ESHRE's data collection: developments in online submission and in achieving greater coverage

- Progress identified in some national registries
- A flurry of legislative updates and introductions

EIM Consortium Chairman Markus Kupka: ESHRE monitoring represents 'around 80%' of total European ART activity

No other organisation in the world has a registry in reproduction to compare with ESHRE. The Society's European IVF Monitoring (EIM) Consortium is in its 15th year of data collection and has now passed the remarkable milestone of more than 1 million live births recorded. The Consortium is presently monitoring around 600,000 cycles a year in an ever escalating total of European ART activity. In 1997, the first year of EIM analysis, just 482 clinics in 18 countries were represented in 203,225 cycles of IVF and ICSI; in 2011, whose data are now being analysed, 1034 clinics in 33 countries were represented.

Speaking in November in Leuven at a closed meeting of Consortium members, EIM Chairman Markus Kupka estimated that the 600,000+ cycles now monitored each year by ESHRE represent 'around 80%' of total European activity - and that, he said, is good enough to provide a reasonably accurate snapshot of what's going on. But achieving a fuller, more detailed picture remains a huge challenge, not just to incorporate those countries with 'ongoing difficulties' in data collection, but also to ensure that the data which are collected accurately reflect the present trends in treatment. For just as ART itself continues to grow in complexity, so the task of data gathering also becomes more complex. Collecting data on a procedure such as 'egg donation', for example, is no longer a simple matter of recording a cycle, but must now acknowledge oocyte and/or embryo cryopreservation, transfer in a fresh or future (non-stimulated) cycle, and outcome, which may well be several years after the initial egg collection cycle.

And hanging over all the Consortium's difficulties lies the continuing challenge of online data collection. So it was good news in Leuven to hear Kupka announce that a Spanish company - which already works with the national IVF registry in Spain, has now been contracted to build a web-based platform to collect the ESHRE data. Plans are that the platform will be introduced in 2015. The same Spanish company will also create a tool to analyse incoming data for the annual report. 'So the whole process will be speeded up dramatically,' said Kupka, who added that the Spanish company will also be asked to create a data-collection tool for those countries with no online system. The current questionnaire is composed of eight modules (most of which are sub-divided) and 20 tables, set out over ten pages - and with a deadline for completion of around six months. For example, data for 2011 were asked for in Summer 2013, with a deadline of 31 December.

However, the Consortium's biggest everyday challenge still lies in data collection from those countries without national registries and with clinics reluctant to divulge their results. Data have never been received from Slovakia or Malta (which only recently joined the Consortium), while Albania, Bosnia, Croatia, Cyprus, Latvia, Romania and Turkey have provided only sporadic details. However, most of these countries were represented in Leuven, and their representatives were able to describe some progress.

Romania

'We want a national register, but there are still problems,' said Ioana Rugescu, who explained that legislation lay with the National Transplant Agency (and was thus based on the requirements of the EU Tissue and Cells directives). Any ART data collected were based on Eurocet forms (see box opposite). A voluntary scheme set up by the embryologists' association recruited only 50% of clinics.

Russia

Data collection is on a voluntary basis through the Russian Association of Human Reproduction and currently includes 138 clinics and around 63,000 cycles, around one-third of them under state control. From 2013 fertility treatment is covered by health insurance - patients can choose their clinic and their insurance company. However, 'around 25%' of data is not reported, and 'the register needs the support of the Ministry', said Vladislav Korsak (who has looked after the registry since its inception in 1995).

Cyprus

ART in Cyprus - around 2000 cycles a year - has been so far unregulated, but legislative proposals last year included a national ART registry and supervision by an ART authority. Historically, there has been a substantial trade in overseas treatments, mainly for gamete donation and sex selection (by PGD).

Malta

Data collection during 2013 (for the treatment year 2011) was Malta's first in the EIM Consortium, following the country's introduction of legislation in 2012 under control of the Embryo Protection Authority. The new legislation is quite restrictive, but treatment (up to three cycles) is fully reimbursed for women aged

25-42 years. Women must be in a stable relationship; embryo freezing is not allowed, but oocyte freezing is 'encouraged', said Jean Calleja-Agius. The new legislation requires details of every cycle to be submitted, with first data available after 2013.

Greece

Greece has consistently submitted data to the EIM , but on a voluntary basis, and with few details of deliveries. Triplet pregnancies have been a feature, with little regulation to guide treatment. Now, said Dimitri Loutradis, the situation is set to change with the introduction in 2015 of a National Authority for Medical Assisted Reproduction (NAMAR). Recently, ART has been hit hard by the financial crisis, with total cycles now at around 8000 per year. NAMAR will introduce a licence/code of conduct system for clinics, with a responsibility 'to collect results', and a restriction on the number of embryos transferred in each cycle (two in under 35s).

Croatia

Croatia has been able to provide registry data to ESHRE for only one of the past six years, but Hrvoje Vrcic reported that legislation introduced in 2012 included the development of a government registry in ART.

Other disclosures in Leuven described significant updates to the regulation and registry systems in some countries. Both Switzerland and Austria are now looking ahead to new statutes, the former with legislation now agreed by Parliament to include PGD, embryo cryopreservation and sperm donation (though not yet oocyte donation). Austria too agreed new draft regulations (just the day before the Leuven meeting!) which would also allow PGD, egg donation and treatment in lesbian couples. 'We were somewhat shocked,' said Heinz Strohmer, 'We now expect things to change dramatically in Austria.'

Poland too is set for dramatic change in its ART legislation. Reimbursement (of treatment and now of medication) has been introduced and a new law is 'waiting in Parliament'. ART has been hampered by religious objection in Poland, but that, with the acceptance of reimbursement, seems now more an academic than practical concern.

Chief among the reasons for inadeqaute national registries was money, with many smaller ART countries with voluntary registries seemingly the most affected. In fact, the split between voluntary and compulsory data collection among EIM countries is fairly equal, with some voluntary systems (Spain and Germany, for example) as comprehensive and successful in their registries as statutory (UK). Indeed, Germany operates its registry on a simple funding formula of 1.60 euro for each cycle started, and 'there's no problem to pay,' said Kupka.

The other main problem identified was an unwillingness to disclose results. Latvia, Ukraine and Slovakia had 'no data . . . and no will to have a registry'. Several delegates, particularly from countries with just a few private clinics, expressed doubts whether these clinics would ever reveal their results, for fear of league table competition.

Nevertheless, despite the problems inherent in a mix of voluntary and mandatory systems, 15 countries do now provide data derived from every clinic - Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, Hungary, Iceland, Norway, Portugal, Slovenia, Sweden, Netherlands, United Kingdom - while most others offer reliable returns from a large proportion of their clinics.

CONFUSION OVER EUROCET DATA COLLECTION

Several countries describing their efforts in ART data collection seemed under the impression that requests from Eurocet to provide ART reports would meet requirements on standards set out in the EU Tissue and Cells directives of 2004. However, there appears no confirmation of this, and said Kupka, 'it is difficult to know what Eurocet's objectives are' in data collection and under what authority it operates.

For its part, Eurocet describes itself as no more than 'a tool aiming to collect data on tissues, hematopoietic and reproductive cells'. Nowhere does Eurocet refer to its (or any) statutory right to collect ART data, only that the 'European Commission encouraged the use of Eurocet portal as a way to fulfil the obligations of the tissues and cells Directives'.

Eurocet is run by the Italian National Transplant Centre and appears to have no formal status within the EU, other than its self-styled role 'to respond to the obligations of the tissues and cells Directives'.

National representatives from the EIM Consortium meeting in Leuven.