

Affordable ART and the Third World: difficulties to overcome

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A coherent strategy is required, donors to cover the costs of a business plan and personnel to provide advice and training and the country must be chosen. An urban environment is preferred with a local link, ideally a University Department with an existing ART programme and a willingness to be involved. Premises, a clinician and an embryologist must be identified, appropriate training arranged and excellent communication systems put in place. Apart from arranging equipment and servicing supplies, management systems and transparent data collection processes must be established. The protocol and local variations have to be agreed. The clinic needs to be related to the local health system, referral patterns must be created and screening processes set up to develop a waiting list of suitable patients. The nature of prior treatments must be defined. At some point, there needs to be a visit of an agreed scientific adviser with or without a donor representative. The number of patients treated in an initial cohort and review details should be determined. A longer term programme, the creation of a local professional network and clear relations with the state health system need to be explored. Any of these stages may constitute difficulties to be overcome.

Keywords: low cost ART; strategy; low resource; developing world; difficulties

Introduction

The stimulus to develop Assisted Reproductive Technology(ies, ART) in the developing world began at a World Health Organization meeting in September, 2001 arranged to review progress in the field over the preceding 10 years and define areas for closer attention. The meeting developed a series of recommendations in public health with regional relevance. They invoked action by governments, policy makers, professionals and the public. One of these was that 'research is needed on innovative, low-cost ART procedures that provide safe, effective, acceptable and affordable treatment for infertility' (Vayena *et al.*, 2002). Subsequently, WHO adopted as policy the implementation of a programme on low-cost ART. To address this defined need, the Low Cost IVF Foundation was established independently in 2006 and has begun to develop a protocol and explore ways in which it might be implemented.

It is not immediately obvious that the Millennium Development Goals (<http://www.un.org/millennium/declaration/ares552e>) can include such a programme, however the last

one is to 'evolve a global partnership for development in co-operation with the private sector, make available the benefits of new technologies—especially information and communications technologies'. And clearly such technologies can include ART.

Although it may not be difficult to establish a new ART centre in a developed economy, it is rather more challenging to do so in a low resource economy, especially where there is little experience of such organizations. Much thought has gone into planning an inaugural clinic by the members of the Low Cost IVF Foundation and this paper addresses some of the issues that have been foreseen as potential problems. Steps in the establishment of a clinic will be described, recognizing that each one may be a source of significant difficulty. When these steps have been implemented, it will be interesting to see whether all problems have been effectively anticipated and forestalled or whether new and taxing issues conspire to compromise our early efforts.

Prior to the Mexico summit on Health Services Research, Travis *et al.* (2004) in an invited contribution, emphasized that the major barriers in establishing a service in the

developing world are the lack of human resources, financing, drugs and supply systems together with the failure to use information that is already available. They went on to point out that the overall policy environment, political instability and the quality of governance pose greater barriers than do resource constraints. These caveats have been kept very much in mind.

Planning steps

1. *A coherent strategy is required*

The whole process from initial soundings through to the funding of an established clinic needs to be planned with appropriate emphasis being given to each step. The details come later, but the feasibility of developing a sophisticated reproductive medicine service in a low resource economy with perhaps little previous experience of complex and meticulous organization must be explored and documented.

2. *A business plan with costings must be formulated*

The physical facilities, staff, equipment and consumables over a defined time period must be estimated. The cost of training, transport, servicing of equipment, provision of educational material, patient recruitment and screening must be allowed for. Documentation and communication with supervisors need to be covered.

3. *Personnel are required for advice and training, recognising travel demands*

There will need to be one or more experts, say, embryologist and clinician, who have the responsibility for training and supervising new staff in a clinic. There will need to be a system for immediate contact in case urgent problems need to be resolved. These experts may not work close by, so arrangements will need to be made for visits and the cost of travel and accommodation supplied.

4. *Protocols and management policies must be defined*

Although a standard protocol may be desirable, there are likely to be local idiosyncrasies that suggest alterations are necessary. If elements are already practised locally, these should be incorporated if feasible. There should be a clear understanding of the reasons for all steps with local anxieties being addressed.

5. *Donors need to be recruited to cover the costs for a specified time*

Before definitive negotiations with a specific location are begun, costings must be available, so that potential donors can be appraised of likely candidate clinics to support. There may be special reasons for a donor to have interests in a particular part of the world or specific links between experts and donors that can be developed.

6. *Locations need to be decided*

The potential is huge. Developing countries comprise North Africa, sub-Saharan Africa and southwest Africa, the northern and eastern countries of South America, Eastern Europe and countries of the former USSR, the Middle East, Iran and Myanmar, South East Asia and Indonesia. This becomes a

little more restricted if one uses the UN Human Development Report, 2007, which highlights much of Africa, especially sub-Saharan Africa, most of southern Africa and the horn of Africa. But even within such large regions one country needs to be selected and within that one city.

7. *Choose an urban environment, linked to an existing infertility clinic framework*

It is tempting to think in terms of providing ART to the huge numbers of the urban poor, but apart from being a logistic nightmare, many such regions have poor infrastructure, such as roads and transport, water, sewage and communications, which should all take priority, as should issues of obstetric services and prevention of maternal mortality, over the more complex forms of assisted reproduction. It would be better to think in terms of a capital city with an established University, where there is already considerable experience of fertility management and where supply chains for equipment, drugs and consumables have been established. Further, the skills of such staff may be crucial in dealing with local supply problems, staff recruitment and in due course, in providing advice and partnership in dealing with government.

8. *Patient screening and selection mechanisms must be in place to create a waiting list*

When the treatment phase begins, it should provide a significant work load for the staff. The best way to arrange this is to bulk up the patients so that batches of patients are treated for a period of time. This will allow reflection, modification of systems, guaranteeing supplies and repairs and permit prediction of future workload. It is imperative that appropriate patients are treated and treated with relevant techniques. To ensure that this happens, a substantial screening process will need to have been operating for some time. That time will depend on the experience of the original infertility clinic, for how long it has been operating and the types of treatment offered. Record systems must be in place so that those placed on a waiting list have known why they were placed on it, have been counselled and can be readily contacted. The level of treatment will need to have been determined, so that only those who have failed simpler methods or initially have more complex problems that require the higher level of treatment offered. Strict criteria will need to be applied, such as for age and duration of infertility, so that the initial candidates have a reasonable prospect of pregnancy. This is to ensure that the method is properly tested and that early successes help to raise the clinic profile. Once these early parameters have been established it will be possible to address more complex problems, but there will be confidence in the system and morale and public confidence will be sustained.

9. *Appropriate premises and staff training must be arranged*

The precise details in relation to the original clinic must be agreed. The physical relations of the existing clinic must be established, whether it is in the same clinic, but an adjacent area, an extension or new premises. Both clinician and laboratory staff must reach an agreed standard. It may be necessary to send trainees away for training or training on

site can be arranged. Details of local or distant supervision and continuing contact must be arranged. There should be some relation to an existing formal training programme, so that upon completion, a successful trainee can use such criteria for validation.

10. *Enthusiasm and altruism are required of staff*

It is evident that, when discussing these concepts in various places, some personnel are doubtful or sceptical and do not wish to participate in such a programme. It should be clear to participating personnel that these techniques will be offered to those who cannot afford the more costly methodology frequently available elsewhere. They will not be offering, at least initially, the methods to those who can afford more costly interventions. It is essential that all participants recognize that their offering treatments to their society members is an exercise in goodwill, a move to spread medical skills to a larger segment of their society and that they are proud to be able to participate.

11. *Excellent communication with supervisors is necessary*

It is vital that all variations in management and outcome are identified and recorded, so that trouble shooting can be effective. Efficient communications with supervisors are crucial to engender confidence in each party and ultimately in the data generated. This must certainly be by e-mail, and ideally by mobile phone.

12. *Reliable delivery of equipment and consumable supplies is essential*

Initial setting up of the clinic is one thing, but reliable supplies and equipment maintenance and repair processes are essential for longer term functioning. This is where the experience of an established clinic in a capital city is more likely to be critical in achieving these aims. Experience will also indicate the nature of likely future problems and allow appropriate anticipatory responses.

13. *Systems for records and data management are mandatory*

A laptop should be used to enter data into a simple spreadsheet to document basic information. The data are to be used for patient monitoring, later review and analysis when the data bulk up. Care must be taken in organising the original data input to ensure that the format is compatible with larger databases, such as the international collation system of the International Committee for Monitoring of ART data (ICMART). When a number of these clinics have been set up, hopefully with methodology that allows the data to be integrated, analyses can be carried out to evaluate the data from low cost systems. These data should also be entered into the ICMART regional and world databases in due course, and ideally from early days. It is also important to have systems that allow trouble shooting when programmes fail to reach expected standards, and particularly for a programme that may fall some way short of the 'successes' trumpeted by the more aggressive and expensive systems.

14. *Relations with other infertility services*

It is likely that other providers will be working in the same locality. The parent clinic may already be in the same Department or hospital. Competition is not the way to describe their respective activities. They are targeting completely different strata of society and will continue to do so until ART has been fully integrated into the health services and funded by the government, which may be a long way off. There may be opportunities for exchange of information, and staff, educational activities in common and social interchange, which should sustain morale, allowing appreciation of a common enterprise. Rather than competition for resources, it would be better to share knowledge and administrative effort to obtain better services for each. It may be necessary for the incoming clinic, as the less well established, to promote communication and co-operation. Patient education could be a shared activity leading to better public information and, indirectly, is a way to enhance political awareness of change and opportunity.

15. *Initial cohort size and the review process should be agreed*

It will take some time to screen patients both economically and healthwise. It is important that those who can afford conventional ART, often the more articulate, do not exploit the new service. Those initially offered the low cost regime should not have had previous ART, as failure of previous treatment would compromise valid appraisal of prospects for pregnancy. A group of say 50 patients should be the initial cohort, to ensure an appropriate workload for the laboratory and nursing support. Perhaps a regular clinic would offer this service intermittently, having screened all their patients to select those appropriate for the new system. Between batches the nature of the clinic's work would be different and planning of these contrasting phases would be separate. Ultimately, there could be continuous activity, but this would depend on actual and perceived success and longer term funding.

16. *Integrate data collection from centres to facilitate early comprehensive review*

It will be essential that the external advisor/supervisor reviews the data. This is to ensure integrity, credibility and self-confidence for the clinic. Data must be able to be sent to a central point for analysis and comparison with other similar centres. It will be a learning experience for all. Recognition of the need for compatibility of datasets is fundamental. Hopefully, the data can be merged and analysed in a meaningful way. That should lead to the presentation and publication in the usual media, a process to be encouraged from the beginning. Only in that way will the possibilities for the extension of the concept and expansion of the facilities become possible.

17. *Modify the programme in the light of results*

Self-critical reflection is crucial to the development of a robust system, so that modifications of the original protocols and techniques can improve results and the patient experience. The more the clinics work on their systems to improve them the richer will be the experience become as information and attitudes are exchanged. This could lead to a major change in

the perception by the community that could affect greater numbers of prospective patients.

18. *Develop links with other health service areas*

There is a concept of Reproductive Health Centres, which includes family planning, management of sexually transmitted infections (STIs), even linking to maternity and neonatal services. The idea is to emphasize the continuity of care and the relationship between these elements. Effective family planning, public and patient education to reduce the blight of illegal abortion and STI and the preparation from puberty for a rewarding reproductive life are the important denominators of a society developing toward fulfilment of each person's potential. These processes should reduce the prevalence of infertility by emphasizing prevention with its feedback on to reducing the overall cost of reproductive health care.

19. *Begin the broader political campaign to promote acceptance*

If and when a Low Cost ART programme can be effective and provide acceptable outcome, then the data must be available for the presentation not only in medico-scientific circles, but also to the wider public. This means not simply patient groups, but the media for public reproductive health education and to sensitize government. Officials of the health service should see the data and should be given the case for integration into the publicly funded provision. A political case will also need

to be presented to become a part of the aspirations of sitting and candidate members of the administration. This argument has been won in few affluent countries, but the impact could be much greater in low resource environments.

To conclude, this list of points is a start. When a number of clinics have established Low Cost programmes, they may be quite different, but more likely in the detail than the principles. There are three steps: firstly, to identify efficiently and cheaply the 50% of couples with infertility who would benefit from ART and concentrate the Low Cost programmes on those that cannot afford the more expensive services; secondly, to deliver effective treatment in the local context and thirdly, to publicise quality data and use it to influence the health systems.

Perhaps the more affluent countries could learn from this approach and offer such a system to their own impoverished populations, which have the same problems.

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