Working Group on Insecticide Treated Nets (WIN)

Meeting on Development, Production and Distribution of Long Lasting Insecticidal Nets (LLINs)

Full Record of the Meeting

Intercontinental Hotel - Sandton Sun and Towers,
Johannesburg, South Africa
23-24 September 2004

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RBM Meeting on Development, Production and Distribution of Long Lasting Insecticidal Nets (LLINs)

Intercontinental Hotel - Sandton Sun and Towers, Johannesburg, South Africa 23-24 September 2004

In recognition of the bottleneck represented by the need to re-treat conventional ITNs to maximise effectiveness, a satellite group of the RBM Working Group on Insecticide-treated Nets (WIN) was established in 2003 to develop a framework for the development, production, and distribution of long lasting insecticidal nets (LLINs). Management Sciences for Health, in collaboration with UNICEF, WHO, RBM, and the Rockefeller Foundation drafted a LLIN business plan and a meeting in Johannesburg was convened to discuss the plan, identify key issues and agree specific action points. This report provides full details of the RBM Johannesburg meeting on development, production and distribution of long lasting insecticidal nets (LLINs). It is a complement to the Meeting Summary Report also available from RBM.

1 Issues, Recommendations and Action Points Arising

1.1 Integrated Forecasting System

An integrated procurement forecasting system is required to facilitate production planning by existing producers and also to illustrate the potential market with a view to encouraging investment and entry by new manufacturers and distributors. The desired characteristics of such a forecasting system include high reliability of estimates, annual or semi-annual updating, the inclusion of both short term and long term forecasts, and clear distinctions between “need” from a public health perspective, and true demand backed by funding availability.

Action: MMSS to work with UNICEF, GFATM, WHO and the private sector to develop an integrated forecasting tool.

Action: Private Sector to work with MMSS towards developing a mechanism for integrated forecasting, initially by contributing to a suppliers’ capacity inventory

Action: RBM MMSS to produce its first report on demand forecasts by January 2005.

1.2 Technology Trust and Investment Facility

A publicly-funded technology trust was proposed to keep industry informed of technological developments, to facilitate access to available technologies, to support safety and health testing, and also to support field testing of new products. It was agreed that the technology trust should not directly support product development.

Action: LLIN satellite group of WIN to investigate the merits of facilitating access to an inventory of potential investors that could support private sector development, production and distribution of loans, and also the merits of facilitating access to low interest loans

Action: LLIN satellite group of WIN to investigate the merits of establishing a technology development and investment fund that will support fundamental research, access to information in the public domain and subsidizing the cost of LLIN testing.

1.3 Assisting Quality Control

Quality control was recognised as a priority issue for manufacturers and consumers, especially in regard to scaling-up LLINs, where there is potential for unscrupulous manufacturers to market non-LLINs as LLINs. At the international level, procurement agencies including UNICEF and Crown Agents are already playing a key role in carrying out factory inspections and verifying adherence to ISO standards. WHO provides tools to support Quality Control assessment, e.g. specifications and validated test methods to verify those specifications. WHO in collaboration with FAO is also trying to build national capacity through development of quality control guidelines and the establishment of designated collaborating centres to assist those countries without national facilities. It was acknowledged that National Standards Bureaux in many countries have insufficient capacity to carry out effective post-registration quality control.

Recommendation: Donors, RBM and GFATM to support the development of LLIN QC testing facilities at the regional and national level in Africa, building capacity in national bureaux of standards

Recommendation: Manufacturers to agree to open door policy towards international inspection

1.4 Other Enabling Environment

National registration of LLINs is a serious bottleneck to scaling-up in several African countries, due to the requirement for local safety and efficacy testing of pesticide products.

Action: WHOPES to hold a meeting in 2005 to optimise its testing methodologies towards fast tracking preliminary recommendations of new products and identifying ways to achieve consensus with national registration processes to accelerate national registration.

Taxes and tariffs remain a key issue for increased production and distribution of ITNs and LLINs more than four years post-Abuja.

Action: Partners at international level to follow-up on Abuja declaration on taxes and tariffs. Need for Harmonisation of tax and tariff policies at regional level (SADC, COMESA, etc). Partnership needed at national level to intensify advocacy and develop local solutions

Action: Partnership should identify key actors to champion the taxes and tariffs issue at all levels

1.5 Strategic Planning

The need for strategic planning by all stakeholders towards scaling-up the development, production and distribution of LLINs was recognised. National policies and strategies developed through a consensus-building process involving all stakeholders should be respected and adhered to and not changed unilaterally as a result of pressure exerted by influential external players. The role of National RBM ITN Task Forces in the strategic planning process was strongly emphasized.

1.6 New Research Agenda

The issue of developing insecticide resistance and the need for future alternatives to pyrethroid insecticides for LLIN treatment to be identified, including the potential for the use of insecticide combinations, was recognised as a key task for the research community, with support from other partners. Related research includes:

- further refinement of long lasting technologies (R&D) and identification of new applications for vector control, personal protection, household pest control and agriculture;
- development and implementation of tactics for management of pyrethroid resistance in malaria vectors;
- search for new insecticides alternative to pyrethroids;
- methods of assessing the longevity of a net and LLINs;
- market research and market segmentation;
- understanding production and distribution cost structures;
- options for the use of subsidy (including free distribution, vouchers, credit, selling LLINs for the price of an ITN or plain net, developing new technologies and their application, investing in manufacture, generic communications, managing the transition from ITNs to LLINs etc); and
- sources of investment capital.

2 Objectives and Expected Outcomes of the Meeting

2.1 Background

In recognition of the bottleneck represented by the need to re-treat conventional ITNs to maximise effectiveness, a satellite group of the RBM Working Group on Insecticide-treated Nets (WIN) was established in 2003 to develop a framework for the development, production, and distribution of long lasting insecticidal nets (LLINs). Management Sciences for Health, in collaboration with UNICEF, WHO, RBM, and the Rockefeller Foundation drafted a LLIN business plan and the meeting in Johannesburg was convened to discuss the plan, identify key issues and agree specific action points.

2.2 Objectives of the Meeting

- Discuss the current status and future prospects of LLIN technology
- Assess the current demand (institutional and consumer) and supply of LLINs as well as estimate the projected demand for 2005-2010
- Identify technical, financial and regulatory obstacles to the development, production and distribution of LLINs with special emphasis on technology transfer and local production
- discuss the public and commercial sectors' perspectives on LLINs
- Outline a framework for scaling up production and distribution of LLINs

2.3 Expected Outcomes of the Meeting

- Issues on development, manufacturing and distribution of LLINs reviewed and a prioritised list of critical bottlenecks or constraints produced
- Mechanisms for demand (institutional and consumer) forecasting outlined
- Challenges and opportunities for stimulating development, manufacturing and distribution of LLINs reviewed, and a set of action points agreed upon
- Complementary roles of stakeholders as well as mechanisms for continued dialogue and collaboration between and among them identified; comparative advantages outlined, and specific opportunities for collaboration determined

- Strategies based on the projected long term demand for scaling-up production and distribution of LLINs outlined, and a preliminary timeline with milestones and focal points developed

3 Summary of Presentations and Discussions

Day One: Thursday 23 September 2004

3.1 Opening Session.

Chair: Dr Awa Marie Coll-Seck

Dr Awa Marie Coll-Seck, Executive Secretary of the RBM Partnership opened proceedings by stating that it was an honour to receive the Honourable Minister of Health for the Republic of South Africa, Dr M. Tshabalala Msimang and thanked her on behalf of all participants for her attendance at the meeting. Dr Coll-Seck requested the Honourable Minister to chair the remainder of the opening ceremony.

3.1.1 Opening Remarks – Dr M. Tshabalala Msimang, Hon. Minister of Health, Republic of South Africa

The Honourable Minister welcomed the Regional Director for WHO/AFRO, Dr Ebrahim Samba, Dr Awa Marie Coll-Seck, distinguished guests and participants to South Africa and conveyed the best wishes of the President of the Republic of South Africa, Thabo Mbeki. Dr Tshabalala Msimang expressed her hope that the objective of the meeting was to take positive actions towards the eradication of the scourge of malaria. The Minister stated that her government was honoured that the meeting organisers had chosen South Africa to host the meeting. She was encouraged by the decision to hold the meeting in Africa, but suggested that in future, consideration might be given to holding similar meetings away from urban centres in the malaria-affected areas of the country, including KwaZulu Natal and Limpopo. The Honourable Minister felt that Sandton was not the most appropriate venue in which to discuss malaria, primarily a disease of less developed rural areas. Dr Tshabalala described malaria as a major killer disease in Africa, with 88 million people in the SADC region living in malaria transmission areas. Of these, 14 million children and 4 million pregnant women are at increased risk from malaria. Malaria claims an estimated 50,000 – 300,000 lives in the African region. African Heads of Government are committed through the Abuja targets to halve the malaria burden by 2010, and already time is running short. The honourable Minister was part of the delegation that attended the Abuja Summit of 2000 and recognised the need to intensify efforts in order to reach those targets, however, she stressed the importance of focussing on saving lives in Africa, rather than on individual targets. This could only be achieved through scaling-up of key interventions, including Integrated Vector Management (IVM), Intermittent Preventive Treatment (IPT) for pregnant women, and prompt and effective case management. The current meeting was designed to address one specific aspect of IVM, namely insecticide treated nets, especially long lasting insecticidal nets (LLINs). ITNs have been proven to be effective, reducing all cause child mortality in children under 5 by 20%, however, there were recognised limitations to the technology, including the need for regular re-treatment of conventional nets, the limited life spans, and the currently limited supply, especially of LLINs. The Honourable Minister stated that innovative ways were urgently required to address these challenges, including through local production, with resulting benefits in terms of economic empowerment for Africans. Dr Tshabalala then described some of the positive results in malaria control that had been achieved in South Africa through the use of indoor residual spraying (IRS). The Lebombo Spatial Development Initiative, a tripartite malaria control agreement between South Africa, Swaziland and Mozambique was launched in 2000 and had already achieved reductions in transmission of up to 96%, using IRS as a major intervention. South Africa, through the LSDI has demonstrated the effectiveness and feasibility of a public-private partnership approach to roll back malaria. Alongside the use of IRS south Africa was the first country on the continent to introduce artemisinin-based combination therapy for malaria treatment, back in 2001. Unfortunately the cost of ACTs may be prohibitive to some countries, therefore there remains a need for other cost-effective interventions. The Honourable Minister concluded by wishing participants every success during the meeting.

3.1.2 Introductory Remarks - Dr Awa Marie Coll-Seck, Executive Secretary, RBM Partnership

Dr Coll-Seck expressed her delight at being present at such an important meeting of representatives from the public and private sectors and welcomed participants in her capacity as Executive Secretary of RBM. She recognised that participants were attending from all over the world, including India, Japan, Tanzania, among others. The objectives of the meeting are to find ways to scale up the production, and distribution of LLINs, a technology that has evolved from the original un-treated mosquito net. LLINs currently represent one of the most effective malaria prevention and control methods available and are the result of a collaboration between the oil industry, the textile and chemical industries, as well as many other partners. LLINs represent a major contribution in the fight against malaria, alongside other interventions, including IPT, IRS, and prompt and effective treatment, including artemisinin-based combination Therapies (ACTs). However, Dr Coll-Seck stressed that the real challenge for malaria prevention is to meet the growing demand for LLINs in order to meet both the Abuja and Millennium Development Goals. Meeting this challenge will require entrepreneurship, innovation, considerable hard work, and the mobilisation of public and private resources. Dr Coll-Seck emphasised the need to bring LLINs close to those who need them most, namely the under 5s, pregnant women, the poorest of the poor and People Living with HIV/AIDS (PLWHA). Dr Coll-Seck acknowledged the achievements of South Africa in malaria control and suggested that it could lead the way in malaria control in the region and support other countries to achieve similar success. The RBM Executive Secretary then expressed her thanks for the kind hospitality shown by the Republic of South Africa and thanked the partners, NetMark, UNICEF, Rockefeller, and WHO for organising the meeting. Dr Coll-Seck then concluded by paying tribute to Dr Samba, who is due to retire in January 2005, and was responsible for the African Initiative on malaria, which ultimately set the scene for the establishment of RBM. Finally, Dr Coll-Seck wished participants every success during the meeting.

3.1.3 Introductory Remarks – Dr Ebrahim M. Samba, Regional Director, AFRO

Dr Samba said that he felt very proud and honoured to have been invited to this LLIN Business Meeting and expressed his gratitude to the government and people of the Republic of South Africa for providing such first class facilities. Dr Samba expressed his pride in having been a party to the recent launch of LLIN initiatives at the African development meeting in Tokyo, alongside Carol Bellamy, the Executive Director of UNICEF and Japanese colleagues from government and industry. Dr Samba described how he had been personally involved in the fight against malaria for 40 years, having decided to attack malaria mosquitoes in the 1970s in The Gambia, as Director of Medical Services. At that time The Gambia was unable to afford drugs, or pesticides, and began work on ITNs at the Medical Research Council. Having discovered the benefits of ITNs, it was quickly recognised that the need to re-treat them was a significant bottleneck. Outside of southern Africa, malaria remains the biggest health problem, even worse than HIV/AIDS. The *Plasmodium* parasite is increasingly developing resistance to the antimalarial drugs currently in widespread use. The newly-developed ACTs are very effective, but are also expensive, and global supply is currently insufficient to meet the needs of all African countries. Dr Samba acknowledged that no single tool or agency can succeed alone and there is a clear need for effective partnership. ITNs, including LLINs, are one of the vital tools in the fight against malaria but there is an urgent need to scale up coverage at community level. Fortunately, the financial resources are becoming available, although current production of LLINs is insufficient to meet global demand. Dr Samba reminded participants that African Heads of State had decided in Abuja to make ITNs available to as many as possible, particularly under 5s and pregnant women, but there is still a long way to go before those targets are reached. Dr Samba stated that one of his final actions before his impending retirement would be to push ahead with efforts to scale up ITNs and LLINs as an important element in the fight against malaria. The key to success lies in making the technology simple,

available and affordable to communities. Dr Samba concluded by wishing participants success with the meeting.

The Honourable Minister of Health, Dr Tshabalala Msimang then closed the opening ceremony by expressing the hope that in the spirit of true partnership, manufacturers would transfer LLIN manufacturing skills and technologies to the historically disadvantaged, and this in turn would assist in bringing down costs.

3.2 Session One – Long Lasting Insecticidal Net Technology, Supply and Demand.

Chair: Don de Savigny

Dr de Savigny welcomed participants on behalf of the RBM Working group on Insecticide Treated Nets (WIN). Dr de Savigny then proceeded to describe how working groups are one of the mechanisms through which the RBM partnership addresses specific technical and implementation areas. In recognition of the fact that the requirement for re-treatment of conventional nets, the WIN group met one year ago and established a satellite group on LLINs, led by Pierre Guillet, with a remit to establish a framework for development, production, and distribution of LLINs and to convene a partnership meeting. The draft business plan has been completed and the current partnership meeting convened. Dr de Savigny then presented the objectives and expected outcomes of the meeting (see section above).

3.2.1 Overview of LLIN Technologies – Pierre Guillet

Dr Guillet began by stating that ITNs are a key malaria prevention and control intervention, alongside others, including IRS, which is appropriate in some epidemiological situations, particularly those found in southern Africa. however, ITNs remain the key intervention for most of Africa. Dr Guillet then presented baseline data on the current situation regarding ITN coverage in Africa, as detailed in the Africa Malaria Report 2003.

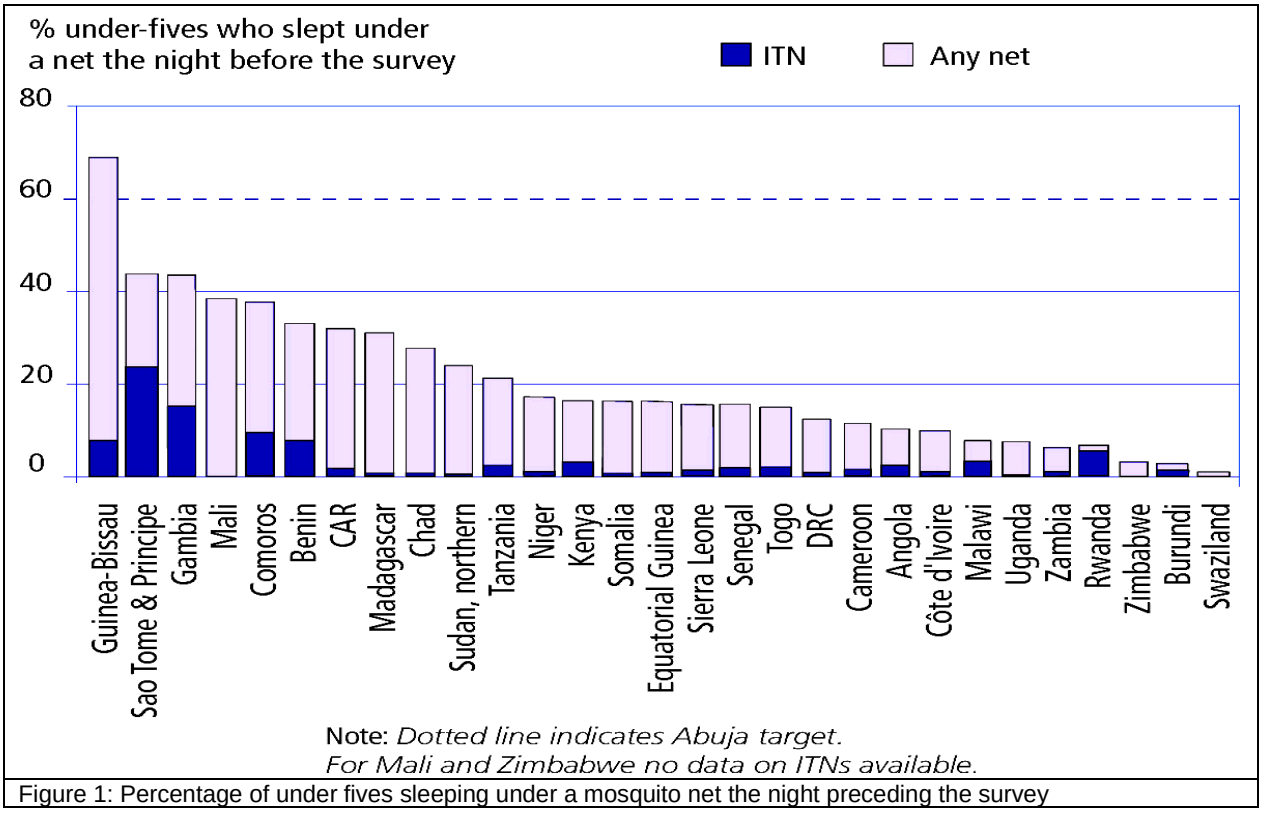

Figure 1: Percentage of under fives sleeping under a mosquito net the night preceding the survey

As can be seen from figure 1 above, net coverage across most of East, Central and Southern Africa was relatively low prior to 2003, Coverage is higher in West Africa, but even where overall coverage is high, the majority of the nets are not treated.

Definition of an LLIN

- A mosquito net, usually treated at factory level
  - with insecticide, either incorporated into or coated around fibres,
  - which resists multiple washes (al least 20),
  - and whose biological activity for personal protection and/or vector control lasts as long as the life of the net itself (e.g. around 3 years for polyester nets, 5 years for polyethylene).

Two main LLIN treatment technologies are currently available:

1. Incorporation: insecticide is mixed with a polymer, which is subsequently used to extrude a mono- or a multifilament yarn
   - Monofilament: advantages - strength, durability. Disadvantages – limited production capacity, requirement for new equipment to manufacture
   - Multifilament: advantages - easy transfer, equipment available. Disadvantages – quality control (QC) issues
   - Both: occupational health issues (handling)

2. Surface treatment: insecticide (mixed in a resin or a polymer) is bound to netting fibres by dipping or spraying techniques
   - Advantages: safety, ease of application, potential for field use
   - Limitations: suitability with different netting materials, long-term efficacy under various field conditions

LLIN technologies are evaluated through the WHO Pesticide Evaluation Scheme, which comprises three phases:

- Phase I: laboratory testing (bio-efficacy, wash resistance, dynamics of insecticide…)
- Phase II: field testing in experimental huts (mortality, impact on vector behaviour comparing unwashed and washed LLINs with conventionally treated nets)
- Phase III: field test at village scale (entomological and epidemiological evaluation as necessary)

WHO recommendations are only valid for products meeting WHO specifications
Only Phases I and II are required for insecticides that are already recommended by WHO for treatment of mosquito nets

Phases I and II testing result in provisional recommendations, and this process takes 1 to 2 years. Provisional recommendations are revisited after few years, equivalent to the effective life span of the LLIN and are confirmed or changed on the basis of results obtained under programme conditions

Two LLINs are currently recommended by WHOPES

1. Olyset net®: wide mesh netting (mesh 56), made of high-density polyethylene monofilament yarn (150 denier) with 2% permethrin incorporated (equivalent to 1 g/m2) (Recommended since 2001, WHO/CDS/WHOPES/2001.4)

2. PermaNet®: multifilament polyester netting (mesh 156, 75 or 100 denier), surface treated with a wash resistant deltamethrin mix (55 mg a.i./m2) (Recommended since 2003, WHO/CDS/WHOPES/2004.8)

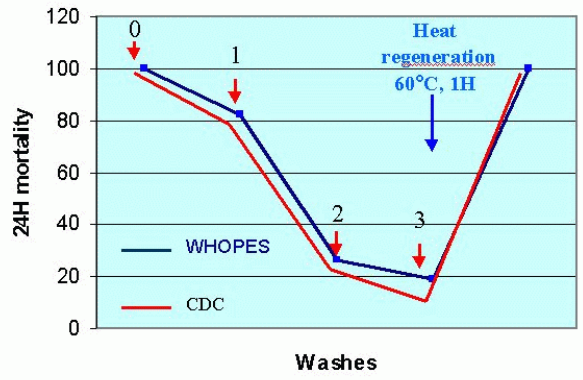

Figure 2: Olyset lab testing: wash resistance and heat regeneration (Phase 1, WHO cones 3 min. exposure)

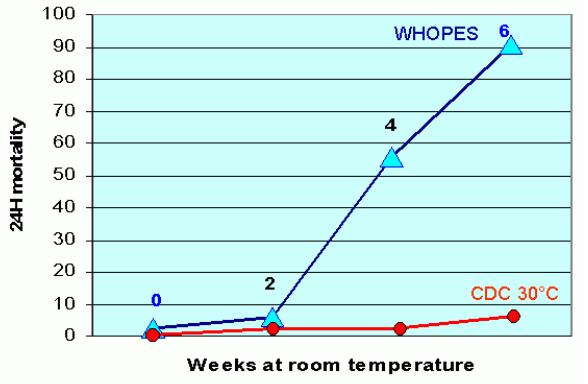

Figure 3: Bioassay with Olyset washed 5 times: spontaneous regeneration at 22-25°C

There is currently limited capacity for laboratory and field testing of Long Lasting Insecticidal Products and this is an important bottleneck that needs to be addressed

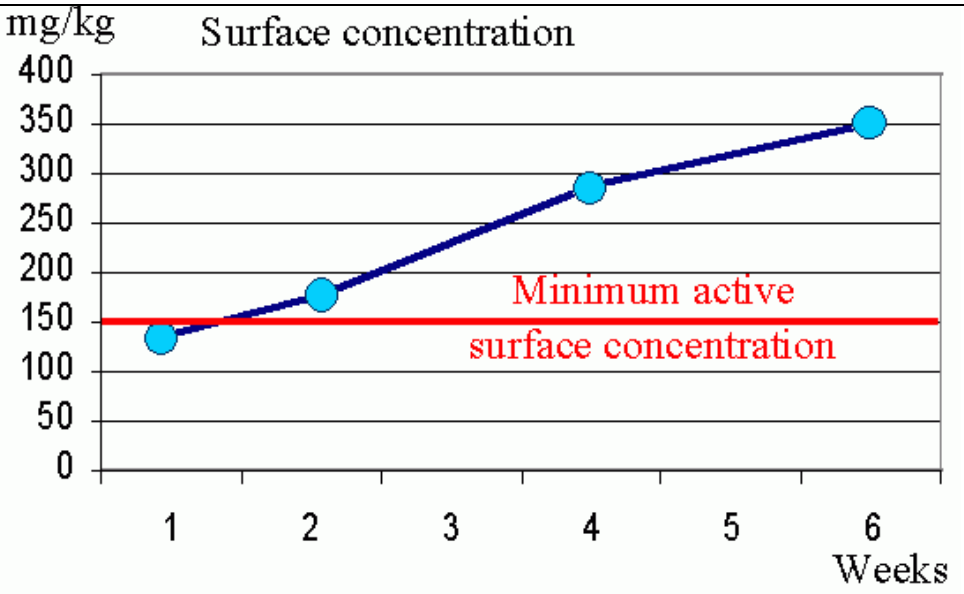

Figure 4: Chemical analysis: migration of permethrin in tropical conditions (30°C) (industry data)

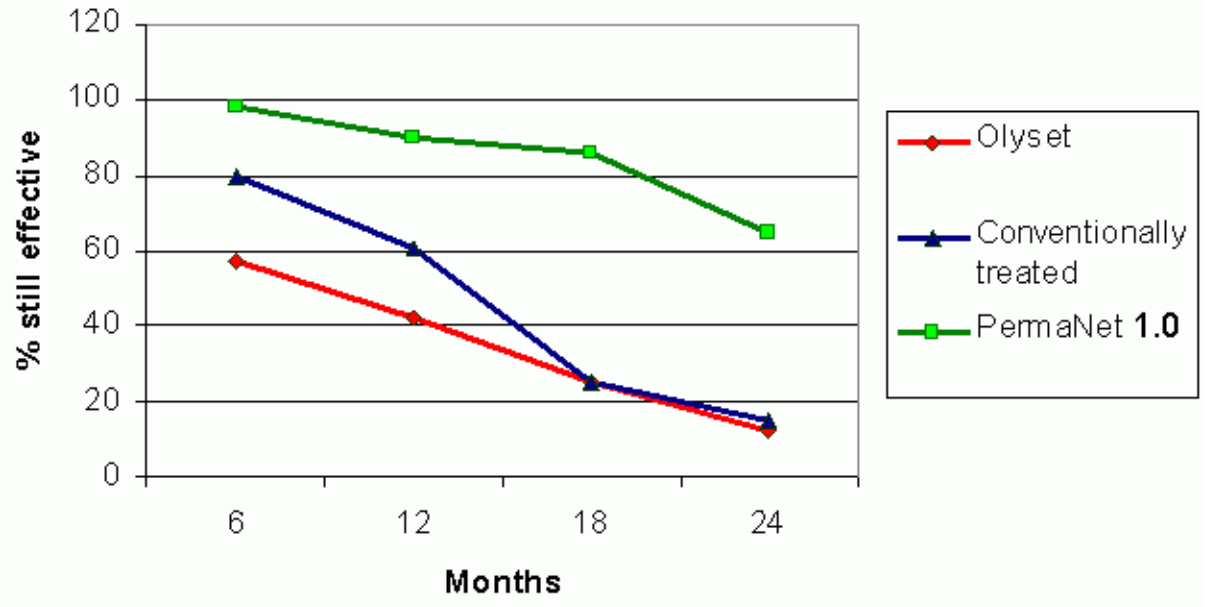

Figure 5: Results of CDC field trial in Kenya (Kaplan Meyer estimate)

At 30ºC Olyset nets take 1-2 weeks to regenerate their insecticidal efficacy following migration of the insecticide through the polymer to the fibre surface. Recent results obtained by CDC in western Kenya, appear to show that the nets did not regenerate. These results from Kenya contradict ALL other results obtained for Olyset.

Epidemiological impact of Olyset® nets have been proven in village-scale trials in Africa

- In Senegal, where the vectors are susceptible to permethrin, Olyset® achieved a reduction of transmission by 93% and a reduction in malaria morbidity by 58% (Faye et al., 1998, Med. Trop., 58, 355-360)
- In Côte d'Ivoire, where the vectors are highly resistant (kdr), the observed reduction in malaria morbidity was similar to that achieved in Senegal at 60.9% (Henry et al., 1999, Med. Trop., 59, 368-372), in the absence of any detectable entomological impact (Doannio et al., 1999, Med. Trop., 349-354). When tested in experimental huts, Olyset efficacy remained unchanged after 3 years of continuous use by villagers (N'Guessan et al., 2001, Med & Vet Entomology, 15, 97-104)

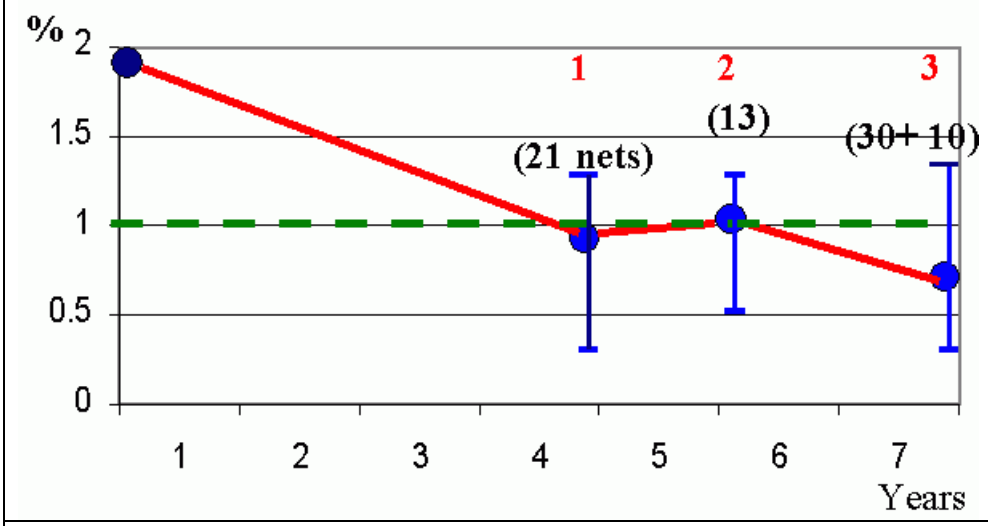

Figure 6: Olyset: residual permethrin content after 4, 5 and 7 years of continuous use in the field (1=Senegal, 2=Cote d'Ivoire, 3=Senegal and Tanzania)

Results after seven years continuous use in Tanzania, showed that 9/10 nets were still effective (KD 60 min > 95 %), even without heat regeneration (Tami et al., 2004, Malaria Journal, 3-19). A village survey of 103 households found 97 % of the nets still in place and used, with 62 % in relatively good condition. In addition, 51% of villagers said that they woulld buy an Olyset net because of its durability.

Permanet Evaluations

In the original evaluation of Permanet 1.0 heterogeneous results were observed in the field. Insecticide uptake and wash resistance varied according to the polyester fabrics used and low wash resistance was observed in a large scale field trial in Uganda (Kilian et al., 2002).

In order to address some of these issues, the manufacturers developed Permanet 2.0 which was assessed in laboratory and field trials and received WHOPES approval at the end of 2003

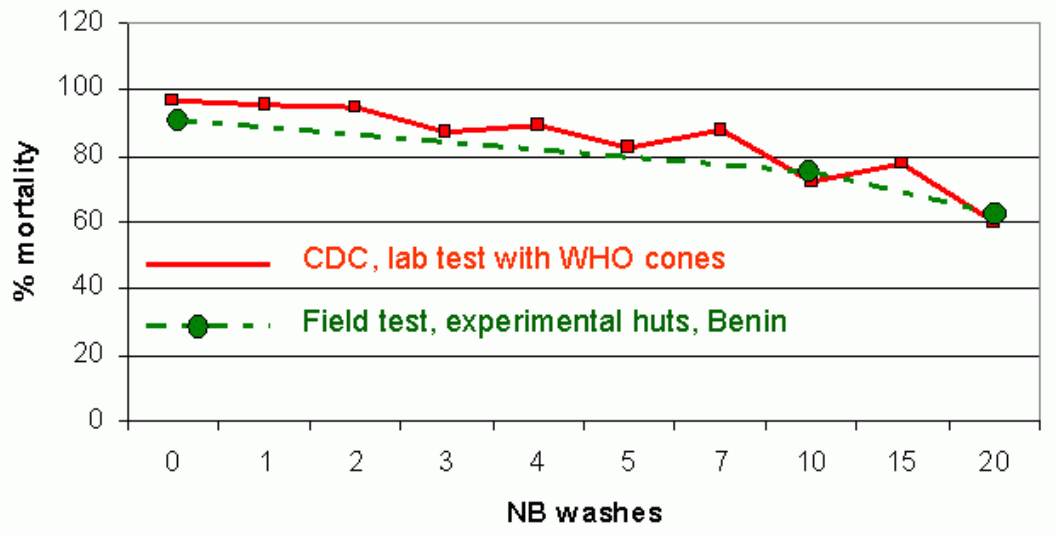

Figure 7: PermaNet2: wash resistance, laboratory and field tests

Key Advantages of LLINs

- LLINs represent a practical option to rapidly increase coverage of target populations with properly treated nets
- LLINs are more cost-effective than conventionally treated nets

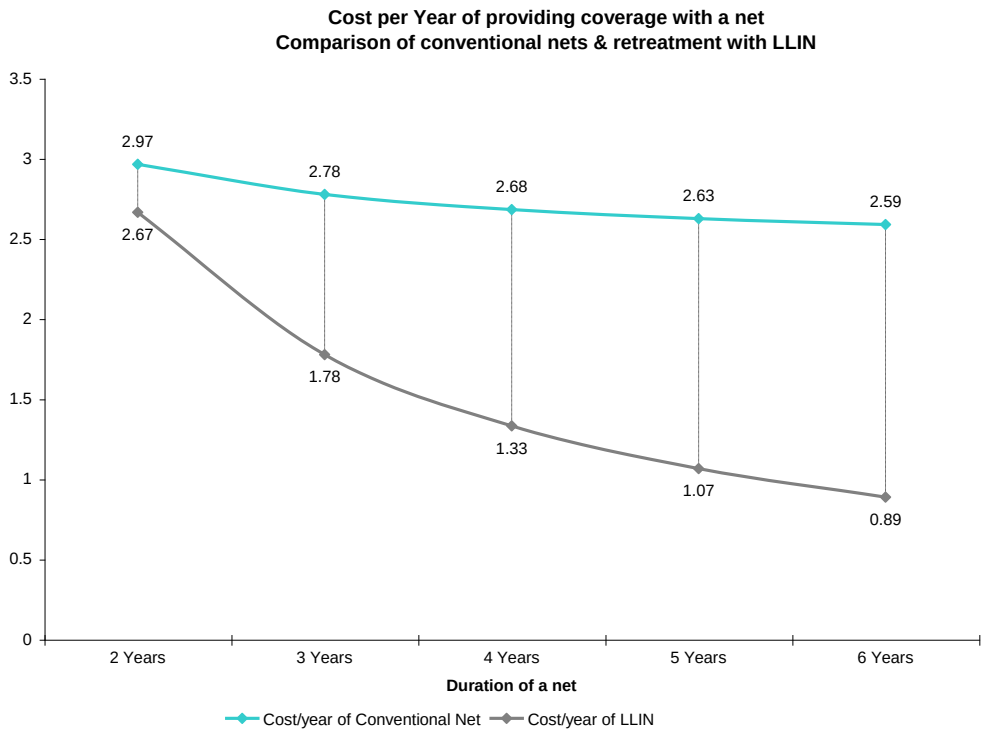

Figure 8: Cost per year of providing coverage with a net. Comparison of conventional nets and re-treatment with LLIN

Recent data from the GFATM show that demand for LLINs from governments has rapidly increased, with some 8 million LLINs (80% of total nets) included in round 4 applications, compared with less than 1 million LLINs (<10%) requested in round 1.

Next steps in LLIN technology development

1. Further refinement of test methods and protocols for accelerated testing are under consideration and a working group meeting is scheduled for early 2005 and will comprise scientists, industry and WHO.
2. Capacity strengthening for laboratory and field testing
3. Facilitating access to information on long- lasting efficacy under programme conditions

Priorities for facilitating technology access and scaling-up local production

- Insecticide incorporated into multifilament yarns (polypropylene, polyester...)
- Kits for long-lasting dipping of nets already in use or for treatment of finished nets at factory level
- Possible use of weaving machines to produce long-lasting netting materials
- Assessment of potential for local production of LLINs in Africa (Business Plan)
- Development of standard operating procedures for local production
- Strengthening capacity for quality control
- Pyrethroid resistance: combination of insecticides on LLINs to prevent or limit the development of pyrethroid resistance and to enhance mass impact of ITNs on vector populations

Other potential applications of Long Lasting Insecticidal products

- Curtains
- Window, door and eave screening
- Jar covers (dengue)
- Screens in agriculture (shading, "netting green houses"..)
- Treated plastic sheeting for internally displaced person (IDP) and refugee camps

- Long-lasting treatment of fabrics (etofenprox, permethrin, repellents..)
- Clothing to prevent tick borne diseases, to protect travellers, refugees, military forces, residents in nuisance areas…
- Long lasting treated hammocks for prevention of forest malaria
- Tsetse traps
- Curtains and screens

A wide range of technologies and potential applications for highly targeted and selective application of active ingredients (insecticides, repellents…) are envisioned, with application to multi-disease prevention, provision of comfort and improving domestic environment as a motivating factor and a vehicle to deliver interventions. Future developments will require creativity, inter-activity and multi-sectoral collaboration. Dr Guillet presented a schematic of the range of partners currently involved in LLIN technology development, production and distribution (Fig. 9).

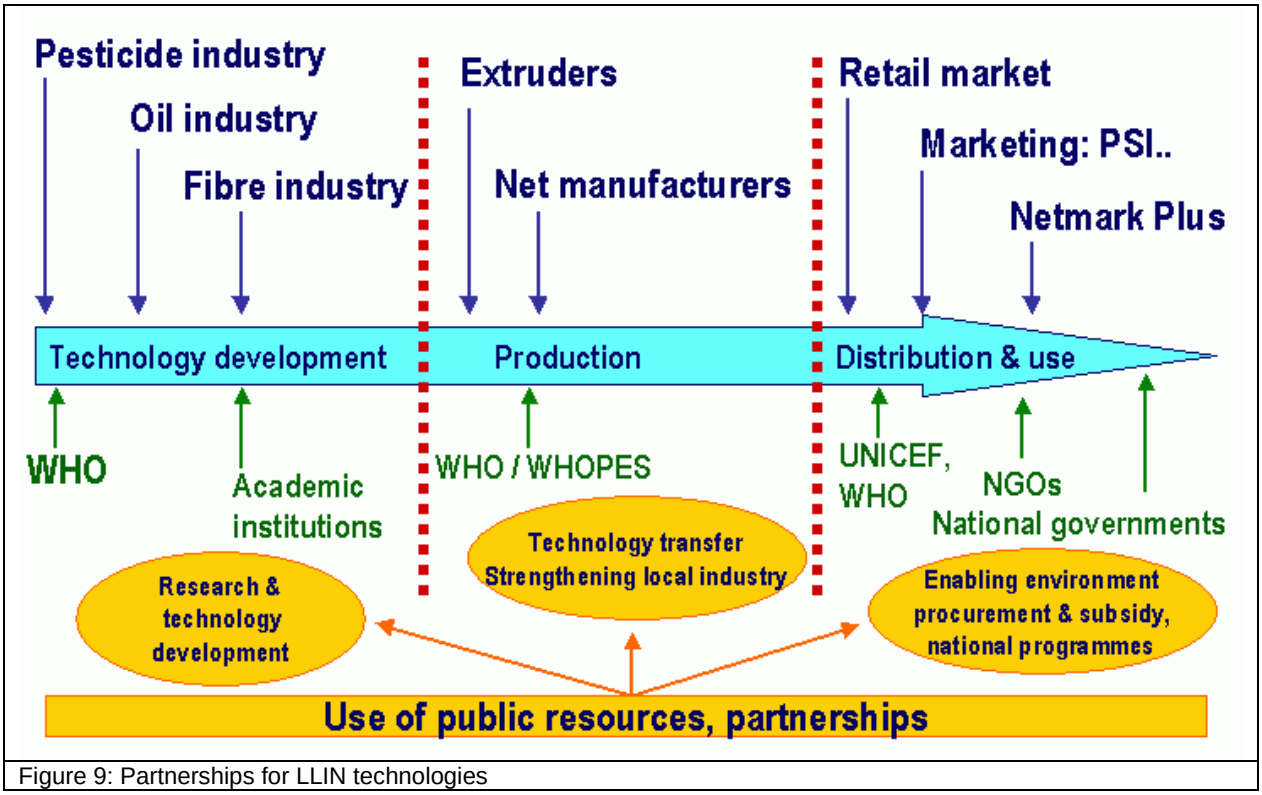

Figure 9: Partnerships for LLIN technologies

As regards the potential for local production of LLINs and technology transfer, Dr Guillet presented the example of Olyset production by A to Z Textile Mills in Arusha Tanzania (Fig. 10).

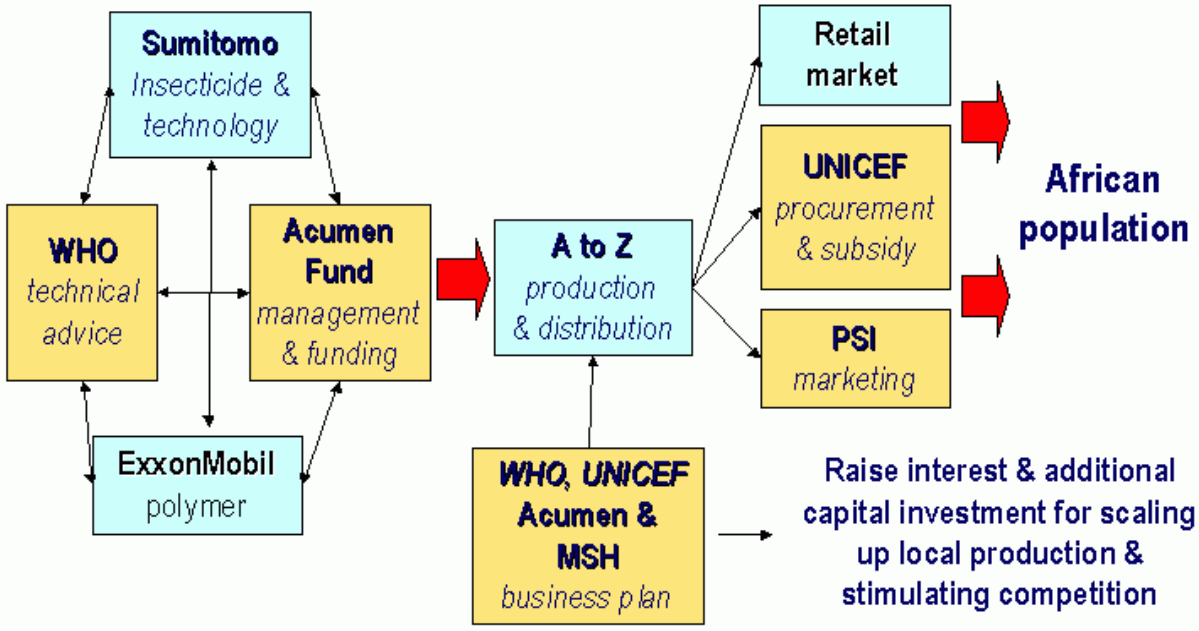

Figure 10: Example of LLIN technology transfer (Tanzania)

Way Forward

- Development of LLINs should be seen as a dynamic process: market growth, economies of scale and competition will result in improved performances and/or reduced prices
- Technology development requires innovative alliances and partnerships
- Private and public sectors joining forces through a network of collaboration
- Public resources are needed to stimulate technology development, strengthen testing capacity and facilitate technology transfer
- Industry and private sector are instrumental for scaling up production and distribution of LLINs

3.2.2 Overview of LLINs Supply and Demand (Institutional and Consumer) – Alan Court

Alan Court's presentation opened with a description of the background to the malaria situation in Africa and the potential represented by LLIN technologies as a control tool. He also presented the graph of net coverage in Africa from the Africa Malaria Report 2003 and described it as a baseline against which progress can be judged, noting that the situation had already changed dramatically in several countries, including Malawi and Eritrea. In Malawi it is estimated that 1.7 million highly subsidised ITNs have been distributed through MCH clinics since January 2003, with net ownership currently estimated at about 43%, with 35.5% of children under five and 31.2% of pregnant women now sleeping under an ITN, according to a national malaria survey carried out in January 2004. The Africa Malaria Report graph also demonstrates that net use is significantly higher in West Africa, although the majority of those nets are untreated, however this represents a clear opportunity for treating those nets, including converting them into long lasting nets.

Alan then proceeded to discuss the issue of forecasting and estimation of the global ITN need. The 2000 estimate was for 30 million ITNs annually in order to meet the Abuja target. Current Global estimates for net production are between 30 and 40 million per year, of which about one-third are LLINs. The importance of obtaining country level data on numbers and coverage of Long Lasting Nets and other ITNs was emphasised as a key component of timely and accurate country level forecasting.

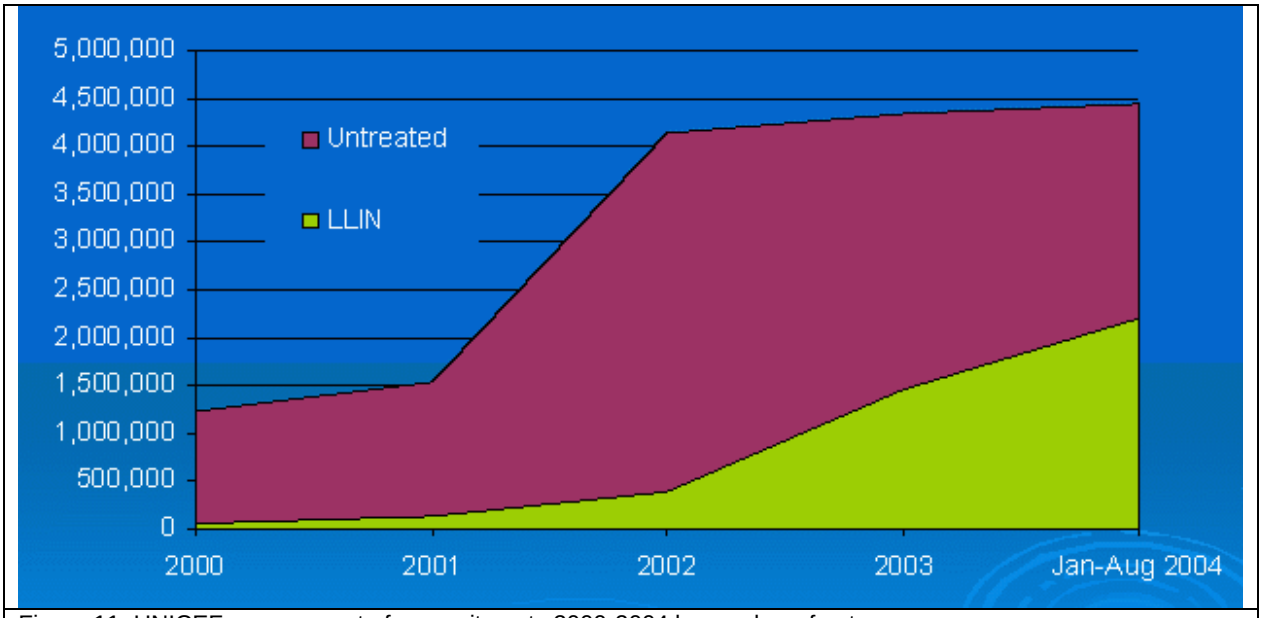

Figure 11: UNICEF procurement of mosquito nets 2000-2004 by number of nets

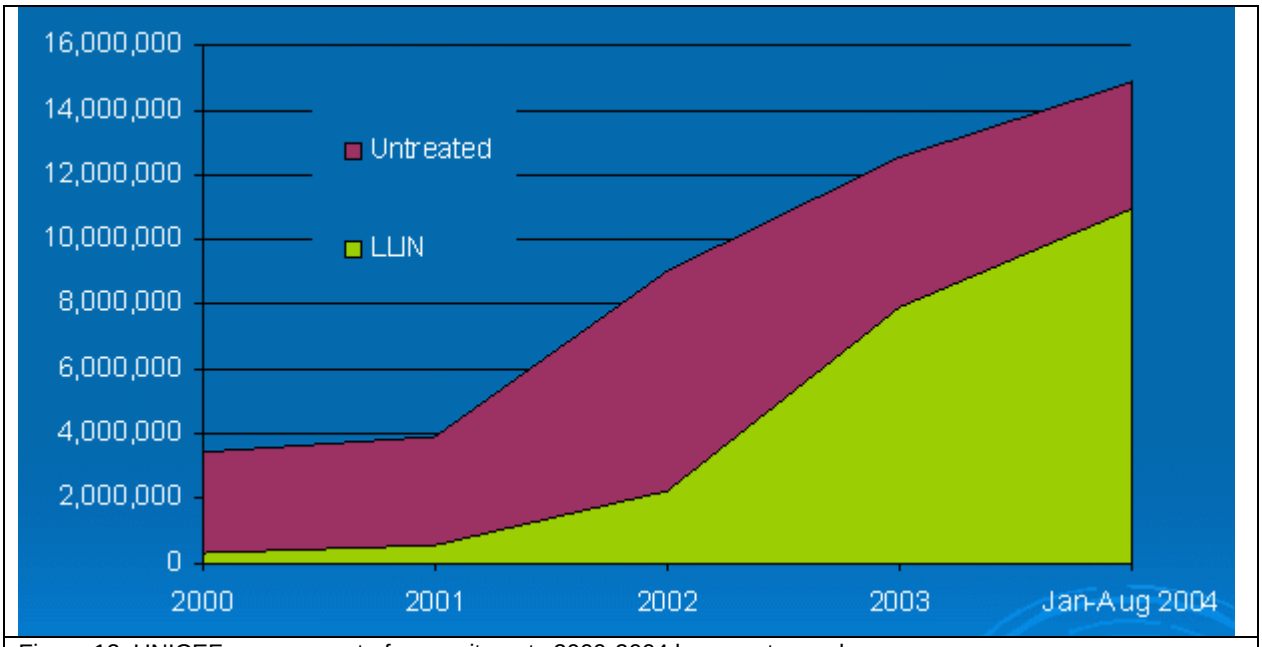

Figure 12: UNICEF procurement of mosquito nets 2000-2004 by monetary value

Figures 11 and 12 above illustrate the pattern of UNICEF procurement of mosquito nets over the period 2000 to mid-2004. The total number of nets procured has remained fairly stable at around 4-4.5 million units per annum since 2002, but the proportion of LLINs procured has increased from less than 500,000 in 2002 to more than 2 million in 2004 and as a consequence the monetary value of UNICEF net procurement has increased to more than US$ 15 million in 2004, despite no significant increase in total number of nets procured.

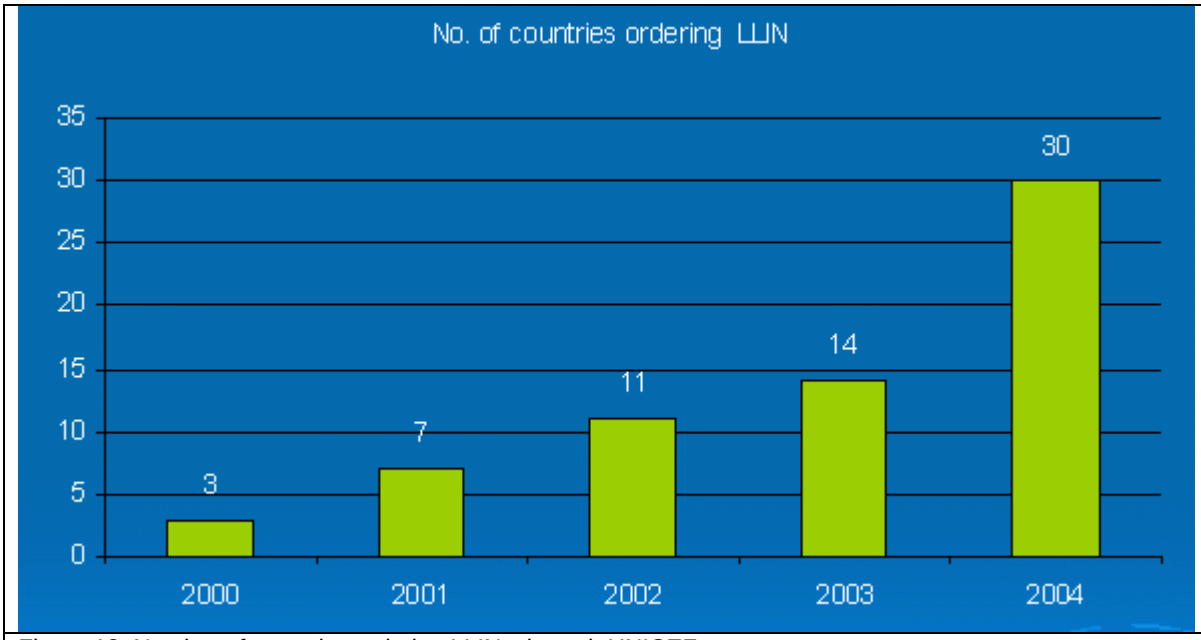

Figure 13: Number of countries ordering LLINs through UNICEF

Figure 13 illustrates the rapid recent increase in demand for LLINs, with 30 countries submitting LLIN orders in 2004.

Opportunities for local production and distribution were identified, in recognition of the fact that locally produced and distributed untreated nets are still widely used in Africa. The potential exists to ensure that Long Lasting technologies are applied to these existing nets in order to increase LLIN coverage significantly (especially in West Africa).

Alan then proposed a number of challenges to governments, international agencies and donors, and the commercial sector:

Challenges to governments

- Accurate and timely forecasting of national requirements for all nets, including LLINs.
- Estimate quantities of all nets in the country, including those requiring re-treatment
- In view of the still limited production of LLINs, there is a need to develop an allocation system for LLINs targeting vulnerable groups.
- Improve resource mobilisation, and timely allocation, disbursement and utilisation of resources to expedite procurement of LLINs
- Ensure a favourable regulatory environment and also quality control

Challenge to the UN, GFATM, NGOs, and Donors

- Faster and timely disbursement of funds
- Support national governments in planning, forecasting, and distribution of LLINs
- Ensure good ex-factory quality control of Long Lasting products
- Support the work of the RBM Partnership's Malaria Medicines and Supplies Service
- Advocate for and allocate more resources

Challenges to the commercial sector

- Scale up production of LLINs and other LL technologies to meet increasing demand
- Maintain quality control to meet WHOPES specifications
- Avoid shortcuts and ensure consistent quality of LLINs
- Continue to develop new and affordable LL products; insecticides, fibres and nets
- Both conventional Nets and LLINs should be scaled up in the short to medium term until sufficient LLINs are readily available

In conclusion Alan stated that a quantum leap is urgently needed in order to provide the 30 million LLINs needed annually for Africa. There is a clear need for timely and accurate country level forecasting of LLINs and resource requirements. Regular communication channels for exchanging information and ideas on Long Lasting technologies needs to be established

3.3 Session Two – Situation Analysis on Long Lasting Insecticidal Nets

3.3.1 Key Findings of the LLIN Business Plan – Denis Broun

Denis opened his presentation with a review of ITN efficacy and the rationale for scaling-up LLIN coverage. He then presented the three main components of the LLIN Business Plan:

Market Analysis
- Understand demand and distribution of nets
- Roles of governments, institutions, and NGOs
- Assess capacity to procure LLINs

Producer Analysis
- Review status of LLIN technology development
- Identify issues relevant to producing LLINs in sub-Saharan Africa

Strategy Development
- Estimate investment needs for increasing LLIN production
- Calculate financial impact of using LLINs instead of ITNs to achieve Abuja targets
- Outline distribution mechanisms
- Outline ways for stakeholders to work towards promoting LLINs

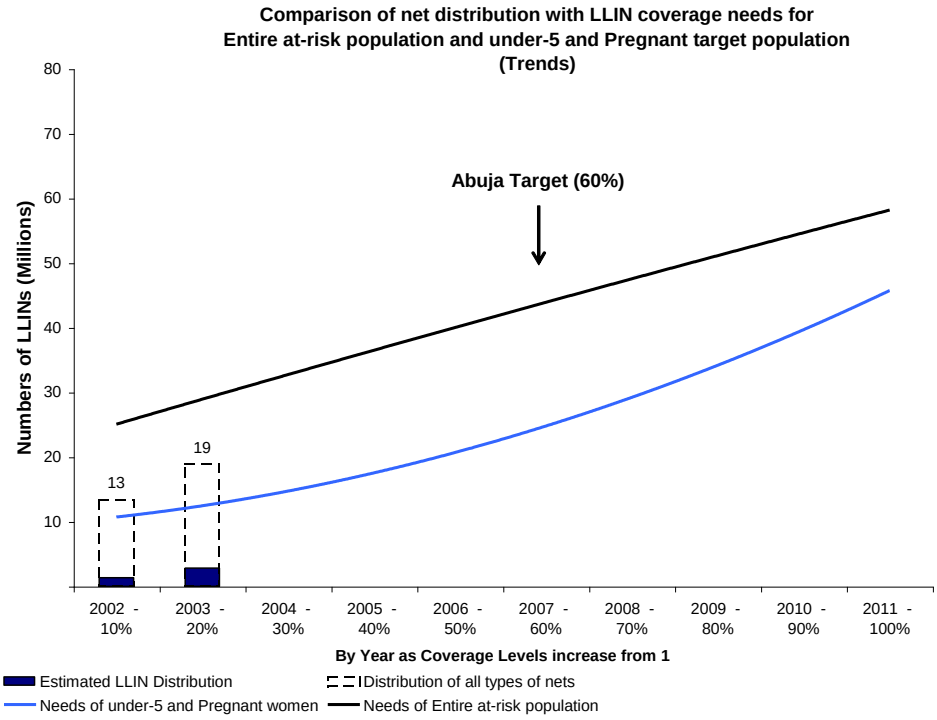

Figure 14: Current levels of net and LLIN distribution in relation to targets

Figure 14 illustrates the current level of progress towards achieving Abuja targets for nets and the distribution of LLINs, and indicates that progress is being made. The total number of nets distributed is increasing steadily year on year, as is the proportion of LLINs distributed (Fig. 15).

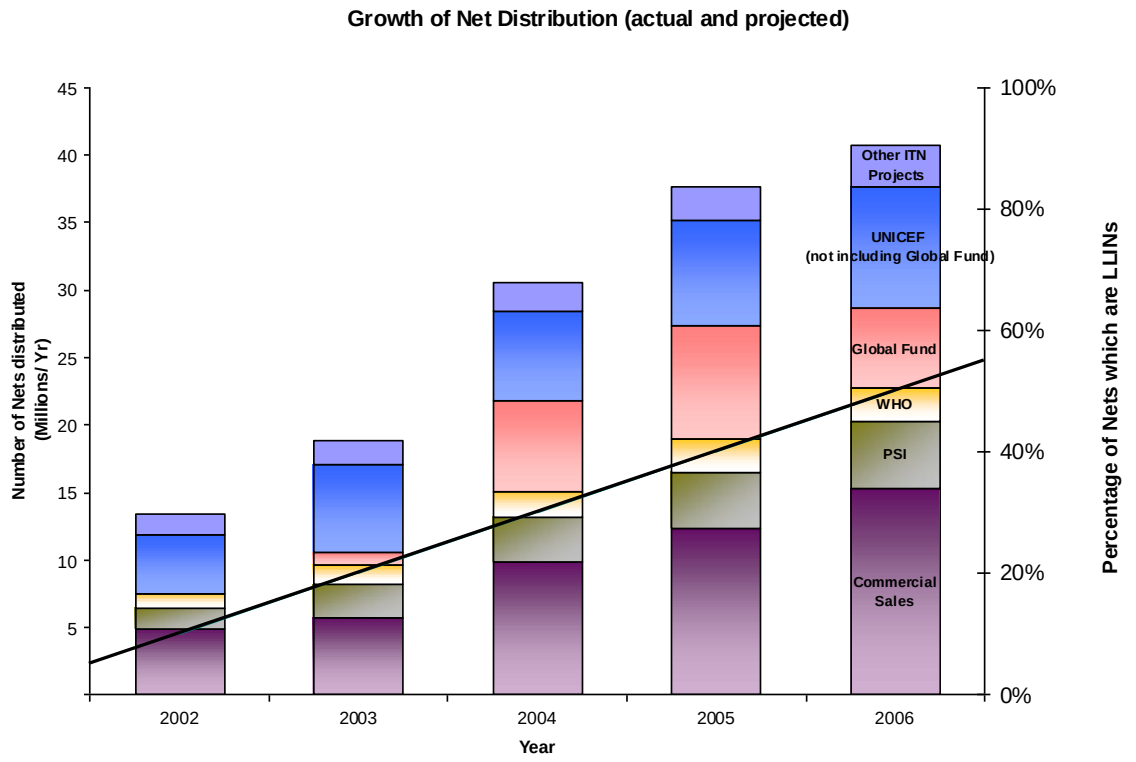

Figure 15: ITN distribution by partner

The distribution chain for delivering nets to consumers was presented and discussed (Figure 16). It can be seen from the diagram that multiple distribution mechanisms are utilised, but these are not always complementary. Most conventional, un-treated nets pass through the wholesaler/retailer arm of the diagram, while others, especially LLINs pass through procurement agencies and public sector channels. Currently there is little evidence of a private market for LLINs. Figure 17 illustrates the funding mechanisms for net distribution.

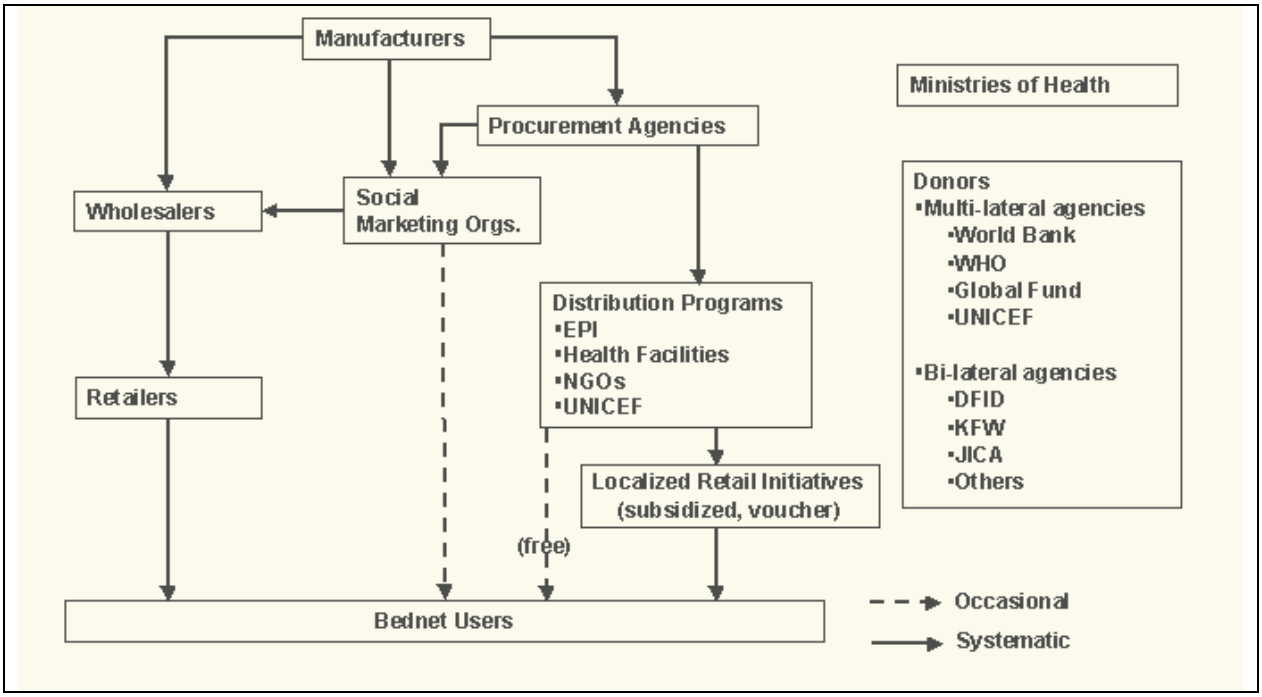

Figure 16: Mosquito net distribution channels

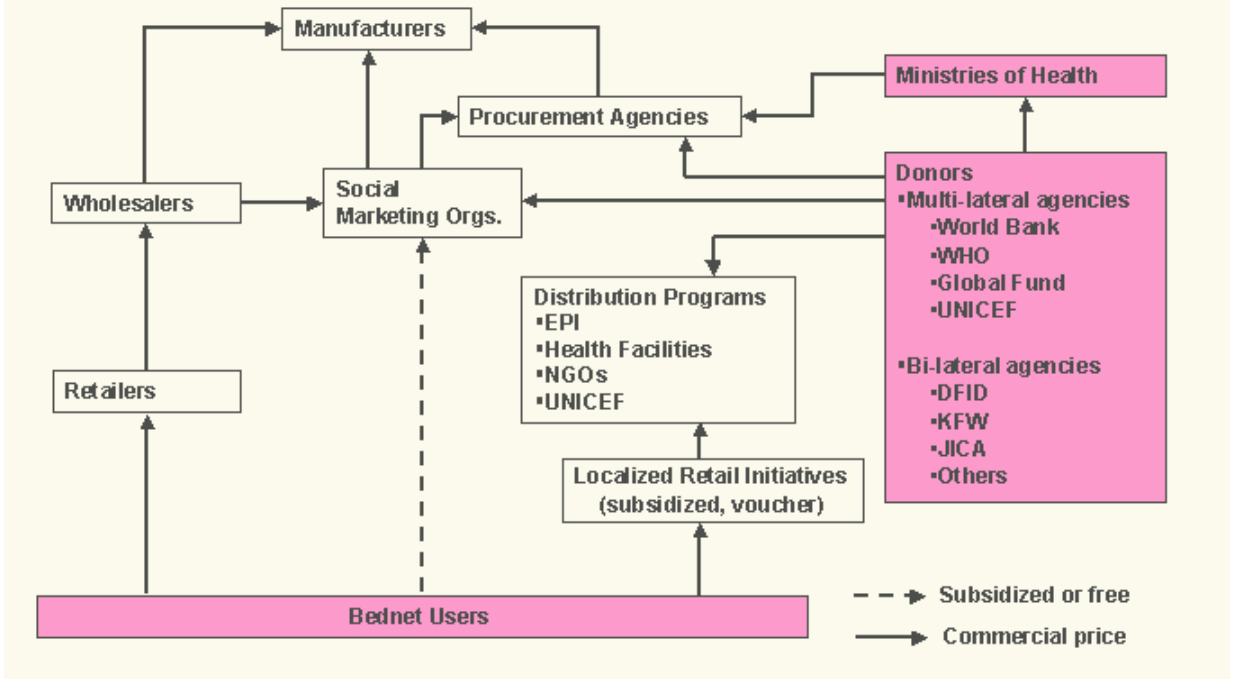

Figure 17: Mosquito net financing mechanisms

Studies in Burkina Faso and Cameroon indicate that net purchase at US$5 per unit can represent as much as 1-2 months discretionary income (income available after food purchase) for the poorest members of society and suggests that mechanisms to reach this sector of the population will be required in the long term.

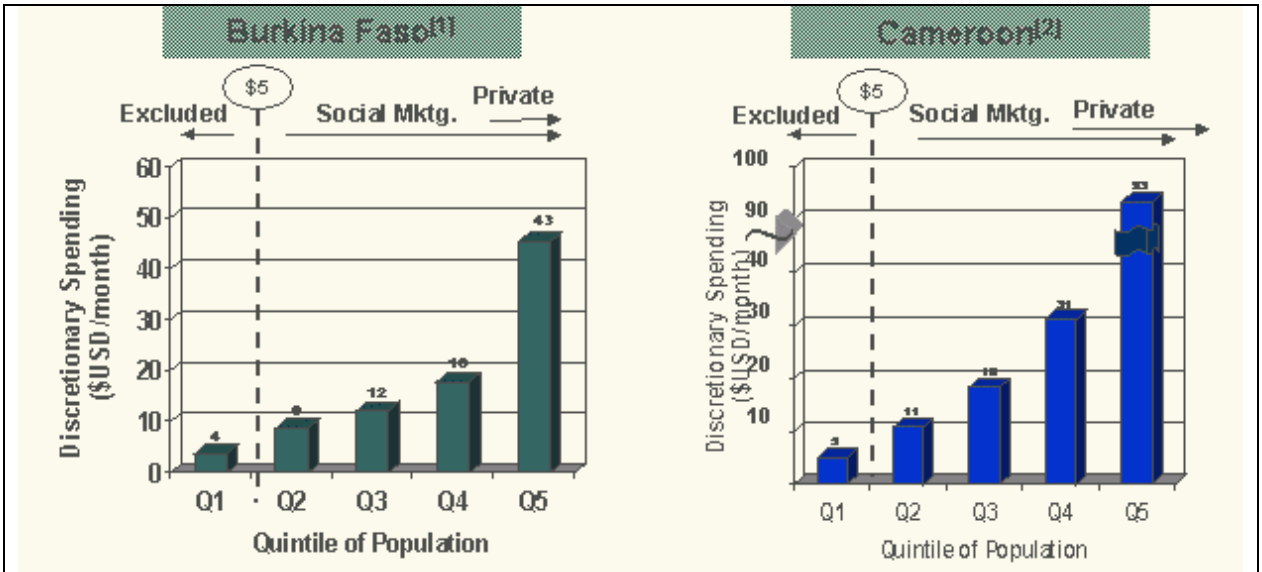

Figure 18: Discretionary spending and potential for coverage by different sectors

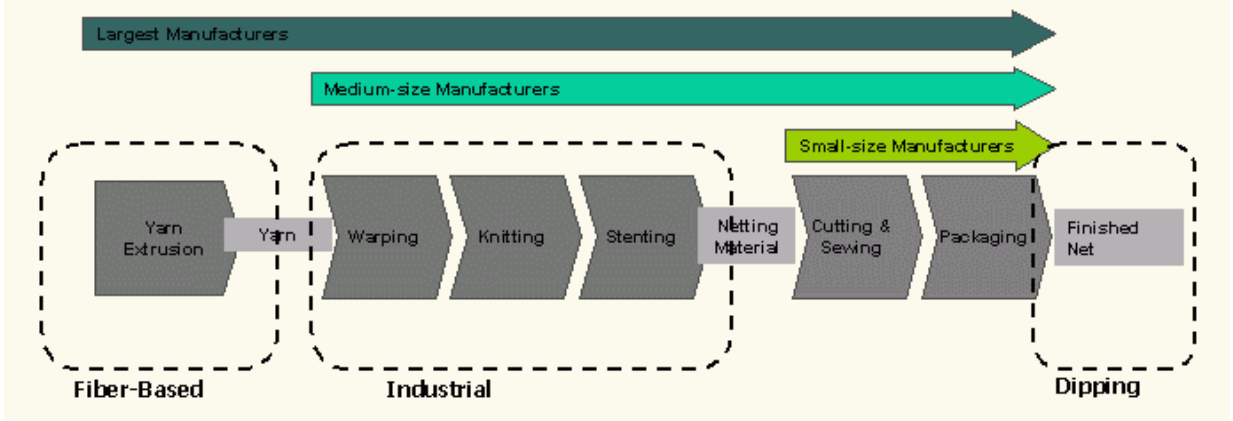

Figure 19: Classification of LLIN manufacturing, by process and by size of manufacturer

Current LLIN technologies can be conveniently classified into three categories depending on the type of production process (fibre-based, industrial, or dipping) and size of the manufacturing enterprise. The range of manufacturing companies involved in LLIN production is varied and includes chemical companies, textile manufacturers, research laboratories, insecticide companies and net manufacturers. The producer analysis component of the business plan reveals that the majority of potential LLIN manufacturers in sub-Saharan Africa fall into the categories of industrial production (warping, knitting and stenting) and post-production dipping with long-lasting insecticides. AtoZ textiles of Tanzania performs the additional step of manufacturing polyethylene yarn for production of Olyset nets under a technology transfer agreement with Sumitomo corporation, that supplies AtoZ with polyethylene pellets.

LLINs as insecticide products are subject to approval by the WHO Pesticide Evaluation Scheme (WHOPES), which tests safety, efficacy, and acceptability of products through three phases:

1. Lab testing
2. Small-scale field testing
3. Large-scale field testing

A fourth phase covers development of specifications for quality control and international trade. An interim WHOPES recommendation is possible after completion of 2nd phase of testing. Institutional buyers usually require WHOPES recommendation, but this is not required for commercialisation in private markets. WHOPES is essential for international standardisation of products but does slow down the process of getting new technologies to scale.

Equipment costs for LLIN production of 1.2 million units per year have been estimated at approximately US$ 1.7M for production of polyester / polypropylene LLINs and US$ 1.3 M for polyethylene nets. The “green field” costs, including purchase of land, construction of a new manufacturing plant, etc. increase the total cost to US$ 2 – 2.5 M. The relatively high cost of establishing a new LLIN manufacturing plant implies that some form of investment support may be required to rapidly increase LLIN production capacity in the short term. The Acumen Fund, for example, could be a potential source of investment funding. The estimated costs to achieve 60% coverage with LLINs of various target groups in sub-Saharan Africa range from US$ 105 million to US$ 310 M. Due to the lack of a requirement for re-treatment, cost savings from the use of LLINs rather than conventional nets with regular re-treatment range from US$ 59 M to US$ 175 M (see table below).

Factor	Cost of Providing 60% Coverage in SSA of—		
	Children Under Five and Pregnant Women	Economically Vulnerable Population	Entire At-Risk Population
Number of persons per Net	1	2	2
Number of Nets (in millions)	80.3	59.0	174.8
ITNs with Retreatment (in USD millions)	$222.9	$163.9	$485.4
LLINs (in USD millions)	$142.6	$104.8	$310.6
Cost Savings with LLINs	$80.3	$59.0	$174.8

The current LLIN market is interesting as demand outstrips supply, in which case one would normally expect to see higher prices, however, since the vast majority of LLIN purchases are made by large institutional buyers, costs have been kept low. This artificial situation is unlikely to persist in the long-term as conventional market forces will ultimately come into force.

3.3.2 Overview of the Commercial Sector's Perspectives on LLINs – Gerhard Hesse

Gerhard began his presentation with an overview of the rationale for scaling-up production and distribution of LLINs with the observation that even high coverage levels with conventional un-treated nets will not have sufficient impact on malaria transmission, whereas even at 25% coverage, ITNs begin to demonstrate significant impact owing to the mass effect produced by reducing the lifespan of the mosquito vectors. Scaling-up requires a scaling-up of capacity for overall net production, plus the provision of technologies for both in-, and post-process LLIN production. Increased production must be accompanied by scaled-up distribution and use of LLIN's

The current WHO definition of an LLIN is: "a ready-to-use pre-treated mosquito net, which requires no further re-treatment during its expected life span (4-5 years?)"

However, the life span of a net will depend on the material from which it is made (Polyethylene is more durable than polyester) and also on how the net is handled. WHOPES guidelines state that after 20 washes the net must achieve 80% mortality after 24 hrs (95% KD after 60 min). This, however, depends on the washing procedure, type of detergent, and the washing frequency. For example: NetMark country surveys in Senegal, Sudan, and Zambia have shown that approximately 50% of users wash their net between once per week and once per month. Frequency of washing is higher in rural areas than in urban areas. At these high frequencies of washing, the 20 washes criterion could be exceeded in as little as six months with weekly washing. These differences in life span between different types of net would suggest that a better definition of LLIN should focus on increased wash resistance, e.g. maintains efficacy for at least 20 washes.

Problems with the current definition raise questions regarding the value of WHOPES evaluations and WHO/FAO specifications, however it is acknowledged that these are:

undoubtedly necessary as quality criteria
undoubtedly necessary as product purchasing or selecting criteria

BUT WHOPES evaluation should not be a delaying factor in the introduction of new LLIN technologies as the market requires increased volumes of nets, and current production capacity for the two approved LLIN technologies remains limited. Some form of WHOPES "fast track" evaluation is required and should be adopted by customers. A meeting is due to be held early in 2005 to further refine WHOPES methodologies and criteria for interim and final recommendations.

In terms of technology development it is the opinion of the private sector that finding a technology which produces good results, e.g. a coating polymer which lasts up to 10-15 washes is not difficult. However, achieving wash resistance in excess of 21 washes needs a special coating polymer or incorporation of the insecticide into the fibre.

Technology inventions for LLINs are a competitive business and are undertaken at various levels (academia, commercial sector, small enterprises, PP partnerships). Inventions need funds, time and partners to develop them to maturity and take them to market in the shortest possible time. The only successful models currently are private-private-public partnerships involving textile manufacturers-pesticide industry, polymer providers-pesticide industry, master batch companies-pesticide industry-net manufacturers and these are funded by the running business. Other technological inventions might not survive due to a lack of funding. The majority of technologies currently in development are targeted to existing models or are spin-offs from existing technologies, as these have the shortest time to market. Under these conditions it may not be possible to find the "magic bullet" LLIN technology.

The Business Plan includes the possibility of establishing a technology trust. The view of the private sector is that given the wide diversity of technology developers, any proposed technology trust should include a co-ordination function. It was proposed that public funds be made available to allow academia or specialised small companies to invent new technologies. The trust could also enhance the transfer of inventions to a marketer, who would develop the product to maturity. A technology trust would of course need to respect intellectual property rights and patents. Large R&D oriented companies, such as chemical or pesticide companies need to evaluate the potential return on investment of developing LLIN technologies, as public health products such as LLINs will remain marginal components of core business, with limited profit potential.

Comparison of LLIN technologies

1. Industrial in process production of pre-treated LLINs

- extrusion technology from master batches (Olyset)
- in-process coating of yarn (PermaNet)

The major advantages of this type of technology are that production capacity can be high and the opportunity for in-house quality control and adherence to international standards exists. Disadvantages include the high capital investment necessary, the potential for occupational health risks, the exclusion of the majority of the existing industry from engaging in this type of manufacture.

2. Industrial post process production of pre-treated LLINs

- Mechanised treatment. Advantages include reduced occupational health risk(?) and the potential for mass treatment of large numbers of nets. Disadvantages include the medium capital investment necessary, and possibly difficulties in technology transfer
- Manual treatment. Advantages include the low capital investment necessary, the suitability for smaller sized industries (net treatment centres, etc) and the relative ease of technology transfer. disadvantages include increased occupational health risk, and lower production due to extra steps in handling an labour-intensive nature of process

Supply and Demand in the LLIN market
The Business Plan quotes figures of 521 M people at risk of malaria, 120 M of whom are classified as vulnerable groups. Given that an average of 2 persons sleep under each net, and the life span of a net is approximately 4 years, the annual requirement for nets is 40-50 M to meet the Abuja targets within 5 years. 2003 capacity is estimated at between 30-35 M nets, of which 4.5 M are LLINs. These figures illustrate the existence of a clear gap between demand and supply of nets, and a huge gap for LLINs. Even doubling the production capacity for the two approved LLINs will not meet demand. However, there are an estimated 100 – 150 M existing un-treated nets in Africa that could potentially be converted to LLINs with post-production treatment with long lasting insecticides

The question was raised as to whether or not a “sleeping” capacity for LLIN production can be accessed in order to rapidly speed up production. This would require certainty and commitment from donors and commitment from “implementers” (e.g. NGOs). It would also require the existence of sustainable private markets rather than the short term institutional market that exists at present. To maintain this capacity active would require planning and forecasting tools, increased investment into up-scaled net production and particularly LLIN production, and investment into new treatment technologies. The issue of the use of public money to support net manufacturers in making the decision to scale-up LLIN production was also discussed. Use of public money would require no discrimination in its application, either by the level of the technology or its location. The public sector must create trust in the market and foster a business environment that allows the private sector to make investments, e.g. through Malaria Medicines and Supplies Service (MMSS), reputable purchasing agencies, guaranteed purchase, transparency, etc. This would serve to “wake up” sleeping capacities, address the problem of the sporadic nature of full capacity production, and support entrepreneurship at all levels.

Gerhard then raised the question of whether we should wait for industrial scale-up of the two approved technologies. In 2005 it is estimated that LLIN production will reach in excess of 5 M p.a. To increase capacity requires financial investment in new high tech plants and establishment of new capacity takes time. To achieve the Abuja target with industrial LLINs would appear to be unrealistic given current production capacity. An alternative would be the conversion of existing conventional nets into LLINs. This requires low tech effective and safe approach, which is available, the use of effective one time net treatment campaigns implemented by a range of partners and approaches. Currently available post-production technologies could potentially convert twice the number of conventional nets into LLINs compared with industrial production of pre-treated LLINs. The public sector could support this sector as it is only likely to be a short-term measure (however, this type of long-lasting re-treatment may be required if high washing frequency reduces the effective life span of the LLIN to periods significantly shorter than the physical life span of the net.

In conclusion,
- Scaling up the production of nets and LLINs has to be enhanced
- Investment scenarios for this have to be created by the public sector
- There is no excuse in not reaching the coverage because the necessary quantities of industrial pre-treated LLINs are not available
- Appeal to donors: do not waste time waiting for the magic bullet, if there are no pre-treated LLINs do not lose interest in field converted LLINs or even conventional re-treatment
- Technologies on all levels are available or will be available in the short term
- Investment scenarios in optimised technologies have to be created by the public sector
- Public sector should take into consideration the implementation skills of the NGO and private sector community

Plenary Discussion
Private sector representatives suggested that the “green field” costs of establishing a LLIN production facility were unrealistic, as this type of investment is not normally undertaken by the industry. A more normal procedure is to look at the potential for conversion of existing facilities. In response, it was acknowledged that conversion of existing facilities would be cheaper, but the aim of the Business Plan had been to present data on the maximum investment required for industrial production, whilst also providing a breakdown of costs to provide potential investors with as much information as possible. The maximum cost example would also cover the technology transfer situation, where construction of new plant in Africa might be required.

The representative of Vestergaard-Frandsen, the manufacturer of Permanet 2.0 LLINs questioned the veracity of the estimates of existing and projected production capacity and stated that sufficient machinery is already available in Asia to produce 160 M units annually. Production of Permanet 2.0 is currently running at 800k per month, with a production target of 2.5 M per month by October 2005, which would significantly raise the estimated annual production figures quoted in the Business Plan.

Concerns over quality assurance issues with regard to conversion of existing LLINs were also raised in recognition of the fact that many different knitting patterns, materials, etc. are used for local net manufacture and these could all play a role in determining the efficacy and effectiveness of post-production LLIN technologies.

The question was asked as to how the figures for demand included in the Business Plan were arrived at. In response, it was acknowledged that the process of forecasting demand in the public health sector is difficult, and usually starts with the size of the population at risk, followed by estimates of what proportion of the total target population can be reached. It was agreed that improvements in public sector forecasting are required. An important component of the forecasting process is to gain an understanding of what industry is prepared to invest if the demonstration of an existing or potential market can be made. Information is required to satisfy industry and potential investors / partners as to the levels of risk and associated potential in the market.

Recycling of netting material at the end of its useful life span and the related economic and environmental concerns was discussed. It was reported that a system of recycling of polyethylene already exists in India. The potential for contamination of the environment with old LLINs was acknowledged, but it was felt that the potential for insecticide contamination was much lower with pre-treated LLINs compared with conventional ITNs.

As regards investment subsidies to stimulate production, it was felt that this depends primarily on the overall strategy adopted by a specific company. Companies that aim to cost-leaders naturally prefer price subsidies, while companies that adopt a strategy of being a product differentiator would prefer technology or R&D subsidies, and therefore there could potentially be a need for both types of investment from and public sector fund established.

3.4 Session Three - Working Groups.

Chair: M.K. Cham
Kabir Cham presented the Terms of Reference and guidelines for the three working group sessions. The purpose of the three working groups was to review critical issues affecting technology development, access and local production; demand creation and marketing; and distribution of LLINs respectively. The objectives were to identify obstacles to, as well as incentives for, the development, production and distribution of LLINs, and the roles of the different stakeholders involved. Working groups were also expected to outline strategic priority

actions needed to make LLINs available at lowest price consistent with a reasonable return on investment for manufacturers.

The process consisted of use of a matrix by facilitators in each group in order to guide discussions and give structure to the discussions. Results of each working group were fed back through presentations and plenary discussion. Working group membership was determined by a process of self-selection.

3.5 Session Four – Keynote Address – Prof. Jeffrey Sachs via Video Link

3.5.1 Fostering Public-Private Partnerships for Public Health Benefits and Economic Development – Jeffrey Sachs, Columbia University and Commission on Macroeconomics and Health

Professor Sachs described his recent experiences in talking to people about malaria in a sub-location of western Kenya. When asked how many households currently had at least one member who was suffering from malaria, almost all of the 200 or so people present responded yes. When the question was asked as to how many households used ITNs, only a handful of those present responded in the affirmative, but all had heard of ITNs and all expressed a desire to use ITNs, although they could not afford them. This community is typical of many in Africa, with no access to markets, little if any income, depleted soils, poor crop yields, no electricity, no sanitation, no farm implements, etc. Prof. Sachs proposed that it was simply not possible to sell ITNs to these communities and that they should be distributed free of charge.

Prof. Sachs then proceeded to summarise some of the positive results of ITN trials, including the recently completed CDC trial in Kenya, which had achieved a reduction in transmission of up to 90% and had demonstrated a very strong mass action effect such that the whole village, and even neighbouring villages benefited. This mass effect means that LLINs should be distributed to all, and not just sold to the “wealthy”.

As an economist, Prof. Sachs re-emphasised the need for mass free distribution of LLINs in Africa in order to achieve overall coverage rates of 80%-90% and ensure impact. LLINs are a technological breakthrough as they do not require re-treatment, previously a significant bottleneck to the effectiveness of ITN programmes. In the past donors have been against this type of approach as they do not like to spend money, hence their support for social marketing, which Prof. Sachs considers to be a bad and unsuccessful approach. Prof Sachs’ personal view is that LLINs should be delivered using 4x4 trucks throughout Africa free of charge to end users, who would also receive training in correct use of ITNs. LLIN distribution campaigns should be implemented in the same way as immunisation campaigns, with national ITN days. The cost of these campaigns would typically be just a few hundred million dollars, or approximately US$1 per capita in Africa. Large-scale distributions would also support production in the private sector.

The private sector is a key partner in malaria prevention as it is the private sector that manufactures nets and insecticides.

RBM is now six years old but has achieved few results at scale, due to a lack of resources. The time is now ripe to develop a strategy, national plans along the lines of EPI programmes, and a budget for mass free distributions to be presented to donors. Current projections show that up to 3 million children die of malaria each year, and there may be as many as 5 billion cases worldwide. Malaria represents a growing public health crisis. South Africa is actually one of the few exceptions, as it has the right ecological conditions and wealth to effectively control malaria. Donors need to realise the scale of the problem and accept that business as usual is simply not enough to control malaria in Africa.

Discussion
During discussions Prof. Sachs was asked whether or not public funding should be used to support scaling-up of production. Prof. Sachs responded that if the market is accurately determined and bids and firm contracts prepared, then financing should not be required to support the private sector.

As regards the idea of mass distribution campaigns, the issue of finding private sector partners willing to invest in short-term campaigns was raised. Prof. Sachs responded that a 10-year situation analysis of market demand was required, along with long-term donor commitment. He agreed that initial production needs would be high, but would level out over time.

One participant suggested that while the mass campaign approach was clearly logical in a situation such as that described in western Kenya, what was the role of mass campaigns in other countries, such as Mali, where high ITN coverage levels had already been achieved through social marketing. Prof. Sachs' response was that a mass campaign approach would still be appropriate as it would free up household resources to purchase other essenbtial goods and services. He conceded that an urban v rural segmentation of the ITN market could be appropriate in some cases, where urban incomes are sufficiently high to allow for ITN purchase.

Day Two – Friday 24 September 2004

3.6 Session Five – Working Group Reports.

Chair: John Meadley

3.6.1 Working Group 1: Demand Creation – Desmond Chavasse

The feedback presentation commenced with a summary of the context in which demand creation for LLINs needs to be considered, followed by the vision for LLINs and the critical issues and bottlenecks.

Context
An LLLIN is twice as effective and twice the price of an ITN, but the point of difference (i.e. the insecticide treatment and its long-lasting effect) is perceived by institutional buyers but not by consumers. Consumer demand will force manufacturers and suppliers to continue to provide "cheaper" conventional nets, even though LLINs are more cost-effective than conventional nets over the lifetime of the net. Consumer demand is likely to drive the traditional net market. Institutional buyer is demand likely to drive the LLIN market. Demand for ITNs and therefore LLINs is extremely price sensitive, as ITNs are effectively luxury goods. The culture of purchase in Africa is primarily for consumer goods, rather than investment goods. LLINs are currently not registered in many countries and the private sector must see a real business opportunity in order to justify expending the effort required to achieve product registration. Substantial public funding is available to promote the transition to LLINs, but it is likely that this funding will reduce over time. Some market segments can afford a commercially priced LLIN now, but some never will and substantial subsidies are likely to be required over a long period, possibly 15-20 years.

Vision
The long-term vision for the LLIN market is for economies of scale, combined with a competitive market, leading to substantial price reduction of LLINs over time. Effective communications combined with improved perceptions of product value (as a result of experience) leads to an increased willingness to pay by consumers. Substantial public funding is efficiently used to bridge the gap between price and willingness to pay in order to ensure

access by the vulnerable in the short-term. Reliance on price subsidy reduces over (a long) time.

Critical Issues, Bottlenecks and Actions

1. Product registration
- LLINs not present in many countries (especially where opportunity is low)
- Bureaucratic and resource intensive process

Action and Actors
- Proactive lobbying for LLINs (RBM)
- Fast track registration through the promotion of WHOPES approved products (RBM /WHOPES)
- Private-sector commitment (PS)

2. Forecasting volumes
- Volume guarantees required to justify investment
- Delays in promised funding delays production scale-up

Action and Actors
- Co-ordinated annual country level forecasts for broad product categories published (RBM/NMCP)
- Particular focus on donors required
- Buffer stocks required. Feasible? (suppliers)

3. Use of subsidy to maximise demand
- Investment in communications or in price reduction? Price reduction can be a key demand creation tool

Action and Actors
- Co-ordinated country level market segmentation plan (Gov/partners)
- Product differentiation through branding (PS/ SMOs)
- Generate data on nature and extent of demand for each segment (PS/SMOs/ academics). Very limited data are available on demand within market segments and this type of data is expensive and time-consuming to compile
- Investment plan required for: generic communications (Gov/ SMOs); price subsidy level for each segment (Gov/SMOs); brand advertising (PS/SMOs)

4. Ensuring evolution of market towards LLINs (away from traditional nets)
- Institutional buying demand vs consumer demand

Action and Actors
- Price LLINs on par with traditional nets (Gov)
- Institutional buyers to focus exclusively on LLINs

5. Quality control
- Consumer needs protection (like drugs)
- National bureau of standards
- Factory level (inspections)
- Shipment level (random sampling)

Action and Actors
- Commission quality control plan of action (RBM)

6. Volatile national strategy

- *Ad hoc* disregard for agreed plans
- Private sector not ready to commit resources/take risks

Action and Actors
- Strengthen national capacity to plan (RBM)
- Designate implementation task force (RBM/Gov)

Other issues identified during the group work included the need to focus on communicating the point of difference between LLINs and conventional nets; promotion of the "prevention is better than cure" message; the need to target communications at opinion leaders and next-generation (school children). The issue of operational research in several key areas, including the question as to whether free nets increase willingness to pay?; perceptions of product efficacy; and patterns of household spending.

3.6.2 Working Group 2: Demand Creation – David McGuire

Critical issues affecting the distribution of LLINs were grouped into the following broad categories – supply, price/cost, enabling environment, partnerships, capacity building, and monitoring, evaluation and research.

Identified Bottlenecks
- Planning for supply (forecasting) and effective communication between suppliers and buyers
- Perceived risk due to unpredictability of market place prevents private sector investment
- Lack of private market, current dominance of institutional markets
- Local transportation, limitations of local distributors (inc. commitment of distributors)
- Registration of new products
- Taxes and tariffs
- Programme management and monitoring capacity
- Competing/different priorities of public v private sectors
- Limited(?) data to clearly guide strategies - free v subsidised v cost-recovery
- Operational costs

Issue	**Action and Actors**
Supply	
• Limited production/ availability of LLINs • Bulk of products increases distribution costs • Long delivery lead times • Complexity of the distribution chain – dependant on multiple actors • Multiple sources and variety of procurement channels	• Supply forecasting and effective communication between suppliers and buyers • Commitment from manufacturers and those procuring/purchasing (NMCP to facilitate - Institutional buyers, donors, commercial distributors Global consolidation by MMSS)
Price/cost	
• Cost Structures and their impact on distribution • Limitations on procurement	• National pricing / subsidies policy (NMCP, RBM CC, ITN task force) • Comprehensive review of total distribution costs for public and private sectors to be factored into budgeting process (commercial sector, NMCP, ITN Task Force, donors)
Enabling environment	
• National ITN policy and associated regulatory issues (pricing, subsidies, cost-recovery, local registration, etc.) • Planning for coverage/targeting to achieve impact • Education and training component • Communication	• Elimination of taxes and tariffs • Streamlined national registration process in co-ordination with WHOPES • Standardised quality control procedures at country level (Advocacy by NMCP, RBM partners to Ministry of Finance and other decision makers and regulatory bodies)
Partnership	
• National leadership and co-ordination among	• All RBM partners to adhere to national policies and

stakeholders • Understanding of respective and common objectives	commitments agreed to in national Task Forces, etc. • (RBM partners and stakeholders at all levels)
Capacity • Need for capacity building throughout public and private distribution networks for management of operations	• Capacity building needs identified and resources made available (RBM partners, donors)
M&E, Research • Need for continual monitoring, evaluation, research (coverage, distribution costs, cost-effectiveness)	• Involve all stakeholders to ensure co-ordinated MER plan for distribution to guide implementation and monitor outcomes of all distribution- related activities (RBM partnership – NMCP, academic and research institutions)

3.6.3 Working Group 3: LLIN Technical Issues – Jo Lines

The current situation with respect to LLINs from a technical viewpoint is that current technology is good but not ideal, and new technical developments are rapidly evolving. Current LLIN production capacity is inadequate and there are several critical, shared obstacles and barriers, however there are also new opportunities for donor support. The goals for LLIN technology development are to foster expansion of capacity of existing technologies; to foster market entry by new producers; and to accelerate development of technologies.

Key Issues and Suggested Actions

1. LLIN Registration

- Costly
- Slow – but to some extent this is inevitable as requires field testing of products with life spans of several years
- Standard tests and wash-wear methods are available, BUT these tests show limited replicability – need to test in multiple centres
- Little knowledge of factors affecting durability in the field, and how to mimic with lab processes. How well do current entomological tests and criteria represent field performance?
- Some products are more LL than others and there may be a future requirement for a revised definition of an LLIN

National LLIN registration is widely perceived as a critical barrier, as currently, EVERY product must be tested in (nearly) EVERY country in order to generate efficacy data. It is not possible to revise the entire registration system as it was developed primarily for agricultural products. A solution might be to treat LLINs as an exceptional case, while maintaining quality standards and safety.

Actions

- Need for Vigorous and Urgent Action at regional and country level, including country-specific lobbying by RBM and Partners
- Harmonisation of processes at regional / sub-regional level
- Removal of the need for country-specific registration data
- Role for African Union / NEPAD
- Further development of standardised (and simplified) laboratory methods and definitions
- Get candidate products into the field early!
- Don’t wait for Phase I / II data Experimental registration and existing toxicological data for established insecticides
- Working Party planned for these issues

2. Access to Data

- Knowledge of basic technical options in relation to costs, existing equipment, etc is not widely available

Actions
- Foster Partnerships between textile / insecticide / technology firms
- Promote access to textile technology expertise

3. Cost of (and capacity for) R & D

Actions
- Support “immature” research – no intellectual property rights (IPR)
- Support testing during development – IPR protected
- Support testing after development – IPR secured
- Support WHOPES / registration data collection

The issue of a technology trust to stimulate new technology was discussed and the following functions were proposed: brokering of private-private and public-private partnerships; fostering access to public domain information; offering subsidised access to testing and other technical support for candidate products, with the proviso that data collected remain confidential; other R&D support (IPR issues); Independent testing of market-ready products; and support to the WHOPES evaluation process.

4. Quality Control
- Post-registration QC of final market product
- Health and Safety in Production
- Need for clear standards (see above)

Actions

The need for regional quality control centres was discussed and potential functions identified, including regional/sub-regional testing and evaluation of market-ready products for registration – incl. packaging and QC of products already on market. It was suggested that such centres should be managed by a Board comprised primarily of National Registration Officers. Actual testing should be carried out by local laboratories.

5. Financing
- Clear need for reliable forecasting that is consistent and reflects donor commitment
- financing mechanisms - guaranteed purchase commitments (long-term arrangements), equity, loans
- Financing Vehicles - Acumen fund, others? Need for a specific mechanism?
- Licensing Issues - e.g. in technology transfer there is potential for competition between the owner and the licensee

Discussion

The issue of a volatile policy environment was seen by participants as being an important issue that to some extent reflects the relative weakness of RBM processes and partnership at country level. However, ad hoc policy change often occurs as a result of external global partners, who do not respect the country level partnership and processes. The solution therefore does not rest solely at country level, but requires global advocacy and support to countries to enable them to make their own national plans and adhere to them without undue external influence

As regards consumer demand, it was reported from Ghana that consumers there do not always go for the cheapest net, and there was evidence from the ITN voucher pilot scheme that a significant proportion of consumers prefer luxury nets. In a related point, a private sector representative stressed the importance of branding as a mechanism for creating trust between

producer and consumer and ultimately in creating demand for products. The role of branding in increasing demand for LLINs should not be discounted.

3.6.4 Malaria Medicines and Supplies Service - Dr Maryse Dugué, Manager

What is MMSS?
MMSS is an initiative of the Roll Back Malaria Partnership to facilitate the access to quality affordable antimalarial medicines and other essential supplies: insecticide-treated mosquito nets, rapid diagnostic tests (RDT), and insecticides. MMSS was established following a consultation by the RBM Partnership sub-committee on access to effective treatment and follow-up consultations with countries in March 2004, following which it was endorsed by the RBM Board.

It functions through the collaboration between the technical departments of UN organizations, technical agencies and donor partners, and is working to support the procurement and supply management efforts for nets, insecticides, medicines and diagnostics urgently needed to achieve particularly the Abuja targets and the MDGs. MMSS collects, consolidates and disseminates information on the demand and supply of drugs and other commodities. MMSS does not procure itself, but establishes links with procurement agencies.

MMSS' Objectives

- to facilitate the search for products that are safe and cost-effective;
- to assist in forecasting, including mapping of resources;
- to disseminate guidelines to assist countries in efficient procurement;
- to assist countries in identifying sources of reliable technical assistance in Supply Chain Management;
- to disseminate information and guidelines on products pre-qualification.

Priorities
- To liaise with industry
- Procurement forecasting for malaria commodities

3.7 Session Six – Scaling-Up Production and Distribution of LLINs

3.7.1 Plenary Discussion – Opportunities, Strategies and Framework for Scaling-Up Production and Distribution of LLINs

During the plenary discussion, the following key issues were identified and discussed and action points were proposed and assigned to specific actors where possible.

1. Integrated Forecasting System
2. Technology Trust and Investment Facility
3. Assisting Quality Control
4. Other Enabling Environment
5. Strategic Planning
6. New Research Agenda

3.7.2 Key Discussion Points Arising

Note: Key Issues, Recommendations and Action Points from the meeting are listed under Section 1 at the start of this document

Forecasting of demand was a major discussion point during this session. Participants felt that it was important to distinguish between short-term and long-term forecasts as these would be used for different purposes. Short-term forecasts with a timeframe of 6-8 months are primarily

useful for planning production and will be used mainly by existing producers. Longer-term forecasts would be more useful to companies making investment decisions. In both cases reliability of forecasts is crucial in developing and maintaining trust. Participants acknowledged that it was probably unrealistic to expect firm mid- to long-term commitments from donors. UNICEF Supply Division presented the forecasting tools that it has developed in order to try to produce rolling 6-monthly forecasts from individual countries. The forms are designed to collect information on orders from all partners and funding sources within a country, although at present UNICEF acknowledged that it had achieved more success in accurately forecasting the requirements of its own country offices, with relatively little input from other partners. The decision to try to improve the forecasting process has already been taken through the establishment of Malaria Medicines, Supplies and Services (MMSS) unit within RBM. MMSS requires inputs from partners and will work closely with UNICEF and the GFATM to develop more reliable and inclusive forecasts. Private sector data should also be incorporated but this is not currently available. NetMark stated its willingness to provide information it collects on private sector requirements. Support to MMSS from the private sector was welcomed. The recommendation agreed upon was for all partners to work with MMSS as a mechanism for integrated forecasting. An initial integrated forecast will be shared via the MMSS website (www.rbm.who.int) for review. MMSS will act as a clearing house for forecasting information and will support mapping of resources, preparation of guidelines for efficient procurement, identification of sources of supply chain management, and dissemination of guidelines on product pre-qualification (pre-qualification of procurement agents is currently in its 2nd phase).

Technology investment and a proposed technology trust were also discussed. Small companies and academics are actively involved in developing technologies, but have difficulty in finding private sector partners to further develop and market ideas. The need for technology development in the LLIN field is not well appreciated, and there is a role for RBM to advocate for R&D investment. The suggestion was raised that a similar body to the Medicines for Malaria Venture (MMV) might be applicable as this had successfully created a research pool for new drug development. However, MMV has been very expensive and there was no agreement as to whether a similar body was required for pesticides / textiles. While a trust fund was accepted as basically a good idea, it would be important to assess whether any investment of public funds will make a real difference. Feedback from the working groups appeared to suggest that technology development is not a major bottleneck. Support to testing and especially field evaluation, however, would be very useful, as would support to identifying alternatives to pyrethroids and carrying out resistance testing. There was also concern that the use of public funding for R&D would potentially remove market incentives.

As regards investment facilities, the Acumen Fund, which provides long-term low-interest loans is an available funding option. Participants felt that there was no need for a specific investment facility, but there was a need for information on existing investors, and a database of investors could be useful. It was also agreed to explore ideas of low interest funds to finance LLIN production with donors, etc prior to the next WIN meeting.

Quality Control was another major topic of discussion. Currently WHOPES carries out product evaluation (though it is not a substitute for external quality verification) and Crown Agents/PSI and UNICEF carry out factory inspections. Quality control was felt to be particularly important in the shift from pre-WHOPES technology development to scaled-up production and also when a manufacturer shifts from being a net producer to an LLIN producer, as this represents a change in business because the textile market is unregulated, while the pesticide market is strongly regulated and LLINS are classified as a pesticide product. National Bureaux of standards in many countries are understaffed and under-resourced and are unable to carry out factory inspections, etc. The proposal was made that a proportion of LLIN funding (e.g. from the GFATM) be assigned to support capacity building of Bureaux of Standards. WHO tries to provide tools for Quality Control, e.g. specifications and validated test methods to verify those specifications. WHO, in collaboration with FAO, is also trying to build national

capacity by developing guidelines for countries to strengthen their standards bodies. Designated collaborating centres have been established to assist those countries without facilities, but all of these centres are currently under-utilised. Off-the-shelf QC to protect consumers is also considered of vital importance to WHO and WHO is trying to ensure that national bodies not only register, but also carry out post-registration quality control of products on shelves. A key component of quality control from a consumer perspective is being able to trust claims made on packaging, etc. and products carrying fake RBM and Netmark logos are already appearing in the market. One manufacturer called on others to adopt an open-door policy towards factory inspections to create trust in the industry. In some cases, quality control issues are only identified several months after the product has gone into use and field testing of samples of nets in use by consumers is a vital component of quality control.

Taxes and Tariffs remain an issue in several countries despite the declaration of Heads of State at Abuja almost five years ago. It was acknowledged that this is a complex issue that goes beyond decisions taken by Ministers of Finance. Taxes and tariffs policies need to be followed-up at country and regional level. However, it was acknowledged that several countries, including some with effective national RBM partnerships and ITN Task Forces had failed to achieve abolition of taxes and tariffs and it is not enough to keep recommending that national RBM partnerships follow-up on this issue. Country partnerships require strong external support and advocacy from global and regional partners to resolve the issue of taxes and tariffs

3.8 Closing Session.

Chair - Dr Awa Marie Coll-Seck

3.8.1 Closing Remarks – Per Engebak, Regional Director, UNICEF ESARO

Per Engebak described the LLIN Business Planning as a milestone event as it was probably the first such meeting at which the private sector was in the majority, with more than 40-participants from a diverse range of companies. This is a key development, as international organisations cannot roll back malaria without the participation of the private sector. Public-private partnership is not a new concept for UNICEF who realised the importance of the private sector in achieving the goals of the child survival revolution that began in the 1980s. The private sector has been influential in changing the way in which many public health interventions are implemented, including immunisation, micronutrient supplementation, and more recently ITNs. Per also reported that during his visits to many countries in the African region he was convinced that significant efforts are being made to roll back malaria. Since the launch of RBM in 1998 funding for malaria has significantly increased and an estimated US$ 236 million is in the pipeline, originating from the GFATM and other sources. The need for continued research and investment in malaria control remains, and it is in the best interests of industry to invest in the sector. Whilst recognising that malaria is one of the biggest killers in Africa, other public health challenges do exist on the continent, including the HIV/AIDS pandemic. This is relevant for efforts to roll back malaria, as recent evidence increasingly demonstrates the links between HIV/AIDS and malaria, whereby HIV infection increases the risks and severity of malaria infection, and malaria infection can increase the risk of HIV infection and its consequences. Currently there are 14 million orphans in sub-Saharan Africa and this number is expected to increase to 24 million in the next six years. It is vital to ensure that these vulnerable children are protected by LLINs. Free distribution to such vulnerable groups does not negate the efforts of the private sector to produce and sell nets. In fact, there is increasing evidence (e.g. from Zambia) that the distribution of free nets to vulnerable groups actually serves to create demand in the wider population. UNICEF will continue to support this policy of free distribution to vulnerable groups, while recognising the importance of other delivery mechanisms, including through the unsubsidised commercial sector. UNICEF will also actively campaign to reduce taxes and tariffs and undertake other efforts to reduce the costs of LLINs to the end users. The proportion of nets procured from African manufacturers has

decreased with the increase in overall procurement of ITNs and this demonstrates a clear need and opportunity for African manufacturers to adapt in order to satisfy changes in markets and demand. Per was pleased to have witnessed the discussions around the importance of forecasting and felt that there was nothing to stop the development of good public sector forecasting models, however he acknowledged that incorporating private sector demand into these models would be more difficult. A clear need exists to scale up production of LLINs in order to meet the increasing demand and this should be matched by efforts to support implementation of national plans and to scale up social communication and social mobilisation efforts, as well educated and empowered consumers are the key to developing commercial markets.

3.8.2 Closing Remarks – Gerhard Hesse, Bayer and RBM Board Member (Private Sector)

Gerhard Hesse re-iterated the key role that the private sector has to play in the public health sector and was delighted to see the range of private sector expertise that had been brought to the LLIN Business Planning Meeting. He acknowledged the contribution of representatives from the textile industry, the insecticide industry, the chemical industry, net manufacturers, etc. Many of the participants were newcomers to this type of meeting, a clear sign of the growing interest and trust in this market segment. Information exchange is a vital component of private-private and public-private partnership development and good communications between older and newer participants in the field should be actively encouraged. Gerhard acknowledged that smaller companies had previously feared that the LLIN industry was high-tech and only open to large and multinational companies. The development of post-production technologies for converting conventional nets to LLINs is a key area to which smaller companies can contribute a great deal. Whilst considerable progress has been made in recent years, the gap between need and supply for ITNs and LLINs still has to be met and the recently launched MMSS could be an important tool for stimulating and supporting the private sector. Increased funding is required to scale up development, production and distribution of LLINs and this requires the commitment of donors. The messages and recommendations arising from the Johannesburg meeting should be shared with donors as a priority. Most manufacturers are not involved in product distribution and so require the support and commitment of implementers on the ground, including NGOs, if coverage is to increase. In conclusion, it was felt that the meeting had been a success and it was hoped that the enthusiasm generated would be carried forward into action.

3.8.3 Closing Remarks – Don de Savigny, Chair of WIN

The Johannesburg meeting was a clear demonstration of the growing trust developing between the public and private sectors around LLINs and will ultimately lead to a win-win-win situation benefiting all partners especially those at risk of malaria. It is hoped that the meeting improved partners' understanding of issues and bottlenecks constraining the development, production and distribution of LLINs and the outcomes of the meeting will be incorporated into the Business Plan and the WIN work plan. The next meeting of WIN will be hosted by UNICEF and will be held in Nairobi on November 30 and will carry forward to the RBM Partnership, the issues and recommendations arising from this meeting.

Don then thanked the facilitator (John Meadley), the rapporteur (John Silver), the sub-group facilitators (Jo Lines, Des Chavasse, and David McGuire), presenters, and all participants. The support and efforts of Netmark, the RBM Partnership Secretariat (Awa Coll-Seck, Patience Kuruneri, Kabir Cham) and UNICEF (Kopano Mukelabai) in organising and convening the meeting were acknowledged. The members of the WIN Satellite Group on LLINs under the coordination of Pierre Guillet were acknowledged as the originators of the idea to hold a LLIN Business Planning Meeting. Finally, particular thanks were reserved for the private sector, who will ultimately play the pivotal role in the LLIN component of global efforts to roll back malaria.