

Reproductive health:  
The impact of public and private sector  
R&D on pharmaceutical products  
and future needs for R&D

Peter Hall, Morges, Switzerland

# Sexual and reproductive health: a newly neglected health issue

Family planning

Safe motherhood

Unsafe abortion

STD prevention and control

Sexual health

Gender issues

Harmful practices

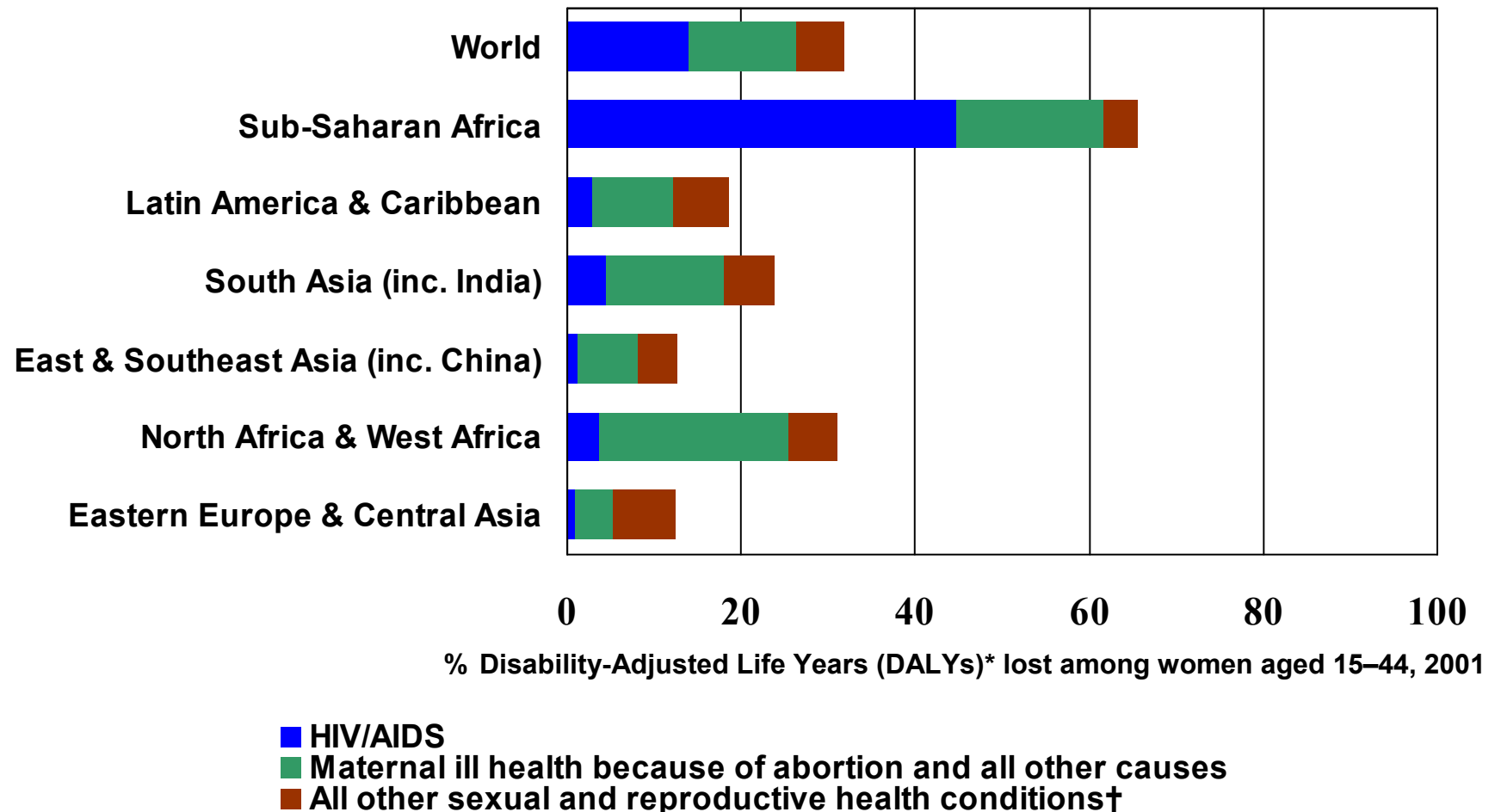
Violence against women

Adolescent and young people's health

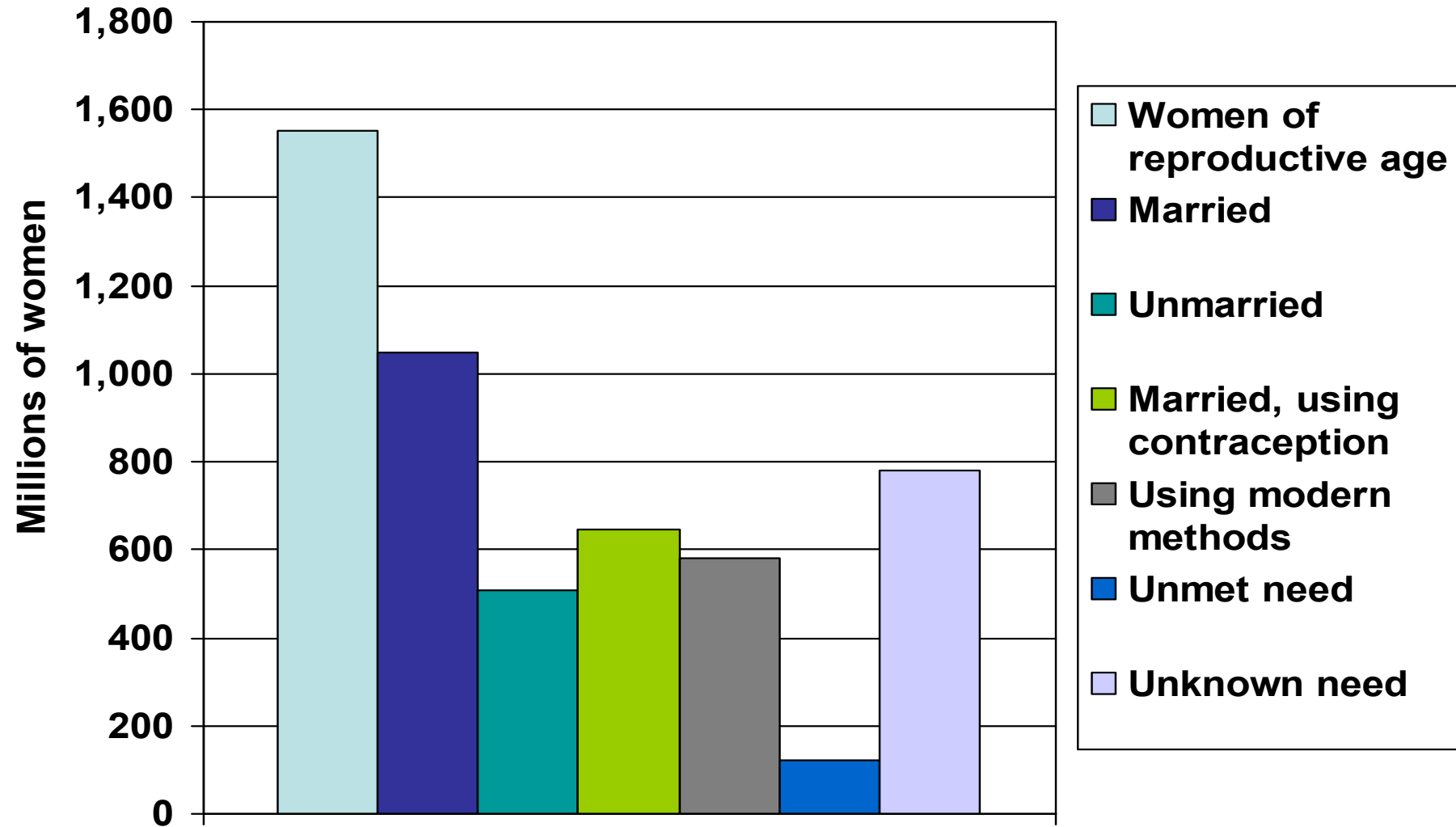
# Unsafe sex and contraception

- Unsafe sex - second highest risk factor to health contributing to 2.9 million deaths (5.2% of total) and 91.9 million DALYs (6.3% of total).
- Lack of contraception - 19<sup>th</sup> highest risk factor, contributing to 149,000 deaths (0.3% of total) and 8.8 million DALYs (0.6% of total). Global burden of disease attributable to unwanted births amounts to 4.6 million DALYs.

# Contribution of sexual and reproductive ill health to DALYs lost in women aged 15-44 by region



# Women of reproductive age and contraception



# Availability of products and needs

	Availability in developing countries	Products developed by	Research and other needs
Contraception	Lack of choice and access	Private & public sectors	Transfer of tech, licensing, health systems research
Drugs for medical abortion	Lack of access and affordability	Private (safety & efficacy by public sector)	Research needed but politically constrained
Microbicides	No product currently available	Public-private partnerships	Funding committed but long time lines

# Availability

	Developed countries	Developing countries and FSU
<b>Contraception</b>	male and female condoms, wide variety of oral contraceptives, injectable contraceptives, Cu-T and LNG-releasing IUD, vaginal ring, emergency contraception, contraceptive patches and implants	male condoms, Cu-T IUD, oral contraceptives, injectable contraceptives, emergency contraception
<b>MF/MS</b>	12 EU countries (all pre-1 May 04 countries, except Ireland, Italy and Portugal), New Zealand, Norway, Switzerland, USA	China, India, Israel, South Africa, Taiwan, Tunisia, VietNam, Azerbaijan, Georgia, Moldova, Russia, Ukraine, Uzbekistan,
<b>Microbicides</b>	17 candidates in clinical trial (five in	Phase III trials)

# Outcomes of public sector research

- Product development:  
Population Council - two implantable contraceptive devices releasing levonorgestrel, Norplant and Jadelle; and two IUDs, , the Cu-T 380A and the levonorgestrel-releasing IUD (Mirena). WHO/HRP - two once-a-month injectable contraceptives, Cyclofem and Mesigyna; and levonorgestrel and mifepristone emergency contraception.
- Clinical and epidemiological studies to investigate the safety and efficacy of products developed by others:  
WHO/HRP - Depo-Provera, Norplant and the Cu-T 380A.  
These studies have helped make products affordable in developing countries; allowed guidelines for optimal use to be developed; and informed both providers and users of the relative safety and use characteristics of these products.

# Outcomes of public sector research

- WHO/HRP and the Population Council played a major role in the use of mifepristone for medical abortion.
- CONRAD and FHI have assisted in making barrier methods available for the prevention of sexually-transmitted diseases and of pregnancy, such as the female condom; two intravaginal devices, Lea's Shield and FemCap; and new non-latex condoms for men.
- CONRAD, the Population Council, and WHO/HRP, are involved in the development of microbicides.

# Outcomes of private sector research

## Contraception:

- Oral and injectable contraceptives, IUDs, vaginal rings, patches.

## Drugs for medical abortion:

- Mifepristone and other anti-progestogens (research stopped for political reasons); prostaglandins, particularly misoprostol.

## Oral contraceptive prevalence and sales by region

Region	Married women of reproductive age (millions)	Oral contraceptive prevalence (%)	Estimated market sales, 2002 (\$ billion)
World	1,043.26	7.3	3.87
Less developed regions	873.22	5.8	1.21
USA	37.74	15.6	1.80
Europe (France, UK & Germany)	109.28 (25.68)	17.4 (39.8)	0.69 (0.47)

# Current issues in private sector and research

## Contraception:

- Increased willingness to undertake R&D on new products due to: a) need to obtain alternative revenue because of impact of generic manufacturers on branded oral contraceptives; and b) less pressure on liability issues.
- BUT little willingness to provide new products at affordable price to public sector in developing countries - even if product developed with public funds.

# Current issues in private sector and research

Drugs for medical abortion:

- Research stopped anti-progestogens for political reasons - donate tested compounds to public sector for continued development?

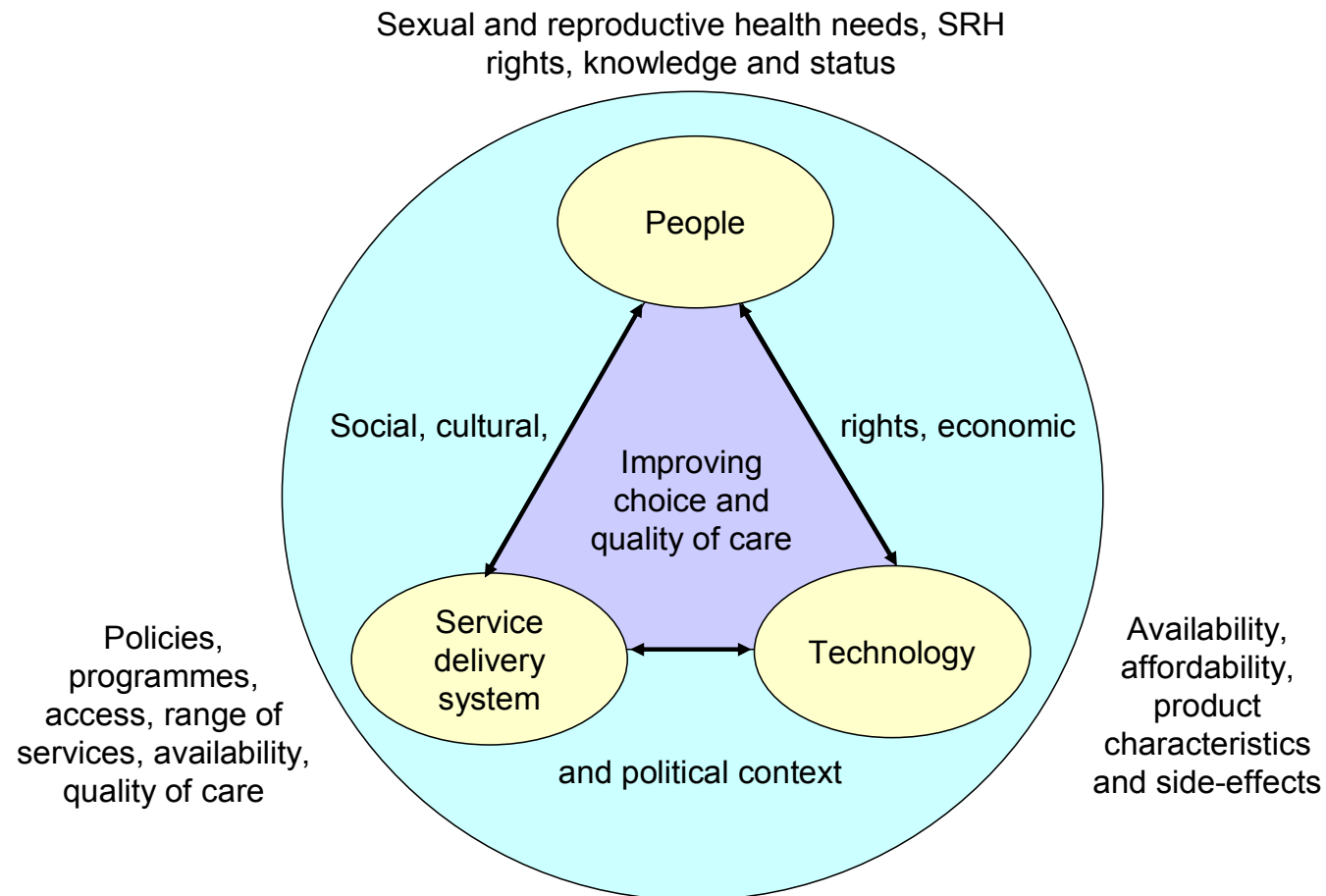
Microbicides:

- Research ongoing by small biopharmaceutical companies and Gilead with public and venture capital funding. Recently Tibotec and GSK have agreed with IPM to develop certain ARVs as microbicides.

# Obstacles to access in developing countries

- Availability of products
- Affordability
- Capacity of health delivery system:  
lack of procurement skills; inability to ensure products are delivered where they are needed; inadequate training of providers; lack of information and counselling

# A systems framework for the development and introduction of appropriate technology



# Research needs

## Product-related R&D needs:

- Microbicides and barrier methods to prevent infection by sexually-transmitted infections, including HIV.
- Male contraceptive methods.
- Identification and development of new moieties which affect sperm maturation or capacitation, prevent fertilization or implantation of the fertilized egg.
- Development of anti-progestogens that are as effective but cheaper than mifepristone for medical abortion.

## Other necessary research:

- Appropriate ways of addressing acceptability when developing new methods; and
- Operational research to ensure that technologies meet peoples needs and how they can be delivered through weak service delivery systems.

## The role of developing countries

- Many developing countries undertake university-based R&D. Few have the capacity to undertake, or have been involved in, drug or vaccine development, except for participation in externally run clinical trials.
- India and China both have a significant public sector R&D capacity, as, to a lesser extent, do Brazil and South Africa and can play a significant role in the R&D of products for reproductive health and infectious diseases.
- India and China need to harness the potential of their pharmaceutical industry to complement this the public sector R&D competence.

# Funding priorities

For short-term impact:

- Health systems research to ensure that technologies meet peoples needs and how they can be delivered through weak service delivery systems.
- Greater involvement of, and support to, developing country private sector manufacturers through: creation of network of qualified generic hormonal manufacturers meeting international GMP and quality standards; transfer of technology of certain products, eg, LNG-IUD; development of license agreements that protect public sector price of product.

# Funding priorities

For impact in next 5-10 years:

- Development of microbicides and barrier methods to prevent infection by sexually-transmitted infections, including HIV.
- Development of anti-progestogens that are as effective but cheaper than mifepristone for medical abortion.

For long-term impact:

- Identification and development of new moieties which affect sperm maturation or capacitation, prevent fertilization or implantation of the fertilized egg.

“Given the interrelationships between sexual and reproductive health and rights and the conditions that are addressed by the Millennium Development Goals (MDGs), (these goals) will not be achieved without much greater attention to sexual and reproductive health, including research in the biomedical, health systems, and social sciences domains and the translation of that research into policies and programmes.”

(Global Forum for Health Research, Mexico City, 2004)