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HEALTH RESOURCE CENTRE

RH COMMODITY SECURITY: ADEQUACY OF THE INTERNATIONAL ARCHITECTURE FOR FINANCE AND SUPPLY

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1 EXECUTIVE SUMMARY

The purpose of this DFID- funded study is to describe the current international system for securing Reproductive Health (RH) commodity supplies, to identify weaknesses and issues and suggest possible ways of rectifying them. This study will later be supplemented with a country-level study, investigating issues at country level.

The study is based on desk research, supplemented by structured interviews (30-90 minute) phone interviews with representatives of key international RH community stakeholders (see list at end of report). Data collection has been hampered by the relative scarcity of detailed, comprehensive, recent, high-quality statistics on RH procurement.

The context within which this study operates is 40 years of international investment in and donor support for developing country RH issues. While very considerable success has been achieved in some areas, it is clear that considerable gaps remain in realizing the 1994 Cairo ICPD goals, particularly in Sub-Saharan Africa, where 25% or more of married women have unmet RH needs, and where contraceptive prevalence in some countries remain in single % figures.

A key reason for this is a lack of funding, where a very considerable gap has opened between ICPD spend plans and actual donor funding provided (a cumulative shortfall of nearly 2/3 by 2001, the latest year for which figures are available).

The remit of this study was to investigate other possible non-funding issues around RH supply effectiveness and efficiency at the international level.

Eliminating issues may be as important as identifying them, and one of the key conclusions of this study is that the supplier architecture itself (i.e. availability of RH commodities from the private sector) is generally not a major constraint on RH commodity supply. This is in marked contrast to the situation within a number of niche medicines, e.g artemisinin-based (ACT) anti-malarial compounds, where substantial donor intervention has proved necessary to encourage sufficient R&D and production capacity investment.

The reasons for this lie within the general market structures for RH commodity supplies. There are two main factors at work here. Firstly, RH commodities are generally highly mature commodities, off-patent and with well understood production technologies, including for source products. This in marked contrast to e.g. artemisinin or most anti HIV products. Secondly, RH products are – with some variations – fairly universal across the globe; an oral contraceptive that works in Atlanta will be equally effective in Abuja. This again in contrast to e.g. artemisinin, which is used against malaria, a specifically developing country disease. This creates the potential of much larger and deeper international markets for RH commodities.

This is borne out by the available market statistics, which estimates current RH commodity markets at around \$14bn annually, including \$4bn of demand from developing countries, including ~\$225m of donor funded demand (plus likely another \$300m of government funded demand). In other words, donor funded demand is only a small fraction of overall demand, and is – in general terms – not likely to be a key driver of R&D and production capacity decisions. This could of course vary by product type, but with the exception of female condoms, very largely donor-funded, most other RH products seem to form a broad, well-supplied marketplace.

The current inflow of producers from emerging/ developing markets, across most major RH categories, is reinforcing supply security and is also contributing to a considerable lowering of overall price levels, in some cases reducing source prices by 50% or more, compared to existing, Western suppliers. This producer inflow is not without its problems, particularly in terms of product quality, but such issues seem transitory and generally manageable through strong emphasis on ongoing quality control.

The overall conclusion in this regard is that a well managed procurement programme can secure RH supplies within most practically relevant categories on good terms (price, quality and delivery time) and that a substantial donor-funded effort to improve the supplier structure and incentives would not provide a strong investment return. However, as with any procurement programme, strong quality control is key, and there is room for improvement on this dimension.

It was also not clear that increased procurement pooling (to achieve economies of scale) was necessarily a major issue. In general, most countries should be able to achieve the minimum economical order quantity for RH products, even without regional pooling. However, insufficient data was available to really test this hypothesis properly, and it should be investigated further at the country level.

A number of issues with the current international architecture were however identified:

- While it was felt that the key capability issues around RH supply security seem to originate at country level, there is a general consensus amongst stakeholders surveyed for this project that so far the donor community has failed to provide sufficient, committed-long-term funding and infrastructure support to help resolve these issues
 - Current commodity procurement arrangements are too short-term or even last-minute, leaving too little time to organize procurement properly, let alone fit into a wider long-term RH strategy. A major reason for this seems to be the generally short term nature of donor budgeting cycles, combined with the difficulties in coordinating between different budgeting cycles and other financing procedures between various donors, agencies and countries involved.
 - While this is important, and detrimental, at the procurement level, it is particularly damaging in terms of long-term capability building, where multi-year committed programmes are required to achieve real impact and traction. The impact of this short-term bias is likely to be an overinvestment in short-term commodity based measures and an underinvestment in long-term country-level and international level-capabilities.
 - This issue is being exacerbated by changing aid instruments at country level, e.g. PRSPs SWAPs and budgetary support.
- There is a “coordination gap” between key stakeholders. There is no overall strategy to properly coordinate resources between countries and regions, with consideration given to an appropriate product mix and short, medium-term and long-term distribution strategy within each country.
- There is a general lack of information up and down the system – particularly at country level – which makes informed decision making very difficult.

- While current donor/ agency procurement arrangements do not seem particularly inefficient or ineffective, it is highly likely that there is considerable scope for improvement.
 - “Tied aid”, restricting buying to the donor home market, may considerably decrease procurement efficiency
 - There is the possibility to expand the monitoring of procurement efficiency and customer satisfaction of key international procurement efforts, including those of the UNFPA

In terms of solutions, there seems to be limited appetite for creating new bodies outside of/ in parallel to/ existing structures.

The following suggestions are made:

1. Current main international procurement actors to analyse existing procurement operations, and identify opportunities for improvement.
2. Expand the data gathering efforts of the RH Initiative.
3. Achieve stable 3- or 5-year funding programmes for RH commodity procurement, likely through a “buffer fund”.
4. Create a powerful advocacy and coordination body in the international RH arena. The obvious vehicle for this would be the RH Supply Coalition.
 - Expansion options for the Coalition – or another coordinating body – to consider include:
 - i. A strong, but lean, permanent secretariat including RH health experts, to build a strong fact base as a platform for both advocacy and efficiency improvements
 - ii. An Executive Director to provide the organization with a visible and credible permanent international spokesperson, and internal organizational drive and momentum.
 - iii. Involvement, possibly with the UNFPA, in the creation of a “buffer fund”, as set out in 3. above. [Though may also prove attractive to involve other organizations/ models, to maximize innovation].
 - Creation of a strategic investment fund (minimum \$25m), to invest in strategic capability building (NOT day-to-day procurement) within the RH arena. Such investments might include:
 - i. Support for certification, technology transfer, quality control measures and other initiatives to expand the supplier base and speed up “trickle down” of technology
 - ii. Support for capability building at international and country level

- iii. Support for strategic initiatives, e.g. regional procurement pooling initiatives

2 INTRODUCTION

This report is the first part of a two-part study commissioned by DFID to develop the evidence base around barriers to reproductive health commodities, with the aim of assisting national and international actions by major stakeholders to improve access and supply security.

This first part focused on the international finance and supply architecture, while the second part will focus on in-country issues, particularly as they relate to the ongoing introduction of aid instruments like PSRPs, SWAps, other forms of budgetary support and “graduation” measures, and implications for availability of RH supplies.

The purpose of this part of the study is to assess the roles and impact of organisations conducting international procurement in the RH field, as well as financing amounts and modes, in fostering a dynamic healthy global market environment for RH commodities. This study also aims to identify key issues for further analysis during the country-level studies.

In particular, this study aims to assess:

- The effectiveness of current international procurement arrangements in terms of the development and maintenance of competitive supply markets;
- The role played by key enabling bodies;

The study also aims to identify:

- Suggested changes of practice by key international actors to facilitate added supply security;
- Suggested changes in international architecture, to explore any improvement opportunities identified.

2.1 Commodity focus

The reproductive health commodities covered include:

- Male condoms
- Female condoms
- Injectibles
- Implants
- Oral contraceptives
- IUDs
- Emergency contraception
- Medical abortion

2.2 Commodity security

Within reproductive health commodity supplies, there seems general agreement that a definition of commodity supply security would include the following:

Choice: An appropriate choice appropriate level of choice between reproductive health commodities, both between short, medium-term and longer-term products and in terms of minimizing side effects and optimising ease and convenience for individual users.

Availability: Available locally, with appropriately trained personnel, without interruptions of supply.

Affordability: Available at a price the user can afford. This will vary with the circumstances of the country and user, obviously very different circumstances apply between emerging middle classes in former Soviet republics and rural women in Central Africa. In many circumstances it will be desirable that contraceptive health commodities are made free at the point of use, and certainly this is the thrust of current DFID strategy. The issues of targeting, i.e. to what extent some level of user charging, can be used to boost resources available for the poorest section of the population is outside the purview of this study.

Quality: Needs to meet appropriate international quality standards. As will be apparent below, there is some seeming tension between this criteria and a desirable expansion of the supplier base to include generic emerging markets suppliers. However, given appropriate quality monitoring and certification procedures this tension would seem more apparent than real – in other words expanding the supplier base should not and does not have to compromise quality standards – assuming the right safeguards are put in place..

One related issue is brand perceptions, where user groups may feel that a shift towards generic products compromises perceived quality. This issue is addressed in slightly more detail below, but should be explored further in the country level study.

3 METHODOLOGY AND APPROACH

This report is based on:

- Desk research of key available literature and articles
- Interviews with 15 major stakeholders
- Available statistical data sources
 - UNFPA website, and websites of other key donors / stakeholders (e.g. USAID, DFID, KfW, JSI etc.)
 - WHO website
 - Planetwire.org

It is notable that there is relatively little good quality statistical demand and supply data available relating to the global market dynamics of reproductive health commodity supplies for developing countries.

Most major agencies and donors, particularly the UNFPA, maintain good quality data series on procurement spend for different types of products. However, outside the male condom area, there seems little publicly available data on numbers of products procured, prices paid and special circumstances (e.g. proportion of emergency procurement), making procurement efficiency calculations for such other products difficult.

Another major issue is the lack of comprehensive supply and supplier market share overviews including the social marketing and private sectors. While the size of the non-donor market will be relatively small in most sub-Saharan African countries (limited to a small urban elite and expatriates) it is by no means negligible – and in several Asian and South American countries with expanding middle classes, private sector spend will dwarf the public sector market.

Overall it is estimated that the total developing country reproductive health commodity market is now approaching \$4bn – with core donor procurement accounting for only about \$200m or 5%, leaving up to 95% of the market unaccounted for through publicly available sources.

It is noted that it was agreed that this report would focus on manufacturing and supply issues for existing products, rather than on stimulating R&D for new products. For an excellent overview of contraceptive R&D issues, see the report “What has been achieved, what have been the constraints and what are the future priorities for pharmaceutical product-related R&D relevant to the reproductive health needs of developing countries”.¹

¹ Commission on Intellectual Property Rights, Innovation and Public Health, Peter Hall, March 2005

4 CONTEXT

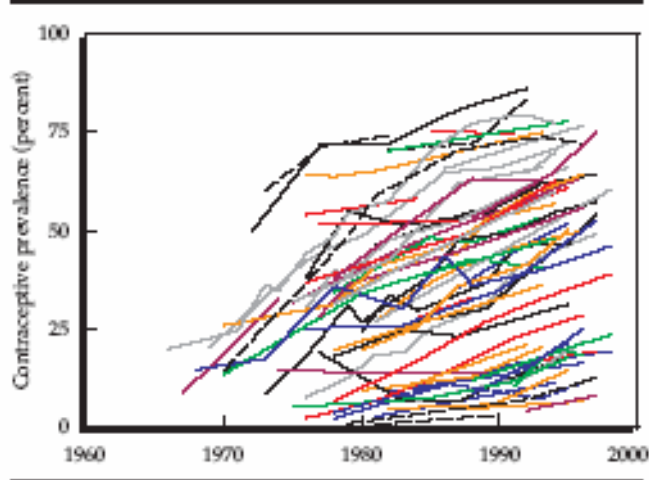
It is worth briefly summarising the overall context in which this study is operating.

Considerable advances have been made in developing country reproductive health, contraceptive prevalence and family planning over the last 40 years, but very considerable work remains to be done, both in terms of improving the efficiency of the current system and in terms of securing sufficient funding overall.

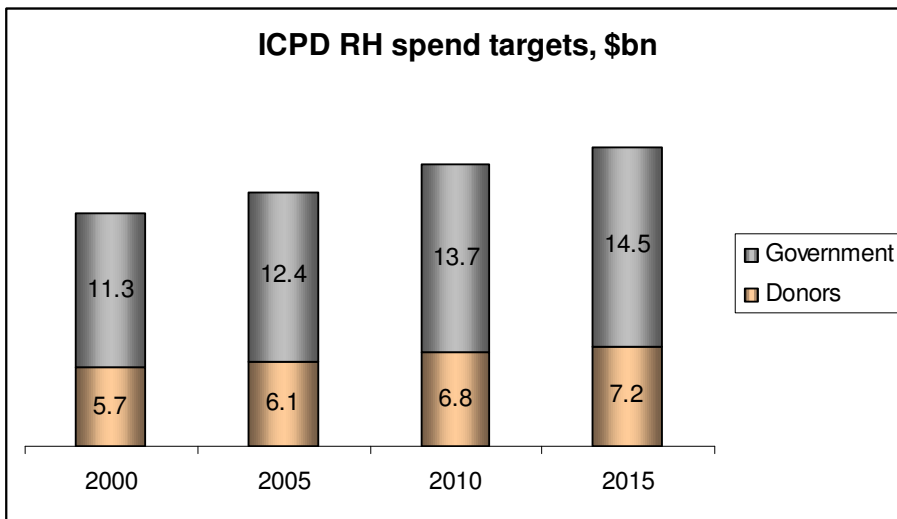
On this latter point, it is estimated that there is a considerable “funding gap” between developing

country contraceptive commodity needs and available donor funds, though the exact size of this gap is contested. Some estimates range it as low as \$60-\$90 million annually², while a number of interview sources for this project estimate it at least two or three times that level; much higher if also considering necessary additional investment in procurement and supply chain capability building at country level, or the commitments made at the 1994 Cairo conference. The ICPD committed targets were as follows:

Figure 2 Trends in contraceptive prevalence among married women, by country, 98 developing countries



Source: UN (1999a); Ross et al. (1999).



² Ross J.A. and Bulatao R.A, Contraceptive Projections and the donor gap, 2001

So far, donor spending to 2001 is estimated at around \$2bn, or around 36% of the Cairo targets³. No data is available on cumulative government spend, but a similar – or even larger – gap may exist.

At the same time, additional funding on its own is not sufficient, as expressed by the Interim Working Group on Reproductive Health Security⁴:

“Even if these funds were available, a secure supply of contraceptives would not necessarily be guaranteed. Reproductive health commodity security denotes an adequate supply and choice of quality reproductive health-related supplies for every person who needs them. Achieving contraceptive security is a complex process that involves not only the allocation of resources, but also forecasting, financing, procurement and delivery. These processes are affected by many factors including quality, coordination and economic and regulatory issues.”

³ NGO contributions to the deliberations of the European Population Forum, Geneva, Switzerland, 12-14 January 2004; see Planetwire.org

⁴ Report of International Working Group on Reproductive Health Security, April 2001

5 REPRODUCTIVE HEALTH COMMODITY MARKETS

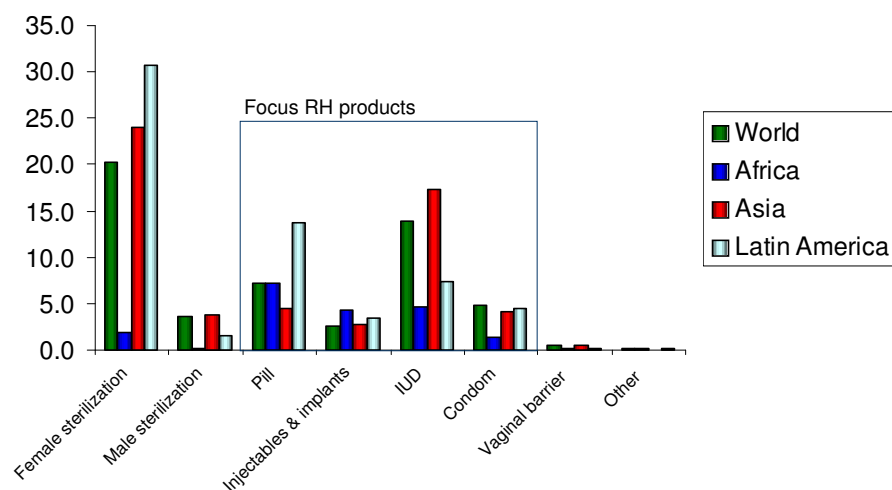
5.1 Demand Situation

Contraceptive prevalence varies widely throughout the developing world. In general, sub-Saharan Africa has by far the lowest prevalence of modern methods and also seemingly the lowest growth momentum particularly in Francophone Africa. Some African countries have modern contraceptive prevalences as low as around 10%, with some regions even lower than this.

Meanwhile, Asian and Latin American countries are often approaching or even exceeding Western prevalence levels. More traditional methods of birth control (e.g. rhythm method) continue to co-exist with modern methods; in recent years a number of African countries, primarily focused on HIV prevention, have started to push abstinence as a central plank of their reproductive health programs.

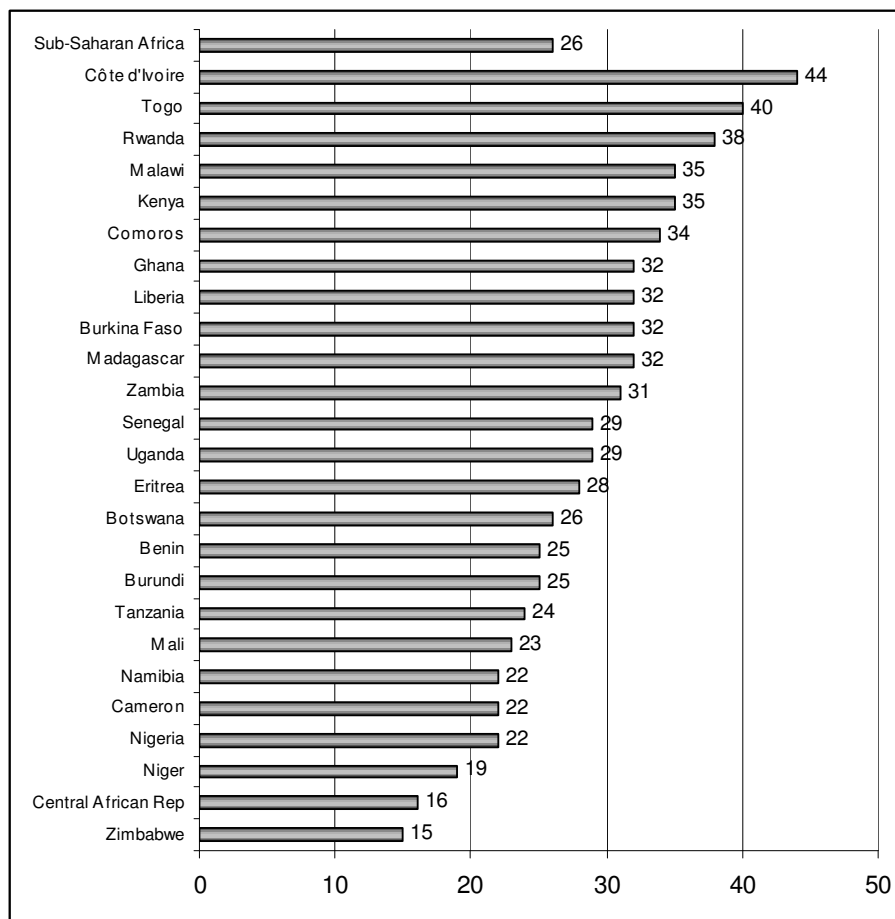
PREVALENCE OF METHOD BY REGION

% prevalence amongst married women 15-49



Source: UN, 2003

In terms of product penetration, there are again significant regional and country-by-country differences. It is notable that Latin American countries seem to emphasize oral contraceptives and sterilization, while Asian countries emphasize IUDs and sterilization. Africa, while having a much lower contraceptive prevalence overall, is relatively ahead on oral contraceptives and injectables/implants. Africa, on the other hand, has a very low prevalence of sterilization.

% of women with unmet reproductive health needs⁵

It is instructive to relate the low contraceptive prevalence in Africa to the % of population of reproductive age with stated unmet family planning needs. The implications of such unmet needs include negative effects on the women and families involved and rapid population growth. For example, the population of Nigeria tripled from 1950 to 1995, and is expected to triple again, to ~340 million, by 2050.

Apart from the impact on overall population growth, it is also important to note that these contraceptive prevalences may only partly reflect actual consumer preferences, and instead reflect a strong push by governments for particular methods (e.g. IUDs in China, Vietnam, sterilization in India and China), or even population control policies (e.g. China's one-child policy).

While particular methods may show a strong dominance, most developing countries will now be providing at least a minimum of choice as set out in the Cairo principles⁶.

⁵ Rosen and Conly, 1998

⁶The Cairo Programme of Action [para 7.2.] defined reproductive health as "a state of complete physical, mental and social well-being and ... not merely the absence of disease or infirmity, in all matters relating to the reproductive system and to its functions and processes. Reproductive health therefore implies that people are able to have a satisfying and safe sex life and that they have the capability to reproduce and the freedom to decide if, when and how often to do so. Implicit in this last condition are the right of men and women to be informed [about] and to have access to safe, effective, affordable and acceptable methods of family planning of their choice, as well as other methods of their choice for regulation of fertility which are not against the law, and the right of access to appropriate

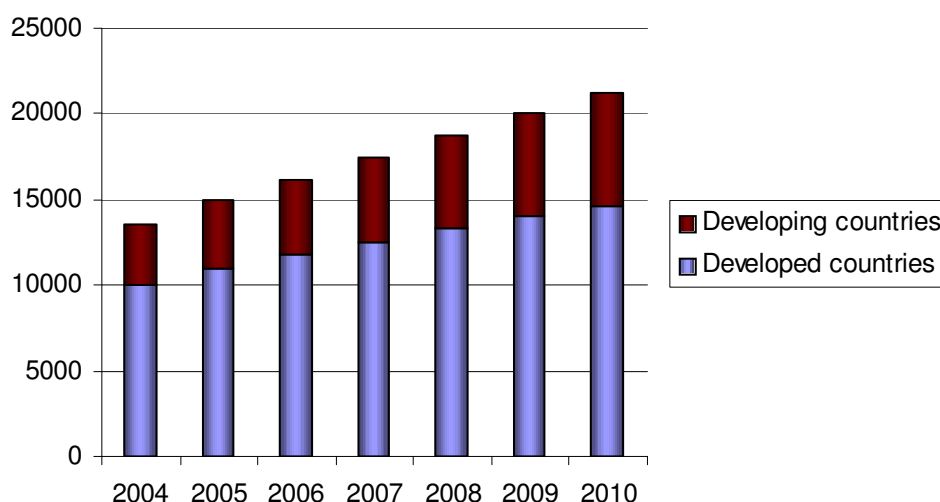
Such a choice will include a mixture of shorter term and longer term methods, typically male condoms, two brands of oral contraceptives (a combination progesterone/estrogen product and a progesterone-only pill), the copper T IUD and – increasingly – injectables and implants and possibly an emergency contraceptive pill and in some instances [e.g. Sri Lanka, India] an medical abortion- pill (mifeprestone).

Developing world use of other methods, including female condoms, vaginal rings, a contraceptive patch etc. is currently extremely limited.

5.2 Market Overview

GLOBAL CONTRACEPTIVE MARKET

\$m, 2005



Source: Global Industry Analysts

Publicly available estimates for the size of the global contraceptive market vary widely, between about \$8bn and about \$15bn, with the bulk of projections clustering around the higher end. About 25% of this demand or \$4bn is estimated to derive from developing countries. Given the much lower unit prices prevailing in developing countries, the value figures above mask the higher volumes consumed by developing countries.

It is notable that a few large and relatively wealthy developing countries (e.g. China, India, Brazil) with emerging middle classes will constitute a large proportion of developing country spend, while Sub-Saharan Africa will constitute only a small fraction– by one estimate [calculated from Rosen/Conly data from 1998] Sub-Saharan Africa contraceptive spend is around \$200m].

health-care services that will enable women to go safely through pregnancy and childbirth and provide couples with the best chance of having a healthy infant."

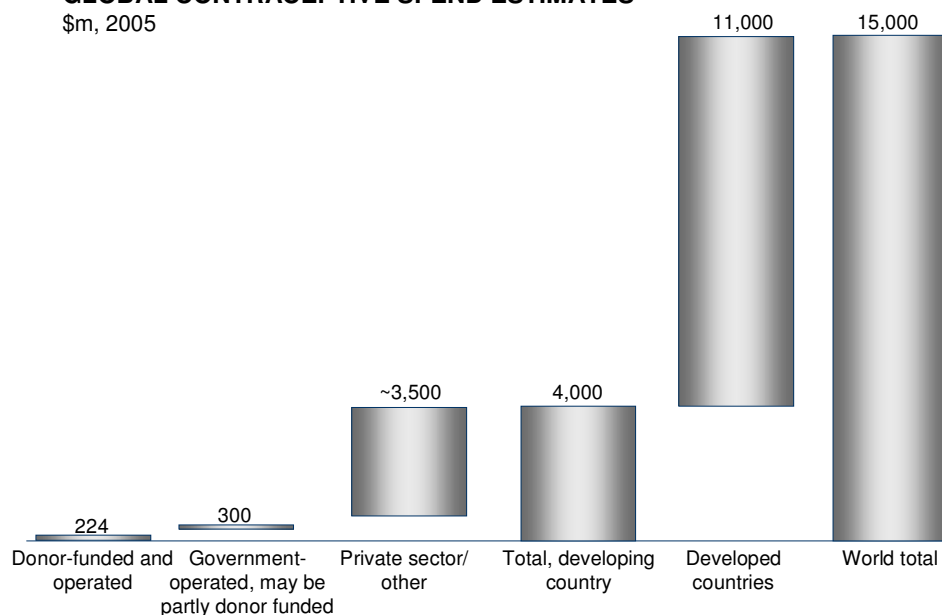
TABLE: Family Planning Spend in Sub-Saharan Africa, 1998, \$m

	Government fp spend, \$m	Government spend as % of total	Implied total spend, \$m
Botswana	0.2	8.3	2.41
Burkina Faso	1.0	18.9	5.29
Central African Republic	0.4	19	2.11
Côte d'Ivoire	0.1	2	5.00
Ethiopia	0.3	3.9	7.69
Ghana	2.1	18.6	11.29
Guinea	1.0	32.3	3.10
Guinea-Bissau	0.2	20	1.00
Kenya	0.8	2.6	30.77
Liberia	0.1	7.7	1.30
Madagascar	0.1	2.5	4.00
Malawi	0.2	4	5.00
Mali	3.7	43.5	8.51
Mozambique	1.0	24.4	4.10
Nigeria	0.7	3.3	21.21
Rwanda	1.2	9.2	13.04
Senegal	0.2	2.3	8.70
South Africa	22.3	64.5	34.57
Tanzania	0.6	5.4	11.11
Uganda	0.3	3.5	8.57
Zaire	0.2	3.8	5.26
Zimbabwe	2.5	16.9	14.79
Total	39.2		208.82

While Sub-Saharan Africa spend may not be that material, the total “Southern home market” spend of \$4bn is significant, as a home market for an emerging breed of Southern generic producers. These are expected to form – as seen below – a highly valuable addition to the donor supply base..

GLOBAL CONTRACEPTIVE SPEND ESTIMATES

\$m, 2005



Source: UNFPA, Global Consultants

Current estimates of annual developing country donor spend range around the \$200m mark (\$198m in 2002), with an additional perhaps \$300m of government-operated but at least partially donor funded spend. This leaves a developing country donor/public sector market of around \$500m or only about 12% of the developing country total.

Unfortunately there are no publicly available figures to split this data by commodity product or by regional/ country level. It is likely for example that donor spend is a very much higher fraction of spend in Sub-Saharan Africa – perhaps as high as 95% or more, though no publicly available statistics exist on this issue

In terms of market characteristics it is generally the case that contraceptive commodities are well suited to long distance international trade. They have relatively low volume/ weight compared to value, can tolerate general transport temperature and other variations and have long shelf lives. Condoms may be somewhat more sensitive than other products, particularly to prolonged exposure to tropical temperatures.

Type of Contraceptive	Required Storage Conditions	Shelf Life
Oral Contraceptives	Store away from direct sunlight in a cool, dry location.	5 years (Ovostat, Marvelon, Organon brands – 3 years)
Condoms	Below 40°C. No long exposure to high humidity, direct sunlight, fluorescent light, or ozone. Don't store near chemicals.	4 years
Diaphragms	Below 40°C. No long exposure to high humidity, extreme temperatures, ozone, or direct sunlight. Don't store near chemicals.	5 years
Injectable	Below 40°C. Away from direct sunlight. Store vials upright.	5 years
IUDs	Below 40°C. Protect from direct sunlight and excessive moisture.	7 years (Multiload brand 3 years)
Norplant	Below 30°C. Dry location.	5 years
Spermicides	Between 15 and 30°C. No extreme fluctuations in temperature or humidity. Cans should be stored in upright position.	3 to 5 years (5 years for USAID-donated, 3 years for others)
Vaginal foaming tablets	Below 40°C.	5 years for USAID-donated, 3 years for others

Source: Center for Disease Control and Prevention

5.3 Characteristics of the Ideal RH Commodity Market

Before looking at the market as it actually exists, it is worth considering what the shape of the ideal market would be.

Ideally, there would be:

- Several, competing suppliers
- Each with large, flexible production capacity
- Producing to high minimum quality standards

With such a supplier market, a good quality procurement operation should be able to secure the supplies it needs, on time, with good quality standards and the best possible price.

There are however a number of additions to this basic scenario.

5.3.1 *Dynamic effects*

Firstly, it is important to consider dynamic effects. A market like the above will be able to deliver product at or close to marginal cost, but will contain little incentive for market entry or invention. R&D and new entry incentives come from markets that are less than perfect, for example through monopoly rents made possible through patent rights. However, there seem to be a couple of reasons why such dynamic effects are a less critical donor consideration for reproductive health commodities versus other health commodities (e.g. ACTs for malaria):

- ACTs have to be developed especially for a specific (very poor) market. Contraceptive products tend to originally developed for a very large and lucrative market and can then be used the world over. In other words, the contraceptive pipeline for the majority of products will be renewed, even without any donor intervention (e.g. ‘push’ funding) on the R&D side.
 - It might be argued that the contraceptive R&D field in the developed markets is not particularly active at present. This is correct, but there will still be a considerable R&D activity attached to a \$15bn+ health market, even if the investment in R&D isn’t as high as the 20% of sales known from other medical categories. Secondly, given that a large variety of RH supplies already exist in the marketplace, R&D is much less critical than in the ACT case, where drugs have to be developed specifically, and from scratch.
- There is a strong and growing private sector market in middle income countries, and many companies with export ambitions. This means that earlier generation contraceptive products will continue to get produced in quantity, even as Western producers might decide to phase out production. This is in contrast to ACTs, where capacity investments are more dependant upon clear and specific long-term donor commitments. For contraceptive health products, production capacity will be installed and expanded, even without donor intervention, and despite strong price negotiation on the publicly-funded share of the market. In other words, current and developing capacity is sufficient to meet donor demand.
- There is clearly work to do at the margins in terms of speeding up the “trickle down” of reproductive health commodities, to avoid the developing world continuously being decades behind in terms of available contraceptive products. However, this is arguably a considerably less critical issue than no product being available at all, which is situation with ACTs at present. There are also complex tradeoffs involved in introducing new – and likely costlier –

contraceptive products. New is not necessarily better, if it competes for scarce budgets and logistics resources with long-established, cheap, well accepted and understood products. This is well expressed in the Deliver report⁷:

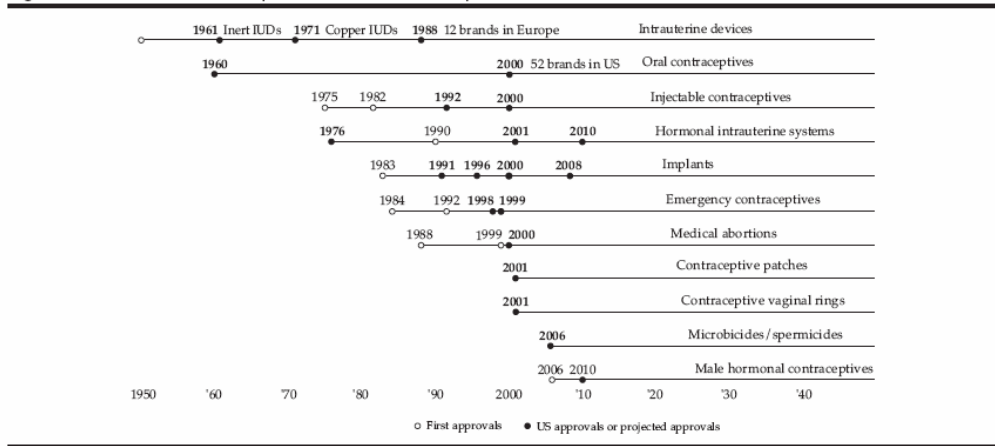
“Experience from other product categories, particularly vaccines, suggests that there are implicit tensions between the goals of maximizing choice, efficient procurement and distribution, introduction of new technologies and maximizing coverage for existing products. [...] Planners and implementers of national contraceptive security programs must pause early on, examine these tensions, and set clear short-, medium-, and long-term product selection goals for the contraceptive method mix and other important groups of RH products.”

5.3.2 Economic externalities

Secondly, there may be economic externalities at work that are not immediately apparent. For example, some argue that it would have very beneficial long term effects on contraceptive prevalence if indigenous African production of major reproductive health commodities were boosted. While the effect on supply security from closer proximity would be limited, the effect on consumer trust and acceptance may be high (“Trust African products”), and such plants might spawn more local plants in the future. While attractive in theory, such industrial policy-making might not be to every donors taste – and it can certainly be risky, as demonstrated by the recent failure of German condom-maker Condomi’s Kenyan manufacturing venture. It is unclear to what extent the German donor KfW was a co-investor in this venture – or to what extent Condomi’s domestic financial problems negatively impacted the Kenyan project.

5.4 Reproductive Health Commodity Supplier Structure

Figure 8 Time line of the development of modern contraceptives



The market evolution of the various reproductive health commodities is key to understanding the current supply structure. During the 60’s, 70’s and 80’s, Northern producers (e.g. Western European, US, Japan, Canada) were the only

⁷ The Deliver Project, December 2003, p. xi

producers of reproductive health commodities. These were sold at profit in Western countries, while surplus production was – generally – made available for donor purchases, often at very significant discount (sold at marginal cost or just above it). The advantage of this system, seen from the donor viewpoint, was that products would be very high quality (produced to Western standards) and relatively cheap, since R&D costs were recovered in the wealthy markets. The disadvantage would be a reliance on the charity or otherwise of Western producers – in several instances only very limited quantities of discounted product is made available, e.g 38,000 Mirena second-generation IUDs being made available for donor market – a drop in the ocean.⁸

However, the bulk of early generation contraceptive products used in developing countries are now fairly mature commodities. Condoms are of course a very old invention, and the technology to produce condoms has been around for several decades. Oral contraceptives, IUDs and to a lesser extent injectables have become mature technologies, generally off patent (though particular production methods and newer formulations may be patented).

Implants and emergency contraceptives are more recent and will often still be under patent (though Norplant, the leading generation 1 implant product, and its successor, Jadelle have come off patent).

More recent inventions and products under development will either be under patent or protected by secrecy.

The increased enforcement of patents currently being accepted by a number of developing countries (e.g. India) clearly restricts the scope for generic production “ahead of time”. Given however the maturity of the key products mentioned above, this does not seem like a critical issue at the moment – these products have been around for well over the normal patent horizon of 20 years.

Another equally important issue is access to the appropriate know-how, technicians and other related infrastructure needed to enter into the supply market. In many cases Western manufacturers will be reticent to engage in technology transfers with potential low cost competitors, even under the terms of a licensing deal. Again however, the manufacturing technologies involved in the older contraceptive products are now so mature that access to the necessary technologies is generally not restricted, even if actually constructing and operating a plant is a far from trivial process. Organizations like the Concept Foundation (see more below) play a very useful role in facilitating technology transfer processes.

Recent estimates of the investment and minimum necessary scale involved in setting up a condom, oral contraceptives or injectable manufacturing plants reveal that entry barriers for production of the most mature products are not very high.

⁸ Commission on Intellectual Property Rights, Innovation and Public Health, Peter Hall, March 2005, p.18

BARRIERS TO ENTRY IN KEY MARKETS

	Capital cost of plant	Other resources required	Minimum efficient scale/ turnover*
Male condoms	•\$4-\$6m	•Skilled latex/ chemical engineers •Skilled labour	•500,000 gross @ 144 condoms (70m) •\$2-\$3m
Oral contraceptives	•\$2.5-\$6m	•Skilled chemical engineers •Skilled labour	•15 million cycles •\$3-\$4m
Injectable contraceptives	•\$3-\$5m	•Skilled chemical engineers •Skilled labour	•5-10 million doses •\$5-\$9m

*Calculated at top end of UNFPA procurement range prices
 Source: Expert interviews, WHO, Gujarat Business Council

A credible contraceptive production plant can now be installed for the cost of a few million dollars, provided the host country has the necessary local skill and infrastructure base. This is relatively small change in the context of production plant investment, and has led to a substantial stream of new reproductive health commodity entrants in low cost countries like China, India, Thailand, Malaysia, Thailand, South Korea, Taiwan etc.

In general, such producers will focus on their home markets in the first instance, and often be unable to produce to international regulatory standards in the first couple of years. However, there is strong evidence that this phase is transitional, and that several low cost market producers are now emerging on an equal quality footing with Western producers – but at much lower cost.

For example, the Bangladeshi procurement authority is said to have been able to reduce annual contraceptive procurement spend by 33% - from \$60m to \$40m – over the last 4 years, without changing the product mix. A key factor in this has been the use of Southern generic suppliers, where for example it was possible to reduce oral contraceptive prices from 21 ¢ to 10 ¢ per cycle.

5.5 Procurement pooling issues

One key element in achieving good procurement prices is buying sufficient quantities in relation to producer scale. A procurer buying a large proportion of plant output will be able to achieve better prices than a buyer buying only a small proportion. In general, production scale is not the only driver of what constitutes efficient scale – transport issues (e.g. filling up a container) or other issues may be involved as well.

In general, trends in technology have tended towards decreasing the minimum efficient scale over time – production runs that were uneconomical 10 years ago may be economical now.

There is insufficient data available to carry out a comprehensive analysis of production scale issues in relation to reproductive health commodity security. However, it is instructive to look at annual demand for various regions in relation to the current estimated minimum productive scale for various types of plant (e.g. a figure of 272% would mean that the annual demand from this country/region would be equivalent to 272% of production capacity for a small plant, i.e. nearly 3 years production. In general, very small percentages, e.g. 2-5%, might indicate that country demand was subscale, and that pooling at a higher – e.g. regional – level was required to achieve the best prices.

ANNUAL DEMAND AS % OF MINIMUM EFFICIENT SCALE PER PLANT

	Condoms	Oral contraceptives	Injectables
Africa	272%	740%	590%
East Africa	86%	189%	236%
Kenya	10%	33%	49%
Malawi	4%	4%	22%

↖
Likely need for pooling to
achieve attractive prices

Assumptions: Contraceptive prevalence for different product types based on regional and country level data from UNFPA; populations from UNFPA, assumed 125 condom uses/ year per user; mixture of 1 month and 3-month cycle injectables; plant minimum efficient scales: condoms 70m/ year, oral contraceptives 15m cycles (@21 pills) a year; injectables/ implants 5m/ year; annual demand for injectables also includes implants and hence will be somewhat high, understating the need for procurement pooling

*Source: UNFPA, Expert interviews, WHO, Gujarat Business Council

Given the not inconsiderable uncertainties attached to the various assumptions used, these figures should be viewed as indicative only. The key messages to glean are:

- For all three types of product, Africa as a whole, as well as the East African region appear to be an efficient scale purchasing area. Pooling at either level should achieve satisfactory prices. In other words, African regions are certainly large enough to form efficient purchasing units. It would need further analysis, on a country-by-country and product-by-product basis, to identify if any significant savings could be made by switching from country level to regional level procurement.
- For injectables, even a country as small as Malawi appears to be an efficient scale purchasing area (22% means that Malawi would be in a position to buy more than 2 months production of injectables).
- For condoms, Malawi does not necessarily appear sufficiently large scale to carry out efficient purchasing, being able to buy only a couple of weeks production. Even Kenya with 10% might be better off pooling at the regional level.

For oral contraceptives, Malawi might again be better off pooling at the regional or subregional level. Kenya, on the other hand, at 33%, should be able to get good prices on its own.

Without actual data, it is difficult to illustrate the effects of further pooling. However, a – highly indicative – estimate could be based on the above mentioned ~\$200m estimate of Sub-Saharan Africa RH expenditure. If it was assumed that 40% of this spend was open to more efficient regional pooling arrangements, and that 10% annual cost savings could be made in this way, the annual savings would be in the order of \$8m.

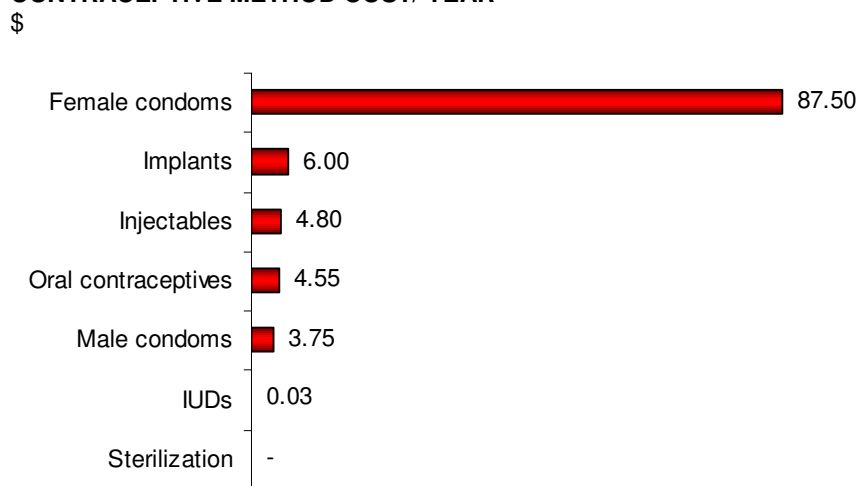
This would then have to be traded off against the one-off cost of establishing regional procurement operations, as well as the loss of flexibility inherent in a pooling scheme.

Given the potentially large sums involved, the issue of regional pooling is definitely worth pursuing for the country level studies. However, a much more solid set of data and investigation of possible implementation issues is required to substantiate any expectations of substantial savings through such an approach.

- Product mix issues

Clearly, the product mix plays a very considerable role in RH commodity security, in that it affects the efficiency of resources utilisation. Some products – generally the long term or permanent methods – are much cheaper than others on a per year basis (but may be entirely inappropriate for the needs of a particular woman/ family). Similarly, extending the range of products available will benefit choice, but may make the supply chain less efficient and effective.

CONTRACEPTIVE METHOD COST/ YEAR



Assumptions: Condoms: 125 uses per year, female condoms not reused, injectables: mix of 1 and 3 months products, product prices average UNFPA range; ignores distribution/ application costs and costs of healthcare personnel

*Source: UNFPA; various

There is no simple right solution between these various tradeoffs, but it is clear that an appropriate use of longer-term methods can considerably decrease procurement cost and hence – everything else being alike – increase the efficiency of resource use. On the other hand, offering just sterilization or IUDs would certainly be cheap but would not be considered offering a proper choice under the Cairo criteria and might decrease overall contraceptive prevalence rather than increase it.

Clearly, choices need to be made, to strike the right balance between efficiency of resource use and the importance of individual choice.

5.6 Issues in Transition to Generic Products

There will be a number of issues involved in transitioning from discounted Western to Southern-produced generic products. At a minimum, the following issues exist:

- Quality. Likely the biggest issue of all. Not all manufacturers have equally stringent quality standards. In particular, the reputation of the smaller scale Chinese manufacturers tends to be variable. The issues can be particularly acute, if the producer decides to use formulations that have not already been subject to proper clinical testing. However, a large and increasing proportion

of Southern manufacturers are now beginning to live up to Western quality standards:

“The situation is changing rapidly, as with other pharmaceutical products, the acceptance of generic products in Western Europe and Asia has opened up huge new markets. This is stimulating significant change in manufacturing, where companies in India and Mexico, and to a lesser extent in China, are complying with, and meeting, modern standards of GMP. [...] This change will eventually have an impact on the production of all products [...]”⁹

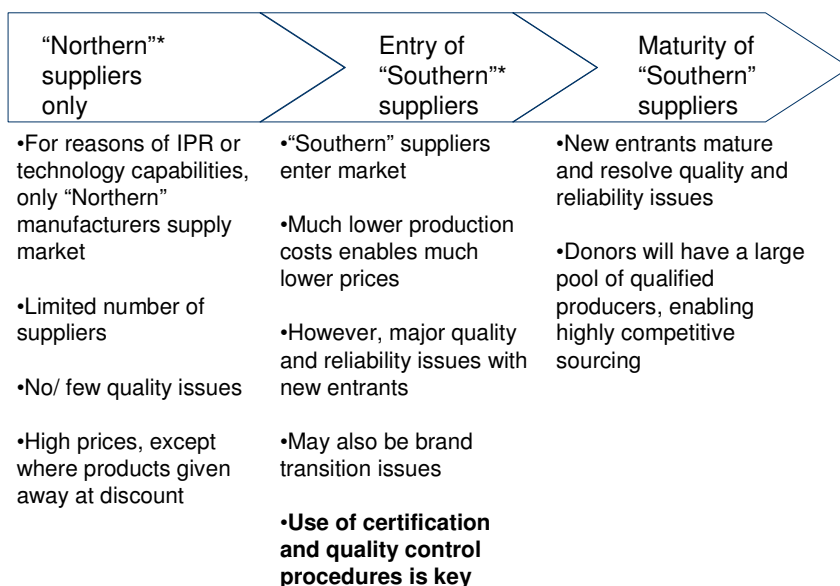
Clearly quality control and ongoing monitoring is key. Certification of plants is also important, but should not be a substitute for quality control on an ongoing basis. A number of experts interviewed for this project felt that both donors and – particularly – country level procurement agencies are currently not being sufficiently vigilant within this area and/or are using the quality concern issue as an easy excuse for not trying to expand the supplier base. Increased involvement of the WHO and other qualifying bodies in pre-qualification and certification would be universally welcomed in the donor community.

It is noted that in the Bangladeshi example cited above, there were initial quality [and delivery delay] issues, though these now seem to have been satisfactorily resolved.

- Production capacity/ reliability. There are a number of anecdotes of generic Southern suppliers being less reliable than their Western counterparts in terms of delivery of sufficient quantities, on time. It is difficult to quantify these issues, and to disentangle them from, for example, effects of poor planning in the procurement function. Nevertheless, it is an issue to be taken into consideration.
- Brand transition. Consumers may not trust generic brands as much as previous brands, particularly if given a different name, packaged less attractively and not properly introduced by primary healthcare workers. There is at least anecdotal evidence of this having been a significant problem in some instances, often led by rumour more than fact. Any transition will require significant planning and may be facilitated by countries or organisations creating their own ‘over-branding’ brand names/ packages instead.
 - A separate issue is that there may be governance issues in brand transitions. Cheaper, no-brand products make side selling less attractive, creating incentives to stick with existing, higher-priced suppliers. In other words, there is much higher value in pilfering from warehouses with branded, Western products, and re-selling or even re-exporting, than there is in pilfering cheaper, no-brand name products. When such problems occur, they can very substantially hamstring RH supply security.

Overall however, if properly managed, an orderly transition to a supplier base including generic Southern suppliers should be possible:

⁹ Commission on Intellectual Property Rights, Innovation and Public Health, Peter Hall, March 2005, p.40

ENTRY OF “SOUTHERN” GENERIC SUPPLIERS

**“Northern” suppliers: manufacturers in developed countries. “Southern” suppliers: manufacturers in developing countries/ emerging markets, e.g. Brazil, India, China

Let us now turn to individual product markets.

6 INDIVIDUAL PRODUCT MARKETS

6.1 Male Condoms

Male condoms (estimated global market size around \$4bn) is probably the most mature of all the contraceptive markets, and has very deep and competitive supplier markets across both Northern and Southern manufacturers.

Currently, the UNFPA has identified 86 major condom manufacturers across the world. There are 14 in India, 13 in Malaysia, 7 in China, with the remainder mainly in the West. Repackaging by private sector wholesalers increases the number of available brands well beyond this number, though donors will only contract with primary manufacturers.

Key suppliers used by the UNFPA include [not all pre-qualified]:

- Condomi (Germany)
- SSL International (UK)
- Karex (Malaysia)
- Hindustan Latex (India)
- Dongkuk Techco (Malaysia)
- Quingdau/ Double Butterfly (China/USA)

According to the UNFPA, it would be desirable to expand the current certified supplier base of around 10 to maybe 20, though it is not expected this would have a major effect on price or other aspects of reproductive health commodity security. The cost [to UNFPA] of pre-qualifying suppliers is relatively low, around \$10,000, but so far the additional funds have not been available. Judging by the interview reactions, several donors would welcome (and fund) a UNFPA lead in this area, if a positive impact on RH security was documented.

Current UNFPA target price range for condoms is between \$2.57 and \$4.44 per gross (@144), depending on quantity, urgency and a variety of other factors.

6.2 Oral Contraceptives

The oral contraceptive market is also a very deep and competitive one (overall estimated size \$8bn/year).

Interestingly, the UNFPA pre-qualified list of oral suppliers includes only Western manufacturers:

- Cilag (Switzerland)
- Gedeon Richter (Hungary)
- Organon (The Netherlands)
- Pfizer (USA)
- Schering (Germany)
- Wyeth-Ayerst [Canada/France/Germany]
- Interestingly, Indian market leader FamyCare is not on the pre-approved list.

However, Southern manufacturers have by now become well established in this arena – viz. the before quoted example from Bangladesh (Southern generic manufacturer reducing procurement price from 21 ¢ to 10 ¢ per cycle, at acceptable quality, following initial concerns).

Oral contraceptives are currently being manufactured in the following countries: South Africa, Iran, Israel, Oman, India, Pakistan, China, Indonesia, Taiwan, Thailand, Brazil, Chile and Mexico.

Current UNFPA target price for oral contraceptives (low dose) is between 23 ¢ and 46 ¢/cycle.

It is noted that some modern specialist/ low dosage products are likely to be less competitive for patent and/or brand reasons, being restricted to Western suppliers. This does not impact oral contraceptive commodity supply security overall, although it does contribute to the slow “trickle down effect” (referred to earlier), whereby new, improved and (usually) more expensive products become only gradually available at lower price to the developing world.

6.3 IUD's

The early generation IUD (Copper T380 A) has a wide and deep global market, combining both Western and Southern suppliers, including:

- Pregna (Brazil)
- Hindustan Latex (India)
- Injeflex (Brazil/ Canada)

It is commonly acknowledged to be far and away the least expensive contraceptive product at only around 32 ¢ (UNFPA target price) plus insertion cost, and has a very large prevalence in a number of Asian countries, with an estimated user base well in excess of 100m.

The situation is clearly different for more modern IUDs, like the Finnish-produced levonorgestrel-releasing IUD marketed in Europe and US as Mirena.¹⁰ This device is marketed at several hundred dollars in the US and Europe, and while it is made available at a public sector price of \$40, this is not attractive to most developing country health authorities – the cost is more than 125 times the cost of the T 380 product. A small number of Mirena devices (11,000) are being provided free and a further 33,000 at a cost of \$27, but this low quantity will make little difference.

It is noted that there have been significant concerns expressed about the safety and efficacy of the Copper T380A device, mainly in the US, with one lawsuit awarding damages of \$18.5m, effectively discontinuing US sales of the device since the late 80'es. Some would argue these lawsuits reflect more on the emotional vagaries of the US jury system than on any inherent weaknesses in the T380A device.

6.4 Injectables

There is a considerable overlap between the producers of oral contraceptives and injectables; producers who manufacture one will generally also manufacture the

¹⁰ See Peter Hall, p. 18

other. Hence the comments made about oral contraceptives above, apply to a large extent to the injectables market. In particular, the potential supplier base is deep and broad and increasingly includes high quality emerging markets suppliers.

The UNFPA target price range for injectables ranges around 78 ¢ to 94 ¢ per vial, with part of the price difference relating to the type of injectable.

6.5 Implants

Implants exist in a number of different versions – early generation versions like Norplant with 6 rods of active substance (levonorgestrel), and more modern versions like Jadelle/ Norplant 2 with fewer rods (typically 2). Both types are now off patent protection.

Norplant and Jadelle development was funded by the Population Council, and production rights are currently licensed to Schering.

The Chinese have developed and are manufacturing an levonorgestrel-based product (150 mg instead of 140 mg) known as Sinoplant.

Other implant-type products include etonogestrel-based Implanon manufactured by Organon in Holland

In addition, the Population Council is working on a Nestorone-based product.

While there are multiple suppliers and hence few issues over supply security, implants remain fairly expensive products, with UNFPA target prices ranging from \$23 to \$35/ set.

More substantial entry of emerging markets producers will be required to bring this price down significantly.

6.6 Female Condoms

Unlike all other products covered in this report, female condoms are currently essentially a single-supplier product, with the Female Health Company [FHC] supplying all products used

Again uniquely for the products covered here, the FHC – while a listed company - is majority owned by a non-profit trust, the Female Health Foundation, with the single aim of improving women's health.

The FHC has entered into a strategic partnership with the UN and various other agencies enabling purchase of female condoms at a heavily discounted price. Back in 1996 this price was around 60 ¢ per product; it is now around 70 ¢. Currently PATH and a Chinese manufacturer are working to develop a product with a cost of around 25 ¢.

The largest current contract is an arrangement with USAID for the supply of up to 25m female condoms.

According to the 2004 FHC annual report there have been no operational issues or any other breakdowns in the supply chain that could be attributed to the FHC (though the report mentions that in-country problems, for example fraud in Brazil, has led to supply interruptions).

Overall it would seem fair to say that given the non-profit nature of the company and its operational track record there are no issues around supply security deriving from the fact this is a single source supplier market.

6.7 Emergency Contraception (Post-Coital Contraception)

There are in the main two methods available: either IUD's or use of oral contraceptives (either estrogen/progestin combination products or progestin-only products).

While packaging and branding may be different, the basic products are the same as those used for non-emergency contraception, and reference is made to the market descriptions above.

6.8 Medical Abortion¹¹

The supply bases for medical abortion products are less developed than those for most of the other reproductive health products investigated here, and are shrouded in considerable controversy. Nevertheless, the entry of Southern manufacturers is set to change this market as well.

The main medical abortion regime combines the products Misoprostol and Mifepristone.

Traditionally, these products have been expensive (\$75-\$250 for Mifepristone alone) or difficult to access. The original patent holder for Misoprostol (Searle) developed the product as an anti-ulcer medication and vigorously fought its use as an abortion inducing product.

However, the patents for both products have recently expired, and a number of Southern suppliers are entering the market, including the four largest Indian pharma companies (Cipla, Nicolas Piramal, Sun Pharma and Zydus Cadilla). All four have international reputations and high GMP standards, and are supplying the products at a fraction of their former cost: \$8 for the 2 combined products, compared to \$75-\$250 from Western manufacturers. This price may still be too high for a number of developing country health authorities, particularly when considering additional dispensation costs.

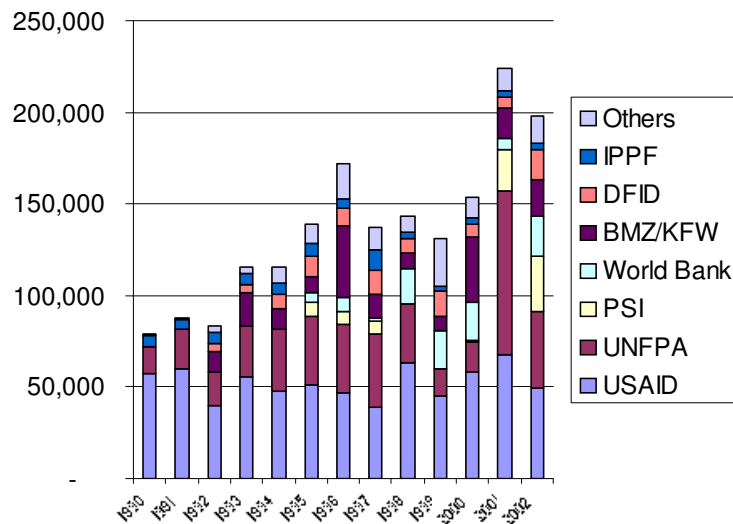
¹¹ This section is substantially based on Peter Hall, p. 34

7 CURRENT INTERNATIONAL PROCUREMENT ARRANGEMENTS

International reproductive health procurement arrangements are varied and complex, with a considerable number of agencies, governments and other actors involved.

The key donors/ agencies, by size of procurement spend, are UNFPA and USAID, with other important players being IPPF, DFID, BMZ/KFW, PSI and the World Bank. A large number of other organisations and governments will also be engaged in procurement within this field. Arguably the most important player is the UNFPA, as it serves as the outsourced procurement provider for a number of other organisations and governments.

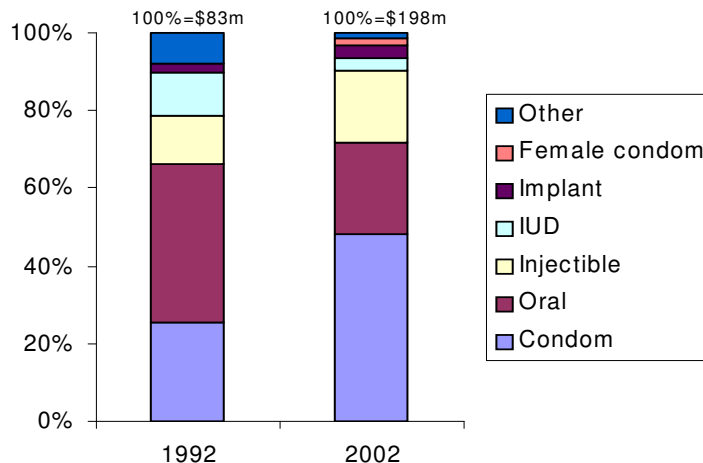
TOTAL DONOR PROCUREMENT SPEND, BY DONOR
\$ '000



Source: UNFPA, interviews, project analysis

Donor procurement spend more than doubled from 1992 to 2002, with condoms and injectables gaining share in the mix.

DONOR PROCUREMENT SPEND MIX
% of total



Source: UNFPA, interviews, project analysis

A full assessment of the effectiveness (and by implication the efficiency) of the system has not been possible within the limited time frame of this study. Such an assessment would require analysis of detailed procurement data, including time series of purchasing quantities and prices, purchasing events and drivers (e.g. rush orders, stock-outs, overstocks) that is not currently publicly available, efforts like the RH Supply Initiative notwithstanding.

The following analysis is based on the interviews and such procurement data as was publicly available, addressing the most important issues identified.

7.1 Funding

It is immediately noticeable from the diagram of donor procurement spend shown on the preceding page that overall donor funding is highly variable from year to year. The funding is even more variable at the level of individual donors (and certainly even more variable at individual donor and programme level).

This variability/ unpredictability effect is exacerbated by the way that budget and financing cycles work. In general, budgeting cycles are as long as 18 months, i.e. normal support requests from implementation agencies and governments have to be filed up to 18 months in advance. Often however, decisions on fund allocations will only be taken at the very last minute, creating uncertainty about funding till the end. On the other hand, it is not uncommon for large donors to reallocate parts of unused funds towards reproductive health commodity procurement towards the end of a year, causing a sudden deluge of funds.

The effects of this uncertain funding on running an effective procurement operation are not hard to imagine. One bedrock of good procurement practice is the ability of the procuring agency to tender for large quantities, with long lead times. Unpredictable funding arrangements will tend to fragment procurements and shorten lead times.

While it is difficult to quantify the effect of such unpredictability, UNFPA unofficially estimates that its average procurement prices could be lowered by up to 10%, if stable multi-year funding arrangements were put in place. Comparable figures for other agencies are not available, but may in fact be even larger, particularly for smaller procurors.

7.2 Coordination

There was general concern that the current level of coordination between donors and agencies was relatively poor, efforts in the RH Supply Coalition and other fora notwithstanding. Part of this lack of coordination is due to differences in opinion over strategies, which could only be resolved at policy level.

There is general consensus however, that much more could be done to coordinate activities, even without increasing overall strategic alignment. Such increased coordination could most usefully be applied in focusing on securing more stable long-term funding, both for commodity procurement and for country-level capacity building.

7.3 Pooling

It is evident that pooling into larger quantities will tend to lower procurement prices. Certainly, the websites of the major procurors, led by the UNFPA, emphasize the role of pooling in their procurement practices.

It is however not clear from the interviews or available data to what extent major procuring agencies are in fact pooling procurements in the most effective and efficient manner possible.

The most likely hypothesis would be that procuring agencies are in fact well aware of the need for pooling, and that such failure of pooling as does occur likely derives from failures elsewhere in the system, for example around fragmented/ unpredictable donor funding, and/or rush procurement requests that could have been avoided through better planning.

One interesting issue is the extent to which regional pooling between governments could improve government procurement efficiency, e.g. through a West African pool, a Southern African pool etc. While this is more properly an issue for the country level study, it should be noted however that a prerequisite for a regional arrangement to work is probably a minimum level of procurement and supply chain proficiency at the participating country level.

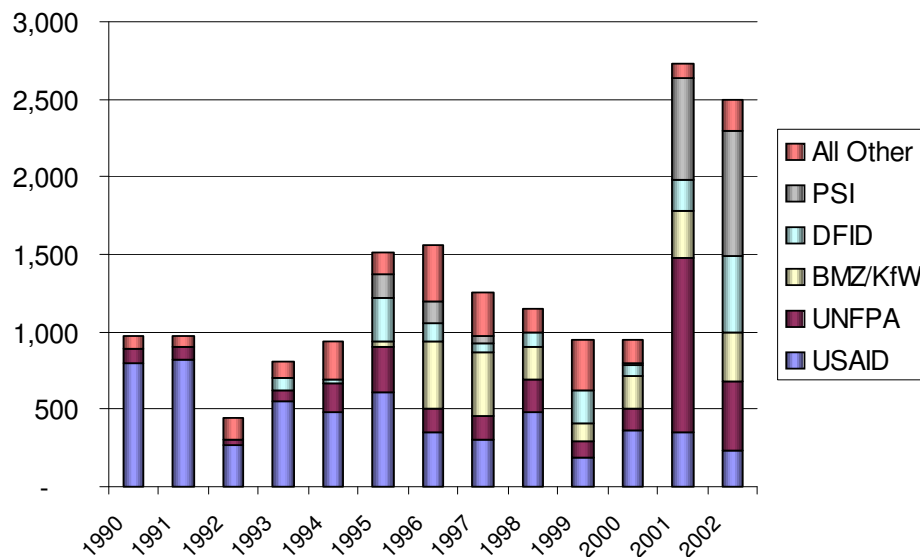
7.4 Prices

Only within the male condom field is there sufficient time series data available to evaluate the average procurement prices achieved.

Over the last 12 years for which data are available, donor procurement has developed as follows:

DONOR-FUNDED MALE CONDOM PROCUREMENT

m of condoms



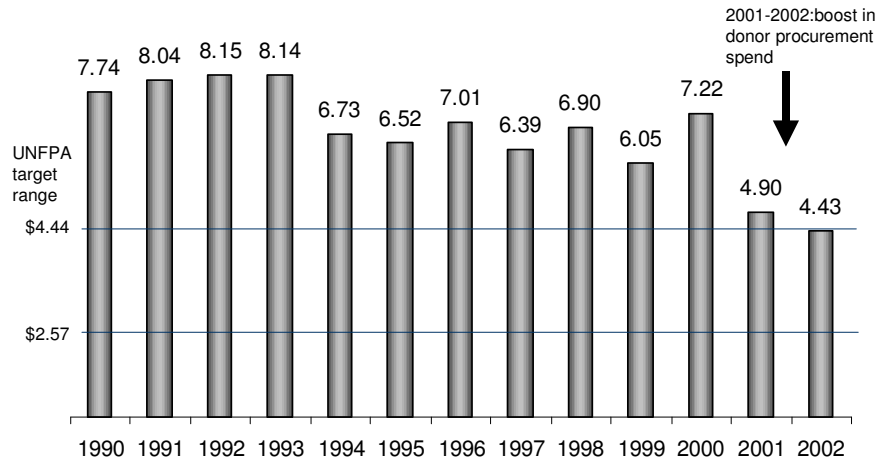
Source: UNFPA, project analysis

It is noticeable that unit procurement of condoms underwent a step change from 2000 onwards, nearly tripling in volume. It is also noticeable that individual donor agency shares of procurement are even more variable year-to-year than at total donor procurement level.

When combined with spend data, the following picture appears for average condom procurement prices. Procurement prices were fairly constant from 1990 to 2000, but then reduced substantially, by about 1/3.

DONOR-FUNDED MALE CONDOM PROCUREMENT

\$ per gross (144); constant 2002 prices



Source: UNFPA, project analysis

On the face of it, this indicates that international condom procurement has become more efficient in recent years.

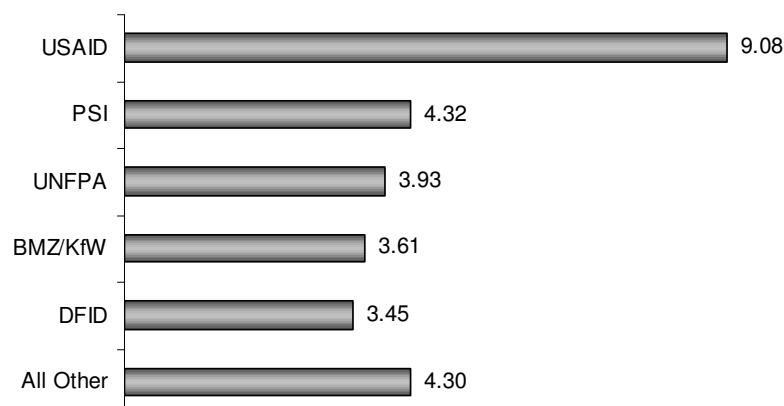
However, the data is not conclusive.

Firstly, unit procurement (as shown above) tripled from 2000 to 2001, and it would have been highly disappointing if this was not in some way reflected in average procurement prices. Secondly, as we have seen, emerging markets manufacturers have become increasingly active, and this may in itself have driven down prices, without much activity from the side of the international procurement community. This may however be an unjustly churlish interpretation. At the very least the procurement community have demonstrated some level of ability to benefit from increased volumes and an expanded supplier base.

It is interesting to disaggregate the data to individual donor/ procurement agency levels. Here it is clear that there are in fact significant differences between agencies, with USAID buying at the highest prices, by quite some margin. This is likely at least partly due to the principle of tied aid (Buy American). Given that the average USAID procurement price is 2.25 times the average price achieved by other agencies, this is in itself quite a substantial inefficiency in the system.

MAJOR CONDOM PROCURORS 2002 – AVERAGE PROCUREMENT PRICES

\$ per gross (144); constant 2002 prices



Note: USAID prices are substantially higher than average. This is likely to be due to their use of tied aid (Buy American), though this has not been confirmed. PSI being higher may be due to part use of tied aid

Source: UNFPA, project analysis

Unfortunately, data was not available to repeat this analysis for the other RH products.

7.5 Quality

The first point to note is that achieving quality requires prioritising quality. There is at least anecdotal evidence that some agencies have been so keen on achieving the lowest possible price that they have placed less emphasis on quality than what would have been appropriate.

There clearly is a price floor below which quality manufacture is not possible, and while this floor may be well below what a number of Western manufacturers can deliver, it may be somewhat above what the poor quality operator is willing to offer.

All agencies interviewed for this project stated that they now prioritise price only at good quality levels, i.e. are no longer going for the lowest possible price, regardless of quality.

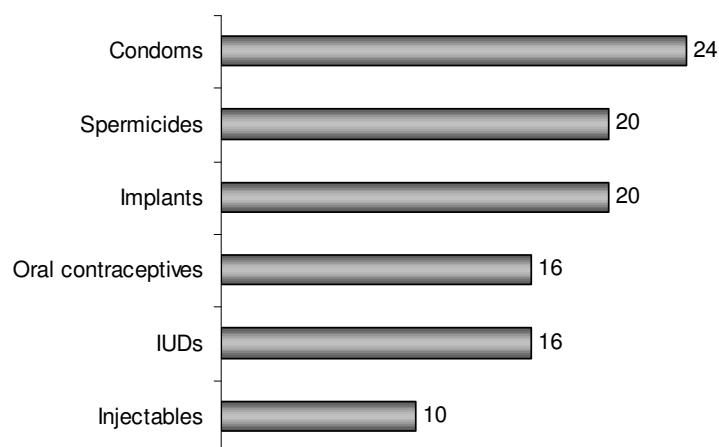
There was insufficient information available for this project to assess whether international procurement agencies are in fact achieving good quality. Some parties expressed concern that insufficient testing is taking place; for example, it may not be enough to just test once at the beginning of deliveries – instead deliveries should be tested at regular (and irregular!) intervals. This issue becomes particularly acute with shipments to country governments with relatively weak in-country quality monitoring abilities.

7.6 Lead Times

There is data on average UNFPA lead times, but it is not possible to see how these have developed over time, or compare to other agencies. Also, the data does not indicate how response time varies by product volume – in general, the larger the volume, the higher the response time.

UNFPA INDICATIVE LEAD TIMES FOR MAJOR RH COMMODITIES

Weeks from placement of order



Source: UNFPA

In addition, the UNFPA operates an emergency response system (GCCP), with buffer stocks of the most common contraceptives, available to fly out at very short notice.

Again, there was insufficient data to evaluate this program in any detail. Anecdotally, it seems effective in that supplies are in fact available at short notice, but whether they are provided at the lowest possible cost is not clear.

7.7 Customer Service

There was some concern, expressed through the interviews, that customer service was not prioritised sufficiently highly within the UNFPA, and that external audits would be helpful to further hone focus on key customer issues. A particular concern seemed to be a lack of senior leadership around creating a really powerful and efficient procurement service line, based on well understood customer needs.

7.8 Market Access/ Structure

As described in the market section, the commercial market for developing country reproductive health commodities is sufficiently large and dynamic that major donor intervention is not required to improve RH commodity security. This is because the commercial market is generally much larger than the donor market – e.g. the total developing country market of \$4bn is a factor of at least 15x larger than donor purchases. There is no reason to believe that any of the individual product markets – with the possible exception of female condoms – are much different in this regard. Hence, donor intervention is not critical to creating a market in RH health commodities

The most important aspect here is for donors to address the quality issue, while keeping up the push on expanding the supplier base with low cost/generic/ Southern suppliers.

There will be product-by-product exceptions, for example in the case of female condoms, where donors/ agencies will wish to work more directly with manufacturers to help shape and influence manufacturing, pricing, commercial and distribution strategies.

Donors/ agencies may also usefully continue to push to accelerate the “trickle down” effect, to introduce newer products as rapidly as possible into the donor reproductive health pipeline. As stated above, there are risks and costs associated with changing the existing product mix. Such an “acceleration” strategy should only be executed as part of a comprehensive overall product mix strategy, which includes thorough consideration of likely supply chain, user acceptance, crowding out and other issues. An acceleration strategy, whereby a much lower number of advanced products crowded out existing much cheaper and well understood products, would not be constructive.

7.9 Information Flows/ Market Monitoring

It is clear that there is very little information available in this area, which will in itself hamstring supply security. For example, there were no time series available on donor purchases by unit or cost, outside of the condom area. There is no comprehensive database of suppliers and market shares, including over time. There is no visibility about the demand pipeline etc., etc.

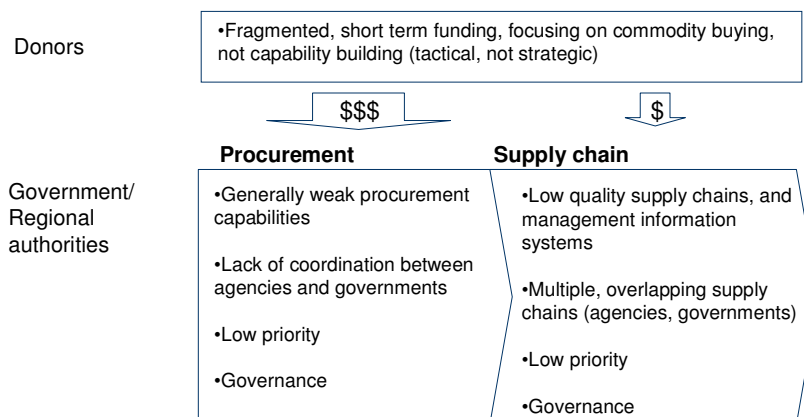
This lack of information causes problems at both the tactical (procurement) and strategic level. At the tactical (procurement) level, it makes it more difficult to pool properly, to provide long lead times and to avoid emergency stockouts. At the strategic level, it makes it more difficult to identify systemic weaknesses and act accordingly.

The RH Supply Initiative is a useful step towards bridging this information gap, but much work remains to be done, both in terms of signing up additional partners (beyond USAID, UNFPA and IPPF) and in terms of capturing additional data.

7.10 Other Issues

There was general agreement that the most serious procurement and supply chain issues now reside at country level. The issues are many and varied, but their root

KEY ISSUES AT THE HEART OF THE REPRODUCTIVE HEALTH SUPPLY SYSTEM



cause seems to be a lack of capabilities/ infrastructure across procurement and supply chain functions within country level primary healthcare distribution systems. Systemic weaknesses are likely to include (but not be limited to):

- Lack of experienced purchasing and supply managers
- Poor market research/ demand information
- Long and weak supply chains (e.g. large, central warehouses, far from distribution points, poor road infrastructure)
- Poor information systems
- Ineffective marketing and distribution strategies
- Weak coordination with private sector

The issues at country level including the effects of PSRPs, SWApS and other similar budgetary instruments merit further analysis.

Regardless of the exact issues identified at country level, there was however a strong consensus amongst the interviewees for this project that part of the problem relates to the international donor community. Suggested particular areas of emphasis are: Predictability in funding, coordination, harmonisation, focus/drive on commodity security, innovation, country capacity strengthening]

There is a general perception that donors disproportionately focus on the short-term tactical (in particular actual commodity procurement), at the expense of longer-term strategic investment in capability building at country level. For example, the UNFPA allocates at most 10% of its annual spend to long term capability building, with the remainder spent immediately on product procurement. However, this is not only a money issue. It about providing stable funding over several years for capability building, rather than just ad-hoc funding from year-to-year. Other aspects of a solution might be increased institutional support for country level capabilities, for example through providing established, proven frameworks, systems and training. This is already done to some extent, but there is felt to be a need for much additional effort in this regard. Finally, donors need to make capability building a clear and visible strategic priority in their reproductive health supply programmes, including follow-up of results achieved under PSRPs and SWApS.

8 ROLE OF ENABLING/ ADVOCACY BODIES

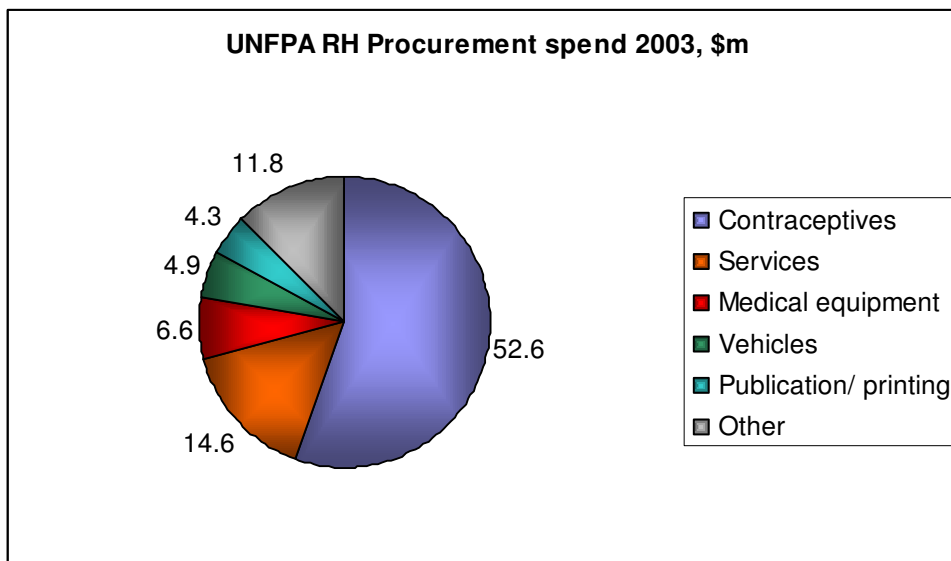
8.1 UNFPA

The United Nations Population fund is the largest and one of the oldest (founded 1969) actor on the international RH scene. The UNFPA acts under a mandate from the 1994 Cairo ICPD to help promote universal access to RH health services, reducing maternal and infant mortality, increase life expectancy, promote primary education and (since 1999) combat HIV/AIDS.

With nine Country Technical Services teams, 112 national offices, and operations in 142 countries, the UNFPA has global reach.

The UNFPA has a uniquely wide role in the RH community, including advocacy, coordination, fund-raising, policy-making and advisory services. According to the UNFPA website, the UNFPA has raised more than \$6bn in funding for RH services since 1969. Importantly, within the remit of this report, the UNFPA also operates its own RH procurement organization.

Based in Copenhagen, Denmark, the UNFPA procurement service provides RH procurement services to the UNFPA itself as well as national aid organizations (USAID, DFID etc.), NGOs, country governments and other public bodies. Its annual 2003 RH procurement budget was around \$95m, of which about 1/3 was sourced from developing countries. Ca. 55% of this spend (or \$52m) was spent on contraceptives.



As the critical player in the international RH community, the efficiency and effectiveness of the UNFPA in carrying out its role is arguably more important than that of any other single international organization. This is particularly visible for the UNFPA procurement organization which, due to its scale, reach and reputation holds a very strong position – almost a monopoly some would say – in the international RH procurement field.

This entails unique scrutiny and responsibilities for the UNFPA. Given this, it is not surprising that the interview process for this report surfaced a number of different

perspective on the UNFPAs current RH procurement strategy and – particularly - service levels. A fuller investigation of the relations between the UNFPA and other donors (procurement customers) lie outside the remit of this report. It is worth pointing out however, that commercial experience indicates that while there are substantial benefits to scale economies in procurement, there can also be benefits in a certain minimum level of competition between procurement agencies, in terms of furthering both customer service and innovation.

The UNFPA is currently developing a multi-annual funding proposal, with a view to achieving more sustainable commodity funding. This proposal is still in its early stages, and has not been analyzed for the purposes of this report. Depending on its final form and subsequent execution/ funding it may however significantly improve the current overly short-term RH funding situation.

8.2 WHO

Another very important role is played by the World Health Organization (WHO) in terms of pharmaco-vigilance, safety surveillance and as a coordinator of certification institutions. It is important to understand however, that WHO is in itself not a regulatory agency, but instead can make recommendations to national structures and for essential drug lists.

Such structures differ depending on the involvement of the host country in pharmaceutical R&D and manufacture. Countries without any R&D or manufacturing, e.g. Zimbabwe, will generally insist on manufacturing country approval, even if they do have their own drug control lab.

There will also often be different perspectives on acceptable risk between developing and developed countries. For example, DMPA has been approved in several developing countries in spite of USAID concern over breast cancer risk – “no point in worrying about this if maternal health is so poor that mothers die young anyway”.

WHO has created a pre-qualification programme, which aims to establish and certify the quality of HIV/AIDS, malaria and TB products that are intended for supply through a number of international agencies. Each product considered must be a legal product in its country of origin, although WHO is willing to approve generic versions of products that are currently still patented in the US, thus threatening the monopoly of the originator companies. The Gates Foundation is currently providing funding to extend this scheme to reproductive health, with WHO as the implementing agency.

WHO also manages the co-sponsored Human Reproduction Programme, (HRP) the main instrument within the United Nations system for research in human reproduction. HRP brings together health care providers, policy-makers, scientists, clinicians and consumer and community representatives to identify and address priorities for research aimed at improving sexual and reproductive health.

8.3 Concept Foundation

The Concept Foundation is an NGO initiated by the WHO to speed up the “trickle down” effect, through licensing technologies and otherwise facilitating technology transfer within the reproductive health arena.

One of the Concept Foundations flagship programmes has been licensing of the once-a-month injectable contraceptive Cyclofem available in developing countries, with over 150m doses distributed since 1993. The Concept Foundation has also developed a portfolio of other products, including HIV diagnostics, emergency contraception and medical abortion products.

It is noteworthy that the operating budget of the Concept Foundation is very limited, at around \$1m per year. In other words, the Concept Foundation is a much smaller actor on the RH scene, than the other agencies mentioned, but is an example of the sort of impact that can be achieved, even with relatively limited means.

8.4 RH Supply Initiative

The Supply Initiative was launched in early 2003 to create a forum in which leading reproductive health organisations can work together to share information, identify the main causes of supply shortages, help coordinate responses, and make recommendations to governments and donors on solving these shortages. The four core members are DSW, JSI, PATH and PAI.

The first phase of the Supply Initiative has been funded by private foundations, including Gates, Hewlett Packard and the Wallace Global foundations.

The Initiative is based in Belgium, where the organisation maintains a small secretariat.

The RH Initiative has a three-pronged strategy of advocacy, support to global donor coordination and improvement of information flows. As part of phase one, the RH Initiative has established a website for information sharing, and is consolidating procurement data from the International Planned Parenthood Federation (IPPF), UNFPA and USAID.

The three organisations are major donors of reproductive health supplies, and work with many of the same clients. Yet, it has been difficult to determine the total of donations made to any particular country because each agency has a different type of information system and operates on a different procurement cycle. The RHInterchange captures procurement information (by country, method and donor) and in the future, will provide forecasts by country. Following the initial phase, other large-scale supply donors, such as the German Reconstruction Bank (KfW) and the UK Department for International Development (DfID), are expected to join the data pool, in such cases where information can be provided, e.g. through Crown Agents [DFID].

The RHInterchange standardises regular transmissions of data from the three above mentioned donor agencies, allowing users to create reports either at a global, regional or country level for user-defined periods of time. Information at any of the geographic levels includes quantity, value, and method.

Via the consolidation and open exchange of reproductive health commodity procurement data, the RHInterchange aims to:

- Improve the collection and use of contraceptive management information by and among major purchasers of contraceptives and condoms for developing countries

- Improve the efficiency and cost effectiveness of participating contraceptive funders' programmes
- Demonstrate the benefits of collaborative planning and management among donors' contraceptive programmes.

8.5 RH Supply Coalition

The Reproductive Health Supplies Coalition is a small group /loose partnership? consisting of many of the major organisations involved in funding and/or providing donated Reproductive Health supplies and services.

It is in its formative stages [both in terms of membership, funding, resources, strategy and governance], and is considering how best to move forward and reach out in a broader way to other organisations relevant to RH supplies security, and develop a role that adds value to existing groups in support of country level action .

The group aims ultimately to include representatives from developing country governments, multilateral and bilateral donors, NGOs, social marketing groups and pharmaceutical manufacturers.

In determining its membership, the coalition “aims to strike a balance between inclusiveness and retaining the capacity of a small group for effective and action planning and timely implementation.”

So far, the Coalition no secretariat, and is mainly funded by in-kind contributions of personnel time from participating agencies/ donors. The Chair is currently held by the World Bank, but a new chair will need to be appointed by autumn 2005.

While the Supply Coalition works closely with the Supply Initiative, they are not one and the same – though some confusion seems to exist about this.

8.6 Country-at-risk-group

Additionally there is an informal Country-at-risk-Group with participation from major donors and agencies. This group focuses on urgent/ emergency situations, and is perceived by its participants to have been at least modestly successful so far.

9 MODELS FOR CHANGE IN INTERNATIONAL ARCHITECTURE

The purpose of this final section is to set out the various suggested changes to the international architecture, in order to best remedy the systemic challenges to RH security at international level identified during the research for this report.

In many ways the challenges to contraceptive commodity security are well known within the stakeholder community, and have been well known for years. What is proving elusive is an agreed prioritization between issues, sufficient funds, an agreed coordinated strategy to resolve them an appropriate forum for an overall coordinated effort.

The key issues identified during this project are:¹²

1. There is a considerable “funding gap” between what is required for RH health commodity security and what is currently provided by donors and others. This gap is particularly manifest for longer-term capability building activities. This gap would persist, even if optimal efficiency was achieved within the current system (which still seems a fair way off). Hence increased effort on advocacy seems required. On the other hand, additional funds on their own would not be sufficient to provide RH commodity security.
2. There is also a “coordination gap” between key stakeholders. There is no overall coordinated strategy to properly coordinate resources between countries and regions, and on an appropriate product mix and short, medium-term and long-term distribution strategy within each country. This will tend to lead to overinvestment in some countries/ activities (with loud voices or high donor affinity) and underinvestment in others (longer term, more complicated, less vocal) issues. Arguably this coordination gap also exists between major issues – it is possible that the introduction of powerful “verticals” for e.g. malaria, TB and HIV/AIDS tends to crowd out investment in less “packaged” issues like reproductive health.

One example of an important prioritisation issue is the current allocation of funds between regions. Anecdotally, Sub-Saharan Africa – which has by far the lowest contraceptive prevalence and the most significant barriers – is allocated about 1/3 of funding overall. Is that enough?

3. The market for RH commodities are generally open and competitive and certainly less of a constraint on commodity security than for vaccines like ACT. That said, donors should continue to work with agencies to appropriately expand the supplier base, and provide continuous strong focus on the need for quality, also from Southern, generic suppliers Priority products to address include oral contraceptives, condoms and injectables.
4. While current donor/ agency procurement arrangements do not seem majorly inefficient or ineffective, it is highly likely that there is considerable scope for improvement. A prerequisite for achieving such improvement would be achieving a much higher level of clarity about procurement data and about customer satisfaction levels.
5. A major possible source of inefficiency in current donor procurement arrangements is the short-term or even last-minute nature of commodity

¹² There is considerable overlap between these issues and the issues identified by the Deliver project in December 2003 – which would seem to indicate considerable buy-in amongst key stakeholders interviewed for this project about the basic accuracy of the Deliver project conclusions

procurement funding. Smoothing the flow of funds might enable up to 10% improvement in procurement efficiency.

It is unclear to what extent increased use of pooling, possibly on a regional basis, could increase international procurement efficiency. It is certainly a worthwhile issue to pursue.

6. The biggest issues around RH supply security seem to originate at country level. This issue is being exacerbated by the current move towards PSRPs, SWAPs and other budget instruments, leaving countries with substantially more responsibility for organizing procurements and supply chains. The diagnostic of this issue will be pursued during the country level study.

What is clear is that there is a general feeling that so far the donor commodity has failed to pursue this issue sufficiently vigorously, in particular by failing to provide sufficient, committed-long-term funding and infrastructure support to help resolve the major issues. Such help as has been provided has been too short-term.

7. There is a general lack of information up and down the system – particularly at country level – which makes informed decision making very difficult.
8. There is insufficient cooperation with and use of social marketing and private sector channels and methods. [This issue is outside the scope of this report, but could be pursued in the country level report.]

In considering the effectiveness of changes to the international architecture to help remedy these issues, it is worthwhile bearing in mind the feedback provided on desired changes during the interviews and from the Deliver project:

- While creating new bodies may be justified in some circumstances, there are significant issues around causing additional complexity and confusion – there are considerable benefits to working within existing systems
- While donors may be initially enthusiastic about new funding vehicles, e.g. a Global Reproductive Health Commodity Fund (or not), there is the risk of donor fund fatigue quickly replacing donor commodity grant fatigue. There also seems to be growing country level suspicion about the proliferation of ‘Global Initiatives’ and lack of clarity about how these respond the needs at country level.
- For any coordinating body to be effective, its members must be aligned on strategy, committed to making the body work and united behind a strong leadership. The body must also have access to – ideally through its own resource – a strong fact base on the issues to enable efficient decision making.

This said, the following suggestions are made:

1. Expand the data gathering efforts of the RH Initiative (including inputs received from the procurement review initiated under 1. above) to get a comprehensive overview of international procurement activity and efficiency, for each agency, and overall.

To the extent the data is not already available, it could prove a good investment to involve an external procurement consultancy, which would also enable benchmarking against external procurement standards as well as

objective evaluation of any real or perceived customer service issues, in order to surface and resolve them as speedily as possible.

Even while no major issues were surfaced around international procurement efficiency, sufficient funds are involved (\$225m) that investment in an agreed, clear and strong international procurement fact base is likely to be worthwhile. The bulk of any investment should however be allocated to country level capabilities – see 3. below.

2. Achieve stable 3- or 5-year funding programmes for RH commodity procurement, to avoid high variability in donor funding impacting negatively on procurement. This will require agreement between donors on overall funding strategy, and could likely be a matter for the Coalition.

It is noted that vehicles like the IFF (effectively securitizing donor flows) are probably less suited to commodity procurement rather than infrastructure investment. Instead, the notion of a revolving “buffer fund” sponsored by donors seems more attractive.

One of the key deliverables of the fact gathering effort set out under 1. above should be how best to target the buffer fund to achieve maximum impact. In particular, the fund needs to be based on a clear purpose and rationale, and defined scope of operation]

3. Create a powerful advocacy and coordination body in the international RH arena. The obvious vehicle for this would be the RH Supply Coalition, though so far this organisation has been fledgling and does not yet have the backing, leadership or resource base required to really make a difference. Given the obvious need for such a mechanism, it would be worthwhile for key actors to reflect on what any underlying issues in building out the RH Coalition might be. While there are clearly major strategy differences between key actors, there would also seem to be enough common ground that a significant expansion of the Coalition was possible.

Expansion options the Coalition – or another coordinating body – should consider include:

- A strong, but lean, permanent secretariat including RH health experts, to build a strong fact base as a platform for both advocacy and efficiency improvements
- An Executive Director to provide the organization with a visible and credible permanent international spokesperson, and internal organizational drive and momentum. [This, and the secretariat above, would require separate, committed funding for a period of say 3-5 years, to attract the right level of staff]
- Control of the donor “buffer fund” [see 2. above] to smooth out flows in international donor funds and make for more effective procurement. Particularly strong coordination with the UNFPA would be required here – the idea is not to set up a parallel procurement organisation, but to create a buffer fund with buy-in from all relevant parties.

- Creation of a strategic investment fund (minimum \$25m), to invest in strategic capability building (NOT day-to-day procurement) within the RH arena. Such investments might include:
 - i. Support for certification, technology transfer [e.g. Concept Foundation], quality control measures and other initiatives to expand the supplier base and speed up “trickle down” of technology
 - ii. Support for capability building at international and country level
 - iii. Support for strategic initiatives, e.g. regional procurement pooling initiatives

10 APPENDIX: LIST OF INTERVIEWEES

- David Smith, UNFPA, Denmark
- Jorg Maas, DSW, Germany
- Ann Janssens, UNFPA, Denmark
- Alan Bornbusch, USAID, US
- Elizabeth Lule, World Bank, US
- Sangeeta Raja, World Bank, US
- Tim Farley, WHO, Switzerland
- Carolyn Vogel, RH Supply Initiative, Belgium
- Terri Bartlett, PAI, US
- Joachim Oehler, CEO Concept Foundation, Thailand
- Dennis Blairman, DFID [Consultant], UK
- Dan Whittaker, DFID [Consultant], UK [IFF issues]
- Eli Alalauf, Wyeth, US
- Carolyn Hart, JSI, US
- Peter Hall, Independent Consultant [formerly WHO], Switzerland