Development of Electronic Data Collection as a Tool for Quality Assessment in Reproductive Techniques in Germany

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ABSTRACT

For quality management in assisted reproductive technology, electronic data collection is well established. Depending on fast progress in hardware development, electronic tools in this field had also developed. As a result, data quality and validity increased. Network architecture will influence new strategies for data collection such as remote data entry systems. To reduce redundancy, prospectivety is implemented in the new software generation of the German in vitro fertilization (IVF) registry. Fifty thousand IVF cycles per year force regular upgrading of database software. The next generation of data collection could be established via the Internet and central database management. The annual report with a pool of data from all reporting clinics provides an overall national picture that could not be obtained by examining data from an individual clinic. Furthermore, the board of the German IVF registry enabled a detailed scientific analysis. Correlations of various parameters had been examined.

For quality assessment, well-established tools are used. Control of the structure, process, and outcome represents the basis of each project (Figure 1).

One of the oldest instruments for quality assessment in medicine in Germany is represented by the perinatal data collection. From a medical initiative in Bavaria, a nationwide uniform tool of quality management has continuously improved since 1975. This initiative was voluntary. Electronic data collection is now combined with administrative tools in delivery rooms. Technical inquiries, scientific content, and significance for practical treatment are discussed by experts during the annual conferences based on the national data pool.

In gynecologic oncology each federal state in Germany tried to establish its own registry. Efforts to create a uniform data set foundered. Even a federal uniform cancer registery law with validity by end of 1999 was not able to establish a base data set (record) for documentation. The efficient structures in the former East Germany could not be adapted to the unified two parts.

From 1992 to 1996, a project in gynecologic surgery sponsored by the federal Department for Health was carried out in 50 hospitals all over Germany with the aim of determining quality indicators. This data collection partly change into legally specified payment documentations.

Further projects were summarized by the federal health department (measures of medical quality safeguarding in the Federal Republic of Germany) and contained further efforts in the fields of mammography, gynecologic cytology, and neonatology, for example.

Guidelines and standards must count as one of the most important topics in quality safeguarding. The German Society for Gynaecology and Obstetrics (DGGG) created a guideline commission for this reason besides a professional group's quality safeguarding. To date, 37 guidelines for gynecology and gynecologic oncology, sterility, conception, gynecologic endocrinology, and perinatal medicine have been published (http://www.uni-duesseldorf.de/WWW/AWMF). Furthermore, a German Cochrane center was established based on the idea of the British epidemiologist who demonstrated in 1972 that for important decisions in diagnostics and therapies, an often incalculable set of information is used.[1] Only scientifically sound investigation results should be binding.

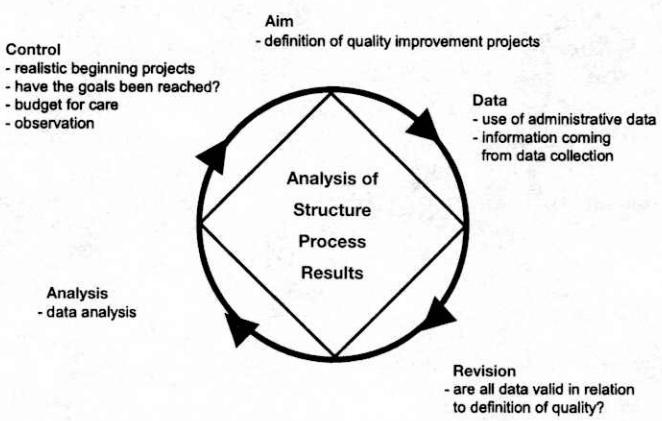

Figure 1. Quality assessment circuit.

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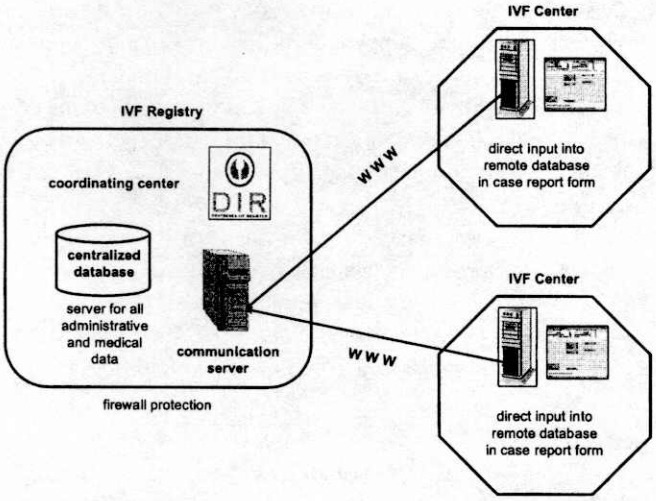


Figure 2. Model of the Web-based data collection tool.

Development of the German In Vitro Fertilization Registry

In 1982, a national in vitro fertilization (IVF) registry was established in Germany. At the beginning, participation was voluntary. Data collection and analysis were performed by the physicians themselves. Since 1998, participation has become mandatory. In 2000, 103 IVF groups participated.

Some specific basic conditions for IVF treatment have been implemented in Germany; these have had an impact on success rates and data collection.[2] German embryo protection was inaugurated in 1991 and allows the transfer of only three embryos. No donor egg or donor embryo program is allowed, and no registry for husband or donor insemination has been established. On the recommendation of the medical association in 1997, only two fresh embryos may be transferred when the woman is under 35 years of age. This should prevent multiple pregnancies.

The registry is located at the Regional Medical Association in northern Germany. Technologic input and data analysis are performed by staff members. The board of the registry has been established since 1983. For each IVF cycle, one Euro is paid by the IVF centers for data collection and statistical analysis.

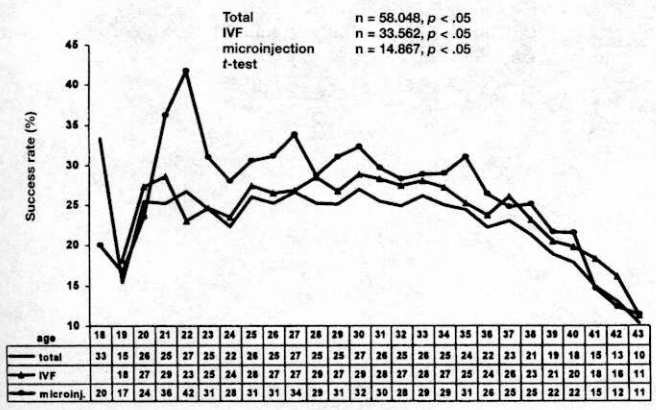


Figure 3. Success rates according on the women's ages.

From 1982 to 1989, a written questionnaire was used, with one part pertaining to treatment and one part to pregnancy outcome.

In 1989, a computerized evaluation of IVF treatments was established by the German IVF Registry (DIR). The first software version was based on a FoxPro© application with a D-Base© platform (IVF-C, Medis). A Windows layout was not performed at this time. From June 1990 to October 1998, this software was updated 18 times. At the end, one record contains 243 items.

In 1998, a new software solution was established based on the Filemaker-Pro© system. Two versions, different in complexity, were developed: one version only collects data for the national registry, whereas a larger version (RecDate) includes a number of items to schedule different processes, perform reports, and handle laboratory control sheets like an IVF center information system. To date, each record of the basic version contains 135 items.

Experiences with these two software solutions will lead to the development of the third generation, with another Web-based database system expected within the next 2 years (Figure 2).[3,4] Different companies will sponsor a system for remote data entry providing real-time data management during IVF treatment. A fast database and sophisticated encryption will lead to an easy and high-quality data entry tool. Editing and managing data will be organized by a central service platform, saving time and money.

Scientific Analysis of Data Collection

The board of the German IVF Registry decided to open data collection not only for an annual printed report but also for scientific analysis. As a first step, files collected with the D-Base© application were analyzed. This analysis did not include the graphs and charts of the annual national report but tried to find prognostic factors and correlation beyond the established performance.

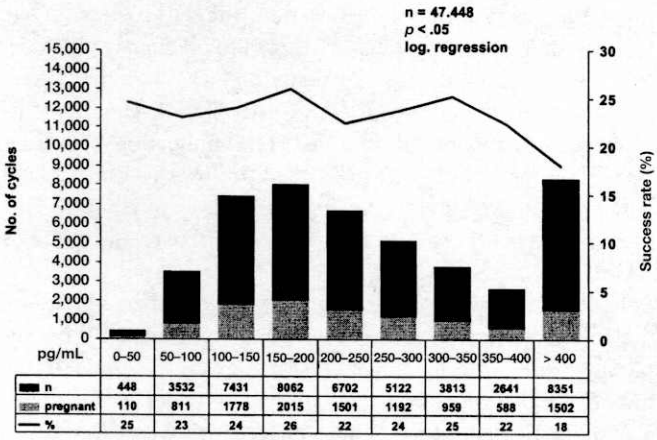
From 66 IVF centers, 84,042 records were collected to analyze data validity and to perform a statistical overview. The observation period was March 1990 to October 1998. Each record included 243 items. For statistical analysis, SPSS© 8.0.0 software was used. Depending on the subject, the Mann-Whitney U test, logistical regression, or chi-square test was performed.

Of the 84,042 records, 92.6% contained the basic information set relevant to statistical analysis. In 6287 records, values such as age, method of treatment, or result of treatment were missing. Well known prognostic factors for the successful outcome of assisted reproductive technology such as duration of

Table 1. Success Rates Correlated with a Change in Treatment

	Treatment Not Changed	Treatment Changed	Σ
Pregnant	15.163 (21.2%)	844 (13.7%)	16.007
Not pregnant	56.450	5.297	61.747
Σ	71.613	6.141	77.754

n = 77.754, $p < .001$, chi-square test.



pg/mL	0–50	50–100	100–150	150–200	200–250	250–300	300–350	350–400	> 400
n	448	3532	7431	8062	6702	5122	3813	2641	8351
pregnant	110	811	1778	2015	1501	1192	959	588	1502
%	25	23	24	26	22	24	25	22	18

Figure 4. Success rates correlated to the estradiol level per oocyte.

infertility (n = 56,353, $p < .05$) or number of transferred embryos (n = 35,503, $p < .05$) could be acknowledged with the collected data, whereas no significance could be observed in sperm concentration before and after preparation (n = 30,636, $p = .232$ and n = 30,636, $p = .171$, respectively).

The success rates corresponding to the women's ages are illustrated in Figure 3. One of the most relevant prognostic factors for IVF and microinjection (including subzonal insemination, partial zona dissection, and intracytoplasmia: a sperm injection) significantly is verified here.[5]

During IVF treatment, it is sometimes necessary to adapt to unexpected situations. Sperm quality on the day of oocyte retrieval may be worse or even better than expected, or a poor response in ovarian stimulation could force cancellation of the cycle. Table 1 demonstrates the success rates depending on the change of treatment. Changes from IVF to complete or particular (not all oocyte) microinjection, from microinjection to complete or particular IVF, and from IVF to insemination are summarized.

One item of scientific interest was the correlation of the pregnancy rate to the estradiol level per oocyte. The estradiol level was measured at the day of ovulation induction. The scale unit was pg/mL. Groups of 500 pg/mL were performed. The kind of drug for ovulation stimulation was not considered.

In 47,448 fresh IVF cycles, logistical regression demonstrated a significant correlation with a maximum estradiol level between 300 and 350 pg/mL per oocyte (Figure 4). In this group, an overall pregnancy rate of 25% was reached.

The second step of analysis will be the investigation of prospective recorded cycles. Therefore, a comparison of the data collected with older and newer software will be performed in consideration of new technical approaches established in the meantime.

Germany has established one of the most modern systems for quality assessment and analysis in reproductive medicine.[6,7] The annual report with a pool of data from all reporting clinics provides an overall national picture. Subjects such as cost effectiveness and profitability will become more important in the future.[8–10]

Acknowledgment

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