

Example for a project draft:

Collection of Quality-of-Life data using a QL-Recorder with a connection to the HIS of a University Clinic

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Target group and goals of the following text

The following text addresses persons who want to draft a project, in which routine outcome measurement is introduced into clinical environments using the Quality-of-Life-Recorder, and where recorded data are imported into an electronic medical record or into a hospital information system.

The text provides examples for possible descriptions of underlying ideas and applicable methods. The example does not try to be optimally written, or to take all necessary issues into consideration. It is not intended to be accepted without any reflection, but just to stimulate and to support you during the generation of your own project drafts and applications.

The example shall contribute to the spread of the Quality-of-Life-Recorder, by simplifying the design of and application for respective projects. The whole example or parts of it may be copied into your own works or may be used as a template based upon its contents, as long as this serves my described intention, and a reference to the original source is included.

At any time, I'm happy to receive suggestions for improval.

* The translated source is dated July, 17th, 2000; only minor adjustments have been made during the translation.

Summary

Within the project, a mobile Quality-of-Life-Recorder (QL-Recorder) shall be prepared which provides electronic versions of questionnaires, of which hitherto paper versions have been used. Patients will fill in these electronic questionnaires; collected data will be imported in the existing hospital information system (HIS) or the existing electronic medical record (EMR).

By using the QL-Recorder instead of paper questionnaires, data are available immediately after completion of a questionnaire by a patient. Data completeness and readability are guaranteed. Any manual data entry is obsolete, and typing errors cannot occur any more. Recorded data are available for clinical or scientific users as a part of the patient record.

Results from individual questionnaire administrations and overviews showing an individual patient's course over time, are provided by the QL-Recorder immediately. Additional evaluations are possible, depending on the available HIS/EMR-solution. Scientific evaluations can be performed based upon the collected data with little effort.

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1 Project goals

Existing questionnaires shall be administered routinely to patients. Collected data shall be available for authorised staff via the existing HIS together with other patient related data. Data shall be used to assess the course of an individual patient's disease over time, and of the success of therapeutic approaches for an individual patient, and also for scientific analyses.

2 Project overview

The project includes the following tasks:

1. Generation of a detailed project draft, including schedules for costs, time, and definition of responsibilities.
2. Setting up agreements among all involved people.
3. Acquisition of additionally required infrastructure (QL-Recorder, optionally with network connection).
4. Selection of existing questionnaires and their transfer to the QL-Recorder:
 - (a) Selection of questionnaires to be used
 - (b) Ensuring that selected questionnaires may be transferred onto an electronic tool (copyright situation)
 - (c) Preparation of questionnaire definition files for the QL-Recorder
 - (d) Preparation of application- or patient specific configuration files for the QL-Recorder
5. Secure configuration of the QL-Recorder, including the provision of accounts for use by staff and patients:
 - (a) Account for patients with merely a limited access to system resources and collected data
 - (b) Account for staff with possibilities for
 - i. Access to previously recorded data,
 - ii. Data transmission to the HIS,
 - iii. Installation of questionnaire definition files,
 - iv. Installation of application- or patient specific configurations
6. Description of possibilities to link the QL-Recorder and the HIS.
7. Implementation of a physical link to be used for data transmission from the QL-Recorder to the HIS:
 - (a) Usage of an HIS printer for immediate printout of questionnaire results and courses over time
 - i. Either, direct use of a network printer with lokal buffering by the printer spooler until a network link is available,
 - ii. Or, local generation of printout files, which are transmitted to a defined place in the HIS and are printed from there, as soon as received, automatically.
 - (b) Provision of a directory in the HIS where files with collected data can be placed:
 - i. as a source for automatic data import into the HIS,
 - ii. as a source for automatic generation of backups of collected data by the HIS,
 - iii. as a source for future external scientific use by authorised persons.
8. Implementation of an interface inside the HIS to import collected data out of ASCII files
or
Implementation of an ODBC-interface to the HIS to provide collected data via ODBC.
9. If the printing is not implemented by using a network printer directly:
Implementation of a service, which prints received printout files automatically.

10. Implementation of display-/printing- and maybe other processing facilities for collected QL data inside the HIS
11. Staff training:
 - (a) Using the QL-Recorder:
 - i. administering a questionnaire,
 - ii. using the print functionality of the QL-Recorder,
 - iii. using collected data locally,
 - iv. transmitting collected data to the HIS,
 - v. using collected data from inside the HIS,
 - vi. data protection.
 - (b) Transfer of own questionnaires to the QL-Recorder.,
 - (c) Contact persons regarding HIS (e.g., when data from further questionnaires shall be imported into the HSI) and QL-Recorder technology,
 - (d) Sources of help and documentation.
12. Patient information and public relations.
13. Documentation:
 - (a) Project draft,
 - (b) Project report,
 - (c) Available documentation,
 - (d) Contact persons,
 - (e) Hardware, Software,
 - (f) Available questionnaires,
 - (g) QL-Recorder manual,
 - (h) Manual covering project specific functionality of the HIS,
 - (i) Description of future advanced possibilities,
 - (j) Test operation and optimization of the first implementation,
 - (k) Plan for transition into routine operation,
 - (l) Plan for evaluation during routine operation,
14. Test operation and optimization of the first implementation.
15. Transfer of the project into routine operation.
16. Evaluation of results during routine operation according to the prepared plan.

3 Detailed description of tasks included in the project

3.1 Generation of a detailed project draft, including schedules for costs, time, and definition of responsibilities

3.2 Setting up agreements among all involved people

3.3 Acquisition of additionally required infrastructure (QL-Recorder, optionally with network connection)

3.3.1 General issues

A Quality-of-Life-Recorder consists of hardware and software and enables the user to administer electronic questionnaires in a way, that patients can fill in these without any introduction or training just as easily, as paper based questionnaires.

However, the QL-Recorder offers a functionality which surpasses that of paper questionnaires by far. Especially, it ensures that during the completion of a questionnaire, no questions are left out, that all answers are clearly readable, and that recorded data are available immediately after completion of a questionnaire for future processing. Moreover, the QL-Recorder can apply evaluation algorithms on the raw data of a questionnaire, and thus deliver computed test results. Moreover, if a printer is connected, it can automatically generate printouts showing the results of an individual questionnaire administration, or an overview including earlier results, showing the patient's course over time.

3.3.2 Hardware and operating system

Depending upon the target patient population, the kind of questionnaires to be used, and the budget, the QL-Recorder hardware can be chosen appropriately.

The minimum requirements are: PC compatible computer with an 80386sx CPU, Windows 3.1 or emulator.

Advantageous features are: portable device, clearly readable screen with a high contrast, touch-screen.

In the current project, the following hardware shall be used:

- Palmax PD-1100 or current successor, mini-notebook computer with pen and touch screen, Cyrix MediaGX-CPU, TFT display with 640x480 pixels, keyboard, sound, 64 MB RAM, 3 GB HDU, optional external floppy-drive and CD-ROM-drive, priced at around 1.500,- Euro.
- Alternatively: Fujitsu Stylistic xxxx, TFT display with 800x600 pixels, keyboard optional (!), priced at about 3.000,- Euro.
- PCMCIA-network adaptor Ethernet 10/100MBit DFE-650, priced at about 130,- Euro.

If the Palmax device is acquired, the low price enables us to afford two devices. A second device might improve the availability and protection of the solution against hardware failure, and would also be useful for staff education or during future transfers of additional questionnaires. On the other hand, expenses for maintaining the devices might rise, because any change or extension of the configuration would have to be performed on two devices.

As operating system, Windows NT 4.0 shall be used. This causes additional costs of 200,- Euro. The operating system comes pre-installed on the hardware.

Using an adequate configuration, even Windows 95 or 98 could be protected against unauthorised use. However, the resulting stability of a QL-Recorder under these systems will probably be much lower, especially, it would hardly be protected against a change or destroying of the prepared configuration from inside the staff account, which must offer more rights than the patients' account, if not the usability of the system for staff should be restricted severely.

An operating system alternative might be Linux. This could save the costs calculated for NT, but might still be more stable and secure. As there is probably little local experience available, additional expenses would be caused by necessary user training. Thus, this should be addressed by a future project.

3.3.3 Application software

The software of the QL-Recorder, AnyQuest for Windows, has been optimised for the task described above. It includes an editor to create and edit questionnaire definition files as well as a comprehensive documentation. It has been developed since 1996, and continuously been updated. Its author has experience with the preparation of electronic questionnaires for patients since 1993.

3.3.4 Project specific add-ons

In the QL-Recorder, specific extensions are installed, which simplify its use, e.g. during data transmission to the HIS. All necessary functionality can be provided by batch- or script-files using resources of the operating system (e.g. the ftp client).

3.4 Selection of existing questionnaires and their transfer to the QL-Recorder

3.4.1 Selection of questionnaires to be used

The following questionnaires shall be used in the project:

1. For patients' self rating:
 - (a) EORTC QLQ-C30 - Quality-of-Life Core Questionnaire, 30 questions
 - (b) HADS - Hospital Anxiety and Depression Scale
 - (c) EWD - Locally developed form to collect additional data
2. For proxy rating:
 - (a) SI - Spitzer-Index

3.4.2 Ensuring that selected questionnaires may be transferred onto an electronic tool (copyright situation)

The selected questionnaires have either been developed locally or are freely available for academic users.

The exact legal situation regarding the copyright, however, is complicated, as available paper questionnaires serve as a basis for electronic questionnaires, which are, in the electronic system written in a different language (the definition language used inside the system), and are in both layout and contents adopted or expanded according to the possibilities of the electronic system.

To avoid any legal quarrels later on, the local project coordinator will nevertheless identify the holders of the copyrights of the paper versions. They will be contacted and asked for their consent for the preparation of the electronic versions of the questionnaires. In this process, it must be considered, in which way the resulting questionnaire definition files shall be made available later on (see below).

Should this consent be linked to unacceptable conditions for an individual questionnaire, the legal situation must be more exactly reviewed, or we must refrain from the use of the respective questionnaire.

3.4.3 Preparation of questionnaire definition files for the QL-Recorder

Selected questionnaires are transferred to an external service provider or a member of the team in a suitable form (paper version, or a suitable file, as far as available), including algorithms for result computation. This material will serve as a basis to create a questionnaire definition file with compatible contents.

The layout of this questionnaire definition file (QDW-file, QDF) will follow standards, which have been set by other questionnaire definition files prepared for the QL-Recorder, in order to render as many questionnaires as possible with a homogeneous appearance as questionnaire definition file.

As far as text contents or graphic contents are specific for the presentation on paper (e.g., "place a pencil mark..."), these will be adopted to the presentation on the QL-Recorder in a suitable way. Several extensions made possible by the presentation on the QL-Recorder (e.g., fields for "I cannot answer this question" and "I don't want to answer this question") are prepared accordingly.

The resulting questionnaire definition files are transmitted to the project coordinator for reviewing and optionally for a trial presentation to patients.

3.5 Preparation of application- or patient specific configuration files for the QL-Recorder

On different occasions, different sets of questionnaires will have to be completed. A number of QL-Recorder configurations will be prepared in such a way, that every configuration can be called for questionnaire administration by clicking the respective icon.

The following configurations will be provided:

prepared configuration	person, to whom the set of questionnaires is administered	occasion	included questionnaires
1	Patient from 20 to 60 years with (\pm suspicion of) malign disease	first admission	C30, HADS, EWD
2	Physician, who admints the patient from (1)	first admission	SI
3	Patient from (1)	Follow up	C30, HADS
4	Physician, who sees the patient from (3) for follow up	Follow up	SI
...

3.6 Secure configuration of the QL-Recorder, including the provision of accounts for use by staff and patients

On the QL-Recorder, different accounts for administrators, physicians, and patients are prepared. They offer the following specific features:

Administrator: unlimited access.

Physician: Access to the QL-Recorder system using AnyQuest for Windows with the possibility to prepare questionnaires, to set up and modify configurations. Access to collected data. Access to AnyQuery for Windows after password check, to display questionnaire results and print them later on. Access to printer control, possibility to stop or resume printing on the connected network printer. Access to the functionality of data transmission to the HIS.

Patient: Access to the QL-Recorder system using AnyQuest for Windows limited to the possibility to use prepared configurations for filling in questionnaires. Access to AnyQuery for Windows after password check, to display questionnaire results and print them later on¹. Access to printer control, possibility to stop or resume printing on the connected network printer².

For all accounts, a screen saver is set up which asks for a password.

3.7 Description of possibilities to link the QL-Recorder and the HIS.

3.7.1 Desired infrastructure on the side of the HIS without wireless LAN

If no permanent network connection (wireless LAN or cabel based) is available, QL-Recorders do not see the whole pool of available QL files during questionnaire administration. Instead, each QL-Recorder sees the files stored on its local harddisk. As soon as a transmission of collected data to the HIS, the generation of a printout via a network printer or the transmission of questionnaire administration results generated on other QL-Recorders from the HIS to a local QL-Recorder³ are desired, this QL-Recorder must be connected to the HIS network.

Actual proceedings must be discussed among users, the QL-Recorder administrator and the HIS administrator. From the QL-Recorder administrator's point of view, the following would be optimal:

The HIS should provide the following services:

¹ Alternatively, this right may be limited to the physician's account only, but this will render several handling issues less comfortable.

² Alternatively, this right may be limited to the physician's account only, but this will render several handling issues less comfortable.

³ This is necessary, when patients are interviewed using multiple devices, and still the QL-Recorder software shall generate complete overviews over patients' courses over time.

Directory for data collection A directory accessible via FTP (suggested name: QLRECORD\ANYQUIN\DATA), in which clearly readable ASCII files containing the recorded raw data and questionnaire results can be stored. In this directory, members of the group: QL-Recorder-Data-Delivering-User, coming from outside, shall have the following rights:

1. Create, enter, and leave subdirectories.
2. Create new files.
3. Write to new files.
4. Read directories.
5. Read existing files.

No User from the above group shall have the right to delete or to overwrite existing files in these directories.

Files transferred to this directory shall be protected against overwriting immediately. To keep the directory clean, all incoming files with extensions other than *.ANQ, should be deleted automatically when they arrive.

Files originating from different QL-Recorders (or from different configurations on the same device) can be identified by the QL-Recorder software during the questionnaire administration by fixed leading characters in the filename. Additionally, and optionally, they can be placed in different subdirectories both when being generated on the QL-Recorder and when being transmitted to the HIS.

An upper limit for the allowed file size may be defined, to protect the harddisk from being filled up by mistake or intentionally. This limit should be chosen depending upon the expected complexity of incoming files, depending itself upon the results generated by the applied questionnaire definition files. Each incoming file usually contains the results of a single questionnaire administration, and will usually not exceed a few KB, so a limit of e.g. 64 KB per file should be sufficient.

A batch job should check the directory for incoming files, import data from these files into the HIS, and either immediately or according to a fixed schedule archive the source files, e.g. via move to a ZIP archive which may be located in another directory, or by providing them for cumulative backup on an external medium. These source files should by all means be conserved, and be kept available easily (which means, without first having to puzzle together data from 12 monthly storage tapes for a year), because they can be used easily for later, over-institutional meta-analyses with built in functionality of the QL-Recorder software. While these original data can provide the full range of originally collected data, any re-extraction of data from the HIS for such a purpose would cause additional expenses, while delivering data most probably incompletely, and in a proprietary format.

If raw data are not archived in a suitable form, over the years a huge number of files will accumulate (one per completed administration of a set of questionnaires). This is especially relevant, if they are stored on a volume with a pre-defined maximum number of storable files (Netware partition, root directory of a FAT partition), or with a relatively low number of individually usable clusters.

To warrant the authenticity of collected data, users should not have any possibility at all, to manipulate files transferred to this reception directory of the HIS, be this renaming, moving, deleting, or overwriting.

Read access rights for this directory and the files therein from outside can be useful for the following purposes:

1. To check whether the transmission was successful.
2. If data are not archived away immediately anyway: access to files in their original format, e.g. for simple use with AnyQuery for Windows, for simple documentation, for scientific evaluation using third party software (e.g. via AnyQuest to Excel, SAS, SPSS...), for analysis involving multiple data collectors and so on.
3. Synchronising local data collections of all QL-Recorders, so that each AnyQuest has available all data from all assessments locally, to generate current overviews of patients' courses over time.

As collected data are stored clearly readable and in ASCII, the following is important: If a patient ID is collected during the questionnaire administration, which renders the identification of the concerned patient easily, either without any tools (e.g., if name and date of birth are collected), or with simple tools (e.g., if an admission number is collected, and unauthorised persons inside the hospital can easily retrieve name and date of birth associated with a given admission number, because the key is available everywhere), then, the reception directory should be protected against unauthorised read access. This may be done by preparing a very specific account like QL-Recorder-user, optionally, specific accounts for separate wards or groups of persons, where specific rights are resembled by local accounts on the QL-Recorders.

Directory with central parts of a reference QL-Recorder installation These directories serve the semi-automatic maintainance of local devices. It is reasonable to provide the contents of the AnyQuest- and AnyQuery installation, including all questionnaire definition files, configurations, program components, as well as start menu entries and desktop icons, which are required by AnyQuest users for a comfortable start of provided configurations. This means that the following directories should be accessible via FTP:

- QLRECORD\ANYQUIN and subdirectories, containing one local AnyQuest-for-Windows installation,
- QLRECORD\WINNT\PROFILES, containing the contents of the desktops and start menus of all users defined on a QL-Recorder.

In these directories, members of the group: QL-Recorder-Updating-User should have exactly the following rights:

1. Enter and leave a subdirectory.
2. Read the directory of available files.
3. Read available files.

In these directories, members of the group: QL-Recorder-Defining-User should additionally receive the following rights:

1. Create or delete subdirectories.
2. Create new files.
3. Write and overwrite files.
4. Delete files.
5. Rename or move files.

This enables authorised users to prepare and upload QL-Recorder configurations, while less authorised users can only download new configurations to their local QL-Recorder (preferably by an automated process). Depending upon available resources, of course, additional parts of a QL-Recorder installation including the operating system might be replicated, but this requires longer communication time (with a lot of overhead), is more difficult to design, more prone to errors, and requires more and more identical hard- and software on all local devices.

3.7.2 Possibilities of the QL-Recorder

Hardware Independently of the actual hardware that you use, it should offer a PCMCIA or Cardbus expansion slot. Here, suitable network adaptors can be inserted. To most currently used networks, you can connect using an Ethernet adaptor for 10/100 MBit and twisted pair cabling. A wireless LAN adaptor can be an alternative. Recently, USB to Ethernet adaptors have appeared, but their data throughput will probably be much slower than the throughput of native Ethernet adaptors.

Another feature which your hardware should offer, is an IrDA-Port. Serial and parallel ports can be used as an alternative to this. Finally, data can be transferred via physical media (floppy-disc, ZIP).

A connection via wireless LAN is the most comfortable solution, and also the one that can be operated most easily. Depending on which hardware is used, it may be rather expensive (in 2001: from about 500,- Euro for an ad-hoc solution to about 300,- Euro per workstation plus about 1.300,- Euro per access point for a high-class solution). Installing wireless LAN infrastructure offers additional possibilities, e.g. for mobile workstations within the existing KIS. These possibilities warrant the treatment of wireless LAN planning and installation as a separate project. Current hardware directly supports 40 bit or 128 bit encryption, but as an alternative, methods commonly used to encrypt traffic over traditional cable bound Ethernet can be used just as well.

Cable bound Ethernet is available at relatively low cost (about 100,- Euro per PCMCIA workstation adaptor) and can be configured in a way, that staff just need to plug in the network connection when they want to connect a device to the network⁴. An Ethernet can transport data faster than all of the following alternatives, and it is the second easiest one in handling after the Wireless LAN.

If IrDA is used, suitable receiving devices (e.g. laptops with network connection or access points) must be available and configured. An infrared connection can be configured so that it is just slightly more difficult to connect, than to an Ethernet, however, configuration may be more difficult and more dependant on an individual system's properties.

Links using serial or parallel cables, or floppy- or ZIP-discs, can require the user to attach a port-replicator to the LQ-Recorder. This, in turn, may require to restart the device which may take a few minutes time. Activation of serial or parallel links, may require some user interaction: as far as I know, under MS Windows, serial and parallel cable connections can not be set up so that they are logically exactly identical to, and handled like, an Ethernet network link. All methods using a physical medium for data transfer, first, require additional time, and second, may add some risks to data protection because temporarily used storage media may be left containing medical data.

As a result from these considerations, in the short term, cable bound Ethernet is probably the best medium to use for data transmission. In the long term, it should be replaced by wireless LAN within another project.

Network protocol As network protocol between the QL-Recorder and the HIS, TCP/IP shall be used. The QL-Recorder must be configured appropriately in co-operation with the HIS administration. On the QL-Recorder, certain accounts must be generated and certain directories must be configured with suitable access rights. If a central definition of these accounts is desired (which might be useful), all QL-Recorders must be configured accordingly by the HIS administration.

Protocols for data transmission As protocol for the transmission of questionnaire administration results and for the download of reference installations, FTP appears to be suitable. Its availability and controlability by scripts is far better than, e.g. those of the Microsoft Network (which, for example, reflects changes in the infrastructure only after very long latency times, quite often does not or only after a long time recognize the servers inside a network, when a client is newly attached, may have difficulties with deciding which host is responsible to manage ressource-lists and so on). If FTP is used, one must take into account, that passwords are used to sign on. These are most probably transferred through the network openly, which may not be a problem in local networks, but asks for the use of encrypted connections for external or wireless transfers. All parts of scripts containing passwords, must be protected from unauthorized read accesses on the local QL-Recorder in any case.

As an alternative, one could consider to carry out a number of experiments in the local network, which would involve a series of disconnections and re-connections of the QL-Recorder to the local MS network. If these experiments could prove that the necessary network ressource provided by the HIS would actually be found reliably and fast after each re-connection, files can be copied directly between the local drive and network drives, instead of using FTP. This would leave passwords (as long as they survive) located somewhere in the shallows of the used Windows-versions, but when recent versions of Windows are used, they would at least be transferred through the network in an encrypted fashion⁵.

⁴ Theoretically, at least. In Windows 95/98, I found it did not always work reliably, and Windows NT comes from the same company.

⁵ Although I remember that recently, an attack has been published showing a fast way to break the password protection of an MS network ressource.

Scripts to control data exchange, should rather be MS-DOS batch files than scripts for the MS Windows Scripting Host, in order to avoid the necessity of the security critical and hardly obvious activation of the latter tool.

The following arguments come from a footnote that has grown too large. All are more important under Windows 95/98 than under Windows NT, but in the interest of generating a portable solution, one should prefer methods working on both platforms, anyway.

- An advantage of the FTP approach is, that one knows exactly, in which text file at which place, a password is located, how it can be protected from unauthorised access, and where such a protection ends. If one wants to do that, with little effort, it can be encrypted itself, and unpacked just in time and only temporarily, for a short period of time, directly before it is made available to the FTP client.
- If the MS Windows network approach is used, the password is probably stored somewhere in the registry, it is encrypted in some way, and sometimes it might appear in clear writing in some swap-file (and where else?) - all of these possibilities are far less simple, less clear, and less well-defined, than a text file.
- If an FTP password located in a text file shall be changed, one changes the file, transfers it to all target systems in the next downloading of the reference installation, and that's it. If one wants to change a password located in the Windows registry of a number of remote machines... well, maybe, this may work as well.
- If one logs in via FTP to a remote machine, and tells FTP to go to a certain directory there, then the machine and the directory have unique names or addresses, and if they are available, one will reach the target directory.
- If one connects a remote drive to a local drive letter via the MS Windows network, in order to access this drive afterwards using a DOS batch command, but the user or another program happen to have blocked the expected drive letter, one ends up with a configuration that can hardly be predicted - and, before ending up there, the user has been confronted with an equally unpredictable number of dialog windows she may or may not understand. In the worst case, afterwards, Windows will try to make all future network connections from that machine using a telephone modem.
- Similar results can present to the user, if one avoids connecting to network drives using local drive letters but tries to use the scripting host instead, when the target machine is temporarily unavailable.

Final communication scripts shall be implemented in co-operation with the administration of the HIS. Additionally, users must be observed to find out whether the chosen method performs well. By means of the provisions made for documentation and for comfortable updating of the QL-Recorders, it is possible to move to another implementation at any point in time.

All scripts and utilities which are required on the QL-Recorder for communication with the HIS, shall be located below QLRECORD\ANYQUIN\COMM\HIS, so that they can be automatically maintained and updated. A script to synchronize the local machine to the reference installation should be available separately from the script for uploading or synchronizing questionnaire administration results.

Additions to the English version of this document, 20010512js:

Using ftp usually involves the transmission of a password in an unencrypted manner over the network. If read access rights to the HIS reception directory are required, additional steps may be warranted to ensure the system against an unauthorised person overhearing the password and later on reading files from that directory. These steps may include: using another protocol that transmits the password in an encrypted manner; or using a VPN for this critical transmission; or removing transmitted data from the HIS reception directory after a short time (this option looks simple, however it severely compromises the benefit of the read access for authorised users, as well); transmission of encrypted versions of *.ANQ files only, which are automatically decrypted in the (authorised) target HIS system or in (authorised) external systems who use the read access. Inside local area networks, the ftp-password related security issue may be of limited importance, but administrators should know about its existence. Constructs only transferring encrypted ZIP archives, which are only decrypted on a system locally and temporarily, e.g. from incoming.zip, to process the contents and transfer them to archived-for-general-use.zip. In this case, be sure to keep the directories used for temporary storage during encryption and decryption clean and/or protected :-).

If data are distributed via a central directory to keep local copies of full collections of *.ANQ files on all QL-Recorders, it may be very comfortable to configure AnyQuest to use a specific prefix for each data origin, and to use the same number of prefix characters on all systems.

Finally, if ZIP/script-based encryption appears too clumsy, there are tools for on-the-fly directory or harddisk encryption around.

3.7.3 Implementation of a physical link to be used for data transmission from the QL-Recorder to the HIS:

3.7.4 Usage of an HIS printer for immediate printout of questionnaire results and courses over time

- Either, direct use of a network printer with lokal buffering by the printer spooler until a network link is available,
- or, local generation of printout files, which are transmitted to a defined place in the HIS and are printed from there, as soon as received, automatically.

3.7.5 Provision of a directory in the HIS where files with collected data can be placed

- as a source for automatic data import into the HIS,
- as a source for automatic generation of backups of collected data by the HIS,
- as a source for future external scientific use by authorised persons.

3.7.6 Provision of storage space for QL data inside the existing HIS

Collected QL data shall finally be included into an existing database for medical data, in order to make them available as part of an electronic patient file. The practical implementation of this functionality depends largely on the design of the existing HIS. The following way is suggested:

For each used QL instrument, which means, for each used questionnaire, a relation of its own is created, which has the same name as the short name of the questionnaire inside the QL-Recorder (or a name, which can be deducted following fixed rules, e.g., when the short name would be too long or would contain invalid characters).

Each data set entered into this relation, contains a portion of the data (or all of the data) which have been stored after one questionnaire administration session in the resulting ANQ file. These data may include:

- once for each questionnaire administration session: collected patient identification⁶, point of time of the questionnaire administration, data source = registered user of the QL-Recorder software⁷
- once for each questionnaire which has been used in the questionnaire administration session: questionnaire used, meta data related to the questionnaire⁸, raw data, additional string data, computed numerical results, computed special string results.

Which data items out of these are finally imported into the database, depends upon the requirements defined by its users, and upon postprocessing abilities offered by the database and other HIS components. A minimal recommendation would include the patient identification, questionnaire identification, point in time of questionnaire administration, and computed test results. This data set would enable physicians to retrieve these parameters as part of the medical record, and to obtain a display showing the patient's course over time. If additionally, some of the offered meta information would be processed, the HIS could also produce diagrams itself. If a database with sufficient performance is used, nothing stands against a full import of all fields.

⁶ detailed patient identification data depends upon the selected configuration

⁷ useful, if data from different sources shall be distinguished or compared

⁸ useful for data postprocessing, e.g.: number of raw data items, number of computed results, minimum and maximum of the range of possible results for a bar graph display

The method used to generate new relations are generated and integrated into the system (including everything related to the data import filter and to the parts of the software, which present imported QL data to physicians), must be clearly documented and should be easy to handle. A good option which can be implemented quite easily, is the automatic generation of new relation(s) when an ANQ file is imported which contains data from a new questionnaire (which means, data from a questionnaire, for which no suitable relation exists). However, this approach requires careful security considerations, to protect the database system against its abuse: one could present a specially prepared ANQ file to the system, causing it to generate a new extremely large relation, or an extremely large number of new relations, and thereby blocking system resources. In any case, all information required to generate new relations automatically (which means, to generate a name for the relation and names for its fields), are already available in the result files produced by the QL-Recorder, and they appear there in a way making it easy to generate and fill new relations immediately.

If relations are not automatically generated or extended by further fields as required, every new or extended questionnaire which physicians want to use, must be announced to the HIS administration. They must look at the resulting ANQ file, and generate or extend the respective relation as necessary.

In addition to the patient-identification-collected-during-questionnaire-administration (PatIDcdQA), each relation should contain another field including the patient-identification-from-inside-the-HIS (PatIDfHIS) which has been associated with the PatIDcdQA during data import. If a valid PatIDfHIS is not yet known when a questionnaire is administered⁹ or when an invalid PatID is entered during questionnaire administration¹⁰, the import routine of the HIS (upon finding, that the imported PatIDcdQA seems to be missing or invalid), can leave this field empty, and ask a human operator to manually associate the imported QL questionnaire administration result to a valid PatIDfHIS.

If no dedicated relations shall be created at all inside the HIS, QL-Results can be handled similarly to results from lab tests. However, it should be kept in mind, that lab tests usually accumulate as one or only a few results per test, while Quality-of-Life questionnaires often have 10 or more dimensions, and in their scientific use (questionnaire development and validation), even raw data (answers to each individual question) must be processed - requiring some 10 or even 100 data fields for each individual questionnaire. According to my opinion, this justifies the creation of an individual relation for each questionnaire.

3.7.7 Implementation of an interface to transmit collected QL data to the HIS

Alternative 1 (preferred): Implementation of an interface inside the HIS to import collected data out of ASCII files Here, the HIS would be enhanced by a routine, which after having been triggered by a manual action, or after a regular time interval has elapsed, or another event has occurred, looks for new ANQ files in the source directory for data import mentioned above and imports them into the HIS database.

Finally, such a routine reads data from a clearly documented ASCII file, which is composed of lines that have the format [section description] |parameter: value. It should offer some additional functionality: interactive or protocol controlled recognition and processing of invalid patient identifications, interactive or protocol controlled extension of the existing SQL database to accept additional data. All necessary information to write such a routine are given in the on-line help file of the QL-Recorder; programming such a routine, may be accomplished within one or two workdays, according to own experiences. Examples which manage the data import for ANQ=>FoxPro_SQL or ANQ=>InterBase_SQL can be made available upon request.

This solution could be prepared very easily. As experts for the HIS would have to prepare a small extension of the HIS, and as no additional components or drivers are required, the result could be achieved very quickly, in a simple way, would be easy to operate, and its stability would only depend upon its own quality.

⁹ A colleague operating a tumor documentation system has experienced, that QL questionnaire administration results from the QL recorder are available immediately, while the entry of other data collected on paper forms into the tumor data base occurs after a delay of up to several weeks. Thus, when he calls the import function the first time, many patients do not exist in the tumor data base yet. His import filter reports the respective question administration results, and either leaves them on hold, until a matching patient data set has been created, or it offers to actively create a matching data set according to the patient identification coming from the QL questionnaire administration results.

¹⁰ This possibility can be made less probable or completely avoided, of a reverse connection between the HIS and the QL-Recorder is implemented, which is described under "future options". It can only be avoided completely, if 1.) either, the QL-Recorder has access to all patient identification codes valid inside the HIS (or can ask a service to validate an individual code) at any time, and, 2.) the new creation of a PatIDfHIS can be triggered or managed from the QL-Recorder. Because these conditions require special considerations to be made, the implementation of such a reverse connection has been moved to the paragraph "future options".

Alternative 2: Implementation of an ODBC-interface to the HIS to provide collected data via ODBC Following this approach, an external program would evaluate *.ANQ files, and then contact the HIS database via ODBC and write the necessary information into the database. This solution would also have to be prepared by people who know the internal structure of the database very well.

In addition to the requirements of the approach described first, this second approach would need ODBC-drivers which would be configured and working correctly, and which would remain in this state throughout the time which the whole system shall be used.

3.7.8 Implementation of the printing function

Immediately after a questionnaire administration session, AnyQuest can compute test results. A printout including text and graphics can be generated automatically. If AnyQuest can access results from earlier questionnaire administrations, it can additionally generate a printout showing the patient's course over time for each individual dimension.

To use the printout function, a printer or an equivalent device is required. This can be provided as follows:

- Provision of a network printer for the QL-Recorder.
- Provision of a local printer for the QL-Recorder.

If a permanent connection to the printer (e.g. via a wireless LAN or when the QL-Recorder is located at a fixed place and permanently connected to a cable network) is not available, it is necessary to set the printer in the printer manager of the QL-Recorder to off-line before each questionnaire administration session. As soon as the connection to the printer is available again, the setting in the printer manager must be set to on-line again. This ensures that all print jobs are collected in the QL-Recorder and printed out as soon as the printer is available again.

- Redirection of printouts into a file on the QL-Recorder, automatic transfer via Batch/FTP to a central system, there: automatic queuing and printout of received printout files or their provision for viewing e.g. by Ghostscript without generating any paper printout at all, or for any other processing¹¹.

According to my experience, the data transfer via FTP may remain available more reliably than a Windows network printer, if the client is disconnected from and re-connected to the network often. On the other hand, such a solution would be more difficult to implement, and would require an especially good documentation. Probably, it would be reasonable to answer the dialog asking for a filename for the printout file when it is generated, automatically¹².

The necessary steps described regarding the off-line operation of a printer are based upon my own experiences with Windows 95 and 98: If the printer (network printer or local IR printer) is not available but not manually stopped in the print manager, both systems will accept print jobs and queue them, but as soon as the printer becomes available again, at least the first one will be printed in a crippled way (Windows 95), or the whole system will hang and require a complete restart (Windows 98). If required, it must be studied how NT behaves here.

3.7.9 Implementation of display-/printing- and maybe other processing facilities for collected QL data inside the HIS - depending on which functionality is already available, what physicians require, and upon local engagement

A desirable minimum functionality would be the ability to display a patient's numeric QL results from inside his medical record.

Another desirable option would be the ability to produce a graphic display of results from a single session, and of a graphic display of the patient's course over time.

All of these functionalities are basically available in AnyQuest or AnyQuery for Windows, but a solution integrated in the HIS might be usable more comfortably for medical staff. Generally, QL results can be handled similarly to other lab results.

¹¹ I can provide batch-files for automatic ftp-upload of printout files generated by Windows 95/98 and for automatic queuing and display via ghostscript on a Linux box upon individual request.

¹² ...I'd have to find out whether this can be accomplished by setting a suitable entry in the system registry. Otherwise, an external tool is definitely available which automatically recognizes and answers dialog windows.

4 Staff training

4.1 Basics of Quality-of-Life measurement

Staff receive a briefing on the meaning and importance of QL measurement and on outcome measurement in general. This is necessary, as, according to my own experience:

- staff motivation and staff compliance are the primary predictors of the quality of data collection (especially, how completely patients will be recruited), and
- staff motivation and staff compliance depend on whether staff know that:
 - relevant clinical parameters are collected from the patient's point of view,
 - which are used directly to optimize both an individual's therapy and global medical approaches,
 - and which are at least as meaningful and as important as other commonly collected diagnostic parameters.

All information for staff education is provided in printed form and in the local intranet.

4.2 Using the QL-Recorder

4.2.1 Administering a questionnaire

4.2.2 Using the print functionality of the QL-Recorder

4.2.3 Using collected data locally, transmitting collected data to the HIS

4.2.4 Using collected data from inside the HIS

For these issues, a comprehensive, illustrated manual is generated. It is provided in a printed form and in the local intranet.

Required operating steps are practised first in a settings where a colleague takes over the patient's role, and afterwards in a small number supervised questionnaire administrations to real patients.

4.3 Data protection

Staff is educated about basic aspects of using electronic data processing devices, data protection, and data availability. Tailored to the locally used system, possible critical issues are described. Correct ways to act which contribute to data protection are described and practised.

All information for staff education is provided in printed form and in the local intranet.

4.4 Transfer of own questionnaires to the QL-Recorder

In the course of the project, local staff (e.g. members of the clinical data processing center) are instructed on how to transfer own questionnaires onto the QL-Recorder.

The abilities which shall be achieved include

- effective generation of questionnaire definition files using available layout templates,
- generation of configurations prepared for specific patient groups or research questions,
- basics of further data processing inside the QL-Recorder,
- preparation of the HIS to import and process data from additional questionnaires.

As far as necessary instructions exceed the information normally provided by the QL-Recorder software, they are provided both in printed form and in the local intranet.

4.5 Contact persons regarding HIS (e.g., when data from further questionnaires shall be imported into the HIS) and QL-Recorder technology

Contact persons with a profound knowledge regarding the applied technology are identified and are introduced to the users of the QL-Recorder. Contact persons from the clinical area with knowledge regarding the aims and methods of the running project are also identified.

All special contact persons are listed in the printed information material and in the local intranet. Their tasks include continuous coordination of the project, training and support of users, mediation among various co-operating parties and communication and, optionally, co-operation with the outside world.

4.6 Sources of help and documentation

A directory of possible sources of help and documentation, including local and external contact persons, printed resources, respective source files, resources in the intra- and Internet, is prepared and stored in a suitable place, and made available in the local intranet.

5 Patient information and public relations

Elements from staff training are transformed in a suitable way to be used for patient information. These resources are provided in printed form, in the local intranet, and in the Internet. The public are informed about ongoing activities during suitable events.

On the one hand, this may increase the good reputation of the clinic. On the other hand, increasing public interest is directed to the question of benefit of medical measures and to research activities in this area.

6 Documentation

6.1 Project draft

6.2 Project report

6.3 Available documentation

6.4 Contact persons

6.5 Hardware, Software

6.6 Available questionnaires

6.7 QL-Recorder manual

6.8 Manual covering project specific functionality of the HIS

6.9 Description of future advanced possibilities

6.10 Test operation and optimization of the first implementation

6.11 Plan for transition into routine operation

6.12 Plan for evaluation during routine operation

All documentation is - if possible - provided both in printed form and in the local intranet.

7 Description of future advanced possibilities

- Reverse connection between HIS and QL-Recorder: the HIS offers a directory of all valid patient identification codes to the QL-Recorder, so that the collection of invalid IDs, which previously would not be noted before QL data import into the HIS, cannot occur.
- Implementing a permanent connection between the QL-Recorder and the HIS via a wireless network.
- If the QL-Recorder has a permanent network connection, it can alternatively call an external validation routine which itself accesses the database directly with the validation request, or it can call an external program that e.g. accepts an electronic patient identification card.
- Use of Linux as a more stable and secure operating system with respective staff training.
- Transfer of additional questionnaires to the QL-Recorder, creation of a questionnaire library, e.g. with intranet-web-access.
- Use of the QL-Recorder during development and validation of new, own questionnaires.
- Extension of its use to other clinical areas, and, e.g., into quality assurance by presenting questionnaires to assess patient satisfaction with care.
- Creation of further facilities for analysis and display of collected data inside the HIS.
- Multicenter data collection and co-operation for data analysis.

8 Test operation and optimization of the first implementation

The first implementation is used for a defined testing period. Its elements may be optimized based upon results of active monitoring of patients and staff using them.

9 Transfer into routine operation

10 Plan for evaluation during routine operation

10.1 Evaluation of the results of routine operation according to the given plan

10.2 Communication of the results of the evaluation

11 Finance plan

This plan describes the costs caused by individual elements or phases of the projects.

[...]

12 Time schedule

[...]

13 Project funding

The following sources contribute funds to the project:

1. Contributions from the institution carrying out the project:
 - (a) paid to external parties:
 - i. for investments:
[...]
 - ii. for services:
[...]
 - (b) covering internally caused costs:
 - i. material:
[...]
 - ii. working time/services:
[...]
2. Support from public sources:
[...]
3. Support from private sources:
[...]
4. Funds from other sources:
[...]

The contributions from the institution carrying out the project are compensated from the following sources:

1. additional revenues expected in the future because of improved infrastructure and qualification:
[...]
2. savings expected in the future because of improved infrastructure and qualification:
[...]

14 Responsibilities and qualification of persons participating in the project

Responsible project co-ordinator: [...]

Project design: [...]

IT-Implementation, consulting and support: [...]

Generation of the import interface for the existing hospital information system: [...]

Generation of display, printing and analysis functionality for the existing hospital information system: [...]

Data analysis: [...]

[...]:[...]

QL-Recorder, Outcome measurement and basics of EBM: Dr. med. Jörg Sigle has developed the QL-Recorder since 1993 in co-operation with the Cancer Centre of the University of Ulm. An important step towards its improvement was begun during his stay at the University of Sydney, 1996. After finishing his studies, he worked as free scientific assistant of the Workgroup Clinical Economics of the University of Ulm with Professor Franz Porzsolt. In Oxford, he acquired basic knowledge regarding Evidence-Based-Medicine (EBM), and designed projects to integrate EBM in the medical education of students and into the continued education of colleagues. He has gathered experience with the use of information technology in practices since 1985, and in the hospital since 1998.