

The Walking Egg project

ARUSHA

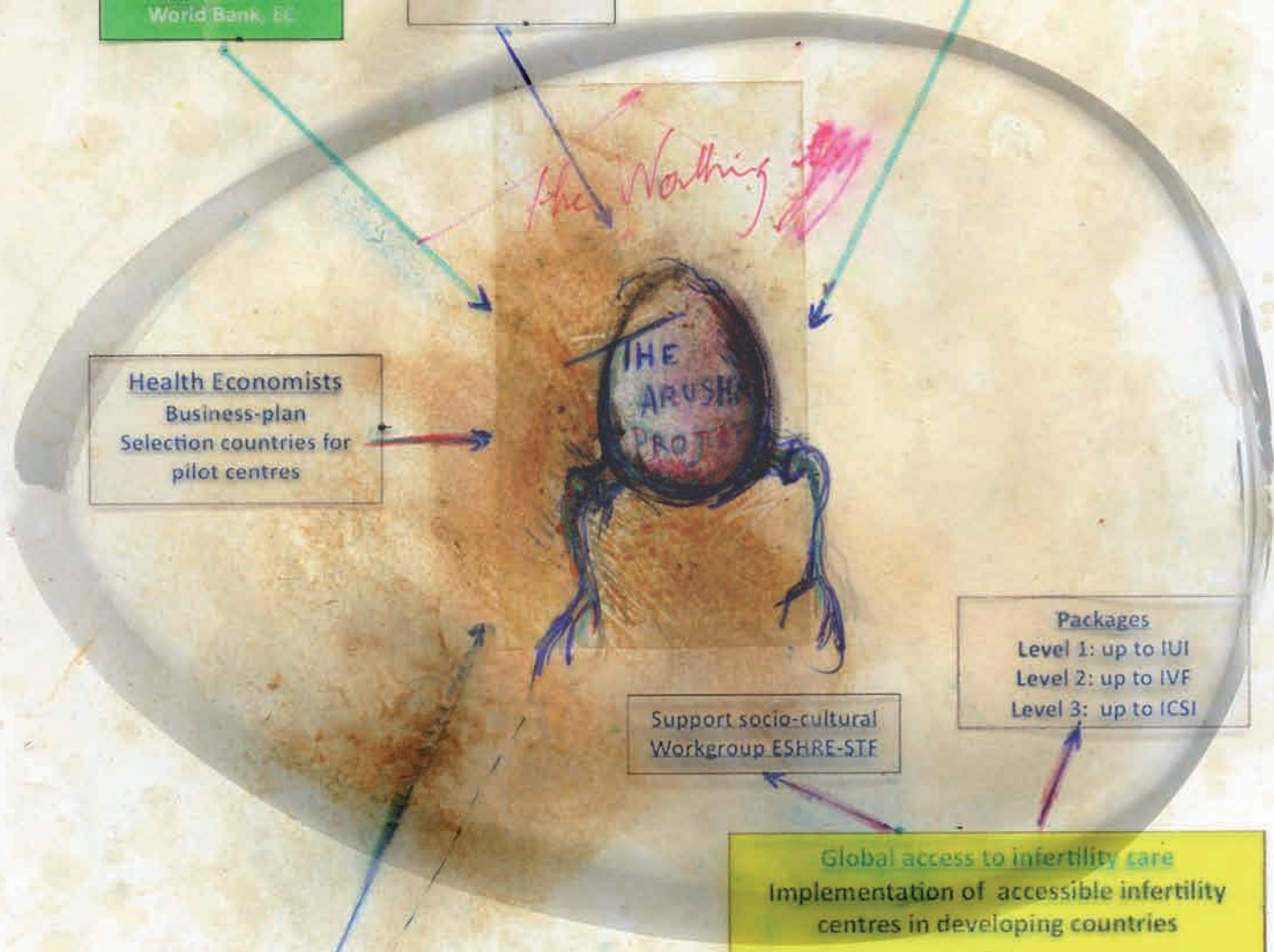
ARTISTIC VIEW.

Willems Ombeliet & Koen Vanmechelen

Partners
WHO - ESHRE
IFFS - ISMAAR - FIGO ...

Potential donors
NGOs, Foundations
World Bank, etc.

Legal support



Health Economists
Business-plan
Selection countries for
pilot centres

Support socio-cultural
Workgroup ESHRE-STF

Packages
Level 1: up to IUI
Level 2: up to IVF
Level 3: up to ICSI

Global access to infertility care
Implementation of accessible infertility
centres in developing countries
→
Go-together of infertility care / family
planning / mother-care programmes

The Walking Egg npo
→ protocols
→ studies simplified methods
→ training courses
→ registration, accreditation,
→ follow-up

{ iron leggs: STRONG
glass egg: FRAGILE

Fertility always comes from outside

Koen Vanmechelen

Global access to infertility care in developing countries: a case of human rights, equity and social justice

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Abstract

According to WHO data more than 180 million couples in developing countries suffer from primary or secondary infertility. The social stigma of childlessness still leads to isolation and abandonment in many developing countries. Differences between the developed and developing world are emerging because of the different availability in infertility care and different socio-cultural value surrounding procreation and childlessness.

Although reproductive health education and prevention of infertility are number one priorities, the need for accessible diagnostic procedures and new reproductive technologies (ART) is very high. The success and sustainability of ART in resource-poor settings will depend to a large extent on our ability to optimise these techniques in terms of availability, affordability and effectiveness.

Accessible infertility treatment can only be successfully introduced in developing countries if socio-cultural and economic prerequisites are fulfilled and governments can be persuaded to support their introduction. We have to liaise with the relevant authorities to discuss the strengthening of infertility services, at the core of which lies the integration of infertility, contraceptive and maternal health services within public health care structures.

After a fascinating period of more than 30 years of IVF, only a small part of the world population benefits from these new technologies. Time has come to give equitable access to effective and safe infertility care in resource-poor countries as well.

Key words: Developing countries, equity, government, human rights, infertility treatment, involuntary childlessness, low cost ART, social justice.

Introduction

As the power of medical technology advances, more and more difficult questions are raised about what sorts of rights to such technologies people might have, especially in resource-poor countries. People surely have a right to basic medical care, therefore global access to infertility care should be seen as a fundamental human right, with respect to socio-cultural, ethical and political differences worldwide.

Although IVF and related procedures get all the public attention, infertility care cannot be reduced to

assisted reproductive techniques alone. Other options are equally important such as a listening ear and psychological support for infertile couples, the availability of basic diagnostic procedures, easy methods of ovarian stimulation and timed coitus, intrauterine insemination, reproductive surgery etc.

The level of infertility care we are aiming for will differ from country to country. Many variables can be important such as the economical and political situation of the country, the level of education and reproductive health care, actual facilities concerning medical care including the quality of the hospitals,

the available equipment, facilities to perform surgery in case of complications, the level of mother care and many others.

It is our aim to describe the facts and our views and vision on the issue of childlessness and infertility in developing countries.

The Facts

The large majority of childless couples are residents of developing countries. According to the WHO it is a silent population of more than 180 million couples facing the consequences of infertility day by day (Rutstein and Iqbal, 2004). Infertility care is probably the most neglected and underestimated health care issue in developing countries. Although the negative consequences of childlessness are much more pronounced in developing countries when compared to Western societies, interest of the international community and local health care providers is still lacking (Ombelet *et al.*, 2008).

In less-developed countries the 12-month **infertility prevalence rate** ranges from 6.9 to 9.3% (Boivin *et al.*, 2007). Substantial geographical differences are noted and these differences can be explained by different environmental, cultural and socioeconomic influences. In Sub-Saharan Africa infertility is caused by infections in over 85% of women compared to 33% worldwide (Cates *et al.*, 1985; WHO, 1987). Approximately 70% of pelvic infections are caused by STDs while the other 30% are attributable to pregnancy-related sepsis (Ericksen and Brunette, 1996). Similarly, many cases of male factor infertility are caused by previous infections of the male genitourinary tract (Kuku and Osegbe, 1989). Both conditions are preferably treated by assisted reproductive technologies but most infertile couples in developing countries can't afford ART because the techniques are too expensive and mostly limited to private centres (Nachtigall, 2006; Murage *et al.*, 2011).

The **consequences of involuntary childlessness** are much more dramatic in developing countries and can create more wide ranging societal problems compared to Western societies, particularly for women. Negative psychosocial consequences are often severe and childless women are frequently stigmatised, isolated, ostracized, disinherited and neglected by the entire family and even the local community. This may result in physical and psychological violence and polygamy (Daar and Merali, 2002; Dyer 2004, 2005; Umezulike and Efetie, 2004; Ombelet *et al.*, 2008). Women are usually blamed for infertility and can be ostracized and assaulted by their families, even driven to suicide or killed (Anonymous, 2006). Because many families in

developing countries completely depend on children for economic survival, childlessness has to be regarded as a social and public health issue and not only as an individual medical problem (Gerrits and Shaw, 2010; Papreen 2000; van Balen and Gerrits 2001, 2009).

Reduced fecundity in HIV-infected individuals has been described and marital instability and polygamy secondary to infertility may in turn increase the spread of HIV-1 infection. HIV is 3 times more prevalent in infertile couples when compared to fertile controls in the same population (Nabaitu *et al.*, 1994; Dhont *et al.*, 2011a, 2011b). **HIV and infertility** share the same determinant of high risk sexual behaviour. Both conditions are more common in resource-poor countries, may lead to stigmatisation and isolation and are strongly influenced by socio-cultural and economic conditions. Treatment options are expensive and in both cases the final result is a diminished population. On the other hand, HIV treatment is becoming more effective and available at lower prices which are not the case for infertility treatment. Awareness, attention, documentation and research of the HIV problem are much more pronounced compared to the infertility problem which remains mainly hidden. Public solutions are being applied for HIV, for infertility the solution is mainly found in the private sector. It is striking, almost fascinating, that budgets for HIV research are huge and the information on HIV is easily available while the contrary is true for infertility.

Do we care? Despite the well documented observations of the social and economic consequences a surprisingly low interest is shown on the issue of infertility and childlessness on a national and international level. The two key arguments against treatment of infertility in developing countries are overpopulation and limited resources.

The argument of **overpopulation** suggests that in countries where overpopulation poses a demographic problem, infertility management should not be supported by the government.

It is well known that the world population is expected to increase from 6.7 billion inhabitants in 2005 to 9.2 billion in 2050 (United Nations, 2007). By 2050, the population of the developing world would be adding 35 million annually, 22 million of whom would be absorbed by the least developed countries. Therefore, national and international health strategies have always focussed on reducing total fertility rates (number of children per woman) while infertility care has received little or no attention (Hamberger and Janson, 1997).

But even if infertility treatment could be made more accessible in developing countries it would probably account for less than 1% of all deliveries.

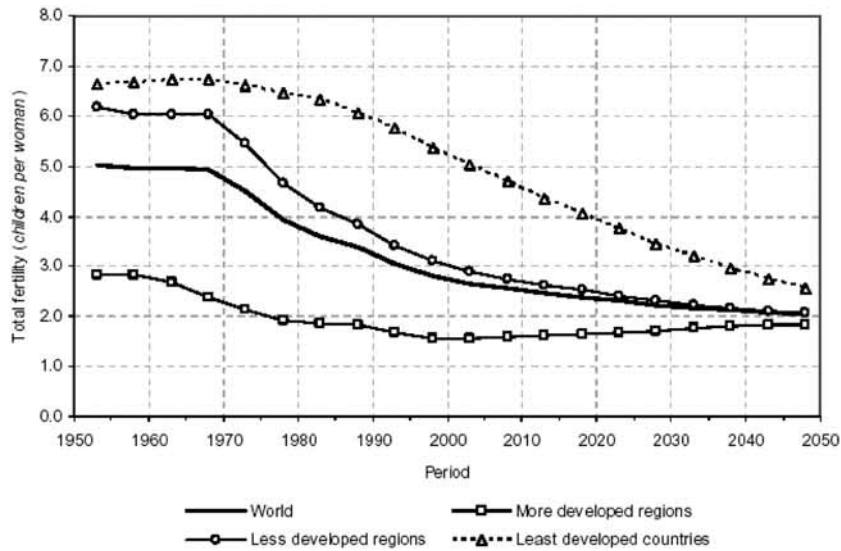


Fig. 1. — Total fertility trajectories for the world and the major development groups, 1950-2050 (World Population Prospects: The 2006 Revision, page 6)

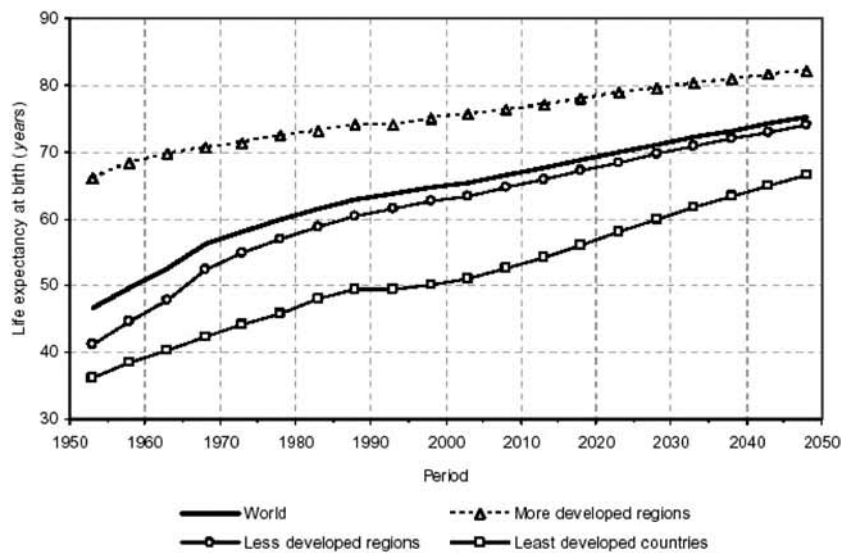


Fig. 2. — Life expectancy at birth for the world and the major development groups, 1950-2050. (World Population Prospects: The 2006 Revision, page 12)

Increasing efforts on family planning and health education can readily overcome this small contribution to the fertility rate. Denying infertile couples access to infertility care is not a fair population restriction policy. United Nations data not only show that the majority of developing countries already succeeded to drop their global fertility rate below 2.5, the data also show that the expected population growth in developing countries is mainly due to an improved life expectancy and not to high fertility rates (United Nations, 2007, Fig. 1, Fig. 2).

To illustrate the complexity of the problem: it is well known that the fertility rate of a specific country is positively related to infant mortality, which is understandable because aged couples will depend eco-

nomically from their children in many developing countries (Palloni and Rafalimanana, 1997).

According to the ‘**limited resources**’ argument it is hard to justify expensive fertility treatment in settings with few resources and more important challenges to deal with. Can expensive techniques be justified in countries where poverty is still an important issue and where health care systems still struggle with the huge problem of infectious diseases such as malaria, tuberculosis and HIV? In most developing countries the reduction of maternal mortality and the promotion of contraception are considered to be the reproductive health priorities (Aboulghar, 2005). Improved “reproductive health education programmes” have proven to be an excellent preventive



Fig. 3. — Some of the most important foundations, NGOs and international societies linked to reproductive health. In none of these organisations “infertility care in developing countries” is mentioned as an issue they support.

tool against overpopulation, sexually transmitted diseases (STDs) and pregnancy-related infections. But even with better education and preventative care programmes, involuntary childlessness will remain an important problem for millions of couples.

Reproductive autonomy is the main argument in favor of the provision of infertility treatment in developed countries. People have the right to decide when, how many and how to have children. Why would citizens of developing countries not have the right to have at least one child, especially if we succeed to simplify the methods of infertility care and make them affordable for a much larger part of the population?

To get **funding for infertility care** is nowadays almost impossible. We recently carried out an internet-search for possible donors. A questionnaire dealing with the scope of their actions and the interest in infertility care in developing care was sent to the most important foundations, NGOs and international societies linked to reproductive health (Fig. 3). They all showed interest in the issue of childlessness in developing countries, but in none of these organisations infertility care has been funded before and no future projects were planned. Considering local governments: it is not only the resource constraint which prevents the providing of infertility services in many developing countries. With the dominant discourse focusing on controlling overpopulation it is no wonder that infertile women are marginalised and consequently excluded from health sector interventions. Infertile women are victims of the systematic process of ‘cultural’ exclusion, but in some countries

they are also ‘institutionally’ excluded (Papreen Nahar, Bangladesh, personal communication).

International statements: promises and promises: “Men and woman of full age, without any limitation due to race, nationality or religion, have the right to marry and to raise a family”. This statement was adopted 60 years ago at the 1948 UN Universal Declaration of Human Rights and can’t be misunderstood: it implies the right to access to fertility treatments when couples are unable to have children. At the United Nations International Conference on Population and Development in Cairo in 1994 the following statement was made “Reproductive health therefore implies that people have the capability to reproduce and the freedom to decide if, when and how often to do so ... and to have the information and the means to do so ...”. In 2004 the World Health Assembly proposed five core statements, including “the provision of high-quality services for family-planning, including infertility services” (World Health Assembly, 2004). The International Federation of Obstetricians and Gynaecologists (FIGO) stated that “women and men have the right to the highest available standard of health care for all aspects of their sexual and reproductive health” (FIGO, 2003).

Political statements and commitments need to result in appropriate actions but progress towards the attainment of these goals on the subject of infertility in developing countries remains however slow. The reasons are multiple and include, among others, the problem of ‘brain drain’, lack of collaboration, budgetary constraints and lack of political commitment

Table I. — Global access to infertility care in developing countries: facts, views and vision.

(DC = Developing Countries, STDs = Sexually Transmitted Diseases, OHSS = Ovarian Hyperstimulation Syndrome, NGOs = Non-Governmental Organisations)

Global access to infertility care in developing countries

FACTS

- Prevalence of infertility: similar to Western countries
- Negative consequences of childlessness are much stronger in DC
- Prevention and alternative methods are not always successful
- ↑ secondary infertility due to STDs and unsafe abortions / deliveries
- HIV and infertility: very comparable on many determinants and final results
- HIV and infertility: very different in how the issue has been treated by the international community
- Global access to infertility care – **arguments contra**
 - Overpopulation
 - Limited resources
 - Problem of funding: “the battle for money” between initiatives on reproductive health care
- Global access to infertility care – **arguments pro**
 - ↑ Demand from developing countries
 - ART techniques can be simplified
 - Social justice and equity

VIEWS

- A need for ↑ reproductive health care education
- A need for ↑ prevention programmes
- Raising awareness: support of media and patients networks needed
- Implementation of more and accessible infertility centres
 - Urgent need for simplified, safe and effective methods (diagnostic procedures and ART)
- Prevention of complications is crucial: OHSS, multiple pregnancies
- Facilities to handle complications have to be available, including facilities for surgery

VISION

- Simplified methods of infertility care will be available in the near future
- The demand from developing countries to introduce ART will increase
- The implementation of accessible infertility centres should be part of an integrated reproductive care programme including family planning and contraception, mother care, and reproductive health.
- Foundations, NGOs and international societies have to be convinced about the value of this project

(Fathalla *et al.*, 2006). On the other hand, the most important non-profit international organisations including Family Health International, WHO, International Planned Parenthood Federation (IPPF) and The Population Council still focus on safe motherhood, the reduction of unsafe abortions, prevention of STDs and HIV/AIDS. The implementation of infertility treatment in developing countries is not a priority for these organizations.

Views

The level of **reproductive health care education** is very low in most developing countries although it is the most cost-effective strategy in the prevention of unwanted pregnancies and sexually transmitted diseases (Lutz and Goujon, 2001). A better education is clearly associated with lower fertility rates and an increasing access to education for women is probably the best strategy for an optimal population

control (Fig. 4). Incorporation of reproductive health education in general health education should be supported by the governments. Data from social researchers have shown that an important barrier to use contraception is the fear for consequent infertility. Family-planning and infertility are clearly linked and should be handled in the same centres. Public education on prevention of infertility includes not only prevention of STDs and pregnancy-related infections, but also life style factors, iatrogenic infertility, environmental pollution and contamination. Education programmes are essential and should be updated.

Prevention of infertility remains the most cost-effective treatment strategy particularly in countries with a high prevalence of pregnancy-related infections and STDs. Advantages are numerous: prevention programmes are more cost-effective and benefit a greater number of people, they are more effective in eliminating the social consequences of infertility

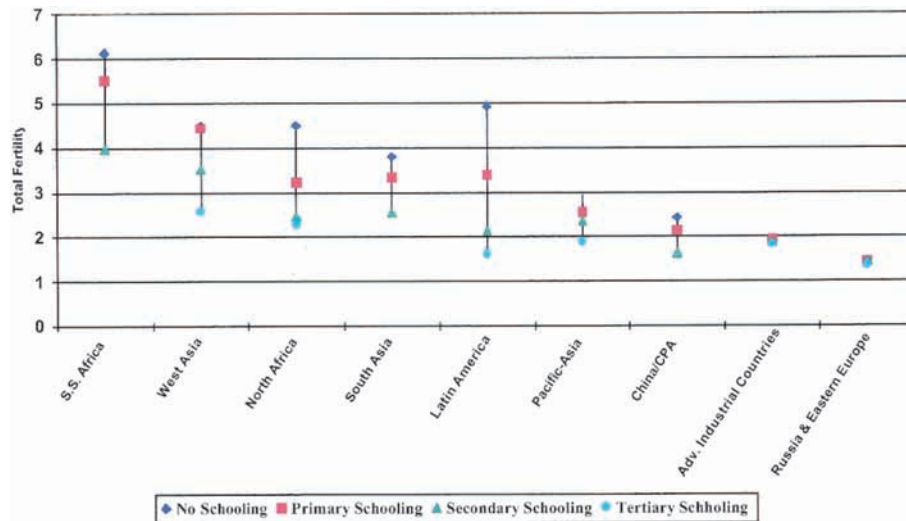


Fig. 4. — Differentials in total fertility by women's education, circa 2000, for selected regions. (replacement level = 2.1). **Source:** Adapted from Lutz W, Goujon A. The world's changing human capital stock: multi-state population projections by educational attainment. *Population and Development Review* 2001;27:323-9.

and will improve the health status of women in other ways. Last but not least, prevention programmes can easily be integrated within existing mother-care and family-planning services.

On the other hand, when resources are exclusively allocated to prevention programmes due to limited resources, millions of childless couples are ignored because prevention will fail in a substantial number of couples. Although it is our belief that the governments should give priority to education and prevention programmes, this does not mean that no money should go to infertility treatment at all, especially if we could make infertility care less expensive and affordable.

From an **ethical and socio-cultural** point of view we have to ask ourselves whether we can justify withholding infertility treatment, including ART, in those cases where prevention has failed. Believing that the arguments of overpopulation and limited resources are strong enough for not helping infertile couples in developing countries doesn't take into account the human rights in general and the reproductive rights in particular (Vayena 2002). Efforts should be made to reduce the excessive social reactions to infertility inspired by pronatalism. Therefore infertility treatment should be part of an integrated reproductive care programme including family planning and contraception, mother care, and reproductive health. Education, empowerment of women and economic prosperity are the most effective solutions to most problems related to both population growth and infertility. Simultaneously, investments in low-cost interventions are justified (Pennings *et al.*, 2009). Reproductive autonomy, justice and equity support our efforts to make ART available and

accessible worldwide subject to political stability and a basic level of medical infrastructure.

Raising awareness is another very important issue and should be done with great care. Most important is to focus on changing the existing moral and socio-cultural beliefs in so far that childless couples are no longer isolated and discriminated. We will need the media, patient organisations and interested politicians to reach this goal. Obstacles will be numerous and will depend on local socio-cultural, political and religious influences. Providing infertility care in developing countries can only be successful if we are able to diminish the socio-cultural, psychological and economic consequences of unwanted childlessness.

Patient support networks already claimed the right to equitable access to infertility treatment all over the world (Dill, 2007). Patients' voices will be crucial when the issue of infertility has to be discussed with policy makers and health care providers.

If we want to **implement accessible fertility services** in developing countries, the first objective is to simplify the diagnostic procedures (Malpani and Malpani, 2002). This can easily be organised in one-day clinics. The suggested work-up is very simple, reliable and comparatively inexpensive. Moreover, all of these procedures can be performed by a small team of health care providers within a short period of time in an inexpensive setting (Ombelet and Campo, 2007).

Implementing **low cost ART** is only possible if we succeed to simplify the methods of treatment in such a way that they still are effective and safe, but affordable. The number of scientific papers on simplification of ART is growing every year.

For the recruitment of oocytes in an IVF programme we should avoid the use of high doses of expensive ovarian stimulation medication such as gonadotrophins, GnRH agonists and GnRH antagonists, if possible. The use of clomiphene citrate, a very cheap oral drug, has been proven in many studies to be an optimal alternative with acceptable results, minimal side effects and a very low complication rate (Ingerslev *et al.*, 2001; Verberg *et al.*, 2009; Aleyamma *et al.*, 2011).

Lowering the costs associated with laboratory procedures, namely fertilization and culture of eggs and embryos, represents another challenge. One possible approach is the use of a 'humidicrib', a plastic box which is commonly used for keeping newborns snug, instead of an expensive laminar flow hood (Hovatta and Cooke, 2006; Pilcher, 2006). For a tenth of the price this box can be modified to be used as a portable, near sterile environment for the handling of gametes and embryos. Expensive cylinders of carbon dioxides required to incubate the embryos may be abandoned in favour of exhaling across the culture medium before sealing it in a plastic bag. This bag, containing the Petri dish with the embryos, can be dropped into a warm bath without the need for expensive incubators. This technique has been successfully used for more than ten years in veterinary IVF (Vajta *et al.*, 1997, 2004).

Other strategies using very simple incubation systems are presently tested and the preliminary results are very promising (van Blerkom, personal communication).

Intravaginal fertilization and culturing is another inexpensive method for low cost IVF (Frydman and Ranoux, 2008). A tube filled with culture medium containing the oocytes and washed spermatozoa is hermetically closed and placed in the vagina. It is held by a diaphragm for incubation for 44 to 50 hours. Over 800 cycles have been published worldwide with a very reasonable clinical pregnancy rate of almost 20% (Frydman and Ranoux, 2008).

Presently we don't know if IVF, even minimal stimulation IVF, is feasible in less than ideal conditions when compared to centres with high standards of laboratory equipment and using standard stimulation protocols. Therefore, studies on simplified, low-cost diagnostic procedures and ART techniques are urgently required in a low-cost setting. We have to avoid that accessible ART doesn't mean poorer quality, otherwise we will create an unacceptable double standard in therapy.

Risks of implementing ART in developing countries include the inability to deal with complications following infertility treatment. Ovarian hyperstimulation syndrome, multiple pregnancies, premature babies, ectopic pregnancies are not uncommon in an

ART programme. These complications should be avoided at all price and the facilities and knowledge of the staff should be adequate to handle these problems. Reproductive tourism by attracting international clients from Western countries because treatment can be offered at lower prices is a real danger and is already reported in India (Vayena, 2009).

We also have to realize that even if universal access to infertility care will be available, **barriers** will always remain considerable. Not only in many Islamic countries (Serour, 2006) but also in Latin America the use of ART is severely restricted because of religious doctrines (Inhorn, 2003). In India a conflict with the normative value of Hindu because of the involvement of a third party which compromises the process of conception has been described (Bharadwaj, 2003). Patients in many non-Western countries upholding traditional belief systems are mostly unfamiliar with the technology of 'modern medicine' and therefore might be not willing to accept ART as such (Qiu 2003). Consequently, traditional healers will play an important role and have to be educated about the new developments in infertility practice. Because they speak the language of the local people and appeal to local cultural belief, their support and cooperation will be crucial.

Vision

Infertility care has to be an essential part of a more comprehensive reproductive health care program including infertility and HIV prevention, family-planning and safe mother-care, a go-together of prevention and treatment programs (Sharma *et al.*, 2009).

December 2007 the Special Task Force "developing countries and infertility" of ESHRE (European Society of Human Reproduction and Embryology) organised an expert meeting on in Arusha, Tanzania: the **Arusha-project** was born! Global access to infertility care is the key message but can only be implemented and sustained if they are supported by local policy makers as well as the international community. Accessible infertility care should only be provided in developing countries if there is a political will to support actions for gender equality and women's empowerment through education.

The implementation of new reproductive technologies will require well-organised education and training programmes. Regular audits and systems of accreditation and registration should be implemented in order to maintain appropriate standards of care in all centres involved.

The need for funding is crucial and is likely to require input and collaboration from various role players. Funding is needed for the fixed costs of new

Table II. — Important challenges for the Arusha Project (C Janisch, 2011, personal communication)

- A coherent strategy is required
- A business plan with clear cost structures must be formulated.
- Personnel are required for advice, training, and implementation.
- Protocols and management policies must be defined
- A Lead Organization should be identified to support the planning and design phase.
- Locations for pilot-projects need to be decided
- Cooperation between different societies is needed
- Organization of scientific studies in the different pilot-countries
- Define service packages in order to convince people to donate knowing exactly what they are paying for
- A voucher scheme can be used to improve the quality of services through the development of an accreditation process and enhanced competition among service providers
- The integration of family planning, safe motherhood care and infertility services will be crucial

fertility centres (building, equipment, ...), the running services (consumables, medication, medical interventions, staff salaries), for training the medical, paramedical and administrative staff and for education the public which implies contacts with schools, politicians, traditional healers and the media (Sallam, 2008).

I hope that the **medical and pharmaceutical industry** will also make relevant contributions such as providing cheap medication, manufacturing of basic ultrasound and laboratory equipment at low price etc. **Foundations** have to be convinced about the value of this project, taking into account the growing demand from the developing countries itself and the case of equity and social justice. Many **International Organizations** have already expressed their will to participate in this initiative such as the WHO, ESHRE, IFFS, ICMART (International Society for Monitoring Assisted Reproductive Technology) and ISMAAR (International Society for Mild Approaches to Assisted Reproduction). All these organization can contribute actively in the realisation of this project. Table II summarizes the urgent needs for the Arusha Project.

Conclusion

The great majority of infertile and childless couples are residents of developing countries. Bilateral tubal occlusion due to sexually transmitted diseases (STDs) and pregnancy-related infections is the most common cause of infertility in developing countries. Consequently most cases of infertility are only treatable by using assisted reproductive technologies (ART) which are either unavailable or very costly and only within reach of the happy few who can afford it.

Prevention remains the number one priority, not only the prevention of STDs but also the prevention of infertility due to unsafe abortions and deliveries.

We urgently need a better public education on reproductive health and raising awareness of health care providers and politicians on the importance of childlessness. Most striking is the total lack of interest of the international society including foundations and non-governmental organizations working in the field of reproductive health is.

Time has come to change policies and to realize that access to infertility care is one of the largest emerging fields in global medicine. The immense problem of childlessness in developing countries requires greater attention at national and international levels for reasons of social justice and equity. Keystones in the successful implementation of infertility care in low-resource settings include simplification of ART procedures in order to establish accessible good quality infertility services at low cost.

To conclude, I believe that global access to infertility care in developing countries can only be achieved when good quality but affordable infertility care is linked to more effective family planning and safe motherhood programmes. Only a global project with respect to socio-cultural, ethical, economical and political differences can be successful and convince those who believe that the issue of overpopulation is still an absolute argument to deny the “forbidden desire” of many childless women in developing countries.

“In a world that needs vigorous control of population growth, concerns about infertility may seem odd, but the adoption of a small family norm makes the issue of involuntary infertility more pressing. If couples are urged to postpone or widely space pregnancies, it is imperative that they should be helped to achieve pregnancy when they so decide, in the more limited time they will have available.”

Mother or nothing – the agony of infertility - M. Fathalla, WHO Bulletin, 2010

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