An electronic health record for infertility clinics

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Objective. To design a user-friendly electronic health record system for infertility clinics (EHRIC) to capture quality data that will allow advanced audit and practice analysis, and to use the captured data for the South African Register of Assisted Reproductive Techniques (SARA) database and as a clinical research function.
Methods. The researcher did personal interviews with fertility specialists and the staff from various fertility clinics in South Africa regarding day-to-day running of an infertility clinic. Collection of annual data to be used for the South African Register of Assisted Reproductive Techniques (SARA) database proved to be a tedious task that is also open to inaccuracy. A local medical software design company designed an integrated system that will collect clinical, laboratory *in vitro* fertilisation, andrology and cryopreservation data.
Results. Phase 1 allowed the researcher to collect demographic and clinical data via a web-based program as well as entering clinical information. Phase 2, when complete, will allow for annual reports according to the SARA requirements.
Conclusion. The paperless infertility clinic is a possibility, but will require commitment and training of all staff involved.

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The comparison of healthcare data between facilities, between provinces, within a country and between countries is vital to the growth and dissemination of health information throughout the world. The infertility fraternity in South Africa (SA) embarked on a programme to begin voluntary collection of data from all the major infertility centres in SA. This was initiated by the Southern African Society of Reproductive Medicine and Gynaecological Endoscopy (SASREG) under the guidance of Professor S Dyer of the University of Cape Town. The data were processed through the Latin American Register of Assisted Reproduction (Redlara) and first published by Dyer *et al.*[1] in 2011.

According to the SASREG website,[2] the current data collected through the South African Register of Assisted Reproductive Techniques (SARA) are presented as the national data. 'National ART [assisted reproductive technology] data monitoring is not a substitute for sound clinical or laboratory research, although it may assist in ART-related research. Answers to the question, for example, "What is the optimal stimulation protocol for ART?" must be derived from randomised controlled trials not from national data registries. It is likely that national anonymous data monitoring will raise more research questions than it will initially help to answer.'

As a byproduct of a patient's contact with a healthcare provider in an infertility setting, information will always have value, whether collected manually or through an electronic health record (EHR). According to the staff from the Aevitas Clinic at Vincent Pallotti, the Cape Fertility Clinic, the Fertility Unit in Port Elizabeth, the Tygerberg Fertility Unit, the Groote Schuur Fertility Unit and Wijnland Fertility (personal communications), collection of the data for the SARA proved to be a tedious task and open to inaccuracy. This will not be the case if the information collected is accurate, relevant, structured and presented in an easily usable electronic form. Accurate scientific data are important to the advancement of science, and it can be argued that proper management of the data, and in particular the quality and accuracy of the data, is the most important element in ensuring scientific integrity and public confidence in research results and findings.

The aim of this study was to develop a viable software program that could assist in the day-to-day capturing of data in any infertility clinic. These data could be used for audit as well as research, and would therefore be highly desirable for specialist practices.

Objectives

The primary objectives were to design a user-friendly, attractively designed electronic health record (EHR) to be used in an infertility setting (electronic health record for infertility clinics, or EHRIC) and to capture accurate quality data that would allow advanced audit and practice analysis.

The secondary objective was that these captured data would form the national SARA database and would have a clinical research function.

Methods

Study design

Bluebird, an SA medical software design company, was approached to help design an integrated system to capture clinical, laboratory *in vitro* fertilisation (IVF), andrology and cryopreservation data.

Sessions with computer programmers from Bluebird were held to incorporate the clinical data into the design of the program. Follow-up sessions were scheduled for testing the prototype, redesigning where necessary, and quality control of the program.

All paper documents currently used in fertility clinics were to be collected, copied and studied. All possible duplication of data was excluded and templates were made during the design phase.

The templates were then supplied to the programmers to design a web-based patient history form that would be accessible over the internet. The completed form could be e-mailed or faxed back to the clinic.

Clinical data

The following data were collected:

- Medical history, i.e. a detailed history of the patient's past health/illnesses including social history and habits. This section also included a family medical history, presenting signs and symptoms, and the history of the present illness or problem.
- Surgical history.
- Current medications, including the name and dose of the medication.
- Diagnostic tests, including the name of tests and/or X-ray, ultrasound, etc. and reports of findings.
- Operative procedures, i.e. all procedures performed in an operating room or day surgery for diagnostic or exploratory purposes or for definitive treatment.
- Physical examinations and assessments, including the results of a physical examination with findings and objective observations recorded, along with a provisional or working diagnosis.
- Main infertility-directed diagnosis.
- Specific fertility factors.

Treatment plan

- **Stimulation protocol.** The type and dose of medication used for ovarian stimulation was captured.
- **Laboratory results.** These were captured on the specific day the test was requested.
- **Ultrasound.** Follicle tracing and endometrial thickness were automatically captured.
- **Procedures.** All procedures done during the treatment cycle could be captured (up to three procedures per day per patient/couple, e.g. follicle aspiration, testis biopsy, embryo transfer).
- **Laboratory procedures.** The method used for fertilisation, e.g. IVF, intracytoplasmic sperm injection (ICSI), gamete intrafallopian transfer (GIFT), was captured, as was confirmation of fertilisation. Daily embryo development and culture up to blastocyst stage was graphically displayed. Embryo transfer was recorded, together with other procedures such as assisted hatching and vitrification of supernumerary embryos.
- **Vitrification dewars (freeze tanks).** All stored gametes and embryos were graphically shown and clearly identified by tank number, goblet number and visitube colour. A full history was kept of the vitrified gametes or embryos.
- **Outcome.** The outcome of the cycle was recorded, as well as any complications that may have occurred.

Data analysis

All data used for the reporting were anonymous owing to the unique personal identifier used.

Results

The preliminary reports are presented in two phases.

Phase 1

In phase 1 the researcher (JLC) was able to collect the demographic and clinical data from a web-based program.[3] Any of the data entered into the program can be extracted at any given time or day. Further functions include:

- **Ordering.** One of the most valuable aspects of the electronic database is the ordering of investigations and prescriptions in the electronic database, which enables monitoring of outstanding results and retrieving patients' prescribed specific medications. Prescription data on EHR have the highest rate of recording.[4]
- **Reports.** The researcher is able to view any group of patients, e.g. the first 30 IVF patients, and recall the indications for the IVF, the number of pregnancies achieved and whether any complications were recorded. These results can be retrieved as daily, weekly or monthly data. Although these results can be extracted from the details entered, a structured report is not yet available and more programming will be necessary.

Phase 2

The proposed templates, still to be developed, will produce a report according to the annual SARA requirements. All results can be displayed per chosen age group, e.g. IVF in patients aged <35 years, 35 - 39 years and ≥40 years. It is anticipated that the phase 2 report on the SARA as well as the research functionality will be available within the next year

Discussion

As far as phase 1 is concerned, the EHRIC improved data collection and record keeping in the Natal Fertility Clinic (personal communication), resulting in a definite saving in secretarial time, and also a reduction in missing records. In the long run it is expected that less storage space will be needed. An added bonus was that all the collected clinical and demographic data were accessible from anywhere via the internet. The data enabled the researcher to create random searches to track the pattern of disease as well as treatment outcomes within the clinic.

Phase 2 of the project is not yet complete. The IT specialist from Bluebird performed the initial phase 1 programming free of charge. Owing to the complexity in the design of the program, as encountered by the researcher, the cost of development was higher than predicted. It has often been stated that the hospital environment and medical practices are the most complex organisation structures ever created.[5] The researcher, although not totally oblivious to the complexity involved in the programming, had anticipated earlier completion of the program. It should not come as any surprise that, traditionally, programming and implementation of successful healthcare information systems have lagged behind commercial banking and other non-healthcare information systems, owing to the required complexity.[5] The IT specialist has requested more time and financial support to complete the programming.

The possibility of incentives to offer support and maintenance and keep the EHRIC program updated should be investigated. This incentive could be offered to clinics that use the program and share their de-identified data through the annual SARA reports. This has been done in the North Shore Hospital System on Long Island in New York[6] and may increase use of the EHRIC.

In order for an EHR to be used to collect data for scientific studies, the following must be adhered to:[7]

The quality assurance of the data is important. If the data entered into the program are of high quality, the reporting will be of similar quality. Data that are of no importance, or not easily retrievable, should not be collected: 'more is not always better'. The infertility

program can be designed to ensure that key data will be edited and validated, and if entered incorrectly data will be flagged. This should provide quality assurance.

- **Precision** means that the data collected should have sufficient detail.
- **Integrity.** Data have integrity when the system used to generate them is protected from deliberate bias or manipulation for political or personal reasons.
- **Confidentiality** means that clients are assured that their data will be maintained according to national and/or international standards, i.e. personal data are not disclosed inappropriately, and data in hard copy and electronic form are treated with appropriate levels of security (e.g. kept in locked cabinets and in password-protected files).

Scientific electronic records should be authenticated by a system that provides security functions which restrict access by requiring system user identification through the use of a login ID, a password combination known only to the person(s) authorised to enter the system. This password system would identify the time, date, and person or persons entering, modifying, or recording data. Scientific electronic records should be unaltered once committed to the system. Procedures must be established and documented for all users to follow. Secure electronic data storage offsite is of utmost importance.

In this study, after completion of phase 1 it was possible to collect the demographic and clinical data from a web-based program. After completion of phase 2 all infertility clinics in southern Africa will be able to produce accurate reports from accurate collected data. The data collected via a web-based program as well as data entered on the treatment cycle page in the EHRIC program will allow extensive audit possibilities and produce annual SARA reports. This should also complete the research functionality of the program. The paperless infertility unit is a possibility, but will require commitment and training of all staff involved.

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