria-tetanus-pertussis (DTP) and tetanus toxoid (TT); manufacturer profiles of the vaccines offered to UNICEF from 1992 to 2006; and WHO pre-qualified hepatitis B vaccine.

Key points made were that in coming years, matured vaccines (DTP, BCG, measles, TT and oral polio vaccine [OPV]) will be in tight supply and there will be significant price increases. For maturing vaccines (hepatitis B), the availability will be good and prices will be unchanged or slightly increased. To avoid shortfalls, there is need for good forecasting, funding and contracting.

The WHO Western Pacific Regional Office strategy for the Pacific and other countries in the Region consists of:

- cooperating with UNICEF and governments on supply contracts;
- promoting financial sustainability principles with countries;
- giving technical assistance to countries on vaccine management systems (forecasting, wastage reduction, cold chain); and
- giving technical assistance to newer vaccine producing countries.
2.1.4 Selected country experiences on access to medicines and vaccines

*Vanuatu, Kiribati, Samoa and Tonga experiences*

Vanuatu’s medical procurement, storage and distribution are difficult because the country’s 200,000 population is spread over 80 islands. In spite of a tiered, fairly well-structured supply mechanism, limitations in the supply system affect both access to vaccines and essential medicines. For vaccines, there are both lack of equipment and lack of maintenance of existing equipment, limited transport and funds to deliver service, no refresher courses, supervision or management training for health workers. For essential medicines, obstacles for uninterrupted supply and access are shortage of internal funds, limited human resources at national and provincial supply services, weak logistics, and lack of monitoring and evaluation. To improve the situation, the government has decided on a decentralization policy, strengthened health sector planning and management, introduced strategic planning, is preparing a human resource development plan, is promoting intersectoral collaboration, and has adopted a national medicines policy.

In Kiribati, access to vaccines and medicines has improved over the last 20 years, but its 84,000 people, living on 16 widely scattered islands and isolated islets, do not yet have regular access. Problems in vaccine and medicine procurement, supply and delivery remain because of poor estimates of needs, expired drugs, uneven distribution and an inadequate delivery system with infrequent boat trips. Big tenders may take up to 10 months to arrive. Vaccines are therefore now supplied from Hawaii. Prescribing is irrational with over-prescribing of antibiotics and high wastage. Prescribed medicines are free and others are at affordable prices. The Cabinet recently introduced fee for service. The EML and treatment guidelines prepared in the 1990s need updating, but there are very few qualified professionals to do this work. Kiribati does not have a national drug policy.

Samoa has two big and two small islands and a population of 178,000. The current EML is from the 1990s, but a new list was drafted in 2003. Samoa has adopted a national medicines policy. Funding of essential medicines is a priority. Six million dollars was allocated for medical supplies in 2003. Vaccines are ordered and supplied yearly from UNICEF. While communicable diseases seem to be under control, noncommunicable diseases are increasing.

Tonga has similar problems in the supply system as other Pacific island countries. In addition, the hospital list of medicines and the national EML are expanding every year. Restrictions are due to funding limitations and not as it should be to application of selection criteria. Usage guidelines for medicines are not in line with standard treatment guidelines, which makes drug need estimation difficult. In 2000, Tonga introduced its national drug policy. Drug registration started then and is almost complete for all drugs on the market in the country. The time and effort it takes to do such work with very limited human and financial resources should not be underestimated.

2.1.5 Issues and challenges

Common issues and challenges from this session’s presentations and discussions among workshop participants include the following:

- long lead-time for delivery (geographical situation);
- shipping information and schedules need to be communicated;
- EPI and cold chain equipment problems, climatic effects and essential medicines packaging;
reason why drug registration is needed (safety, efficacy, quality);

• consequences of decentralization in drug procurement, rational drug use and quality assurance – could result in non-adherence to national standards in such important areas as quality assurance and control;

• very few doctors and other health professionals to promote rational drug use – need for a good leader and improvements in planning, target setting, and monitoring of drug and therapeutic committee work in hospitals;

• no system for regular budget and expenditure reviews of pharmaceuticals, vaccines, and other supplies and related operative costs (further discussed under Financing) – need to define source and scope in measuring national per capita expenditure on medicines; and

• need to “revisit” and use long-time existing WHO guidelines and methodologies, e.g. applying criteria in selection of essential medicines, using methodology on “how to assess drug use”, etc.

Success factors noted:

• several EMLs are up to date;

• more than half of the Pacific island countries now have national medicines policies (Annex 5) and several have EPI policies;

• health facilities have been empowered to manage order, e.g. active vaccine ordering in Samoa;

• budgets for medicines and other medical supplies improved to realistic levels, or towards better levels, in at least one country – Solomon Islands;

• an information system in Fiji is providing feedback on what is going on in the supply system; and

• good support is being provided by partners, e.g. UNICEF vaccine supply.

2.2 Examples of inter-country collaboration

2.2.1 Fiji pharmaceutical bulk procurement scheme: Experience with the small island states

The Fiji bulk procurement scheme started as a drug revolving fund into which the Ministry of Finance put half a million US dollars as initial capitalization costs. The main objective was to provide quality pharmaceuticals at a reasonable price to the Fiji public. The scheme created modest profits over the years and has been successful in establishing a list of accredited suppliers. It has a limited list of 25 items. Prices came down as volume of procurement increased. When the scheme extended its services to the small island states (SIS) of Tuvalu, Cook Islands, Nauru and Kiribati, it faced a number of challenges such as timely delivery, lack of customer focus, and competition with other distributors both locally and abroad. Future extension to Guam and the Federated States of Micronesia present similar challenges plus the fact that United States Pharmacopoeia (USP) requirements have to be met.

With extension of services, warehousing and business practices became inadequate and improvements were needed. This workshop was told that water leakage has been fixed, overloading has been reduced and problems of limited storage space have been partially solved by staggering deliveries in split shipments. The New Fiji Pharmaceutical Service Centre (built with the support from the Japanese International Cooperation Agency, or JICA, and scheduled to open in May 2004, see below) will also greatly improve the working environment, temperature control, stock and information management and quality assurance.
The presenter and chief pharmacist of Fiji Pharmaceutical Services informed the meeting that when SIS members recently reviewed their "action points" from the last two SIS meetings, they noted the Fiji bulk procurements scheme's improvements in storage conditions and in quality assurance (pre-qualification process and quality testing at the Australian medicines regulatory agency, Therapeutic Goods Administration [TGA]). They also noted that there had been partial achievements under action points concerning method of payments, monitoring and evaluation, and in the selection of 20 drugs for Tuvalu. Actions concerning insurance, mark-ups, ordering and delivery schedules, and better communication with SIS members were yet to be achieved.

Three options of procurement models for the Fiji pharmaceutical bulk purchase scheme were put forward: (1) a purely commercial relationship, (2) a bulk purchase co-operative with pooled funding into an independent store, on contract; and (3) a central buyer with autonomous/independent relationship to those using the services. The presenter elaborated on advantages and disadvantages under each option.

Some examples and lessons learnt from three bulk pooled procurement programmes in different parts of the world showed that pooled purchasing is not enough; that a strong procurement system is required (credible, transparent, prompt payment, etc.); that political commitment and active participation of client countries are necessary; that payment agreements and procedures must be clear and adhered to; that there must be a strong, autonomous procurement secretariat; that the EML is harmonized; that quality is assured through tests, purchasing agreements and supplier pre-qualification; that performance of suppliers and clients is monitored; and that procurement methods include restricted international competitive bidding, informed and coordinated buying and direct negotiating.

Tuvalu's collaboration with the Fiji bulk procurement scheme was formalized in 2001. The workshop learnt about some initial problems concerning back orders, need for a system for expired drugs and need for more efficient communication. But the Tuvalu representative reaffirmed that his country had largely benefited from participation in the bulk procurement scheme. Among some recommendations to Fiji were to strengthen the partnership and reduce mark-ups.

2.2.2 New Fiji Pharmaceutical Services Center: JICA support

The JICA representative gave an overview of JICA's support. He told participants that the budget for Japan's grant aid to Fiji for the New Fiji Pharmaceuticals Services Center (NFPS) is 1 billion 59 million Japanese Yen. He further noted that JICA's project and its grant aid for construction of the NFPS is part of JICA's ongoing contribution to promote prevention and control of infectious diseases in PICs. This covers support for EPI, elimination of lymphatic filariasis and TB control. The JICA technical cooperation scheme supports EPI national action plans, systems for maintenance and repair of cold chain, systems for supply management, and systems for medical waste management. JICA assigns expertise, provides supply and equipment and training. Training for NFPS staff will include vaccine management, cold chain workshop, and the use of the Center's new management information system, its "Logistic Management Guide" and "Software Development for Inventory Control".

The resident architect from the Japanese consortium of consultants designing, equipping and building the NFPS gave details of the new warehouse and centre. Construction started in December 2002, completion is scheduled for March 2004 and opening for May 2004. The total floor area of the new warehouse is 5150 m² compared to the old one of 3670 m², and the new bulk area is 1560 m² compared to the existing one of 890 m². Data on equipment, functions,
environment and vaccine storage, and photos taken throughout development of the NFPSC, demonstrated a great gain for future pharmaceutical services in Fiji and its collaborators.

2.2.3 Summary of discussions under the Fiji bulk procurement scheme and the NFPSC

Vaccines: These will be included in the pooled procurement scheme when the NFPSC information system becomes operational. The centre is going through a vaccine accreditation process together with a WHO consultant. Several components are being looked at. The old system scored only 47% when it was tested. One deficiency - weak documentation - is now being addressed. An independent person will come to verify that the system is in line with WHO standards.

Essential medicines: Fiji Bulk procurement scheme uses only manufacturers that have been pre-qualified (no traders). The WHO questionnaire is very helpful in this process. An accreditation system is also under way for essential medicines – a first in the Region.

Pooled procurement: It was generally felt that the lessons learnt from the cooperation have increased confidence among the participants in the Fiji pooled procurement scheme, and that there was goodwill and commitment to make arrangements work (and work well). The question on long-term aspects for expanded participation in the scheme was raised. In contrast to the SIS, larger ones like Papua New Guinea and Solomon Islands felt they were not likely to benefit from a two-tier delivery system. But in considering options, it was recommended that cooperation on regional contracting, a combined purchasing power with multi-drop delivery, could be an alternative option worthwhile exploring. Economy of scale could be achieved in such contracting, benefiting also those that did not want add-on costs for bulk storage, and dependency on one store.

2.3 Human resource development (HRD) in support of improving access to essential medicines

Issues, challenges, approaches and management of human resources were presented. Focus was on the role, education and continued development of the pharmacist in support of improving access to essential medicines. Four WHO consultative groups had discussed this topic in 1988 (New Delhi), 1993 (Tokyo), 1997 (Vancouver) and 1998. The groups had specified technical and managerial areas and functions in which skills and knowledge of pharmacists were needed. The 1997 group had identified the “seven-star pharmacist” as caregiver, decision-maker, communicator, leader, manager, life-long learner and teacher. The Western Pacific Pharmaceutical Forum, which met in Shanghai in March 2003, stressed the role of the pharmacist in public health and recommended to include relevant subjects on this in pharmacy education curricula.

The presenter outlined approaches to keep health care professional staff in the public sector, e.g. by paying adequate salaries, by giving opportunities for career development and in-service training; and by ensuring policy-makers’ support for adequate funding for this. Examples of pre-service and in-service training programmes were also given. For example, curricula for health care workers should include the principles and specific topics of national medicines policy. And in-service training should include, among others, training in drug supply and vaccines management.

Cited among the examples for international training and development were: drug and therapeutic committee courses, the Asian course on problem-based pharmacotherapy teaching, and the recent regional workshop on the “Development of Pharmacy Curriculum for countries in
the ASEAN and Western Pacific Region" (October 2003, Penang) that specified outcomes and strategies for improving the pharmacy curriculum.

The speaker ended by raising several questions: (1) did the current curricula in PICs adequately prepare the pharmacists for the described roles, expectations and needs; (2) what can schools of pharmacy do to better respond to the changing role of the pharmacist and the need for better pharmaceutical services; (3) what are the needs and priorities for HRD in PICs; and (4) can these needs be met through collaborative activities in education and training?

2.3.1 Summary of discussions and key points under human resource development

Participants gave several examples of difficulties that the PICs face in educating and keeping health care personnel, pharmacists and doctors in particular, and in providing in-service training. The Federated States of Micronesia and Palau, for example, do not have a single pharmacist and it would take six years to get one if education started today. Instead, short-term solutions have to be found and those who now work in Palau’s health care system are taught to handle pharmaceutical supply and services. Fiji, on the other hand, turns out 63 medical doctors each year – 33 leave the country. And out of its 26 pharmacists, six remain in the public sector. Tonga has very few pharmacists and is now training assistant pharmacists locally. Solomon Islands will shortly reopen its two-year pharmacy officer course. In this, graduates are expected to carry out certain technical functions, whereby they would complement the professional and managerial role of the pharmacist. Participants at the meeting from Japan and Australia suggested that their large output of professional pharmacists could be “tapped” for service in PICs. The setting up of a kind of essential medicines regional collaborative workforce for pharmacy professional and technical education could thus be explored – suited to the special conditions and needs of a developing island country. Another collaborative PIC activity suggested was to exchange information on training needs, on existing training programmes and institutions. Other key points made were:

- PICs need to address both long-term and short-term solutions for pharmacy education and training, and align various local initiatives, even creating a single core curriculum for the University of South Pacific and the University of Papua New Guinea. A regional curriculum advisory panel could be set up to look into this.
- Various short courses and distant learning packages could be used as intermittent solutions for training in rational drug use and essential medicines supply (e.g. Aberdeen course, MSH/IDA course, Commonwealth Pharmaceutical Association training package and Solomon Island pharmaceutical officer course)
- Regional pharmacy curricula should include elements on WHO and other statements of the role of pharmacist, on access of essential medicines and also include training in practical application of rational drug use, supply management and other elements that will tend to improve the skills that are known to enhance access to essential medicines.
- It was also proposed that donors and non-PIC institutions do more to ensure return of trained staff to national health systems. For example, universities, immigration authorities, professional societies and boards to recognize PIC needs better and cooperate to meet them.
- Finally it was also recommended that PICs should make more use of schemes of service for pharmacy/essential medicines management staff, to improve conditions and enhance recruitment and retention. Existing standards in, for example, Papua New Guinea, Fiji and Australia could serve as resources for PIC development and application.
2.4 WTO/TRIPS and access to essential medicines

Established in 1994, WTO entered into force in 1995 to replace the General Agreement of Trade Treaties (GATT). All 146 WTO members are bound by multilateral agreements. One of these agreements, TRIPS, impacts access to essential medicines. It applies to research and development of active ingredients and of finished pharmaceutical products and includes process patent and product patent protection. Minimum standards have been set under TRIPS in the field of intellectual property and enforcement obligations. All members must incorporate these standards into their national intellectual property legislation within a set time frame.

Among articles of the TRIPS Agreement with greatest relevance to pharmaceuticals are: article 27 (patentable subject matter), article 31 (compulsory licensing), article 33 (20-year minimum protection), article 39 (data protection), articles 65 and 66 (transition arrangements for developing country WTO members), articles 66 and 67 (transfer of technology and technical cooperation) and article 71.1 (review). Although there are some exceptions under article 27, pharmaceutical products are not exempted. They are no longer excluded from patent protection. This has an effect on general access to essential medicines, especially HIV/AIDS drugs, which because of their high costs—until recently with some exceptions and only in a few countries—are totally out of reach for the majority of people affected with HIV/AIDS. The speaker gave examples from Thailand, Brazil and South Africa. These countries had tried various methods, including attempts to use compulsory licensing in order to manufacture generic equivalents and parallel import. These efforts lead to substantial reduction of prices for products offered by trans-national companies (TNCs) in May 2000. An Indian generic firm offered even lower prices for the same antiretroviral medicines (ARVs), and 39 TNCs withdrew their case against the South African government in 2001.

At the Fourth WTO Ministerial Conference in November 2001, the Doha Declaration on the TRIPS Agreement and Public Health came out, reaffirming the right of WTO members to use, to the full, the provisions in the TRIPS Agreement" that provide flexibility for the purpose of protecting public health and "in particular" promoting "access to medicines for all". The presenter quoted and discussed Paragraph 6 in the Doha declaration, worth including here, as it is still an outstanding and contentious issue after the Cancun WTO meeting negotiations broke down at the end of 2002.

Doha Declaration, paragraph 6: “We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”

An implication for PICs, where only Fiji is a WTO member, is that a national legislation on all intellectual property rights was required from 1 January 2000. But Fiji, being a developing country that previously did not protect pharmaceutical products, has until 1 January 2005 to do so. In case it is not possible to complete the process of enacting national legislations, extensions could be granted. For least developed countries, legislation on patent protection for pharmaceutical products can be delayed until 1 January 2016. At the end of 2002, more than 45 countries were not members of the WTO.

This very comprehensive and concise overview of a complex and, to many meeting participants, unfamiliar topic gave further details relevant to pharmaceuticals under the TRIPS Agreement (e.g. compulsory license, compulsory license due to national emergency, parallel imports, data protection, etc.). Strategies for both member and non-member countries were proposed.
At the end of this session's discussions, it was proposed: that PICs explore mechanisms to achieve international access to patented products under TRIPS; to look into how PICs would benefit from joining WTO; to examine if TRIPS obligations could have adverse effects on health in PICs; and to recommend PIC governments to review national patent legislation in accordance with the TRIPS Agreement and public health protection, involving intersectoral stakeholders.

2.5 Financing and improved financing and planning in management and supply

2.5.1 Financing essential medicines and vaccines

This session included the view of a health economist and the views and experiences of improving financing of central medical stores in PICs (the case of Solomon Islands).

Planning and financing of essential medicines and vaccines: health economist view

Allocation of public sector budgets for financing essential medicines and vaccines is generally insufficient in the Western Pacific Region, resulting in more and more people having to pay a high percentage of their income for pharmaceuticals. Because basic information on sources of funding and levels of expenditures (especially for the private sector) for essential medicines is not readily available, it is almost impossible to understand how to address efficiency concerns. A first step is to understand and define the meaning and scope of “financing of essential medicines and vaccines”. This involves identifying sources of finance (public, out-of-pocket, health insurance, voluntary and other local financing, donor financing and development loans) and their mechanisms.

The health economist introduced the concept of the financial sustainability equation, in which need, sustainable financial resources, costs and quality of care are balanced to benefit population health gain. What often happens when this equation is out of balance is that access to essential medicines is reduced with subsequent decline in quality of care. Of particular current concern is the increasing shift to out-of-pocket payments for pharmaceuticals. For example, in Asia, 50% to 90% of total pharmaceutical expenditure is borne by households – direct out-of-pocket payments. Before starting to explore how things might change, one should aim to make better use of existing resources and undertake an expenditure analysis “to get a picture of what is going on now”.

The speaker gave examples of cost analyses undertaken in Samoa, Tonga and Cook Islands. There, the percentage of diabetes-related medication were found to represent 4% to 5% of the pharmaceutical budgets (drugs and other), and up to 7% for anti-hypertensives in the case of Samoa. Although cost analyses per se have their limitations, they help to understand what one is doing and serve as basis for planning and subsequent actions.

Participants were also interested to learn about the Region's training programmes on health care financing now being developed and foreseen to include among others, a base training programme in financial planning, management and budgeting.

In the discussion that followed, participants agreed to the need to plan for and review pharmaceutical and other data, proposing to use a common methodology and format in which to present such data. They recommended introducing such reviews in their own national health care systems and also to exchange information on this and other key information within PICs. A draft expenditure format for data presentation with the working title “pharmaceutical and supplies expenditure review” was proposed and is included as Annex 6 in this report. Annex 7 shows another draft tabular format with data from a few PICs concerning “pharmaceutical and supplies expenditures as percentage of total health budget”.
Improving the financing of central (national) medical stores in PICs

This presentation created much interest as it centered on a new and different way to improve financing of Central Medical Stores (CMS) – a business model operation, which the Solomon Islands has adopted and which could be used elsewhere in PICs. The presenter showed how typical CMS in PICs have unusual capital requirements that have not typically been recognized by local governments. In the presenter’s opinion, capitalization issues are thus the foremost keys to success in improving access to essential medicines in the PIC. He stressed that unless and until correct capitalization formulae are developed and applied by the government health and treasury departments, PICs will continue to be unable to service a growing population and genuine increases in demands with basic health care commodities.

Fixed and operating capitals were analysed as well as the need to strike an appropriate balance between and within these capitals, such as capitals for stocks and ordinary and special operating costs. The peculiarity of the PIC complete logistics cycle is that it is much longer than regular business cycles such as those on the mainland. This affects lead-time. Bulk sea freight generally takes 6–8 months demanding total stock capitalization of 2 x lead + buffer (about four months) equalling 16 or 20 months respectively. Taking an average of 18 months, capital is thus required for this length of time. Annual estimation will therefore not work, nor will annual allocations; a business cycle of 18 months is necessary, as in the Solomon Islands where accrual accounting now has been introduced. The speaker also proposed to recapitalize the whole health system. A five-step model for improving availability of money for essential medicines supply in PICs was reviewed. More details and examples of how medical store capitalization works are set out in the first of a series of discussion papers prepared by the presenter.

Among other common PIC approaches that the Solomon Islands representative suggested to be explored were: cooperative regional contracting; subregional Essential Medicines (EM) Policy cooperation; regional pharmacy education strategy; common EM regulatory practices; standard data sets and information exchange.

Key points from the discussions that followed the presentation under financing essential medicines and vaccines

- The Solomon Islands’ model should be applied in other PICs.
- The first discussion paper on essential medicines in PICs on national health medical supply operations is very informative and useful and should be followed by others.
- In presenting the case to the government for an 18-month business cycle, the aid of senior officials in the Ministry of Health must be assured. Explain, motivate and back up with figures and examples why capitalization and accrual accounting are needed for medicines and other supplies in the public health care systems in PICs. “One is financing services and one is buying more health services.”
- The aim is not to keep enough stock for 18 months. The actual amount of stock on hand is much less. The point is not to get cash but to get a “bigger and longer government commitment” and adopt and apply a new concept.

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2.5.2 Management and problems in supplies in the Pacific

The country example from Papua New Guinea illustrated a big problem in securing sufficient funding for essential medicines (EML of 1430 including vaccines) for its five million people using a health service system of 19 provincial hospitals, 700 health centres and 2234 aid posts. Weak logistics (transportation and distribution), inadequate estimates of needs and late deliveries were some of the problems encountered in Papua New Guinea.

2.6 Rational drug use and quality assurance of medicines

2.6.1 Challenges of rational drug use in Western Pacific countries

Not originally on the agenda, this topic was added during the workshop, as irrational drug use is widespread in the Western Pacific Region and participants wanted to become familiar with innovative strategies to combat this and challenges of rational drug use. A 1988 WHO definition served to recall what constitutes rational drug use, i.e. "The rational use of drugs requires that patients receive medicines appropriate to their clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and the community." Among examples of irrational drug use are: overuse of antibiotics, indiscriminate use of injections and IV fluids, multiple or over-prescription, and antibiotics for non-bacterial infections, acute respiratory infections (ARI), acute diarrhoea, etc. Multiple factors play a role in irrational drug use practices such as those deriving from providers, from patients and communities, from health care system and from information and pharmaceutical promotion.

As briefly mentioned earlier (2.1.2 Regional strategy) several strategies exist to improve drug use: educational, managerial, regulatory and financing strategies. For interventions to be effective, they must focus on specific problems, address the underlying problems, use a problem-solving approach, be repeated and interactive and provide feedback to providers. Often interventions are conventional, unfocused and done in isolation, such as providing training alone, or distribute treatment guidelines without field-testing and without training and evaluation of impacts, etc. Innovative strategies that have proven effective are: small group interactive learning that is problem oriented and focused on problem solving; monitoring and feedback of practices; on-site supervision; combined and multiple interventions and consumer empowerment. Among the long list of specific recommendations made at the International Conference on Improving Use of Medicines (ICIUM) in Chiang Mai, Thailand in 1997 are some considered to be of great relevance to PICs, including:

- develop and use national (hospital) Standard Treatment Guidelines (STG);
- develop, revise and implement EML (or hospital formulary);
- establish Pharmacy and Therapeutics Committee with defined responsibilities for monitoring and promoting quality use of medicines;
- implement problem-based training in pharmacotherapy;
- encourage consumer involvement;
- develop a strategic approach to improve prescribing in the private sector; and
- establish a system to monitor key pharmaceutical indicators.

The discussions revealed the need to carry out comprehensive assessments in the pharmaceutical sectors in PICs, as well as provide further regional training for researching and addressing quality use of medicine. WHO would assist in this and also in applications of existing WHO methodologies and guidelines, such as "How to assess drug use in health services and communities", how to develop standard treatment guidelines (Malawi example), how to
how to introduce and use indicators for monitoring drug use, how to develop material for consumers, how to implement a national medicines policy, etc.

It was recommended to develop and adapt therapeutics (treatment) guidelines to promote quality prescribing and cost effective use of essential medicines. The work and publications on rational drug use could also be shared through creation of a regional database/collection/library of these, towards a possible common approach to common health needs across PICs. Effective operation of Drug and Therapeutics Committees is well known and documented to enhance rational use of drugs. It was recommended to define local PIC benefits of this; to identify strategies to motivate such effective operation; and to direct appropriate resources towards further and better data generation through drug utilization research (DUR) and rational drug use assessments. A PIC focal group on rational drug use should also be established to link to other centres of collaboration/excellence such as those in Malaysia, Indonesia, Sweden and the United Kingdom, and those that are part of the International Network for Rational Use of Drugs (INRUD).

2.6.2 Quality assurance

The two presentations under this topic discussed the framework for, and a practical approach to, quality assurance of essential medicines in PICs. Quality assurance mechanisms are integral parts in each of the four areas of the drug management cycle: selection, procurement, storage and distribution, and in the use of medicines. The drug regulatory control agency should only give marketing authorization or register a product after it has been evaluated for safety, quality and efficacy. A core principle of pharmaceutical procurement is to select reliable suppliers who provide quality products. This is best done by international tenders restricted to pre-qualified suppliers and by using the WHO Certification Scheme. To quote one of the speakers, “Quality assurance is about getting it right: it involves drug registration/good procurement practices, information exchange, good transport and storage. Quality control of received products is only part of quality assurance and probably the most expensive part”. There is not yet a drug quality control laboratory in the Pacific. Fiji uses a contract with TGA, the Australian drug authority, but the costs are high because TGA operates on full cost recovery. The Western Pacific Regional Office no longer promotes the use of WHO collaborating centres for quality testing as it turned out to be unrealistic.

Characteristics of PICs are that they do not have local manufacture but import; that only some countries like Fiji, Papua New Guinea and Tonga have established a drug registration system; that they purchase through international tenders; that they are geographically far from suppliers; and that they all have tropical climates with high temperatures and humidity. Establishing an appropriate quality assurance system is therefore of utmost important. How can PICs work together on this?

Responding to this question, the workshop made the following major points, which lead to recommendations, selection of priority areas for collaboration and setting up of working groups (see Annexes 8 and 9):

- A common approach to supplier and/or product registration should be sought, towards harmonization of requirements for PICs and possible mutual recognition. The idea of eventually having a key "collaborating centre" for PIC medicines registration for data sharing came up.
- Regarding quality testing, a business case for random sampling/testing of PIC-received stocks should be developed. Identify laboratories that can do quality testing
or explore new laboratory sites and cost any work and laboratory on the provision of appropriate basic tests only.

- With regard to improvement of own quality assurance mechanism, each country should define their own improvement programme, leading to better quality assurance and reduced need/demand for quality testing if quality-testing facility proves prohibitive in the end.
- A joint PIC policy in essential medicines procurement with a common quality assurance approach and standards needs to be worked out. For example, in the case of disposal of expired pharmaceuticals, commercial means will be explored.
- For the purpose of achieving the more long-term goals described above, an important short-term term activity was proposed. The workshop thus recommended exploring the establishment of an electronic PIC information data-exchange for essential medicines and vaccines, via DIEFPIC (Drug Information Exchange for Pacific Island Countries), and have this become part of the existing international E-drug network. Quality assurance data and other information exchanged in PICs could then serve as source for the work on harmonization and development of future PIC registers of authorised products, suppliers, importers, etc.

2.7 Vaccine management: Pacific prospective of current vaccine situation and vaccine security

2.7.1 Vaccine management: challenges and issues

This presentation and a number of others under the vaccines agenda items was given by the Suva WHO officer of the Expanded Programme on Immunization. He recalled that current challenges in vaccine management are:

- high costs of new vaccines;
- need to improve injection safety;
- proper cold chain management;
- good vaccine arrival inspection;
- accurate estimates;
- wastage reduction;
- cold chain equipment; and
- effectively using donor assistance.

Data (2002) from WHO–UNICEF Joint Reporting Forms show that several but not all PICs pay for their vaccines, but many do not have budgets for injection safety equipment. Quality data are needed for good vaccines estimates. There are continued stock outages in the Pacific. Projections should be made for 3-to-5-year campaigns and current stock balances should be taken into account. The UNICEF Vaccine Arrival Report (VAR) or similar, must always be used to assess if vaccines are in good condition upon arrival in PICs. Cold chain improvements are necessary throughout PICs; approximately 10 countries accepted and used super cooled DTP vaccine in 2003. Super cooled DPT (less than zero degrees) is hard to suspend, which is what health workers, and not the national level, detected. Freezing destroys hepatitis B vaccine. Wastage rate is high and poorly reported in PICs. Wastage of unopened vials can be prevented through appropriate cold chain, stock management and transport. Wastage of opened vials can be reduced through adoption of proper administration techniques and other measures. WHO field guidelines on monitoring and reducing vaccine wastage (V&B/03.18) should be followed. WHO multi dose vial policy (MDVP) significantly reduces vaccine wastage if applied, but is implemented in just over 50% of PICs. Cold chain policies have been adopted in a somewhat
higher percentage of countries, but only 35% of the countries have a cold chain inventory. Thus, essential for cold chain equipment management are to develop a policy, to map ideal inventory, to map inventory plus status, and to plan (five years) for gap and replacement.

In the discussion that followed, workshop participants clearly recognized problems in vaccine management in their countries. In sharing experiences, Guam, for example, reported that it could buy only products approved by the Food and Drug Administration (FDA), which generally are very expensive. Kiribati has problems with vaccine wastage, particularly in the outer islands; it needs to reassess its vaccine policy and will ask WHO to provide a consultant for this. Solomon Islands need to retrain its health workers. On a positive note, Samoa reported that its “open vials policy” has helped to reduce wastage. The session presenter stressed again, however, that the main wastage to prevent is cold chain wastage. Cook Islands questioned its current schedule for measles vaccine, which is different from what WHO recommends. The presenter informed that this and other relevant vaccine policies and topics would be discussed at an upcoming WHO meeting in Auckland.

2.7.2 Vaccine store management: Effective Vaccine Store Management Initiative (EVSMI) training course

The speaker, from the Fiji Pharmaceutical Services, outlined the content of a training course on Effective Vaccine Store Management Initiative, commonly referred to as EVSMI and developed by WHO and UNICEF. Two major messages to get across to those taking part in training are that the primary cold store of an immunization system is a most critical element, and that all vaccine equipment should be procured, installed, operated and maintained to the highest international standards. Other criteria for proper vaccine management are: that high standards must be maintained at lower-level stores, that staff must be responsible and adequately trained for the tasks, that EVS must be based upon quality assurance principles, and that documentation—book keeping and records—must be reliable.

The presenter then reviewed pre-shipment and arrival procedures included in the training course, such as reading and correctly interpreting indicators and correctly filling the VAR. In maintaining correct storage temperatures for the vaccines, staff should also know what actions to take when storage temperatures are incorrect, to have a contingency plan and to document accurately. Having enough storage capacity for safety stock levels and for cold storage is of course also part of EVSMI. So is maintenance of buildings, equipment and transport and effective stock management. This means maintaining complete and accurate records of all stock transactions, adopting good warehousing practices, not least documentation. To have reliable delivery to intermediate stores, staff must be trained in proper planning, in documentation and in undertaking preventive measures to minimize damage during distribution. Standard operating procedures must be available for ordering vaccine, receiving a vaccine shipment, and managing vaccine during storage, distribution and transport. Staff must also be trained to follow these procedures and to keep records. Five steps to follow to improve the quality of vaccine store management are: (1) set a quality standard; (2) establish a general approach; (3) establish standard procedures; (4) instruct and train staff; and (5) keep good records.

2.7.3 EVSMI: 10 global criteria and cold chain certification

In this presentation, workshop participants became more familiar with the cold chain certification process and got a summary review of the 10 global criteria against which accreditation is measured.

Within the WHO–UNICEF EVSMI, the cold chain is a network of cold/freezer rooms, refrigerators, freezers and cold boxes organized by teams of people throughout the world. WHO
sets performance standards. Staff at a facility appraises its practices by going through a process of self-appraisal to find out if the cold chain standards are being met. If so, it requests the visit of external assessors who determine if the 10 global criteria are being met and award a certificate and plaque if this is so.

The global criteria specify consistency and compliance with standards over a 12-month period and cover the areas discussed under the training course presentation above (2.7.2).

2.7.4 Cold chain policy and management

Situation and experience of Solomon Islands

Solomon Islands entered the Vaccine Improvement Initiative (VII) in 1995. Solomon Islands defaulted in 1999–2000. JICA assisted by donating a new cold room “kit” in 1998. Installation and costs were not included. The cold chain management in the Solomon Islands lies outside the national medical store. From a national (central) stock, vaccines are supplied to health services via province hospital pharmacies. Kerosene fridges are used in all non-powered sites. In 2000–2002, the VII default remained unpaid which has yet to be addressed. During this time period, provincial deliveries of vaccine and fuel for the fridges were also irregular. Provinces had not allocated budgets for monitoring and support of the cold chain management, and national-level planning for cold chain equipment was weak.

In April 2003, Solomon Islands introduced a draft cold chain policy that was redrafted in October the same year. The goals and objectives of the Solomon Islands' policy are to improve cold chain management and vaccine security. Priorities and responsibilities have been defined in the policy, standards for cold chain reviews and upgrading set, as well as standards and specifications for cold chain management. The policy covers storage conditions, cold chain equipment, vaccine stock levels, cold chain temperature monitoring, transportation, and maintenance of equipment and cold chain management.

The 2003 National Health Conference of the Solomon Islands reviewed the draft cold chain policy and the country is now starting to implement a 2004 activity plan. Implementation includes communication of standards to EPI and cold chain co-ordinators, at province and at vaccine delivery centre levels. A national cold chain co-coordinator will be appointed, training provided and a national inventory of cold chain equipment undertaken.

The Solomon Islands representative concluded his presentation by saying that the international VII is “excellent but a heavy tool for small units”. Staffs have to get used to the concept and techniques; however, there is no doubt that it is needed and will be implemented in Solomon Islands.

The workshop participants showed much interest in the described tools and methods used in the VII and the many elements needed to achieve successful cold chain management. Later, in the group work, they chose these areas as priorities for collaboration (Annex 9).

2.8 Vaccine shipments and arrival reporting

In this session, the Suva WHO/EPI officer reviewed the WHO guidelines for international shipments, the VAR, the monitors that measure thermal exposure and the shake test for vaccine freezing. He also explained the practical exercise in which the workshop participants were going to complete a VAR.
The *Guidelines on the international packaging and shipping of vaccines* (WHO/V&B/01.05), produced in January 2002, replaces the guidelines set in 1992 and all previous revisions. They are jointly endorsed by UNICEF and WHO and relate specifically to the international shipment of vaccine to countries implementing the Expanded Programme on Immunization. They include and specify standards for insulated packaging, standards for storage volume, standards for labelling and packaging and standards for shipping procedures.

2.8.1 UNICEF Vaccine Arrival Report (VAR)

For checking vaccine arrivals from UNICEF, the Vaccine Arrival Report (VAR) is used. The *Guidelines for the use of the Vaccine Arrival Report in UNICEF shipments* were produced in April 2002 and include background, development, implementation and procedure to be followed for reporting vaccine arrivals.

The speaker went through the procedures for reporting vaccine arrivals. As summarized on page 3 in the above mentioned guidelines, they are: arrival of vaccines and customs clearance; inspection of central cold stores/airport; VAR completed and signed; VAR sent to UNICEF Country Office; and copy of VAR sent to UNICEF Supply Division, Copenhagen. The Supply Division then checks against indicators whether arrivals are OK or defective in which case they take certain measures.

The *Vaccine Arrival Report*, enclosed as Appendix 1 in this report, is divided into seven parts for completion: (1) advance notice; (2) flight arrival details; (3) details of vaccine shipment; (4) documents accompanying the shipment; (5) status of shipping indicators; (6) general conditions of shipment; and (7) name and signature of authorized inspection supervisor and Central Store or EPI Manager.

2.8.2 Simple tests to check vaccine quality

Vaccines are sensitive to heat and to freezing, some more than others. The speaker reviewed and demonstrated the three vaccine temperature monitors for vaccine shipment, which are used in assessing temperature effects: (1) Vaccine Vial Monitors (heat); (2) Cold Chain Monitor Cards (heat); and (3) Freeze Watch Monitors (freezing). The workshop learned about the purpose and methods for using these monitors including what to do when a vaccine vial must be discarded, in the case of heat or freezing damage. Questions and discussions followed on the use and interpretations of monitoring results before the next item on the agenda—the practical exercise to complete a VAR.

2.8.3 Practical exercise to complete a VAR

The workshop participants split into groups and completed a VAR that was based on data prepared for the purpose of training. Each group received a set of documents that arrived with a vaccine shipment. The information consisted of an invoice, a packing list, a quality control release on oral poliomyelitis vaccine, a transport document, and inspection results carried out at the primary vaccine store. The groups reviewed these documents, filled in the vaccine arrival report and decided whether they had to take any actions.

This practical exercise gave participants a good chance to interact, discuss among themselves and exchange experiences. Prizes distributed for correct VAR completions (WHO tee shirts and UNICEF mugs) were much appreciated.
2.9 Group work review of draft recommendations and decisions on priority collaborative activities

The workshop split into two groups, one on essential medicines and one on vaccine, reviewing first a long list of annotated recommendations and then deciding on 3–4 priority areas for collaboration. Under each chosen priority area, the groups were asked to state objectives and expected results, to propose methods of cooperation, to give structure for collaboration (e.g. a coordinator for each area with a selected number – or all of countries collaborating), to specify follow-up/review of cooperation, to state roles/actions of country/WHO/others and give a time frame.

The two groups put their draft proposal results into a tabular format for presentation in plenary.

2.10 Plenary review of priority collaboration and draft recommendations

The proposed priority collaboration areas were presented and reviewed in plenary. The groups’ detailed and final results are in Annexes 8 and 9, but summarized below, for easy reference.

Summary of essential medicines priority collaborative areas and activities

1) Information exchange using DIEFPIC – explore e-drug link – WHO to provide criteria and rules for participation – time frame 2004

2) Procurement – consistency, quality assurance, prices – specified country working groups, WHO technical support if required – explore regional contracting – SIS&BPS continue and strengthen – time frame 2004

3) Human resources – workforce planning, development, and training – specified country working groups – transfer and tailor make – explore funding

4) Quality assurance
   (a) Drug regulatory and registration harmonization – specified country working groups
   (b) Quality control testing – short term, and explore regional long-term testing

Summary of vaccine priority collaborative areas and activities

1) Vaccine Improvement Initiative (VII) – improve management and function of VII – form regional group – form distribution centre like Fiji store – increase country responsibility to pay for vaccines – technical support from WHO and others – March 2004

2) Cold Chain Management – country updating of their CCM – perform cold chain inventory and seek funding – establish cold chain training centres – establish Cold Chain Management Standards and Policies – seek country agreements to harmonize support – country funding for a cold chain manager – country visits and technical support from WHO and others – January 2005
(3)  *Regional communication network* – improve cooperation and communication with information on successes, issues, problems – start a list service for information exchange – (WHO to start list service, UNICEF to provide support)

In plenary, the participants finally jointly reviewed all the annotated recommendations. All annotations have been incorporated or reflected in the relevant sections above. They are generally not repeated below in 3.2, the condensed and summarized recommendations below.

3. CONCLUSIONS AND RECOMMENDATIONS

3.1 Conclusions

The Workshop on Improving Access to Essential Medicines and Strengthening Vaccine Security for Pacific Island Countries, held in Nadi, Fiji, from 25 to 27 November 2003, provided an excellent opportunity for participants to become updated on issues, strategies and development under these two areas. Combining two highly relevant topics in one workshop turned out to be very good, as participants could benefit from a broadened exchange of views and experiences. The priority areas with details (Annex 8 and 9), selected by participants for PIC collaboration to improve access to essential medicines and for strengthening vaccine security, and other recommendations should now become the basis for action and implementation, starting in 2004.

3.2 Recommendations

3.2.1 Essential medicines

E-drug network and information exchange

(1) The workshop recommended exploring the establishing of an electronic PIC information data-exchange for essential medicines and vaccines, via DIEFPIC (Drug Information Exchange for Pacific Island Countries), and have this become part of the existing international E-drug network.

Pooled procurement

(2) It was recommended that cooperation on regional contracting, a combined purchasing power with multi-drop delivery, could be an alternative option worth exploring within pooled procurement. Economy of scale could be achieved in such contracting, benefiting also those that did not want add-on costs for bulk storage, and dependency on one store. The further strengthening of SIS and Fiji Bulk Procurement Scheme was also recommended.

Human resource development

(3) It was recommended that PICs should address both long-term and short-term solutions for pharmacy education and training, and align various local initiatives, even creating a single core curriculum for the University of South Pacific and the University of Papua New Guinea. A regional curriculum advisory panel could be set up to look into this.
(4) Another collaborative PIC activity recommended was to exchange information on training needs, on existing training programmes and institutions.

**Quality Assurance**

(5) It was recommended that a common approach to supplier and/or product registration and a joint policy in essential medicines procurement should be sought, towards harmonization of requirements for PICs and possible mutual recognition. For example, in the case of disposal of expired pharmaceuticals, commercial means should be explored. The idea of eventually having a key “collaborating centre” for PIC medicines registration for data sharing was raised.

(6) Regarding quality testing, the workshop recommended to develop a business case for random sampling/testing of PIC received stocks; further to identify laboratories that can do quality testing or explore new laboratory sites and cost any work and laboratory on the provision of appropriate basic tests only.

3.2.2 Vaccines

*Vaccine Improvement Initiative (VII)*

(1) It was recommended to use VII and mechanisms in procurement of new vaccines.

*Cold Chain Management (CCM)*

(2) It was recommended that every country should update their CCM, perform functional cold chain inventory and look for funding to meet cold chain needs.

*Establishment of a regional communication network*

(3) It was recommended that cooperation and communication should be improved through exchange of information on successes, issues, problems – with WHO starting a list service and UNICEF providing support.

3.2.3 Other essential medicines recommendations:

*Human resource development*

(1) Regional pharmacy curricula should include elements on WHO, on the role of pharmacist, on access of essential medicines, and include training in practical application of rational drug use, supply management, etc.

(2) Donors and out-of-PIC institutions should step up efforts to ensure the return of trained staff to national health systems. For example, universities, immigration authorities, professional societies and boards should recognize PIC needs better and cooperate to meet them.

(3) It was also recommended that PICs make more use of Schemes of Service for pharmacy/essential medicines management staff, to improve conditions and enhance recruitment and retention. Existing standards in Papua New Guinea, Fiji and Australia, for example, could serve as resources for PIC development and application.
WTO/TRIPS and access to essential medicines

(4) The workshop proposed that PICs should explore mechanisms to achieve international access to patented products under TRIPS; to look into how PICs would benefit from joining WTO; to examine if TRIPS obligations could have adverse effects on health in PICs; and to recommend PIC governments to review national patent legislation in accordance with the TRIPS agreement and public health protection, involving intersectoral stakeholders.

Financing and improved financing

(5) The workshop recommended introducing pharmaceutical and other data reviews in their national health care system, using a common PIC methodology and format and exchange such information within PICs (draft expenditure formats are included in annexes 6 and 7).

(6) It was recommended that the Solomon Islands’ model for improved financing of central medical stores, including essential medicines, should be applied in other PICs. The model covers capitalization, accrual accounting and an 18-month business cycle. In presenting the case for an 18-month business cycle to the government, the aid of senior officials in the ministry of health must be assured.

(7) The first discussion paper on essential medicines in PICs on national health medical supply operations and improved financing was considered very informative and useful and should be followed by others.

Rational drug use

(8) Comprehensive assessments in the pharmaceutical sectors in PICs are needed, so is regional training for researching and addressing quality use of medicine. It was recommended that WHO assist in this, in applications of WHO methodologies and guidelines (e.g. “How to assess drug use in health services and communities”) and in developing/adapting therapeutics (treatment) guidelines to promote quality prescribing and cost effective use of essential medicines.

(9) Work and publications on rational drug use could also be shared through creation of a regional database/collection/library of these, towards a possible common approach to common health needs across PICs.

(10) It was recommended to define local PIC benefits of drug and therapeutic committee work; to identify strategies to motivate such effective operation; and to direct appropriate resources towards further and better data generation through drug utilization research (DUR). A PIC focal group on rational drug use should also be established to link to other centres of collaboration/excellence such as those in Malaysia, Indonesia, Sweden and the United Kingdom, and those that are part of the International Network for Rational Use of Drugs (INRUD).

Quality assurance

(11) With regard to improvement of own quality assurance mechanism, each country should define their own improvement programme, leading to better quality assurance and reduced need/demand for quality testing if quality-testing facility proves prohibitive in the end.
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AGENDA

1. Opening ceremony
2. Introduction: Workshop objectives, expectations and methodology
3. Access to essential medicines and vaccines: Global perspectives
4. Current regional vaccine situation
6. Experiences from selected countries on access to essential medicines and vaccines in Pacific island countries:
   - Papua New Guinea
   - Samoa
   - Tonga
   - Vanuatu
   - Kiribati
7. Experiences in intercountry collaboration: Fiji Pharmaceutical Bulk Purchase for Small Island States
8. Presentation of the Facility of the New Fiji Pharmaceutical Services Center and Future Plan to contribute to Access to Essential Medicines and Vaccines
9. Experiences from countries:
   - Tuvalu
   - Niue
   - French Polynesia
10. Human resource development in support of improving access to essential medicines: The need for reorienting conventional pharmacy curricula
11. WTO/TRIPS and access to essential medicines: Exploring options for Pacific island countries
12. Financing essential medicines and vaccines
13. Improving financial planning for medicine supply
14. Medicines supply management and monitoring: Problems in supplies of essential medicines in the Pacific
15. Framework for quality assurance of medicines
16. Practical approach to quality assurance of essential medicines in the Pacific
17. Current vaccine situation and vaccine security: A Pacific perspective
18. Effective Vaccine Stores Management Initiative
19. Cold chain store certification – Fiji experience
20. Cold chain policy and management – Solomon Islands’ experience
21. Vaccine arrival reporting
   - Explanation of simple tests to check vaccine quality
   - Description of UNICEF Vaccine Arrival Report (VAR)
22. Feasible strategies and recommendations for collaborative activities to improve access
23. Closing
WORKSHOP ON IMPROVING ACCESS TO ESSENTIAL MEDICINES AND VACCINES IN PACIFIC ISLAND COUNTRIES
Nadi, Fiji
25–27 November 2003

TIMETABLE

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<td>0730</td>
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<td>Importance of access to medicines and vaccines: WHO increased emphasis on country support (R. Chen WHO representative, Fiji.)</td>
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<td>10. WTO/TRIPS and Access to Essential Medicines: Options for Pacific Island Countries (Jakkrit Kuamporn) - Discussion</td>
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<td>21. Group discussion on feasible strategies and recommendations for collaborative activities to improve access</td>
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<td>Challenges of rational drug use in the Western Pacific Countries (B. Santos)</td>
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</table>

ANNEX 3
LIST OF DOCUMENTS/PRESENTATIONS

WPR/ICP/HRF/5.1/001/PHA(2)/2003/IB/1 - Information Bulletin No. 1
WPR/ICP/HRF/5.1/001/PHA(2)/2003/IB/2 - Provisional list of Temporary Advisers, Consultant, Observers/Representatives, and Secretariat

WPR/ICP/HRF/5.1/001/PHA(2)/2003.1a - Provisional Agenda
WPR/ICP/HRF/5.1/001/PHA(2)/2003.1b - Provisional Timetable
WPR/ICP/HRF/5.1/001/PHA(2)/2003.1c - Programme of Activities
WPR/ICP/HRF/5.1/001/PHA(2)/2003.2 - Access to essential medicines: - Global perspective
WPR/ICP/HRF/5.1/001/PHA(2)/2003.3 - Current Regional Vaccine Situation
WPR/ICP/HRF/5.1/001/PHA(2)/2003.5a - Experiences from selected countries on access to essential medicines and vaccines in Pacific Island Countries – Papua New Guinea
WPR/ICP/HRF/5.1/001/PHA(2)/2003.5b - Experiences from selected countries on access to essential medicines and vaccines in Pacific Island Countries – Samoa
WPR/ICP/HRF/5.1/001/PHA(2)/2003.5c - Experiences from selected countries on access to essential medicines and vaccines in Pacific Island Countries – Tonga
WPR/ICP/HRF/5.1/001/PHA(2)/2003.5d - Experiences from selected countries on access to essential medicines and vaccines in Pacific Island Countries – Vanuatu
WPR/ICP/HRF/5.1/001/PHA(2)/2003.5e - Experiences from selected countries on access to essential medicines and vaccines in Pacific Island Countries – Kiribati
WPR/ICP/HRF/5.1/001/PHA(2)/2003.6 - Fiji Pharmaceutical Bulk Purchase for Small Island States
WPR/ICP/HRF/5.1/001/PHA(2)/2003.7 - Facility of the New Fiji Pharmaceutical Services Center and Future Plan to contribute to Access to Essential Medicines and Vaccines
WPR/ICP/HRF/5.1/001/PHA(2)/2003.8a - Experiences in inter-country collaboration – Tuvalu
WPR/ICP/HRF/5.1/001/PHA(2)/2003.8b - Experiences in inter-country collaboration – Niue
WPR/ICP/HRF/5.1/001/PHA(2)/2003.8c - Experiences in inter-country collaboration – French Polynesia
WPR/ICP/HRF/5.1/001/PHA(2)/2003.9 - Human resource development in support for improving access to essential medicines – The need for reorienting conventional pharmacy curricula
WPR/ICP/HRF/5.1/001/PHA(2)/2003.10 - WTO/TRIPS and access to essential medicines - Exploring options for Pacific Island Countries
WPR/ICP/HRF/5.1/001/PHA(2)/2003.11 - Financing of essential medicines and vaccines
WPR/ICP/HRF/5.1/001/PHA(2)/2003.12 - Improving financial planning for medicine supply
Medicines supply for management and monitoring
- Problems in supplies of essential medicines
  in the Pacific

Framework for quality assurance of medicines
Practical approach to quality assurance of essential
medicines in the Pacific

Vaccine security: A Pacific perspective
Effective Vaccine Stores Management Initiative
Cold chain store certification – Fiji experience
Cold chain Policy and Management
Simple tests to check vaccine quality
UNICEF Vaccine Arrival Report
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# Pharmaceutical and supplies expenditure review

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<td>travel/transport</td>
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<td>Total Health Expenditure</td>
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</table>
Country examples of drugs and vaccines etc. - as percentage of total health budget

<table>
<thead>
<tr>
<th>Percentage of total health budget</th>
<th>NAURU</th>
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<td>%DRUGS &amp; VACCINES</td>
<td>3.60%</td>
<td></td>
<td>6.83%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% MEDICAL SUPPLIES</td>
<td>2.16%</td>
<td></td>
<td>0.02%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>% REAGENTS</td>
<td>0.55%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>APPLIANCES</td>
<td></td>
<td></td>
<td>0.2157%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>DIALYSIS</td>
<td>9.92%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Per capita expenditure drugs and vaccines (only)

| PER CAPITA DRUGS & VACCINES      | 39.7 | 27.8 | 9.9  | 5.4 | 8.3       | 22.92| 3.26 |
| PER CAPITA HEALTH EXPENDITURE    | 690.909091 | 483.63 | 144.705882 | 79.585 |         |     |     |

NAURU - no private sector / no insurance sector
FIJI -- some private and insurance provision
MARSHALLS - no private/insurance
SOLOMONS no insurance/no private/no out-of-pocket expenditure
### Essential medicines: PIC Priority areas of collaboration

<table>
<thead>
<tr>
<th>Area of collaboration</th>
<th>Objectives</th>
<th>Methods of collaboration</th>
<th>Actions by countries/time</th>
<th>Actions by WHO/time</th>
<th>Role of other partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information exchange</td>
<td>Rapid dissemination of information related to medicines and vaccines to improve the Pharmaceutical and vaccine services</td>
<td>Sub group of e-Drug? (Beverly Snell) DIEF-PIC</td>
<td>Active participation</td>
<td>Provide criteria and rules for participation</td>
<td>E-drug</td>
</tr>
<tr>
<td>Procurement</td>
<td>Consistent QA Best value and stable prices</td>
<td>Formation of working groups (Fiji, Tonga, Solomon, PNG, Samoa)</td>
<td>Provide a list of top 20/50 By $ &amp; by volume Compile tender requirements Look at the VII model? Negotiate contract</td>
<td>Technical support if required Providing information on similar schemes</td>
<td></td>
</tr>
<tr>
<td>Human resources</td>
<td>Workforce planning development Pharmacists</td>
<td>Formation of working groups (Fiji, Workforce planning development Marshall Islands, Palau, Fiji, Tonga, Solomon islands)</td>
<td>Provide information on training needs Exchange info on existing training programmes Communicating training needs existing institutions</td>
<td>Transfer and tailor-make MSH, IDA, INRUD, training etc. to the Pacific Explore funding for ongoing courses</td>
<td></td>
</tr>
<tr>
<td>Drug regulatory</td>
<td>Assure quality of medicines in the Pacific</td>
<td>Formation of working groups (Tonga, Fiji, Vanuatu) Harmonization of registration requirements Joint QC testing</td>
<td>1. Sharing of information on existing mechanism for registration and QC testing 2. Exploring combined contracting Laboratory for QC testing (short-term) 3. Explore the feasibility of setting up a Regional QC lab 4. Explore collaboration with existing laboratories</td>
<td>Technical support</td>
<td>AusAID, JICA</td>
</tr>
</tbody>
</table>

---

ANNEX 8

WPRO workshop Fiji November 25/27 2003
## Vaccines: PIC Priority areas of collaboration

<table>
<thead>
<tr>
<th>Area of collaboration</th>
<th>Objectives</th>
<th>Methods of collaboration</th>
<th>Actions by countries</th>
<th>Actions by WHO</th>
<th>Role of other partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>VII</td>
<td>- Improve management and function of VII</td>
<td>- Forming regional group for recommendations to UNICEF - Forming distribution centre like Fiji store</td>
<td>- Go back to countries to discuss taking over responsibility of paying for vaccines</td>
<td>- Country visits - Technical support/assistance - Donor coordination to final goal</td>
<td>- UNICEF same support as WHO - JICA - CDC - French Government</td>
</tr>
<tr>
<td>Cold Chain Management</td>
<td>- Every country to update their CCM - Every country to perform functional cold chain inventory For every country to look for funding to meet cold chain needs</td>
<td>- Establishment of cold chain training centres - Establishment of standardization of policies and equipment</td>
<td>- For countries to develop agreement to harmonize support - Look into funding to support a cold chain manager</td>
<td>- Country visit and technical support</td>
<td>- UNICEF same support as WHO - JICA to have continued support</td>
</tr>
<tr>
<td>Regional Communication Network</td>
<td>- Improve cooperation and communication with successes, issues and problems</td>
<td>- Starting with a list serve</td>
<td>For every country to utilize the list serve by providing and sharing info to the groups on points of interest - Discussion group leaders will be on a rotational basis</td>
<td>- WHO to start list serve for participants to join the discussion groups</td>
<td>- UNICEF to provide support</td>
</tr>
</tbody>
</table>

Timeline: March 2004 for VII
Timeline: January 2005 for Cold Chain Management
Timeline: January 2004 for Regional Communication Network

WPRO workshop Fiji November 25/27 2003