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•*Clinical Experience* • Optimising workflow in andrology: a new electronic patient record and database

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Abstract

Aim: To improve workflow and usability by introduction of a new electronic patient record (EPR) and database. Methods: Establishment of an EPR based on open source technology (MySQL database and PHP scripting language) in a tertiary care andrology center at a university clinic. Workflow analysis, a benchmark comparing the two systems and a survey for usability and ergonomics were carried out. **Results:** Workflow optimizations (electronic ordering of laboratory analysis, elimination of transcription steps and automated referral letters) and the decrease in time required for data entry per patient to 71% \pm 27%, P < 0.05, lead to a workload reduction. The benchmark showed a significant performance increase (highest with starting the respective system: 1.3 ± 0.2 s vs. 11.1 ± 0.2 s, mean \pm SD). In the survey, users rated the new system at least two ranks higher over its predecessor (P < 0.01) in all sub-areas. **Conclusion:** With further improvements, today's EPR can evolve to substitute paper records, saving time (and possibly costs), supporting user satisfaction and expanding the basis for scientific evaluation when more data is electronically available. Newly introduced systems should be versatile, adaptable for users, and workflow-oriented to yield the highest benefit. If ready-made software is purchased, customization should be implemented during rollout. (*Asian J Androl 2006 Mar; 8: 235–241*)

Keywords: electronic patient record; andrology; workflow management; Androbase; PHP scripting language; MySQL database

1 Introduction

During the last decade databases (DB) used as electronic patient records (EPR or electronic medical records [EMR]) have been established in clinical care units (frequently as parts of larger Clinical Information Systems [CIS]), essential for clinical and laboratory data storage, ordering, keeping track of appointments, automated creation of referral letters, accounting and man-

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agement [1–3]. The implementation of such systems leads to structured documentation using predetermined input masks with the advantage of retrieving concise data more easily and faster than from paper medical records [4]. In today's widely networked environments with computers available at every workstation, data can be accessed from everywhere in the clinic or even over the Internet. Therefore, the time needed to access information is reduced, which, in combination with workflow optimization, can improve quality of care [5, 6].

Aside from the direct advantages in routine work for physicians and nurses, EPR provides a profound basis for evaluation and quality assurance of processes and, last but not least, for scientific analysis: detailed accumulation of patient data makes retrospective analysis as

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well as selection of patient populations for prospective studies possible [7] and data mining becomes feasible [8, 9]. To investigate genetic influences a reliable crosslink between clinical and genetic data is required [10], with the best alternative having both available using one query.

The basis of an EPR is a DB system (DBS) consisting of: 1) the DB itself, containing actual data and providing physical storage capabilities; 2) the DB management system (DBMS), comprising user-functions by interfaces (graphical user interfaces [GUI] and application programming interfaces [API]) and administrative functions for maintenance; this part manages all input masks and report outputs; and 3) the data dictionary (DD), containing metadata describing tables, relationships and access authorization. When dealing with patient data, high security requirements must be met: authorization of users (including password protection) and ensuring that storage of the DB is safe from direct illicit access (bypassing the GUI) are basic necessities.

Since 2000, our institute has used Winsperm [11, 12], based on Microsoft Access, to store patient data. A new system was developed for several reasons: mainly, performance of the backend Microsoft Access in a multiuser environment with client/server architecture was moderate, with poor response times during daily work. The lack of adaptability/extensibility of the commercially protected program (individual changes are not possible; improvements in coordination with other centers using Winsperm are time consuming because they have to be integrated into future versions that might have to be purchased) to specific needs was a cause for rejection by users. As a newly established system, Androbase demonstrates the usefulness of a tailored, workflow-optimizing EPR and DB for patient care and research.

The aim of the present study was to improve workflow and usability by introduction of a new electronic patient record and DB.

2 Materials and methods

The first step in developing a new system was a thorough demand analysis by small workshops, starting with the assessment of Winsperm, which was already in use. Every section using the DBS (patient admission and administration, physicians, semen and hormone laboratory, histology and molecular biology) was involved in the analysis. Improving areas that were cumbersome or too complicated and functionally inadequate, including lacking data fields and having general handling issues (e.g. patient selection and input verification), were emphasized. To achieve a concise system, unnecessary functionality was identified. Furthermore, the technical basis for the new system had to be determined: the CIS of our university clinic (ORBIS OpenMed, GWI AG, Trier, Germany) was not used because it was overloaded with unnecessary functions and lacked adaptability. Moreover, scientific evaluation and quality control would have depended on the central IT-department for reasons of security and privacy. Use of a DBS comparable to RecDate (Serono International, Geneva, Switzerland), used in centers for assisted reproduction, was discussed but rejected because of start-up costs (Filemaker Pro, FileMaker, Santa Clara, CA, USA: 100 €/client (> 15 necessary), 600 \in for the server, totaling at least 2 100 \in).

In the end, the overall cost-benefit-analysis led to the decision to use MySQL (MySQL AB, Uppsala, Sweden, http://www.mysql.com) as a relational DB (DD is innately provided) and a DBMS based on the internet technologies HTML (http://www.w3.org) and PHP scripting languages (http://www.php.net). All of these are open source solutions that are freely available, eliminating software costs. Building input masks, reports and all other components of the DBMS were carried out using Dreamweaver (version MX 2004, Macromedia, San Francisco, CA, USA), which was already available at our institute (price for educational institutions: $210 \in$, for all others: 470 €), on standard PCs with a Windows XP operating system. The test-server was set up using Apache (http://www.apache.org). For help with programming, the software packages have valuable online resources. In addition, SELFHTML (http://www.selfhtml. org) was used as documentation for HTML.

The planning phase took 2 months and the programming phase took 3 months. Subsequently, extensive testing was performed with validation of data entry and storage. Programming jobs were distributed among two of the authors (FT and CML) and the expected timeframe (6 months) was met with a final rollout phase of 2 weeks, including training of staff. Installation of software was not necessary on the client computers because only a web browser is required, which is an integral part of every operating system (e.g. Microsoft Internet Explorer in Microsoft Windows distribution or Safari in Mac OS X).

An electronic user survey was performed 2 months after rollout, evaluating ergonomics and usability as well

as time and effort spent with the two DBS. As we used the survey *a posteriori*, we separated the first round concerning Winsperm and 4 weeks later the same questions were asked about Androbase. A modified version of the published questionnaire [13] was set up according to DIN EN ISO 9241/10 [14], which defines ergonomic demands for work with computers. This questionnaire specifically tests for software ergonomics and comprises questions regarding task adequacy, self descriptiveness, controllability, expectancy conformance, error tolerance, learning usefulness and individualization. These areas are rated from "--" to "+ + +" in seven steps by the participants (n = 13). The survey was augmented with two questions about time of total daily use and time for data entry per patient.

2.1 Benchmark

Because hardware changed during the development process and operating systems differ between previous and current systems, benchmarks were conducted on standardized PCs (Intel Pentium 4, 2.66 GHz, 512 MB RAM for client and server with Windows XP connected over a TCP/IP network with permanent IP addresses) and repeated five times for each form.

2.2 Statistics

For statistical comparison, the paired *t*-test or ANOVA followed by the Tukey test (benchmark) and the Mann–Whitney *U*-Test (survey) were performed using the software program SigmaStat 2.03. Data entry time was individually compared per user with the Wilcoxon signed rank test because data was not normally distributed. For all tests, P < 0.05 was considered statistically significant.

3 Results

3.1 Database system description

The release version of Androbase consists of 38 tables (roughly each table marking one area of use) with nearly 900 fields. (Winsperm has 114 tables and approximately 1 000 fields). Other major differences are summarized in Table 1 (e.g. patient chart, laboratory workflow and sources of error). Approximately 100 PHP-pages were programmed for input/output as GUI (DBMS). Overall costs for design and development (programming and testing) were estimated as approximately 7 000 \in (labor costs for two people). Data migration (including approximately 16 000 patients, approximately 41 000 ejaculate and 31 000 hormone records) from Winsperm was done outside clinic hours to maintain patient care and raised no technical difficulties, but was time-consuming because of data-harmonization; in particular, the default values in selective lists had to be managed individually and by hand.

Major structural changes in the DB were introduced concerning ejaculate/cryopreservation (stored in one table as the cryo-results relate to the ejaculate) and histology (right and left testicular biopsies in one row). Input of diagnoses was revised to fulfill international standards: one primary diagnosis is mandatory for every patient at a given time; secondary diagnoses are optional.

Genetic data (approximately 7 000 DNA samples with a detached numbering system, approximately 4 000 screening records for AZF-deletions and several hundred other genetic results [e.g. FSH-/LH-/androgen-receptor polymorphisms]) stored in separate lists (Microsoft Excel) were integrated and linked to clinical data. Stringent validation was applied by double-checking the new relationship between the two numbering systems (surname, name and birth date had to be concordant or were otherwise checked manually).

The DB is stored on a Linux system provided by the university clinic's IT center, fulfilling data security guidelines.

To introduce the new system username/password combinations were allocated. These are recorded as us-

Table. 1. Comparison of the andrology database systems Winsperm and Androbase.

	Winsporm	Androhasa
	winsperm	Allulobase
Patient chart	Handwritten and	Only printout forms
	printout forms	
Laboratory workflow	Seven steps	Five steps
Sources of error	Three transcriptions	One transcription
Administration	_	Referral letters
		accounting
Development	Only by author and	Promptly by demand
	in future updates	
Tables / fields	114/1 000	38/900
Response time	Up to 3.6 s	Constantly below 1 s
Installation per	Full Microsoft	None
client	Access and	
Backend	Winsperm software	Open source
(database)	Commercial	

age logs with every data entry or change. Basic training took approximately 1 h, mainly because of self-explanatory workflow, intuitive handling, user guidance through data entry restriction/validation and accurate error messages. Further short training sessions (30 min) took place with special interest groups according to need.

Standard operating procedures exist to introduce new staff to the main functions; detailed instructions are given by authorized members of the clinic in the different sections.

Main areas of use are:

1) management of patient personal data

2) documentation of

• clinical data (case history, examination and sonography)

- laboratory data (semen and hormone analysis)
- genetic screening data
- testicular histology
- diagnoses using ICD-10 [15]
- 3) (semi) automated generation of referral letters
- 4) electronic ordering of ejaculate/hormone analysis and genetic screening

5) statistics

6) accounting with health insurance companies (according to EBM/EBM2000Plus [16], which applies to 90% of German patients)



Figure 1. Workflow in comparison between Winsperm (left) and Androbase (right) database system (DBS): processes and documents filled in dark grey resemble paperwork or manual order. Both sides apply to ejaculate and hormone analysis; in each process one transcription is saved. Doubled printed forms are no longer kept and, all things considered, workload of every department is reduced.

3.2 Workflow optimization

Workflow optimization saved time (data from survey, n = 13 participants: time for data entry per patient $[7.0 \pm 1.5 \text{ min using Winsperm}]$ was significantly reduced to $71\% \pm 27\%$, P < 0.05; time of total daily use did not significantly change) for two major reasons: overall performance was optimized by switching ordering to electronic procedures integrated into the new system. Paperwork was abolished and routine processes were tightened (Table 1, Figure 1). After noting history and performing an examination, physicians electronically request laboratory analysis (ejaculates, hormones and genetic screening) on a single order form, resulting in separate to-do-lists for every section. These lists show the status of the request (in-process or finished) and are linked to an input form transferring data collected by the physician (e.g. medication and duration of abstinence) by selecting the patient's name. New record sets can only be created this way (after being ordered), leading to a closed system, with every step being traceable. Simultaneously, manual transfer of a patient's records can be reduced as they are no longer required in the laboratories. In addition, as a result of demand analysis, the printed reports now exactly suit the physician's needs and contain more information. As a consequence, one transcription step for each analysis (ejaculate/hormones) is eliminated (Figure 1), preventing data input errors incurred by typing. Data entry has become obligatory, ruling out the possibility of missing records. From 2000 to 2004, the rate of missing/inconsistent hormone/ejaculate exams averaged 14%, and were either missing in the DBS or in the patient's paper record. This was determined by randomly checking selected records (n = 50). Moreover, data quality should increase because of newly incorporated novel validation routines (e.g. if sperm motility of all four World Health Organization categories fails to total 100%, it is not accepted as input) [17].

The DBS and consecutive workflow optimizations were stressed as important improvements within the certification process (TÜV, DIN EN ISO 9001 : 2000 [18]) for 2005.

Accounting, as another newly introduced function, relieves physicians and medical secretaries alike: performed services are checked on the accounting form and the DBS produces fully automated printouts at the end of each quarter.



Figure 2. Androbase and Winsperm benchmarks compared: time till screen shown was measured (n = 5, values given as mean \pm SD). All results were significantly different (${}^{\circ}P < 0.01$, ${}^{b}P < 0.05$). Highest time savings become obvious in starting the system, which helps integration into routine because of instantly available functionality.

3.3 Benchmark

Time till forms are shown on screen and ready for data entry was measured comparing Androbase and Winsperm (Figure 2). All results were significantly different for each system (for the start screen, ejaculate/hormone analysis and histology was P < 0.01 and for sonography P < 0.05). The greatest difference became obvious when starting the systems $(1.3 \pm 0.2 \text{ s}$ $vs. 11.1 \pm 0.2 \text{ s}$, mean \pm SD). Time to access different forms of Androbase was uniform (0.6–0.8 s), whereas in Winsperm significant differences exist (access time varying from 1.1–3.6 s, P < 0.01).

3.4 Usability

The user survey (clinicians n = 4, technical assistants n = 6 and medical secretaries n = 3) rated Androbase over Winsperm (Figure 3) for all sub-areas (task adequacy, self descriptiveness, controllability, expectancy conformance, error tolerance, learning usefulness and individualization) at least two ranks higher (P < 0.01).

4 Discussion

EPR have been established for some time to store patient data either as an alternative or complement to paper records. Their immediate benefit is faster access to relevant information and improved care [5, 19]. We report the introduction of a new, patient-centered DBS



Figure 3. Usability and ergonomics of the previous and current database system (mainly graphical user interfaces) tested by user survey according to DIN EN 9241/10. Rating was done on a seven-point scale ranging from "--" (insufficient) to "+ + +" (ideal) for seven sub-areas. Androbase was rated at least two ranks higher over Winsperm for all sub-areas (P < 0.01).

consisting of an EPR with workflow-oriented extensions especially adapted to an andrology clinic.

We could confirm instant time savings through establishing a new DBS and switching to recent technology that is freely available: considerably reduced startup and shorter response times are useful for integration into standard routine, whereas Winspermusers had to wait longer for results to appear on screen (Figure 2). The moderate performance and the cumbersome interface (GUI) of Winsperm (overloaded with functions that were never used) prevented its regular use in daily routine. Therefore, only laboratory data (ejaculate and hormone analysis, histological examination) were documented, resulting in a rudimentary EPR. Androbase can be integrated into daily work and decrease the workload of physicians, scientists, medical secretaries and technical assistants alike by incorporating an electronic ordering system (reduction of paperwork), streamlining workflow (no duplicate paper forms) and adding useful data fields (all necessary data available on screen). Additionally, inconsistencies between electronic and paper patient records are reduced because the printed forms are generated directly from the DBS (no transcribing necessary). The comparison of the DB between the two systems with, at present, distinctly fewer tables but the same order of magnitude of fields shows a reduction in functionality and a gain in data entry (Table 1). Elimination of superfluous functions results in a more concise GUI adding to overall better acceptance of the system. All these advantages follow from an in-depth demand-analysis preceding development of the software.

The evaluation of the user survey might be limited because of a positive bias towards the self designed and developed system and the time savings might be partly explained by changes in computer hardware and software during development process. However, survey results demonstrate two facts: the actual amount of time using the new DBS did not significantly change, so the added functionality and integration into workflow is balanced by reduced time to enter data per patient; and usability of Androbase exceeds Winsperm in all categories, leading to better acceptance and user satisfaction. Overall, usability and ergonomics have both benefited from improvements and adaptation to our needs.

Generation of letters in Androbase was newly introduced into routine and accounts for the motivation of physicians to enter clinical patient information, completing the data available electronically. Additionally, maintenance of diagnoses became mandatory and more reliable as these are required for accounting and creation of letters. As diagnoses are the prerequisite for identifying homogenous patient cohorts, keeping the DBS up-to-date is also important for scientific evaluation

With MySQL as DB, evaluation principally needs programming knowledge to build queries using SQL as language; however, by providing an extensive search form covering most stored data fields, queries can be performed by the GUI. Exporting the whole DB to Microsoft Access is also possible anytime, switching to its graphical interface if desired.

Overall, construction of a specific and highly adapted DBS meets needs by appropriate integration into well-rehearsed processes. This shortens the orientation phase for users, leads to user satisfaction by rapid acquaintance and helps to maintain productivity. Preset software might even complicate daily work by overwhelming users with unnecessary functions or inflexibility. Longer time till rollout has to be taken into account for development of specific software, but as adaptations are often essential, a period of customization should be scheduled when planning to use standard software as well. Costs for developing new software might be, depending on the product, balanced by costs for acquisition and support. In the present study, expenses totaled approximately $7\ 000 \in$ for the invested time on development, which is difficult to compare to other systems: The price for Winsperm is negotiable (but in a similar range) and, to our knowledge, no other equivalent and highly adaptable DBS are available.

The DBS was not adaptable for special results (e.g. results of genetic screening), a leading to non-standardized and scattered data storage. Integration of this data improves scientific analysis of possible influences on andrological diseases (e.g. infertility). Moreover, all future results will be directly inserted into the established system, raising the possibility of data mining [20].

With further improvements, today's EPR can evolve to substitute paper records, eliminating the limitations of paper records and overcoming inconsistencies as a result of doubled bookkeeping, saving time (and possibly costs) and supporting user satisfaction. The basis for scientific evaluation expands when more data is electronically available. Newly introduced systems should be versatile, adaptable for users, and workflow-oriented to yield highest benefits. On-site maintenance of software strongly supports the continuous process of further optimization as not all specifications can be considered before new software is established and workflows often change rapidly because of new situations. If readymade software is purchased, adjustments to special conditions in the surrounding domain ought to be implemented during rollout.

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