Critical Issues Pertaining to the Gender Dimension of Biotechnology Policy

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1. Introduction

> 'Most of the benefits of science are unevenly distributed as a result of structural asymmetries between countries, regions, social groupings and between the sexes. As scientific knowledge becomes a crucial factor in the production of wealth, what distinguishes the poor (be it people or countries) from the rich is not only that they have fewer assets but that they are largely excluded from the creation and benefits of scientific knowledge.'
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> **Declaration on Science and the Use of Scientific Knowledge** World Conference on Science for the 21st Century a New Commitment, convened by UNESCO and the International Council for Science (ICSU) in Budapest, 1999.

Knowledge has long been seen as a major determinant of economic growth.[1] In the era of modern science, characterised by technical advances in biotechnology and information and communication technologies, it has been argued that knowledge has become the principal source of competitive advantage between and within countries. In the developing world, the development of national technical capacity has proved to be a key determinant of economic growth and poverty reduction.

Biotechnology is a knowledge-intensive area of science and technology which is held by many to offer very considerable promise for the improvement of the health, food security and environment of the world's poor. It encompasses an expanding series of enabling technologies (see Box 1) which have the potential to raise productivity across a range of industries including healthcare, agriculture, food, fine chemicals, pulp and paper, waste treatment and waste disposal.[2] Many of these developments are highly relevant to poverty reduction in the developing world. However, the political, economic and social context for the introduction of applications arising from biotechnology is not straightforward. Many groups including consumers, farmers, non-governmental organisations (NGOs), and others have opposed the introduction of some forms of the technology because of concerns about possible adverse effects on human health, the environment, biodiversity, and traditional farming practices, as well as privacy in healthcare and implications for ownership and sharing of benefits of genetic resources. National and international regulations have been introduced in many parts of the world which aim to assuage some of these concerns and ensure responsible use of the various technologies.

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[1] Commission on Intellectual Property Rights (2002) *Integrating intellectual property rights with development policy*. DFID, London.

[2] The definition of biotechnology devised by the OECD has been widely accepted. It defines biotechnology as "the application of scientific and engineering principles to the processing of materials by biological agents". OECD (1982) *Biotechnology: international trends and perspectives*. OECD, Paris.

Box 1. Principle technologies falling within biotechnology

Gene amplification DNA sequencing DNA synthesis Diagnostics kits DNA probes Protein synthesis Protein sequencing Protein crystallography Monoclonal antibodies Cell/tissue culture and engineering Purification/separation techniques Electrophoresis Transgenic plants and animals Gene therapy Gene antisense technology Biotransformation Enzyme engineering

Given its possible applications in heath and food security, biotechnology may raise specific issues that concern gender as well as biological differences between men and women. Gender refers to the distinct roles that men and women are assigned in any society.[3] The knowledge and experience acquired through these distinctive roles both within the household and the wider community leads men and women to have different needs and aspirations. Moreover, differences in their living and working conditions, the distinct nature of their tasks and their entitlement to resources exposes men and women to different health risks. The gender-specific nature of development has been increasingly highlighted by most organisations concerned with the promotion of development and human wellbeing. How then should the development of biotechnology policy take account of the gender dimension in the developing country context?

About 70% of the world's poor are estimated to be women and there is increasing evidence that improving their livelihoods and health can bring direct benefits to their families.[4] Research over the past 20 years has demonstrated that in the developing world, women play a central role in the production of food and the provision of healthcare, fuel, fodder, water, and income.[5] Applications in biotechnology are already well established in agriculture and food production in several parts of world.

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[3] Some of the biological differences are related to reproduction in that women are vulnerable to health risks associated with pregnancy and childbirth. Marked differences between the sexes also occur in the incidence and prognosis of a wide range of diseases. For example, women are more likely to be infected with HIV than men through sexual intercourse and are more susceptible to auto-immune diseases while men experience higher rates of heart disease. See, for example Doyal L (2002) *Sex, gender and the 10/90 gap in health research*. Briefing Document, the Global Forum for Health Research, Arusha, Tanzania, 12-15 November 2002.

[4] See for example: Consultative Group on International Agricultural Research (CGIAR) (1998) *Net worth: research with the rural women of Bangladesh*. CGIAR, Washington DC.

[5] UN Commission on Science and Technology for Development (1995) *Missing Links: Gender Equity in Science and Technology for Development,* IDRC, Ottawa, p. 29.

Although advances in healthcare in the form of approved biotechnology-based medicines and genetic tests are growing rather more slowly than predicted, R&D in these areas is heavily reliant on the use of biotechnology. The majority of these applications are confined to industrialised countries but they will inevitably spread to developing countries, particularly the more advanced such as India, Brazil, China, and South Africa in the next few years. Some have already arrived. In taking account of biotechnology, policy makers concerned with development will be faced with a range of critical issues relating to gender.

This paper surveys existing research on the impact of biotechnology in a number of important areas relevant to development policy and gender. Agriculture, health, traditional knowledge and biodiversity are highlighted. The paper concludes by making a series of recommendations about the need for further research.

2. Agriculture

2.1 Background

Many of the current needs of the developing world arise from a mix of political, economic and social problems. For example, with regard to food emergencies, the FAO has listed war and other forms of armed conflict as the exclusive causative factor in 10-15 developing countries during the last three years.[6] Problems also arise in some countries from worsening economic conditions for agriculture, resulting from the failure of national agricultural policies and of private organisations that could fill the void of state services. There are instances of poor governance, and of corruption. Such problems urgently need to be addressed. However, it is likely that even if and when they are resolved, substantial difficulties are still likely to remain for agriculture in developing countries, for example with regard to challenging climatic conditions. In this context, some have argued that biotechnology has a role to play.

Of the six billion people alive today, more than one billion live on less than the equivalent of $1 per day and a further two billion exist on less that $2 a day.[7] Close to a million are chronically undernourished and a high proportion of these are women and children.[8] In the developing countries, 11 million children under five die every year and malnourishment is estimated to cause at least half of these deaths.[9] Under-nourishment also causes widespread disability. Some 250 million children suffer partial or total blindness caused by deficiency of vitamin A and over 400 million women suffer from chronic anaemia caused by iron deficiency, leading to stillborn or underweight babies.[10]

With a projected world population of eight billion or more in 2020, the view is widely held that new approaches to agriculture and improved crop varieties will be needed to double the agricultural output necessary for food security. Projections by the FAO indicate that 680 million people, 12% of the developing world's population, could be 'food insecure' in 2010. Although food insecurity is expected to diminish in East and

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[6]FAO (2003) Foodcrops and shortages. Global information and early warning system on food and agriculture. Available: http://www.fao.org/giews/english/fs/fstoc.htm.
[7]World Bank (2002) Attacking poverty. World Development Report 2000/2001, Oxford University Press, New York.
[8]FAO (2001). *The state of food insecurity in the world 2001*. FAO, Rome.
[9]UNICEF (2001) *Progress since the world summit for children: a statistical review*. UNICEF, New York.
[10]Rush D (2000) Nutrition and maternal mortality in the developing world. *Am J of Clinical Nutrition* 72;212S-40S

South Asia and Latin America, it could accelerate substantially in sub-Saharan Africa, West Asia and North Africa. Some critics point out however, that despite increasing populations, over the past 35 years, *global* food production has outstripped growth in population by 16%. It is argued therefore that current global food production is sufficient to provide food for the world's population, if only inequalities in access to food were eliminated.

Since 1960, most people in the developing world have experienced very substantial increases in employment and access to food. This has largely been achieved through progress in enhancing crop yields through the agency of the Green Revolution. Despite these improvements, the unmet needs remain vast. Over 800 million remain underfed. In addition, continuing population growth is increasing these needs rapidly. Meanwhile the benefits of the Green Revolution, primarily in the form of yield improvements, are slowing and with them the growth in employment and the availability of cheap food staples which are needed to alleviate world hunger. The underlying causes, including groundwater exhaustion, micronutrient depletion, and low level pest build up, have proved very hard to manage through conventional plant breeding. Ultimately, many agree that a sustainable increase in the field performance of food staples depends on higher yield potentials.

However, alleviating hunger and malnutrition is not merely a question of increasing the availability of food. Food insecurity arises mainly because, even when food is available, the poor cannot afford to buy it. There is therefore a compelling case to improve staples production by raising food productivity on small farms in developing countries to provide employment income. The improvement of crops to resist insects, fungal and viral attacks, and water stress has considerable potential to improve employment income.

2.2 The potential of biotechnology

Many experts take the view that new routes to rapid yield enhancement will almost certainly involve the application of biotechnology-related approaches, namely the development of new genetically modified (GM) varieties[11], the use of embryo rescue techniques and tissue culture. Others disagree, pointing out that alternative approaches including conventional plant breeding, integrated pest management, expansion of areas under cultivation, increased fertiliser (inorganic and organic) and pesticide (synthetic and biopesticides) use offer safer and more appropriate means of raising yields. However, proponents of agricultural biotechnology doubt whether such strategies will suffice to revive the faltering pace of staples yield, and productive employment to the level required.[12] In this section, the potential applications of two leading forms of biotechnology are reviewed: tissue culture and genetic modification (GM). Consideration is then given to the arguments of others who dispute these claims.

Tissue culture: proponents of biotechnology argue that early applications of biotechnology in developing country agriculture tell us that successful developments

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[11]Genetic modification allows selected individual genes to be transferred from one organism into another, including genes from unrelated species. The technology can be used to promote a desirable crop character or to suppress an undesirable trait.

[12]Nuffield Council on Bioethics (1999) *Genetically modified crops: the ethical context*. Nuffield Council on Bioethics, London, UK.

are possible, that they will have an impact on local and possibly national economies and that employment income can be generated as a result. They cite by way of evidence the fact that tens of thousands of farmers in Africa, many of whom are women, are now growing food crops produced by tissue culture. This is a technique whereby many thousands of plants can be regenerated from the cells of a single plant so that they are genetically identical. This is the form of biotechnology that has, to date, provided the greatest benefits to poor farmers.[13] The mass propagation of disease-free superior plants through the application of tissue culture techniques is thought to be particularly useful for tropical crops such as sweet potato, cassava and banana which require vegetative propagation. The use of these techniques in banana has already improved food production and generated income for small-scale farmers, in Kenya.[14] In some crops, it is claimed that the mass production of clonally propagated material is likely to generate employment opportunities for women. For example, one study observed that women were preferentially recruited to undertake such propagation tasks, being more adept and patient that the men who were initially hired to do the work. However critics argue that the creation of plant varieties which are genetically uniform is unwise, as such crops may be highly vulnerable to mass infection by single strains of diseases and pests. Others point out that many crops such as the banana are already highly vulnerable to pathogens such as the Black Sigatoka fungus,[15] from which it can be inferred that the gains from growing GM-resistant plants will be greater than the possible losses from infection by other agents.

Tissue culture and hybridization: the use of tissue culture technology in combination with hybridization techniques has resulted in new rice varieties which are reported to be doubling yields in upland farms in Guinea. African scientists at the East African Rice Development Association (WARDA) have crossed Asian and African varieties, combining weed-competitiveness and drought-tolerance respectively into new hybrids whose low fertility has been increased by a technique known as embryo rescue.[16]

The technique of marker-aided selection allows plant breeding goals to be achieved more quickly though the identification of known markers on the crops' DNA which are known to be close to the gene of interest. Scientists believe that diseases such as maize streak virus – which is the most serious disease of maize in Africa – can be addressed more easily through the use of marker-aided selection to locate resistance genes and backcross them into local varieties.[17] The same approach is being applied to identify the genes associated with drought tolerance which have proved difficult to manipulate using conventional techniques. This form of biotechnology generally attracts less criticism from opponents because it extends the basic approach of conventional plant breeding.

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[13]Conway G (2002) Biotechnology and the war on poverty. In Seralgeldin, I and Persley G *Biotechnology and sustainable development: Voices of the South and North*, Proceedings of a Conference at the Bibliotheca Alexandrina, Alexandria, Egypt, March 16-20, 2002, CABI Publishers, Wallingford, Oxford.

[14] Wambugu F and Kiome R (2001) *The benefits of biotechnology for small-scale banana farmers in Kenya.* ISAAA Brief No. 22. International Service for the Acquisition of Agri-Biotech Applications, Ithaca, NY.

[15]Conway G (2003) From the green revolution to the biotechnology revolution: food for poor people in the 21st century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf.

[16]Jones M P (2002) Basic breeding strategies for high yielding rice varieties at WARDA. *Japanese Journal of Crop Science*, 67:133-136.

[17] Jeffers P (2001) Maize pathology research: Increasing maize productivity and sustainability in biologically stressed environments. International Maize and Wheat

Genetically modified crops: genetic modification (GM), one of the most controversial applications of biotechnology is perceived by many as being fundamentally distinct. Genetic modification allows selected individual genes to be transferred from one organism into another, including genes from unrelated species. The technology can be used to promote a desirable crop character or to suppress an undesirable trait. Many scientists believe that GM crops may offer the best route to higher yield potentials and resistance to stresses that conventional breeding alone has not yet managed to address. These include biotic stresses such as fungi and viruses together with abiotic stresses such as water and temperature stress, salt, iron, and aluminium. Despite an acute need for responses to these stresses, less than 10% of the 25,000 of the GM crop trials in 1997 took place in developing countries. Very little research is being directed towards the needs of the developing world largely because much of the investment derives form the private sector in industrialised countries.

The area devoted to growing transgenic crops has been steadily increasing since 1996. In 2001, 52.6 million hectares were harvested in 13 countries by 5.5 million farmers.[18] Ninety per cent of these farmers were small scale farmers in developing countries, the great majority being in China. In 2001, over 5 million poor farmers in China grew over 1.5 million hectares of Bt[19]cotton (i.e., insect-resistant cotton). The benefits that were derived from the use of these GM varieties were estimated to be a saving of $330 to $430 per hectare as a result of reduced inputs from pesticide applications and higher yields.[20] Bt cotton has also been grown in South Africa over a three year period and provides the only practical experience that African smallholder farmers have had with GM Crops. In KwaZulu Natal Province, 90% of the smallholder cotton producers grew Bt cotton in the 1999-2000 growing season. Increased yields, increased profits and significant reduction in pesticide use were achieved.[21]

Despite these benefits, the use of *Bt* cotton carries a number of risks. Concern has been expressed with regard to what some perceive as the undue influence of multinational agrochemical and seed companies. Corporate control of seed markets and ownership of technologies are important issues. For example, the company Monsanto has made 90% of the patent applications for genes relating to the improvement of cotton.[22] Currently just 10 companies control approximately 85% of the global agrochemical market.[23]

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[18] James C (2001) Global review of commercialized transgenic crops 2001. ISAAA Brief No 24, International Service for the Acquisition of Agri-Biotech Applications, Ithaca, NY.

[19] Cotton attracts a variety of insects and pests which farmers seek to control in order to prevent substantial losses in yield. A variety of compounds are used as insecticides or pesticides. One example is based on the naturally-occurring soil bacterium *Bacillus thuringiensis (Bt)*. *Bt* produces a protein which causes a toxic reaction in the guts of insects or pests when they digest the protein. While such a reaction does not occur in humans, it strongly affects cotton bollworm, maize borers or potato beetles, pests that devastate many crops worldwide. Researchers have produced *Bt* crop varieties in which genetic modification has been used to insert a gene that enables the plant to produce the protein that is toxic to the target insects.

[20] Huang J, Rozelle S, Pray C, and Wang Q (2002) Plant biotechnology in China, Science 295:674-677.

[21] Ismael Y R, Bennet R, and Morse S. (2001) Farm level impact of Bt cotton in South Africa. *Biotechnology and development monitor* 48:15-19.

[22] Genewatch (2001) Genetic engineering: A review of developments in 2000. Briefing No. 13. Tideswell, Derbyshire: Genewatch.

[23] AEBC (2002) Looking ahead - An AEBC horizon scan. London: Department of Trade and Industry. London.

Critics of *Bt* crops note the possibility that pests may eventually acquire resistance to such crops.[24] The cotton boll worm has been monitored for *Bt* resistance in China since 1997, and resistant mutants have not yet been reported.[25] However, resistance is likely to develop if the first generation of plants remains in cultivation for long enough. The use of *refuges* is one way of addressing this. To slow down the emergence of resistance, many regulatory schemes require that sufficient acreages of non-*Bt* crops are grown close to the *Bt* crops, so as to allow refuges for insects which can mate with potentially *Bt*-resistant insects. The establishment of refuges for *Bt* cotton farms in Australia is well regulated and has been successfully implemented.[26] However, while the monitoring of such refuges seems feasible in the case of large-scale commercial farmers, it may be considerably more difficult to assess whether the great number of small-scale farmers in developing countries are growing sufficient acreage of non-*Bt* crops. Other approaches to avoid pest resistance might be to use two or more *Bt* genes,[27] or to carry out research into new insecticidal genes that could eventually take the place of *Bt*.[28] However, so far *Bt* varieties have remained resistant for considerably longer periods than had initially been anticipated.

Transgenic technology is also being applied in research to produce GM food crops which have improved nutritional traits relevant to developing countries. The most notable example is that of 'Golden Rice'. Here, beta-carotene, the precursor of Vitamin A, has been introduced into the rice grain, a procedure which would not have been possible through the application of conventional plant breeding. This was achieved through GM technology which transferred a bacterial gene and two genes from the daffodil into the rice grain, which resulted in the synthesis of nutritionally significant levels of beta-carotene in the grain.[29] This variety of rice has now been released to several breeders in several Asian countries so that the genes can be transferred into local rice varieties. Vitamin A deficiency affects over 200 million people and over 14 million children suffer permanent damage to their sight as a consequence.

Opponents, however, have questioned whether the amount of ß-carotene in Golden Rice would actually be sufficient to make a significant contribution to improved vitamin uptake.[30] Also, the bio-availability of ß-carotene from Golden Rice is unknown, which means that it is not yet clear to what extent the human body can make use of ß-carotene when it is eaten in Golden Rice. Some point out that to make

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[24] Wu K (2002) Agricultural and biological factors impacting on the long term effectiveness of Bt cotton, in *Conference on Resistance Management for Bt Crops in China: Economic and Biological Considerations*. April 28, 2002. Raleigh, NC: North Carolina State University.

[25] Jim Peacock, (2003) in *Towards sustainable agriculture for developing countries: Options from life sciences and biotechnologies*. 30-31 January 2003. Brussels.

[26] Jim Peacock, (2003) in *Towards sustainable agriculture for developing countries: options from life sciences and biotechnologies*. 30-31 January 2003. Brussels; Gould F (1998) Sustainability of transgenic insecticidal cultivars: Integrating pest genetics and ecology, ***Ann Rev Entomol 4***3: 701-26.

[27] Bowen *D et al*. (1998) Insecticidal toxins from the bacterium Photorhabdus luminescens, *Science* 280: 2129-32. The transfer of genes via pollen to or from a cultivated crop to other crop plants, wild relatives, other plant species or other organisms.

[28] Nester E *et al*. (2002) 100 years of Bacillus Thuringiensis: a critical scientific assessment, in *100 years of bacillis thuringiensis, a paradigm for producing transgenic organisms: a critical scientific assessment*. November 16-18. American Academy of Microbiology: Ithaca, NY; Shiva V (27 Mar 2002) Soil Association's International Sir Albert Howard Memorial Lecture.

[29] Ye X, Salim A B, Kloti A, Zhang J, Lucca P, Beyer P and Potrykus I (2000) Engineering the pro-vitamin A (beta-carotene) biosynthetic pathway into rice endosperm*, Science 287:393-305.*

[30]Greenpeace (2001) Vitamin A: Natural sources vs 'Golden Rice'. Available: http://archive.greenpeace.org/~geneng/reports/food/VitaAvs.PDF. Accessed on: 20 May 2003.

use of the vitamin, an adequate intake of fat is needed. Others claim that the yellow colour of the rice may not be compatible with cultural preferences, and that Golden Rice will therefore be rejected.[31]

There are several other developments underway which proponents of the technology consider likely to benefit agriculture in the Third World. For example, one of the most important potential advances for biotechnology is considered to be the introduction of apomixis into crop plants. This procedure would enable plant reproduction to be achieved without sexual reproduction, with the results that the progeny (seeds) would be genetically identical to the mother plant. The advantage here is that farmers would be able to select the seeds of crop plants which had beneficial characteristics for subsequent planting. These seeds would breed true and allow the creation of several locally-adapted, superior varieties.

Predictions that genetic manipulation of plant genes in cultured plant cells would lead to substitutions of raw commodities exported from developing countries have raised concerns over the past 10-15 years. Examples cited as likely candidates included vanilla and other food ingredients provided form natural sources. Concerns have been voiced that such developments, already seen in the substitution of fructose syrup[32] for sugar cane during the 1990s, would be very damaging for the economies of exporting countries. As yet however, very few applications appear to have commercial potential.

2.3 Barriers to the application of agricultural biotechnology

Despite the promise that biotechnology is considered to have in many quarters, there are formidable barriers to its safe and effective application for improving the productivity of small farmers in developing countries. Four are particularly important. They are: uncertainty about the long term effects of GM technology on health and the environment; incomplete or absent regulation for the containment and release of genetically modified organisms (GMOs); the impact of EU regulation on exports from developing countries; and insufficient funding for R&D in crops relevant to developing countries. These are each considered below.

Uncertainty about the long term effects on health and the environment: any deliberation about the benefits of a technology clearly also needs to address likely risks. Some commentators take the view that possible implications of GM crops for the health of consumers have not yet been sufficiently examined even in the developed world. In a common, but controversial, interpretation of what is known as the *precautionary principle*, critics argue that GM crops should not be used anywhere unless there is a guarantee that no risk will arise.[33] There is some concern that the technique of genetic modification poses risks to human health that differ from those implied by other forms of plant breeding. It may be the case that the intended effect of conferring a particular trait by insertion of specific gene sequences brings with it unintended effects, which could result from, for example, disruptions in existing

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[31]Five Year Freeze (2002) Feeding or fooling the world? London: Five Year Freeze; Koechlin F (2000) The 'Golden Rice' - a big illusion? Third World Network. Available: http://www.twnside.org.sg/title/rice.htm.

[32]Tombs M P (1990) *Biotechnology in the food industry,* Open University Press, UK, p.53.

[33]British Medical Association (1999) The impact of genetic modification on agriculture, food and health: an interim statement. London: BMA. Oxfam (1999) Genetically modified crops, world trade and food security: Oxfam Great Britain position paper. Oxford: Oxfam

genes in the modified material.[34] Proponents of GM technology reply that unintended effects are not specific to the use of genetic modification. They are often encountered in conventional breeding, and in particular in the case of mutation breeding.[35]

Other concerns relate to the fact that some forms of genetic modification involve genetic material that is foreign to the organism which is modified. Often, viral sequences are used to facilitate the insertion of a specific gene sequence. For example, the cauliflower mosaic plant virus is used as a *promoter*, which means that a short sequence of the genetic material of the virus is inserted together with a particular gene, to facilitate its expression (this function is also known as 'switching on' the gene).[36] Some people regard this as a threshold that should not be breached, because in their view, an organism has been created that has not previously existed in nature. Such concerns are even stronger where genes are inserted from another species.

Similar demands are made with regard to the impact of GM crops on the environment. Critics point to the risk of potentially irreversible effects on *biodiversity*, which refers to the variety of plants, animals and other organisms that exist in nature. Genetic material from GM crops could be transferred to other plants and organisms leading to unpredictable transformations. Critics therefore argue that unless there is certainty about the absence of such risks, neither field trials nor commercial planting should take place. With regard to the use of GM crops in developing countries, this concern is perceived to be of particular importance. Many regions are the *centre of origin* of modern crops, such as cotton or maize. These regions usually comprise a considerable variety of crops and wild relatives, which might be irreversibly altered by the transfer of genetic material from GM crops.[37] Critics also assert that encouraging the adoption of GM crops by developing countries demonstrates a lack of sensitivity to their vulnerable position. Many such countries urgently need to address issues of food security and may be tempted to hastily adopt a technology that could pose severe risks.[38]

Particular controversies surround the use of GM crops such as Golden Rice, which can provide increased levels of crucially important micronutrients – in this case vitamin A. Although many consider that Golden Rice could make a valuable contribution where other means of obtaining sufficient levels of vitamin A are more difficult to provide, it is not yet clear how effective the approach will be. It is essential that reliable empirical data from nutritional and bioavailability studies be obtained as a priority. In addition, the cost-effectiveness, risks, and practicality of such approaches in comparison to other means of addressing deficiency of micronutrients need to be evaluated.

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[34]See FAO and WHO (2000) Safety aspects of genetically modified foods of plant origin. Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology World Health Organization, Geneva, Switzerland 29 May – 2 June 2000. Geneva: WHO, See Section 4.3 for a more extensive discussion of this issue. See also Royal Society (2002) Genetically modified plants for food use and human health - an update. London: Royal Society. p. 6.

[35]The Royal Society notes two examples: celery and potatoes. (Royal Society (2002) Genetically modified plants for food use and human health - an update. London: Royal Society. p. 6.)

[36]Royal Society (2002) Genetically modified plants for food use and human health - an update. London: Royal Society. p. 8; Independent Science Panel (2003) The case for a GM-free sustainable world. London: ISP.

[37]FAO electronic forum on biotechnology in food and agriculture (2002) Background paper to the 7th conference, 31 May -6 July 2002. FAO. Available: http://www.fao.org/biotech/C7doc.htm.

[38]Independent Science Panel (2003) The case for a GM-free sustainable world. London: ISP

The impact of EU regulation: the freedom of choice of farmers in developing countries to adopt GM crops is restricted by the agricultural policy of the EU. Consumers in the EU have resisted attempts to introduce GM crops and GM food and as a result there has been a *de facto* moratorium across the region on both. At the same time stringent regulation to ensure that GM food in the future is thoroughly labelled and traceable to the original farm is being implemented across all member states. Developing countries might be reluctant to use GM crops because of fears of jeopardising potential export markets. They may also not be able to provide the necessary infrastructure to comply with the EU requirements for traceability and labelling. If developing countries decide to use GM crops for domestic use only, problems may arise for exports if GM crops and non-GM crops cannot be easily separated. Small amounts of GM produce could mix with non-GM produce that are stored for export. Since EU regulators currently suggest a low threshold for the labelling of produce as 'GM' (from 0.5 or 0.9 % presence of genetically modified material), non-GM produce might have to be labelled as GM. If current attitudes among EU policy makers and consumers prevails, this would result in a considerable disadvantage to exports from developing countries on the European market. Policy makers in developing countries are therefore faced with very difficult choices. If a national policy that allows the responsible use of GM crops for domestic use is adopted, it might well be perceived as promoting unsafe foods, and, in addition, could result in the loss of EU export markets.

Direction of the research agenda: There are also concerns about how and by whom GM crops are developed and delivered. The substantial benefits which accrued in developing countries from the Green Revolution were largely the result of research undertaken in the public sector. But most research on GM crops is being undertaken by a relatively small number of private companies. Although there is significant work undertaken in the public sector, many of those who fear the use of GM crops worry that research will be directed primarily towards commercial users in developed countries. The concern is that only large-scale industrial farmers will benefit, while the needs of small-scale, resource-poor farmers in developing countries will be neglected.[39]

International organisations (such as the CGIAR), some national organisations and foundations such as the Rockefeller are undertaking research on agriculture relevant to developing countries and particularly, small farmers. However, sole reliance on the public sector to undertake the necessary research will not be sufficient. For example, research which seeks to apply GM to smallholder food staples will not be adequately addressed with the current balance of research incentives and institutions. The long-standing neglect of these staples by researchers adds to the problem. For example, little research has been undertaken on yams because they are thought to be unpromising. They therefore remain so. Research capacity in the majority of developing countries is very limited. For example, the share of funds for global R%D expended in sub-Saharan Africa was only 0.4% in 1996/97.[40]

Policy makers seeking to transfer GM crop research to help defeat poverty need to consult not only with researchers but also with the poor farmers, many of whom are

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[39] Five Year Freeze (2002) Feeding or fooling the world? London: Five Year Freeze.
[40]UNESCO (2001) *The state of science and technology in the world 1996-1197.* UNESCO Unit for Statistics, Canada.

women. Swaminathan (2001) has suggested that pre-breeding centres in the developing world should be established to engage in the production of GM crops which combine novel genetic combinations with location-specific crop varieties through participatory breeding with local farmers.[41] Some initiatives such as the DGIS programme funded by the Netherlands government has specifically been devised to direct research on agricultural biotechnology relevant to small-scale farmers through the involvement of farmers themselves. The programme has also been sensitive to its strengths and weaknesses.[42] However, a recent study by the World Bank suggests that poor people do not want merely to be consulted about or participate in, the programmes of external sponsors. The majority want external funding to be directed to the development capacity in indigenous organisations which advance their own interests and ideas.[43] Major investments are needed to ensure that biotechnology is directed towards the needs of those developing countries that would be willing to deploy new crop varieties and technologies. Although the private sector can make a contribution, (and some companies already have), the major lead must come from governments of developed countries and international organisations. There is also scope for the formation of the public-private partnerships that have been established for neglected diseases.

Opposition from consumers to the adoption of GM crops and the use of GM foodstuffs has not been confined to developed countries. In India there has been vociferous opposition to GM crops from some quarters, namely NGOs and some farmers. Nevertheless the Indian government has recently approved GM cotton which has been modified to resist insect pests. In Africa, the Government of Zambia has recently rejected food aid in the form of GM maize. One of the reasons for the rejection was the concern that local farmers might use the maize grains for seed leading to the possible presence of GM material in maize exports in subsequent years. There was also concern about possible long term effects of the food on health. Zambians eat maize often three times a day. Although the fact that no adverse effects have been reported in the US from eating GM food over the past eight years, US citizens do not generally eat large quantities at a time and there were concerns that the US experience could not be readily applied to the Zambian context.

The adverse reaction to GM food prevalent in Europe has made the possible adoption of GM crops by some developing countries more complex. Countries such as Brazil which export agricultural products to Europe are keen, on the one hand, to retain the GM free status of their exports; but on the other, to introduce the technology where it is likely to be beneficial – such as raising productivity on farms which serve the domestic or US market.

Predicting whether biotechnology is likely to have a significant impact on global food security as a whole is difficult. The large scale adoption of non-food GM crops in China is somewhat exceptional. It is possible that the initial cultivation of Bt cotton in India will expand rapidly and be followed by the introduction of other GM crops, but

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[41]Swaminathan M S (2001) Ecotechnology :managing global and local challenges of food insecurity and poverty . *Development*, The Society for International Development, Sage Publications, 1011-6370 (200112) 44:4;17-22 020143

[42]Commandeur P (1997) The DGIS Special Programme on Biotechnology. *Biotechnology and Development Monitor*, 31:611.

[43]Narayan D, Chambers R, Shah M K and Petesch P (2000) *Voices of the poor: Crying out for change.* World Bank, Washington DC.

the prospect of such developments remains uncertain. At the moment, only non-food crops are being grown on a significant scale in the developing world. In Africa, where increases in yield are urgently required, rapid uptake seems unlikely unless much greater effort is made internationally. On balance, it does seem probable that there may be localised applications in the short to medium term. However, as Conway has pointed out, the question of whether it is wiser to draw on biotechnological advances in the context of contemporary plant breeding to improve agriculture, rather than achieve this aim by way of more effective use of resources and alternative methods, is hardly ever a question of either/or'. It is mostly a situation of 'both/and': 'the best technology is the one that will safely get the job done in the simplest and least expensive way possible'.[44] Thus, while in some cases organic farming has the potential to improve substantially agricultural practices of small-scale, resource-poor farmers, it seems highly unlikely that it can solve all the problems.[45]

Over the past two decades, policy makers, economists and social scientists have contributed to the idea that sustainable development[46] should be a goal of development efforts. The realisation of economic growth, coupled with pressure from population growth has led to a serious decline in natural resources and degradation of the environment, particularly in developing countries. One goal of sustainable development is the maintenance of genetic diversity and biological productivity.

2.4 The question of gender and agricultural biotechnology

Although there are substantial literatures on the implications of the introduction of, on the one hand, agricultural biotechnology to developing countries, and on the other, gender and agriculture, relatively little attention has been given to the intersection of the two. The previous section has reviewed developments in biotechnology relevant to agriculture in poor countries. Can some of the findings from gender studies in agriculture and development policy be applied to the case of biotechnology? Women produce nearly 80% of all food crops in sub-Saharan Africa, 70-80% in South Asia and 50% in Latin America and the Caribbean.[47] They also produce at least 50% of the labour required for cash-crop production and contribute significantly to animal husbandry.

Recognition of the significant role of women in agriculture has led to donors sponsoring a considerable amount of research over the past 20 years on women farmers in sub-Saharan Africa, Latin America and East Asia, although other areas in West Africa and West Asia have received much less attention.[48] However, many

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[44]Conway G (2003) From the green revolution to the biotechnology revolution: Food for poor people in the 21st century. Speech at the Woodrow Wilson International Center for Scholars Director's Forum. March 12, 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf.

[45]Pretty *et al*. found improvements in food production occurring through one or more of four mechanisms: intensification of a single component of a farm system; addition of a new productive element to a farm system; better use of water and land; improvements in per hectare yields of staples through introduction of new regenerative elements into farm systems and new locally appropriate crop varieties and animal breeds. (Pretty J, Morison JIL and Hine RE. 2003. Reducing food poverty by increasing agricultural sustainability in developing countries. *Agric. Ecosys. Environ.* 95(1), 217-234.)

[46]Defined by the Brundtland Commission (1987) as the ability of society to meet the needs of the present generations without compromising the ability of future generations to meet their own needs.

[47]See Jacobson J (1992) Gender bias: roadblock to sustainable development. Paper 110, Worldwatch Institute, Washington DC and Karl M (1998) Enrolment of women in higher agricultural education : case studies from Cote d'Ivoire, Jordan, Nigeria, Philippines and the Caribbean (Part 1). www.fao.org

[48]El- Fattel L (1996) *Women in agriculture in West Africa: a review of the literature*. CGIAR Gender Programme, Working Paper No 10, CGIAR, Washington DC.

projects which aimed to take gender into account have made less progress than anticipated because they failed to appreciate the complexity of women's roles in households and communities. Some lessons have been learned as a result of this research and the fact that 'gender matters' is widely accepted. Despite these advances, women still show relatively low rate of adoption of new crop varieties and improved management systems. When new technologies have been introduced into communities in developing countries, an inbuilt gender bias towards the employment of men has sometimes led to further marginalisation of women.[49] Even basic factors determining supply and demand for female labour in poor rural communities are not well understood.[50]

Doss draws three conclusions from a comprehensive review of the relevant literature.[51] First, it is very difficult *a priori* to predict the impact that the introduction of a new agricultural technology will have on patterns of labour, land and resource allocation between men and women. Because the impact will often be very different, it is crucial to understand these factors in the setting in which a new technology is being introduced. Secondly, agricultural researchers need to continue to involve farmers in the development of new varieties or technologies. Thirdly, better baseline studies of households and communities, including information about land allocation, labour and the welfare of individual household members are needed before new agricultural technologies are introduced. All three conclusions would appear to be particularly pertinent to the introduction of GM crops in particular.

3. Women's indigenous knowledge, biodiversity and intellectual property rights

3.1 Background

Human societies have always produced, refined and passed on knowledge from generation to generation. This indigenous or traditional knowledge has an important role in cultural identity and is generated by communities to allow them to adapt to their specific agroecological and socioeconomic environment.[52] In the developing world, traditional knowledge is essential to the food security and health of millions of people.[53] Full recognition of local knowledge systems is considered to be central to the issue of sustainable and equitable development. Traditional knowledge is fundamentally different from knowledge arising from research in modern science and technology in that it is generated and managed by the users of the knowledge. Not surprisingly, local knowledge and skills held by women often differ from those held by men. Several such examples have been highlighted in previous studies.[54] The use

[49]For example see Shaleesah A and Stanley V A (2000) Involvement of rural women in aquaculture: an innovative approach. *The ICLARM Quarterley*, 23 (3):13-17 July-September 2000, which discusses the introduction of aqualculture (fish breeding) into rural communities in India

[50]See for example Rahmen S (2000) Womens' employment in rural Bangladesh: composition, determinants, scope. *Journal of rural studies,* 16:497-507.

[51]Doss C (2001) Designing African technology for African women farmers: Lessons from 25 years of experience. *World development,* 29:2075-2095.

[52]The terms' indigenous knowledge' and 'traditional knowledge' are used interchangeably.

[53]Commission on Intellectual Property Rights (2002). Integrating intellectual property rights and development policy, DFID, London.

[54]Appleton H etal. (1995) Claiming and using indigenous knowledge. In 'Missing links: gender equity in science and technology for development'. UN Commission for Science and Technology for Development. International Development Research Centre/UNIFEM.

and protection of this form of knowledge is often of particular interest when considered from the perspective of gender.

3.2 The gender dimension

Women in developing countries frequently rely on traditional knowledge to provide healthcare based on medicines derived from plants and other materials. In this section two important uses of indigenous knowledge are considered. These are: first, the use of biodiversity in the development of plant varieties and second, traditional medicines and their use. The consideration of indigenous knowledge is particularly relevant to gender for two reasons. As already noted, many small farmers in the developing world are women and the development of local varieties and use of genetic resources is therefore especially relevant to this study. Secondly, women are often responsible for healthcare in local communities and will therefore tend to play an important role in the development and use of traditional medicines. Women are also responsible for routinely undertaking ethno-veterinary care of livestock using traditional preparations based on a variety of locally plant resources in a number of countries, including Morocco.[55]

In the case of knowledge about plants, women have long played a key role in the sustainable use of biological resources,. However their contribution has been relatively unnoticed by researchers. Shiva and Dankelman (1992) show that women in Dehra Dun, India were able to identify over 145 species of trees in the locality. In Sudan as many as 60 fermented food products prepared by women form an important part of people's diet (Diar, 1991). In Tonga, women have adapted food production techniques to use 47 indigenous plants whose leaves are used for relish and over 100 tree species with edible parts. Traditional processes are also important: for example in south western Nigeria, cassava processed into gari is the most important staple food. In a study by Luery et al. (1992), the traditional gari processing was found to be more efficient than mechanised systems in terms of cost, returns, and relevance to the needs of the village economy. However, it has been observed that the introduction of new technologies is reducing the traditional sphere of influence that women have exercised in growing and using plants in rural communities in many developing countries. Shiva and Dankelman suggest that the role of such women is being reduced to that of labourer as they lose control over production and access to biological resources. Few programmes in research have studied women's indigenous knowledge in the science and technology area: women are often viewed as *recipients* of knowledge rather than *generators* of knowledge.

Rights to indigenous knowledge

It is only recently that the international community has begun to recognise the importance of indigenous knowledge. This has largely arisen because of the recognition of the need to promote, preserve and protect its specialised nature which was in part a response to the international attention given to a number of cases concerning indigenous knowledge. These cases have generally arisen in the context of "biopiracy" which is defined as "the appropriation of the knowledge and genetic resources of farming and indigenous communities by individuals or institutions seeking exclusive monopoly control (usually patents or plant breeders' rights) over

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[55]Davis D (1996) Gender, indigenous knowledge and pastoral resource use in Morocco. *Geog. Review*, 86: 284-288.

these resources and knowledge".[56] Some genetic resources are seen as potentially valuable sources of new medicines. In terms of international governance, the concept of Farmers' Rights to local varieties of crops developed by them was introduced by the Food and Agricultural Organisation (FAO) into its International Undertaking on Plant Genetic Resources. In 1992, the Convention on Biological Diversity (CBD) was established to promote and preserve indigenous knowledge particularly in the context of genetic resources.[57] Although these two international instruments have been advanced over two decades, mechanisms for the protection of traditional knowledge have not yet been agreed.

Intellectual property rights and traditional knowledge
Intellectual property rights lie at the heart of much of the discussion and debate about traditional knowledge. Issues have focussed on questions relating to ownership and access to genetic resources and the associated knowledge and the sharing of benefits arising from utilisation. Because of the prominence of a number of cases of 'biopiracy', the issue of indigenous knowledge has been at the forefront of the general debate surrounding intellectual property and development policy. In the next section, the nature of indigenous knowledge and the purpose of its protection is discussed, together with three illustrative cases.

3.2 A definition

Indigenous or traditional knowledge is difficult to define and it is therefore not surprising that there is no widely acceptable definition. As has been observed, while much indigenous knowledge is old, it is continually revised and refined. The groups that hold indigenous knowledge are very diverse: they may be individuals, groups or communities; they may be indigenous or descendants of later settlers. The knowledge may take a diversity of forms: medical treatments and practices, agricultural technologies and techniques, literary or artistic works.

The World Intellectual Property Organisation (WIPO) has identified the following concerns of those who hold traditional (indigenous) knowledge:

- concerns about the loss of traditional knowledge and the reluctance of younger members of communities to carry forward traditional practices;
- concern about the lack of respect for traditional knowledge and the holders;
- concern about misappropriation of traditional knowledge, particularly where there are no arrangements for benefit sharing;
- lack of recognition of the need to preserve and promote the further use of traditional knowledge.[58]

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[56] Definition from The Action Group on Erosion, Technology and Concentration (ETC Group).
[57] Article 8J of CBD provides that "Members should respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices". Source: http://www.biodiv.org/convention/articles.asp
[58] WIPO (1999) *"Intellectual property needs and expectations of traditional knowledge holders",* WIPO Report on Fact-Finding Missions 1998-1999, WIPO, Geneva (Publication Number 768E).
Source: http://www.wipo.int/globalissues/tk/report/final/index.html

3.3 Intellectual property rights: case studies

Of the controversial cases concerning appropriation of indigenous knowledge and genetic resources, turmeric, neem and Ayahuasca are amongst the most instructive. In the example of turmeric which is used as a spice to flavour Indian cooking and has properties as an effective ingredient in medicines, cosmetics and a colour dye, two Indian nationals in 1995 in the US were granted a US patent on the use of turmeric in wound healing.[59] The Indian Council of Scientific and Industrial Research (CSIR) asked the US Patent and Trademark Office (USPTO) to re-examine the patent, arguing that turmeric had been used for thousands of years for healing wounds and rashes and that its medicinal use was therefore not novel. The USPTO upheld the CSIR objections and revoked the patent. This was a landmark case, as it was the first time that a patent on indigenous knowledge of a developing country had been challenged successfully. In a similar case involving the neem tree which has long been used as a natural medicine, pesticide and fertilizer, the European Patent Office (EPO) granted a European patent to a US company for use of neem as a fungicide.[60] A group of international NGOs and Indian farmers filed a legal opposition against the patent arguing that the fungicidal effect of neem had been known for centuries. The patent was revoked by the EPO in 2000. In the third case, shamans of indigenous tribes in the Amazon Basin used the bark of the species Ayahuasca to produce the ceremonial drink with healing properties. A US citizen patented an alleged variety of the species which he claimed as a new and distinct form.[61] The Coordinating Body of Indigenous Organizations of the Amazon Basin (COICA), an organisation which represented over 400 indigenous groups, protested that the patent be revoked because of the sacred nature of the species. In 1999, the USPTO rejected the patent claim, but it was subsequently overturned.

There is wide agreement that the custodians of traditional knowledge should receive fair compensation if it leads to commercial gain. There is also agreement that steps should be taken to conserve traditional knowledge, to continue to conserve the environment and biodiversity, and further that sustainable agricultural practices have an important role to play in development. Above all, there has been considerable support for the prevention of the appropriation of traditional knowledge and the avoidance of biopiracy. However, it has been pointed out that a single solution is unlikely to be able to meet this wide range of concerns and objectives. Several bodies including WIPO, the CBD, UNCTAD and WTO are currently discussing the protection of traditional knowledge. It is unlikely that a single one body such as WIPO will have the capacity to deal with all aspects of traditional knowledge and that a multiplicity of measures will be needed to protect, preserve and promote traditional knowledge.

Recommendations from the Commission on Intellectual Property Rights (CIPR)[62] include the establishment of digital libraries of traditional knowledge for use in patent offices to take account of the unwritten nature of much traditional knowledge and national developments relating to the patent system. Given that much traditional knowledge relating to health and agriculture will reside with women, there may be a

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[59]US patent no. 5,401,504.

[60]Patent no. 0436257 was granted to the US Corporation W.R. Grace and the USDA.

[61]US Plant Patent 5,751 granted in June 1986 to Loren Miller.

[62]Commission on Intellectual Property Rights (2002). Integrating intellectual property rights and development policy, DFID, London.

need to assess their role in the transfer of non-codified knowledge into codified form, to afford protection from potential foreign inventors. Recognition of the need to promote awareness of the value of microbial genetic resources, animals and plants was highlighted at the Regional UNESCO Forum for Women, Science and Technology in Latin America and the Caribbean.[63]

A related set of issues concern access and benefit sharing of indigenous knowledge. The CBD seeks to promote the conservation of biodiversity and the equitable sharing of benefits arising from the utilisation of genetic resources.[64] Guidelines on access and benefit sharing for countries drafting national legislation have now been agreed by the Governing Body of the CBD[65], but there are practical and conceptual difficulties in putting benefit sharing into practice. For example, the resources in question are frequently not owned by any particular group, or they may sometimes be distributed across many countries so that benefit-sharing arrangements may be impracticable. One mechanism to protect the use of resources relating to traditional knowledge of developing countries would be for all countries to revise their legislation to provide for the adoption of the obligatory disclosure of information in patents of the geographical source of genetic resources on which inventions are based.[66] The importance of Geographical Indications was highlighted in the Basmati case, a variety of rice from India and Pakistan.[67] Because geographical indications may be of particular importance to some developing countries who may have comparative advantage in agricultural products, and constitute a category of intellectual property alone which extends beyond the protection of traditional knowledge, there is a need to access the best ways of strengthening forms of protection currently offered.

How important are genetic resources in the enterprise of biotechnology today? Particular attention was given to the potential of biodiversity to provide chemical libraries for the pharmaceutical industry and novel genes for the seed industry in the early 1990s. Increased awareness of the need to protect sovereign rights contributed to the development of international agreements. In general, it is fair to conclude that the advent of combinatorial chemistry, whereby vast chemical libraries can be synthesised, has diminished commercial interest in the screening of natural compounds found in biodiversity. However, genetic resources in the form of germ plasm for plant breeding are likely to remain of critical importance to the agro-biotechnological industry. Control over the access to germ plasm of major crops such as rice and maize and protection of key constituent genes remains controversial.

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[63]UNESCO (1999) Forum for women, science and technology in Latin America. In UNESCO (1999) Women in science and technology – towards a new development? UNESCO, Paris.

[64]CBD Article 1.

[65]Bonn guidelines on access to genetic resources and fair and equitable sharing of the benefits arising out of their utilisation. Source: http://www.biodiv.org/decisions/default.asp?lg=0&m=cop-06&d=24

[66]Commission on Intellectual Property Rights (2002). Integrating intellectual property rights and development policy, DFID, London, p.87.

[67]The US company RiceTec was granted a US patent (US5663484) relating to rice varieties, some of which had characteristics similar to Basmati lines. Concerned about the potential effect on exports, India requested a re-examination of this patent in 2000. As a result, a number of claims covering the Basmati varieties were withdrawn.

4. Biotechnology and Health

4.1 Background

Conventional health technology has greatly reduced the burden of disease and increased life expectancy in developing countries. Between 1960 and 1995, life expectancy in the low income countries improved by 22 years.[68] Oral re-hydration, vaccines for smallpox and polio, and vitamin A supplementation have all contributed to dramatically reduce mortality and morbidity in millions of children. Despite these achievements, the burden of preventable disease in the developing world remains very high. In 1998, almost one third of deaths in low and middle income countries were due to preventable or treatable communicable diseases, maternal and perinatal conditions and nutritional deficiencies. The Global Alliance on Vaccines and Immunization (GAVI) estimates that worldwide there are 2.9 million deaths each year from diseases for which effective vaccines exist. The great majority of these deaths occur in the developing world.[69] Tuberculosis infects almost one third of the earth's population. Each year, nearly 10 million new cases and two million deaths result. Two billion people live at risk of malaria. As yet, there are neither conventional therapies for curing HIV/AIDS nor vaccines for malaria or a range of other diseases which are endemic to poor countries. Many have pointed to the potential of biotechnology to address some of these intractable problems.[70]

Much of the investment that has been made in biotechnology over the past two decades has been directed to health-related applications in the developed world. The prospect of novel drugs brought to market more quickly, new diagnostics and new vaccines have driven the enormous commercial and public sector interest in biotechnology. Although some of these expectations are over-optimistic, some medical applications are already in use. The diagnosis and prevention of several diseases caused by a single defective gene through prenatal diagnosis are well advanced, and over 100 new or improved medicines and vaccines based on recombinant DNA technology are in use. These include recombinant erythropoietin or EPO, growth hormone and insulin and vaccines for hepatitis A and B. Although some 250 million people worldwide have been treated with these recombinant products,[71] little research has focused on diseases of the poor in developing countries such as malaria, tuberculosis and HIV/AIDS.[72] Many developing countries are simply not available to fund treatments with existing therapeutics. Not surprisingly, the pharmaceutical industry and the biotechnology companies have focussed their R&D investments in markets where they can expect a reasonable return.

5.2 Diagnostics

The development of technologies based on PCR, a means of rapidly amplifying targeted DNA sequences, is being applied to the diagnosis of a steadily expanding

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[68]Commission on Macroeconomics and Health (CMH) (2001) Macroeconomics and health: investing in health for economic development. CMH, Washington DC.

[69]See www.vaccinealliance.org/reference/globalimmchallenges.html.

[70]See for example, WHO (2002) Genomics and world health. WHO, Geneva and Daar A et al. (2002) The top ten biotechnologies for improving health in developing countries. *Nature Genetics*, 32:229-232.

[71]Feldbaum C (2002) Some history should be repeated, *Science* 295:975

[72]Pecoul B et al. (1999) Access to essential drugs in poor countries : a lost battle? *JAMA* 281:361-367; The Global Forum on Health Research (2002) *The 10/90 report on health research 2001-2002*, Chapter 5, p. 89-98. Global Health Forum, WHO.

number of diseases. At present these applications are largely restricted to the developed countries where they are used in prenatal diagnosis, pre-implantation diagnosis, and for both the prediction and confirmation of clinical diagnosis in children and adults. The tests currently in use have been described as generally unsuitable for use in developing countries where there is often a lack of refrigeration, electricity and clean running water.[73] In a recent report, the WHO concluded that important areas of health provision based on this technology could be developed without delay. Two examples are considered to illustrate the potential of biotechnology-based diagnostics in the developing country setting.

Blood disorders: a prime example is the sickle cell diseases and the thalassaemias which are the world's commonest diseases caused by a single gene mutation. Affected children receive a mutated gene from each of their carrier, and therefore symptom less, parents. Many thousand children die from these diseases in the poorer regions of the world. Simple and cheap techniques to detect carriers of thalassaemia mutations already exist. Severe forms of the disease require those affected to have lifelong transfusions and costly drug treatments, generally well beyond the resources of the health services of developing countries. Several countries have opted for pre-natal screening and if the parents find it acceptable, termination of pregnancies which involve affected fetuses.[74]

In the case of sickle cell anaemia, the situation is rather different. Common in sub-Saharan Africa where it is estimated that up to 300,000 affected children are born each year, this disease results in episodes of bone pain, serious complications, and infections. The majority of these children in rural regions are thought to die early in life. However, there has been considerable success in diagnosing and treating newly born infants with penicillin leading to a marked reduction in mortality of sickle cell disease in Europe, the Caribbean, and North America. The establishment of one central reference laboratory to undertake neonatal screening and the availability of oral penicillin treatment would, it has been suggested, have a major impact on the survival of patients with sickle cell disorders in Africa, the Middle East, and India. Molecular screening techniques are cheap and straightforward, but would require support for major education programmes for local clinicians and the public. In this way, the establishment of programmes for pre-natal diagnosis of blood disorders could serve to be a valuable model of cooperation for the transfer of knowledge and technology between the developed and the developing countries, and for the reduction of an increasing burden for public health and for families, particularly the mothers of affected children.

Diagnosis of infectious diseases: the application of the techniques based on PCR to the diagnosis of infectious diseases is less certain. Early work suggests that the diagnosis of diseases such as dengue fever and leishmaniasis may be quicker and cheaper.[75] The techniques have also proved valuable in identifying pathogens which are difficult to culture or monitor, such as hepatitis C and herpes simplex infections.

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[73]WHO (2002) Genomics and world health. WHO, Geneva
[74]Op. cit. p.82
[75]Harris E and Tanner M (2000) Health technology transfer. *British Medical Journal*, 321:817-820

4.3 Treatments for infectious diseases: drugs and vaccines

In general, not much attention has been paid to gender differences in infectious tropical diseases. More recently, there has been a growing realisation that gender roles influence two important aspects of infection to tropical diseases: the degree of exposure to vectors and access to the resources needed to protect individuals from the consequences of infection.[76] Biological differences between men and women may mean that the same disease may be experienced in different ways. For example, malaria is a significant cause of maternal mortality, miscarriage and stillbirths. It also contributes to chromic anaemia in pregnant women. Differences in working and living conditions may also lead to different experiences of disease. A recent study in Nigeria showed that infection of girls with schistosomiasis is highest at the age of 15 when they receive the greatest exposure to the water-borne parasite, while engaging in water-related domestic and agricultural tasks. After adolescence, the rate of infection drops in males but not in females, when domestic exposure is likely to continue.

Socio-cultural traditions may discriminate against the interest of women: polygamy and lack of rights over their children make women particularly vulnerable.[77] Social factors may also result in inferior access for women to health services for the diagnosis and treatment of infectious diseases. Women are more likely to be constrained by a lack of transport and a lack of funds to pay fees for clinical services. Women with disfiguring diseases such as leprosy may also be reluctant to consult health service providers though fear of stigmatisation.

HIV/AIDS, malaria, and tuberculosis are the cause of one quarter of all deaths amongst young children and adults in Africa and south-east Asia.[78] The statistics about HIV/AIDS are well known. Some 40 million people are infected, 25 million of them in Africa. Seven out of every 10 are women or children. Nearly 3 million died of the disease last year alone. In Africa the HIV/AIDS epidemic has been enormously damaging – the average life expectancy in several African countries has fallen by a decade. High rates of infection have also been predicted in the short to medium term for India, other countries in Asia, and China.

Women of child bearing age are the group in which the epidemic is spreading the fastest, and where the impact in terms of mortality is greatest. Each year nearly 1.5 million women die and a further 2.5 million are infected. In recent years there has been a substantial increase in the infection of women, particularly those infected by their husbands, who often resist using condoms. In sub-Saharan Africa, of the 26 million pregnant women in 2001, 2.5 million were infected with HIV. Pregnant women frequently pass the virus to their infants during birth and through breastfeeding. Assuming a transmission rate of 20%, more that 500,000 of the infants born to these mothers will be HIV positive.[79] Many of these infants and those from the 80% not infected at birth will be orphans within 1-2 years of their birth. The

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[76] Doyal L (2002) *Sex, gender and the 10/90 gap in health research*. Global Forum for Health Research, Arusha, Tanzania, 12-15 November, 2002

[77] Page S (2001) Promoting the survival of rural mothers with HIV/AIDS: A development strategy for southern Africa. *Development,* 1011-6370 (2000112) 44:4 40-48.

[78] WHO (2002) Infectious diseases report. WHO, Geneva.

[79] Global Health Council (2002) MTCT-Plus: *Spearheading HIV/AIDS prevention & care for mothers & children*, Global Health Council, www.globalhealth.org

epidemic in Africa has created a large numbers of orphans and many grandparents now have to bring up after their grandchildren.

The biggest difficulty in devising vaccines or therapeutics for HIV concerns the high degree of variation exhibited by the virus. The more common variant, Type 1, has eight clades. Within each clade, high mutation rates generate thousands of variants in a single patient. So an effective vaccine or drug would need to be effective against very broad genetic spectrums. Clade B is more common in North America and Europe, clade E in South East Asia and clades A and C in Africa. Anti-retroviral medicines (ARVs) can keep the virus in abeyance but cannot cure the disease. Treatment with three of these drugs in combination, called triple therapy, has been very successful in developed countries. As a result of these drugs, far fewer patients in developed countries are now dying of AIDS and therefore there is less commercial incentive to find a vaccine.[80]

The minimal annual cost of ARV therapies, even at deeply discounted or generic prices which do not cover R&D costs, far exceed the annual health expenditure per capita of most developing countries. Current health expenditures in low income developing countries average $23 per capita per year, while the cheapest ARV triple therapies are now approximately $200 per year.[81] Thus without extra funding for medicines and health delivery services, treatment will remain unaffordable even at the lowest generic prices for HIV/AIDS patients in the developing world. Only a mere 230,000 of the six million estimated to be in need of ARV treatment in the developing world receives it; nearly half of these people live in Brazil.[82] A further complication is that tuberculosis is the leading cause of death amongst HIV-infected people. For these diseases, and other diseases endemic to developing countries, the primary issue for biotechnology is how to mobilise resources for R&D from the public and private sector to develop new medicines, vaccines, and diagnostics. Once these interventions are developed, the challenge for policy will be how to ensure access to them for those in need.

Pregnant women are placed in particularly difficult situations when faced with the option of coming forward for treatment with ARVs. In some countries such as Thailand, the drug Nevirapine is can be given to the mother during labour and to the child after birth where it can be 40-80% effective in stopping transmission of the virus at the cost of approximately $4. The uptake has however been disappointing. Two possible reasons have been suggested. First, if a pregnant woman is tested in a healthcare clinic to see if she would benefit from treatment with Nevirapine, she faces the prospect of having to tell her husband if she is HIV positive. In many societies in developing countries, a woman who is HIV positive will be perceived as the person who introduced AIDS into the household, despite the fact that it is usually the husband who is the primary source of infection. Women in this situation are at risk of

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[80]Conway, 2003.

[81]Commission on Macroeconomics and Health (2001) *"Macroeconomics and health: investing in health for economic development"*, WHO, Geneva, p.56. Source: http://www3.who.int/whosis/menu.cfm?path=whosis,cmh&language=english; and Médecins sans Frontières (2002) *"Untangling the Web of Price Reductions: A Pricing Guide for the Purchase of ARVs for Developing Countries"*, MSF, Geneva. Source:http://www.who.int/medicines/organization/par/edl/access-hivdrugs.shtml

[82]HO Press Release (WHO/58), 9 July 2002. Source: www.who.int/inf/en/pr-2002-58.html

being ostracised from their home. The prospect of such an outcome is thought to deter many pregnant women from coming forward for HIV testing.[83]

Secondly, the lack of provision of treatment for HIV positive mothers may provide a further disincentive for participation in programmes to prevent mother to child transmission (MICT) of the virus as well as a moral dilemma for sponsors. Sponsors wishing to direct funds to help ameliorate the effects of the AIDS epidemic in developing countries have found themselves having to choose between supporting initiatives on the prevention of HIV infection or the care of infected patients.[84]

A number of donors, including the Rockefeller Foundation, have concentrated on prevention and in particular on finding vaccines for the African subtypes of the virus. The development of new vaccines is a key objective to which the potential of biotechnology is being directed. The DNA sequencing of the HIV genome and the study of the virus' molecular structure are critical to the development of new vaccines. The International AIDS Vaccine Initiative (IAVI) is one of a new kind of public-private partnerships that brings together public funding with the knowledge and technologies developed by the commercial biotechnology sector. Established in 1996, eight new HIV vaccine projects are under development.

HIV infection could be prevented by changes in sexual practices, but this is very difficult to achieve in countries where men often refuse to wear condoms, where male infidelity in marriage is often tolerated, and where wives often cannot refuse to have sexual intercourse with their husbands. There have been some notable successes in prevention. For example, in Uganda the age of first sexual intercourse has increased over the past few years, a development largely attributed to leadership shown by the government in a public campaign over the past decade about the dangers of HIV infection.

One of the most important ways in which technology can protect women who are at risk of contracting HIVAIDS from their husbands, and in turn infecting their babies, would be through the development of effective microbicides. A microbicide is a gel or a foam which can be inserted into the vagina to protect from HIV as well as other sexually transmitted infections. Altogether, more than 50 potential microbicides are in development pipelines at biotechnology companies and universities. The Rockefeller Foundation has also set up a public-private partnership which aims to help define research priorities and enhance funding for the development of microbicides.

However, effective vaccines and microbicides for Africa are estimated to need at least 7-10 years of development. During this time many women in developing countries will become infected with HIV. A challenge for donors is to expand the necessary health infrastructure in developing countries to enable the treatment of mothers as well as infants. The MICT-PLUS programme, sponsored by several foundations,[85] is

[83]If the husband is the first to die in a family infected with HIV/AIDS, the wife will often not inherit his property. Many such women, often from households based around smallholder farming will frequently be dependent on the charity of relatives. Their prospects for survival are poor and AIDS-related infections are likely to appear within two years.
[84]Conway G.(2002) *A slow cure*. World Link, May/June 2002, p. 12-14.

[85]Including the Bill and Melinda Gates Foundation, the Packard Foundation, the Rockefeller Foundation, the Hewlett Foundation, the MacArthur Foundation, the Kaiser Family Foundation and the Robert Wood Johnson Foundation

responding to this challenge articulated in the "Kampala Call to Action" released at the International Conference on Global Strategies for the Prevention of HIV Transmission from Mothers to Infants (see Box 2). Although $100 million is being raised by the MICT-PLUS programme over the next five years to treat mothers

Box 2. The MICT-PLUS Programme

Objectives include:

- Improved survival and well-being of HIV-infected mothers
- Improved pre-natal care for all women
- A dramatic reduction in opportunistic infections
- Involvement of local communities in shaping programmes

Projections for 2006 based on a steady expansion:

- 20 million pregnant women of child bearing age to have access to MICT-PLUS services
- Half a million pregnant women to also receive treatment for common infections and tuberculosis
- A quarter of a million mothers to have their lives extended through ARV therapy

providing medicines for TB and ARVs for HIV/AIDS, the fact remains that the use of anti-retrovirals is beyond the healthcare budget of most developing countries. If MICT-PLUS successfully proves the concept, more funds may flow, however. The establishment of the Global Fund against Aids, Tuberculosis and Malaria by Kofi Annan, UN Secretary-General, is a step in this direction. Biotechnology also may provide opportunities for the application of new technologies to develop new medicines and vaccines for tuberculosis, malaria, and other infectious diseases of the poor. The genomes of the TB bacterium, the malarial parasite, *Plasmodium*, and the mosquito, *Anopheles*, have all recently been sequenced. Knowledge of the particular patterns of gene expression in pathogens and the definition of virulence genes is beginning to provide new prospective drug targets and assist the development of new vaccines where conventional approaches have failed.[86]

For example, the genome of the organism causing meningitis B has already started to provide new candidates for vaccines and several promising DNA-based vaccines for the prevention of malaria are at an early stage of clinical testing. As we noted in the context of HIV vaccines, the investment solely from the private sector is unrealistic

[86]WHO (2002) Genomics and world health, p. 48. WHO, Geneva.

and in recognition of this, a number of public-private partnerships have been established.[87]

A major drawback of the conventional means of delivery for vaccines by injection is the risk of contamination by viruses such as HIV and hepatitis. A chronic shortage of needles means that re-use is common in the developing world. Alternatives to injections such as powdered or edible forms of vaccines will be needed.[88] The fact that tuberculosis is the leading cause of death in HIV-infected individuals means that many of those affected will be women. Other diseases, including malaria, affect both sexes equally. However, the fact that children are particularly susceptible to malaria places a heavy burden on women as the main caregivers.

The urgent need for biotechnology-related research to address the disease burden of the poor is compelling, but the funding for such research is simply not in place. The fact that only 10% of the world's R&D for health is directed towards 90% of the world's population is well known.[89] The Macroeconomic Forum on Health recently called for a Global Fund of xx million to address the health burden of the developing world. The Commission recommended the funds be directed towards a significant scaling up of global R&D the diseases of poor countries and also stressed the need for research into reproductive health (for example microbicides) as well as improved management of life-threatening obstetric conditions.

5. Training

5.1 Background

The historical development of civilisation in Asia, the Middle East and Europe has common features with respect to the social status and roles of women. The belief in the superiority of men has persisted for centuries, even as societies have evolved. Women have often been expected to live under the authority of their fathers if they are single and their husbands if they are married, effectively giving them the status of a minor throughout their lives.[90] This status still persists in some parts of the world, particularly in developing countries. One outcome of this social order is that differential preparation tends to be accorded to young men and women in relation to their roles in society.

5.2 Science education

Developments in biotechnology require expertise in a range of disciplines including biology, medicine, chemistry, engineering, physics as well as law. One of the greatest obstacles to the education of women in science in the developing world is the lack of opportunity for education. Reports suggest that one in three women in the world are illiterate – partly a consequence of the fact that many more boys attend school than girls.[91] For example, in Burkino Faso, data from 1997-98 indicates that 12.9% of boys

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[87] For example, several anti-malarial drug candidates are under consideration at Medicines for Malaria Venture (MMV,) and the Global Alliance for TB Drug Development has licensed a promising drug candidate.

[88] Daar A et al. (2002) The top ten biotechnologies for improving health in developing countries. *Nature Genetics*, 32:229-232.

[89] Global Forum on Health Research (1999) The 10/90 report on health research 1999. The Global Forum on Health Research, Geneva.

[90] Wemple S F (1993) *Women in Frankish society marriage /the cloister*. University of Pennsylvania.

[91] UNESCO (1999) *Women in science and technology – towards a new development?* UNESCO, Paris.

attend secondary school compared to only 7.4% of girls; 1.7% of boys gain a college level education, compared to only 0.4% for girls. In addition over 50% of girls drop out before completing their education at primary school. These differences are reflected in an illiteracy rate of 52% for men and 72% for women.[92]

Several interventions have been suggested to reduce the stereotyping of the science curriculum. The main objectives of FEMSA (Female Education in Science and Mathematics in Africa) are to promote the participation and performance of girls in science, mathematics and technology, by mounting interventions in classes in both primary and secondary schools. In several countries 'science clinics' have been established to enable female high school students to gain 'hands on' experience of scientific activities under the guidance of experienced women scientists. Clinics have been organised in Botswana, Ghana and several other African countries. It has been observed that these two forms of intervention require dedicated application by scientific communities over the long term if they are to have an impact.

The differential preparation has been influential in the curricula in formal education where girls have traditionally been steered away from science and technology.[93] This gender-based approach to education still persists in many countries where curricula for girls tends to de-emphasise the physical sciences, although the proportion of females enrolled in the natural sciences, engineering and agriculture at the third level varies widely from 48% in Jamaica to 6% in Zambia.[94]

The achievement of gender equality in science and technology will need to take into account the strong cultural and social traditions which influence the status of women. Where women have entered science, it has generally been the life sciences and not mathematics or the physical sciences. In 1991-92, the majority of women graduating in science from the US were from the biological sciences. Members of the Third World Organisation for Women in Science (TWOWS) have shown a similar pattern of disciplinary choice.[95] While the fact that women show a preference for the life sciences in developing countries might be thought of as an advantage for the development of capacity in biotechnology, there is also a concomitant need for chemists, physicists and engineers to develop and apply the wide range of technologies which fall within this broad area.

While there are significantly less science students at the undergraduate level in many developing countries, the proportion of women enrolled in Ph.D. programmes is even less. One reason for the low numbers is due to the fact that many women find it difficult to combine marriage and children with doctoral research. Several initiatives have been set up to respond to this issue. TWOWS, under the sponsorship of SAREC, established a programme in 1998 to provide grants for women with masters degrees in science for 'sandwich style' Ph.D.s, which allow more flexibility for women with families. However, many female post doctoral researchers from developing countries

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[92]UNESCO (1999) Women, science and technology in Africa: Ougudouga, Burkino Faso, 25-28 January, 1999. In (1999) *Women in science and technology – towards a new development?* p.49. UNESCO, Paris.

[93]Mathubu L P (1999) Science: the gender issue. In '*Women in science and technology – towards a new development?*' UNESCO, Paris.

[94]Van Crowder K L (1996) *Enrolment of women in agricultural studies in intermediate and higher education.* www.fao.org

[95]Commandeur, 1997.

obtain their Ph.D.s overseas, and many do not return. Some countries, such as the USA, work hard to attract foreign scientists (including from developing countries) to participate in their national science system. The resulting “brain drain”, or loss of trained individuals to developed countries is a serious problem and difficult to address.

An initiative of WISTAN (Women in Science Networks in Africa at the University of Swaziland) aims to strengthen research collaboration between individual women scientists by creating research groups of women who can make collective contributions, even if individual members are slowed down by family responsibilities. These kinds of developments can enable women to increase their research publications, essential if they are to compete with men for the senior posts in universities. The lack of women at the scientific leadership level of academic and other research institutions where policies that guide the practice of science are formulated is a cause for concern. While some progress has been made in the training of women in science and technology, much remains to be done. An excellent set of recommendations to promote and strengthen the development of women scientists are set out in the Ougadouga Declaration and Action Plan made at the UNESCO Forum in Burkino Faso, 1999. There have been calls for specific action relating to gender and training in biotechnology. For example, attention has been drawn to the need to direct efforts to achieve a critical mass in the representation of women in policy making and decision-making at all levels, including the regulatory and economic fields relating to biotechnology.[96]

5.3 Policy making

Research and its applications which involve biotechnology are among the most heavily regulated in the life sciences. Effective and responsible use of biotechnology depends upon regulations to control the containment and release of GMOs, (including plants, animals and microorganisms), the use of genetic resources, and the protection of novel products and processes by patents. Not only do countries wishing to apply biotechnology need to provide a national regulatory framework, they increasingly need to become signatories to international agreements. The participation of developing countries in the negotiation and membership of international agreements such as TRIPS, the International Undertaking on Plant Genetic Resources, and the CBD (including the Biosafety Protocol) has highlighted the need for experienced and skilled professionals who have expertise in public policy, science, economics and law. Many poor countries lacked sufficiently trained teams of experts at the time of the TRIPS negotiation and the lack of attention directed to the particular needs of developing countries in the ensuing agreements have been partly attributed to this deficit. Nor is the provision of resources for training by the institutions administering international agreements necessarily a solution.

The case of the World Intellectual Property Organisation (WIPO) provides a useful example. WIPO is the principal international institution responsible for organising the negotiation of IP treaties and their administration. About 90% of its funding comes from the private sector by way of fees paid by patent applicants under the Patent Convention Treaty and not from member governments (as in the case of the WTO or

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[96]The International Forum of Women of the Mediterranean, Network UNESCO (1999) *Women, science and biotechnology: what does the future hold for the Mediterranean?* 29-31 January, Turin, Italy.

other UN agencies).[97] Its founding charter charges it to pursue objectives solely concerned with the promotion of intellectual property rights (IPRs), within which development issues are not emphasised. As might be expected, WIPO is a vigorous advocate of stronger IP protection in developing countries, and little attention has been paid to the possible adverse implications of such policies. The technical assistance it provides has been criticised for being insufficiently integrated with other development programmes. In general, lack of coordination between multiple donors in providing technical assistance may lead to unnecessary duplication or even conflicting advice. In Vietnam for example, eight different donor agencies provided IP-related assistance in the country between 1996-2002.[98]

Policy-making for the successful deployment of biotechnology, as in many other areas, is complex. Formulation of biotechnology policies to promote development objectives would need to be based on an analysis of the country's science base, its industrial structure, the nature of agricultural production, healthcare and education needs, and the indigenous biodiversity. However, the expertise and evidence base necessary to carry out such tasks are often in short supply. Institutional capacity is generally weak in many developing countries and there is a lack of well qualified and experienced officials. In particular, women are likely to be under-represented because of family commitments, lack of educational opportunities, and lack of opportunity to gain experience in leadership in administrative positions. **Greater attention should given to the assessment of training needs to ensure the effective participation of women in policymaking roles associated with the national and international governance of biotechnology. It is recommended that the GAB consider whether it might be the appropriate body to undertake such an assessment**.

5.4 Local training

Encouraging the dissemination of knowledge and skills is also vital at the local level. As we have said, there is wide recognition that the adoption of new crop varieties, new agricultural practices, novel health-related interventions, and the raising of awareness of issues concerning biodiversity and traditional knowledge need to involve the user communities, particularly women. The development and application of information technology in developing countries has the potential to play an important part in this process linking men and women with scientists at the local, national and global level.[99] Swaminathan (2001) suggests that a radical re-structuring of agricultural extension services and input supply services is required. He envisages a 'village knowledge centre' based around the village Panchayrat, using computer-aided extension methods. These centres could be owned and run by women from underprivileged sections of society who are trained to use computers and manage the knowledge centres. The linkage of these knowledge centres to local radio stations could help further to bridge the knowledge gap.

Some external sponsors have specifically targeted capacity building in biotechnology-related research and applications in developing countries. For example, the Ministry

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[97]CIPR (2002),pp.157.

[98]Leesti M and Pengally T (2000) Institutional issues for developing countries in intellectual property policymaking, administration and enforcement, CIPR background Paper, CIPR, London, pp.44.

[99]Swaminathan M S (2001) Managing global and local challenges of food insecurity and poverty . *Development*, The Society for International Development, Sage Publications, 1011-6370 (200112) 44:4;17-22 020143.

of Foreign Affairs in the Netherlands has funded a substantial programme in Andhra Pradesh, India which is directed at the needs of small scale farmers in rain-fed districts. Areas under study by over 100 scientific staff include tissue-cultured plants, animal health and production, vermiculture, biopesticides using local bacteria, and biofertilisers, all of which are directed towards the sustainable development of agriculture.[100]

6. Conclusions

We have seen that there is very considerable potential for biotechnology to improve the quality of life for poor people. The burden of disease in developing countries could be greatly diminished by greater access to existing interventions as well as the development of new treatments for major diseases and conditions. Research for new and cheaper medicines, vaccines, and diagnostics will be accelerated by the application of biotechnology which is already thoroughly integrated in the drug discovery process. Food security could also be improved by the application of biotechnology in agriculture. However, the experience of biotechnology in the least developed countries to date is minimal, and is likely to remain so unless there is much greater investment by governments, NGOs, and industry. Middle income countries such as India, China, Thailand, and parts of Latin America are likely to show much more rapid adoption of some forms of biotechnology, particularly in the area of GM crops. Cuba also has a well developed biotechnology programme for the development of vaccines and other areas related to health.

Although progress in these countries can provide us with some insights, we should not forget that the context for the development and application of biotechnology is particularly complex. Trade, intellectual property rights, the development of appropriate regulatory frameworks, and consumer acceptance are all important issues which will be influential in the adoption of the technology.

In the case of *agricultural biotechnology,* there is insufficient information and experience available to judge the likely impact on women in developing countries. Outside the USA, only China and Argentina have significant experience in cultivating biotechnology-related crops on a large scale. In non-democratic China, the state will play a significant role in the adoption of such crops by small farmers, while in Argentina it is the large farmers growing GM animal feed which are behind its widespread use. Neither example may be particularly useful for drawing broad lessons for developing countries. There is relatively little experience of these technologies in Africa and much of Asia. However, there are a number of pointers which can guide us in thinking abut such an assessment. Improved yields in cash crops will deliver general benefits for individuals and their families. The fact that many women are farmers and heads of households suggests that some of these potential benefits would tend to be directly available to them. It is reasonable to argue that the two main areas of application – GM crops and tissue culture technologies – will both have broadly the same potential outcome as conventional plant breeding, i.e. increased production. Women as well as men will undoubtedly benefit.

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[100] Siva Prasad K and Pakki Reddy G (1999) Capacity building in the Andhra Pradesh Netherlands Biotechnology Programme. *Biotechnology and Development Monitor,* 39: 6-9.

The findings of research investigating the potential impact of traditionally-bred crops on women are therefore likely to be valuable and relevant. Previous research has already shown that women in some poor environments are less likely to adopt new crop varieties than men. The involvement of women farmers by researchers in the development of new GM varieties may be crucial for their successful adoption in some countries. However, previous research also tells us that generalisations about the impact of new agricultural technologies on patterns of labour, land, and resource allocation are unlikely to be valid.[101] **To answer the question whether crops (or other products such as biopesticides) produced by means of biotechnology raise distinctive issues over and above those posed by conventional products in terms of adoption by women, requires further research.**

In health, there are some areas where the introduction of new products developed through the application of biotechnology would be gender neutral, as would new therapeutics for trypanosomiasis, Chagas' disease, and leishmaniasis. New treatments or vaccines for diseases such as malaria would have direct benefits for both sexes, but indirect benefits would accrue additionally to women as the main carers of children. New vaccines to prevent common diseases of childhood would also be a source of indirect benefit to mothers. Low-cost genetic testing for common, disabling blood disorders could also offer reproductive choice to parents who are at high risk of having affected children.

In the case of HIV/AIDS, women are the fastest growing group in terms of morbidity and mortality. Seven out of every 10 deaths caused by the virus are women or children. We have seen that women in developing countries are often poorly placed to prevent themselves from being infected by their partners. Effective microbicides could enable women to protect themselves and their children, whom they often infect in during childbirth or breastfeeding. In the same way, effective vaccines for HIV/AIDS would benefit men but particularly women and children. We can conclude, then, that the successful introduction of biotechnology-related products would in several instances show particular benefits for women. The newly established public-private partnerships such as IAVI which are dedicated to developing such treatments for neglected diseases in developing countries, have a crucial role to play in this respect. But these efforts will not suffice. As noted earlier, there is an urgent need for the significant scaling up of global R&D on the diseases of poor countries. **It is recommended that a detailed analysis be undertaken to identify more clearly those categories of disease where gender is relevant in the context of the application of biotechnology.**

With respect to *traditional knowledge*, a relatively small number of highly publicised cases of 'biopiracy' have led to considerable sensitivity about the use of natural resources in developing countries by foreign organisations. The value of biodiversity in biotechnology in relation to drug discovery and bioprocessing is uncertain. The widespread and longstanding use of traditional medicines made from plant and animal materials in many developing countries, is based on traditional knowledge which is often uncodified. Some of this knowledge is held by women to a greater extent than

[101] See Doss C (2001) Designing African technology for African women farmers: Lessons from 25 years of experience. *World Development,* 29:2075-2095.

men, and a small percentage may concern chemical compounds of potential interest to the pharmaceutical industry. Although the actual value of the raw materials is likely to be low, the possibilities for research collaboration and training may be worth pursuing. Relatively little attention has been paid to particular role of women in the guardianship of traditional knowledge relevant to biotechnology. **It is therefore recommended that a study which both reviews existing roles and explores the possible expansion of those roles in the codification of the knowledge is undertaken.** The same observations apply to plant genetic resources which are of particular value to the seed industry.

The need to build capacity in both research and management of applications associated with biotechnology in developing countries has been increasingly recognised over the past 15 years. Prospects for the successful deployment of biotechnology in global health and food security clearly depend on major investments by wealthy nations. But it will also depend on the capacity of the poorer nations to absorb, adapt and implement new technologies to meet national and local needs. Specifically, skills and expertise are needed for the adaptation of crop technologies developed for Northern markets, the need for collaboration in externally sponsored clinical trials, the need to assess the possible potential of traditional knowledge and genetic resources, and the need to develop, negotiate and administer national regulations and codes of practice relating to trade, intellectual property, protection of biodiversity and release of GMOs.

Women have been particularly disadvantaged in science education, both at the secondary and tertiary level. The numbers of women pursing science in higher education is generally low and the numbers enrolled in postgraduate degrees even lower. Role models of women in senior academic and government posts are scarce. These observations are not unique to the developing world but they are relevant where resources are scarce and attitudes concerning the traditional roles of women mitigate against their participation in S&T. The fact that women in some developing countries have shown a tendency to favour the life sciences rather than physics and chemistry offers an opportunity to ensure that these students have the option of taking courses in biotechnology as part of their degrees. **It is recommended that an exploratory study be undertaken to determine the extent to which existing surveys of science education in women are relevant to developing capacity in biotechnology.**

Countries undertaking **r**esearch in biotechnology and using biotechnology products and processes are increasingly required to pay attention to the implementation of national and international regulations governing. Capacity in policymaking tends to be weak in developing countries and women are likely to be under-represented. **An assessment of training needs to ensure the effective participation of women in policymaking roles associated with the national and international governance of biotechnology is recommended.**