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COMMENTARY

Is global access to infertility care realistic? The Walking Egg Project



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Abstract Until very recently, the problem of infertility in developing countries has been ignored at all levels of healthcare management. Because many preventable or treatable diseases still claim millions of lives, and due to limited resources, provision of infertility care is not on the resource allocation agenda at all, prevention of sexually transmitted diseases remaining the number one priority. Tubal infertility due to sexually transmitted diseases, unsafe abortion and post-partum pelvic infections is the main cause of infertility. Most cases are only treatable with assisted reproduction technology, which are either unavailable or too costly. In December 2007, an expert meeting was organized in Arusha, Tanzania by the Walking Egg non-profit organization in co-operation with ESHRE. The meeting was the start of a global project aimed at increasing diagnostic and therapeutic options for childless couples in resource-poor countries. From the start, the Walking Egg Project has approached this problem in a multidisciplinary and global manner. It gathers medical, social, ethical, epidemiological, juridical and economic scientists to discuss and work together towards its goal. The final objective of the Walking Egg Project is the implementation of infertility services in many developing countries, preferably integrated in existing family planning and mother care services.

KEYWORDS: assisted reproduction, infertility care, IVF, one-day diagnostic phase, resource-poor countries, sociocultural factors

Infertility is a global reproductive health problem. Recent data on the worldwide prevalence of involuntary childlessness indicate that 52.6—72.4 million couples could benefit from some form of medical intervention to achieve a pregnancy (Mascarenthas et al., 2012), the 12-month infertility prevalence rate in less-developed countries ranging from 6.9% to 9.3% (Boivin et al., 2007). The consequences of involuntary childlessness are usually more dramatic in developing countries when compared with Western societies, particularly for women, an observation explicable by differences in: (i) sociocultural values surrounding procreation and infertility; (ii) the economic impact of being childless; and (iii) the availability and

affordability of infertility treatments. These negative consequences include stigmatisation, isolation, being ostracized, disinherited and neglected by the entire family and even the local community (Dyer et al., 2007; Gerrits and Shaw, 2010; Ombelet et al., 2008; Van Balen and Gerrits, 2001). Many families in developing countries depend completely on children for economic survival and so childlessness can be regarded as an important social and public health issue (Dhont et al., 2011; Dyer et al., 2007; Ombelet et al., 2008).

The most important reasons for infertility in developing countries are the high incidence of sexually transmitted diseases (STD), which affects both men and women, and pregnancy-related infections, due to unsafe abortions and home deliveries in unhygienic circumstances, mainly in rural areas. The high prevalence of genital infections in developing countries is commonly compounded by a

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complete lack of diagnosis together with incomplete, inappropriate or no intervention at all. Yet, severe male infertility due to STD and female infertility as a result of tubal block can only be treated by 'expensive' assisted reproduction technologies, which are not available at all or only within reach of those who can afford it (the fortunate few), mostly in private settings (Ombelet et al., 2008). On top of this, marital instability and polygamy, as reactions to infertility and childlessness within the conjugal relationship, may increase the spread of HIV1 infections (and STD) (Dhont et al., 2011).

Despite the severe burden associated with childlessness in developing countries, infertility care remains a low priority for local healthcare providers and community leaders (Fathalla et al., 2006; Ombelet et al., 2008). A shift in attitude towards providing infertility care in developing countries has resulted in attempts to explore low-cost treatments suitable in resource-poor settings, a positive and crucial development. According to Vayena (2009), future steps should consider studies on national infertility needs, the position of infertility services within comprehensive reproductive health programmes and equitable access to infertility care.

Promises, promises, promises ...

'Men and women 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 65 years ago in the 1948 UN Universal Declaration of Human Rights. Relevant reading of this 'right' shows that people should not have (legal) barriers to founding and raising a family. Whether this right also generates a duty to states to offer a particular type of service remains debatable. The human rights argument was used to argue for lifting the prohibition on offering IVF to the population in the recent case brought against Costa Rica (Zegers-Hochschild et al., 2013). Thus, the Inter-American Court of Human Rights (the Court) has ruled that Costa Rica's Supreme Court judgment in 2000 prohibiting IVF violated the human right to private and family life, the human right to found and raise a family and the human right to non-discrimination on grounds of disability, financial means or gender. The jurisdiction of the Court is widely accepted in Latin America, and legal systems of member states of the American Convention are inclined to defer to its rulings. The Inter-American Court's landmark human rights decision, structured upon robust scientific evidence, directs states and governments on the reproductive rights they must provide and must not ban. This may open new pathways in the defense of women's rights worldwide (Zegers-Hochschild et al., 2013).

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). Political statements and

commitments require appropriate actions, but progress towards the attainment of these goals with regard to infertility in developing countries remains almost non-existent. The reasons are multiple and include; (i) the problem of 'brain drain'; (ii) the lack of collaboration between non-governmental organizations, civil society groups, the government and the research community; (iii) budgetary constraints; and (iv) lack of political commitment (Fathalla et al., 2006). The most important international non-profit organizations (NPOs) including Family Health International, World Health Organization (WHO), International Planned Parenthood Federation and The Population Council still focus on safe motherhood, the reduction of unsafe abortions, and the prevention of STD and HIV/AIDS. The implementation of infertility treatment in developing countries is not a priority for these organizations, which means that provision of infertility care and providing assisted reproduction services are not on the resource allocation agenda (Vayena et al., 2009).

Milestones

The first important initiative to highlight the implications of childlessness in developing countries was a meeting, 'Medical, Ethical and Social Aspects of Assisted Reproduction', organized by the WHO in 2001 (Vayena et al., 2002). Among many different recommendations it was stated that; (i) infertility should be recognized as a public health issue worldwide, including in developing countries; (ii) policy makers and health staff should give attention to infertility and the needs of infertile patients; (iii) infertility management should be integrated into national reproductive health education programmes and services; and (iv) assisted reproduction treatment should be complementary to other ethically acceptable, social and cultural solutions to infertility. However, progress towards the attainment of these goals remains slow. Infertility prevention remains the main objective of the WHO and the budget for infertility-related reproductive health programmes is even now very limited. A second milestone was the foundation of a Special Task Force on 'developing countries and infertility' by European Society of Human Reproduction and Embryology (ESHRE) in 2006. This initiative was important in convincing many infertility specialists of the need for accessible infertility care in developing countries.

The Walking Egg: a non-profit organization

As described above, there are plenty of reasons for starting a project to emphasize the magnitude of the problem, to raise awareness of the suffering caused by infertility, and to seek solutions, which can be accepted and adopted by politicians and healthcare providers. This is why The Walking Egg NPO was founded. The main goal of the Walking Egg Project is to make infertility care in all its aspects widely available and accessible and, from the outset, the Walking Egg NPO has opted for a multidisciplinary and global approach towards the problem of infertility in developing countries. This project can only succeed if the calculus of infertility care in terms of availability, affordability and

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effectiveness is changed radically from how it is currently provided (Ombelet and Campo, 2007). An expert meeting on the topic of developing countries and infertility held in Arusha, Tanzania, December 2007, was the first project of the Walking Egg NPO in co-operation with the ESHRE Special Task Force (ESHRE Monograph, 2008). It was concluded that, for infertility care in developing countries to be implemented successfully, the following actions and objectives are essential.

Ethical and sociocultural aspects

Ethical considerations and debates on infertility in developing countries are scarce (Pennings et al., 2009). The Walking Egg NPO aims to perform studies that collect and stimulate research on social, cultural, ethical, religious and legal aspects of infertility in resource-poor settings that would facilitate adoption and access to treatment in each country. Achieving this goal requires something unique with respect to infertility treatment, namely, an international network of social scientists active in reproductive medicine in general and in the developing world in particular (Ombelet and van Balen, 2012).

Economic aspects of infertility in developing countries

Loss of economic security is a well-known and important consequence of childlessness but has never been studied thoroughly. If a woman does not bear a child, families may take away a woman's social security, as well as any gifts or inheritance she might have received during marriage. Although many sociological and epidemiological studies refer to this problem (Rouchou, 2013; Wiersema et al., 2006), reliable data are lacking. The Walking Egg NPO aims to organize observational studies in many resource-poor countries to collect data on the economic consequences of childlessness.

Reproductive healthcare education

Public education on prevention of infertility that includes lifestyle factors, such as STD and measures to avoid post-partum and other infections, has to be improved. Therefore the incorporation of proactive reproductive health education in general health education is mandatory. In this regard, it is self-evident that raising the awareness of healthcare providers and politicians of the importance of reproductive health education and prevention of infertility is equally essential.

Simplifying techniques of diagnosis of infertility: a simplified one-stop clinic

The feasibility of a model of centralized expertise with a one-stop diagnostic strategy in developing countries will be examined. The one-stop approach implements the responsibility of diagnosis and immediate management policy. The consequences of the results for the management

of the couple have to be discussed on that same day (Ombelet and Campo, 2007).

Developing low-cost and effective ovarian stimulation protocols for intrauterine insemination and IVF/intracytoplasmic sperm injection

The stimulation protocols that are most appropriate for intrauterine insemination and IVF have to be determined with respect to safety, efficacy and cost. Based on findings in the literature, feasibility studies have to be performed to examine the value of such protocols in resource-poor settings.

Developing simplified culture systems for clinical IVF

Lowering the costs associated with laboratory procedures, namely fertilization and culture of eggs and embryos, represents a significant challenge in both developed and developing countries. As part of the Walking Egg Project, we developed a new simplified method of IVF culturing, termed the ^tWE laboratory method (^tWE stands for 'the Walking Egg'). Using this new system can avoid the high costs of establishing IVF laboratories typical of high-resource settings that are dependent upon a well-developed infrastructure common in developed countries (Van Blerkom et al., 2013). Up to July 2013, 15 healthy babies have been born as a result of this simplified method, four of them were born after transferring one frozen—thawed embryo. The miscarriage rate was 6.3% (1/16).

Challenges to implementing accessible infertility services into (existing) reproductive healthcare programmes

The ultimate aim of the Walking Egg Project is to establish low-cost fertility services in developing countries with affordable, effective, safe and standardized diagnostic and therapeutic procedures and protocols. The integration of infertility management into sexual and reproductive healthcare programmes combined with very significant reductions in costs are considered prerequisite to implementing 'new reproduction technology' in developing countries. Simplifying procedures and minimizing the complication rates will be mandatory if new treatments are to be made available and accessible, especially outside the private healthcare sector.

Organization of training courses

Training courses have to be organized on a regular basis with emphasis on the diagnosis and prevention of infertility in developing countries, hysteroscopic surgery, the clinical aspects of intrauterine insemination and IVF and the laboratory aspects of IVF/intracytoplasmic sperm injection. Following training, quality control, regular audit and systems of accreditation and registration should be implemented in order to maintain appropriate standards of care.

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Data registration

Studies on the prevalence of existing childlessness in developing countries have to be performed. Country profiles, with data on current resources for infertility, need to be obtained, as such information is virtually non-existent and is essential in order to select countries with the best possibility for successful implementation of the first pilot centres. It is our aim that within each pilot-centre, clinical data will be registered and, when possible, be made available online on an ongoing basis from the start of operation.

Advocacy and networking

Global access to infertility care can only be implemented and sustained if supported by local policymakers and the international community. Many international organizations have already expressed their desire to collaborate with the Walking Egg Project, including WHO, ESHRE and ISMAAR (International Society for Mild Approaches to Assisted Reproduction). We will also need the media, patient organizations and interested politicians to effect changes in the existing moral and sociocultural beliefs that result in the isolation and exclusion of infertile couples.

A global project to combine education, family planning, maternal and reproductive health care and infertility diagnosis and treatment

According to the Walking Egg Project philosophy, fertility services have to be integrated within the context of health-care clinics or hospitals dealing with contraception, family planning and good-quality maternal care. Walking Egg pilot centres will pay special attention to health care education, maternity- and child-care, prevention of unsafe abortions, promotion of safe deliveries and the prevention and treatment of STD and HIV. We believe strongly that only a global

ADVOCACY & NETWORKING

↓ burden of disease

- Meetings with politicians, healthcare providers, ...
- Media: movies, testimonies, soaps, ...
- · International Day of Infertility
- PhDs/papers in peer-reviewed journals/lectures
- · Organization of scientific meetings
- International Scientific Journal: Facts, Views & Vision in ObGyn

SERVICE DELIVERY

training & capacity building

- Selecting pilot-centres → search for funding
- Search for Public-Private Partnership
- Training courses for medics, nurses and laboratory personnel, administrators
- Implementation of "WE low-cost IVF centre (level 1/level 2)
 - → Combining infertility care, FP, MC and RHC education

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RESEARCH & INNOVATION

study projects

Non-medical

Research on different aspects of infertility care

- Ethical
- Religious
- Sociocultural
- Epidemiological
- Economical
- Political
- Law

Medical

- Feasibility studies on:
 - o 'tWE one-step diagnostic phase
 - o 'tWE lab simplified IVF
- `tWE packages for IVF/IUI
 - o Strict protocols
 - o Manual for diagnostic phase
 - o Manual for therapeutic phase
- o Documentation/registration

Figure 1 The Walking Egg Project at a glance. FP = family planning; IUI = intrauterine insemination; MC = mother care; RHC = reproductive health care; ^tWE = the Walking Egg.

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project that encompasses all major aspects of reproductive health can be successful if infertility care is to be accepted, affordable and effective in low resource settings.

The future

Figure 1 gives an overview of the activities to be undertaken by the Walking Egg Project in the near future. To realize its objectives, the following actions are designed to raise awareness of involuntary childlessness: (i) academic publications; and (ii) lobbying efforts directed at the donor community, politicians, funding agencies and research organizations. The project is currently involved in the development of new and novel methods to make infertility diagnosis and infertility treatment accessible and affordable to a much larger part of the population in need (Van Blerkom et al., 2013). A prototype modular ^tWE centre for infertility treatment that will serve as a training centre will be built in Genk, Belgium. This freestanding clinic is designed for simple assembly and to fit within a container for transport. An analysis comparing the new ^tWE laboratory method with classical IVF is in progress and will be the subject of a separate report in the near future.

Just more promises, promises, promises?

According to Millennium Developments Goal 5, universal access to reproductive care, including both contraceptive and infertility care, should be adopted by the year 2015. To date, nothing has been done to help childless couples in developing countries. The magnitude of childlessness in developing countries has dimensions beyond its prevalence and aetiology. Differences between the developed and developing world are emerging because of the different availability of infertility care and the different sociocultural values surrounding procreation and childlessness. There is a growing belief that individual health needs of impoverished people have a place next to their public health needs. Although reproductive health education and prevention of infertility are number one priorities, the need for accessible diagnostic procedures and new reproduction treatments is very high.

Genital tract infections are the most important cause of infertility in developing countries and the need for both preventative healthcare measures and accessible treatments is clear. New technologies can only be successfully introduced if the governments can be persuaded to support their introduction. This will largely depend on our ability to optimize these techniques in terms of availability, affordability and effectiveness.

The Walking Egg NPO aims to raise awareness about childlessness in resource-poor countries and to make infertility care in all its aspects, including assisted reproduction treatment, available and accessible to a much larger population than is currently served. By simplifying diagnostic and IVF laboratory procedures and by modifying the ovarian stimulation protocols for IVF, assisted reproduction techniques can be offered at affordable prices. As evidence-based, affordable solutions begin to drive global guidance within both public and private healthcare systems, access to care for the infertile couple will become one of

the largest emerging fields in global medicine. Although many studies suggest that the cost per treatment cycle can be reduced substantially, actual costs will ultimately be determined by location, the extent of government support and, in the most optimistic scenario, whether the international donor community comes to realize the magnitude and consequences of involuntary childlessness in the developing world. With this project, we want to provide a workable and effective model by which the aforementioned 'promises, promises, promises' can be fulfilled.

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Declaration: The author reports no financial or commercial conflicts of interest.

Received 4 September 2013; refereed 21 November 2013; accepted 21 November 2013.