

# Using the QL-Recorder to measure Quality-of-Life

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19th May 2001

## 1 Target group and goals of this text

The following text addresses physicians practicing medicine or working in research, decision makers in political positions or in hospitals, health-insurers and people from the pharmaceutic industry, specialists in medical documentation, information technology consultants, and finally, staff who administer questionnaires to patients. As this is a very heterogeneous target group, individual readers may feel that some paragraphs are difficult to understand, while others seem to be trivial.

The technology which is introduced, appears very simple in its practical use; however, it is sophisticated and offers a variety of creative possibilities. Looking at it while it is being used enables you to understand it very easily. This is, why the WWW and CD-ROM resources contain documentation, video clips and evaluation software. We can support you practically as well, so that after a short phase of intensive planning and getting used to these tools, you can receive rewarding results very fast.

## 2 The problem to be solved

If questionnaires are used to assess restrictions or changes in Quality-of-Life or patient satisfaction in multiple dimensions, these questionnaires usually have to be copied, presented to the patient, checked for completeness, and evaluated using existing formulas. If results shall be used to assess a therapy in the individual case or for quality assurance, it may be necessary to plot a course over time, or to compare one patient's results with those of a whole group of patients.

All of these tasks require working time, which is, in most cases, not deliberately available in practices or in clinics.

## 3 Available technology and its possible benefits

### 3.1 History

Since 1993, we have been developing the Quality-of-Life-Recorder. As an abstract concept, this tool makes measurement of Quality-of-Life (QL), storage of data for scientific purposes and provision of results for practical use as simple, as, for example, using an audio-tape-recorder.

Currently, there are two technical implementations of this concept available. Each of them can be integrated in the working environment of its users, and can be customised for individual projects. This task can be supported professionally.

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The translation source is dated July 17th, 2000; only minimal changes were made during translation.

As a variety of hardware can be used, it is possible to establish a working routine Quality-of-Life measurement even with very small budgets. On the other hand, sophisticated research projects, including multicenter electronic data collection with automated (encrypted) transmission of data to a study center via the internet, and immediate presentation of results in the WWW for authorised users, can be implemented using available components.

Data collected with the Quality-of-Life-Recorder in different studies and using different questionnaires can be merged later on without the necessity of prior planning of this step, and this can be done very easily. This can enable you to perform meta-analyses or cross-validations of questionnaires.

Still, using electronic questionnaires implemented by the Quality-of-Life-Recorder is at least (!) as simple as using paper questionnaires, for both staff and for patients.

### **3.2 The QL-Recorder using AnyQuest for DOS**

The original Quality-of-Life-Recorder for DOS uses a digitizing tablet. A printed questionnaire template is placed on this device. Patients read questions from this questionnaire template, and, using an electronic stylus, click at one of the answer fields printed next to each question. If they want to correct an answer, they can just click at another answer field. The PC records all given answers, checks entries for completeness, calculates results according to the correct algorithms for the respective questionnaires, and stores all data. Automatically, a printout can be prepared for both the current session and for the patient's course over time.

Generally, the system is used directly by the patient. However, it can also be used to record the contents of paper questionnaires in a time-saving way, if these have been completed in peripheral centers lacking the electronic equipment, or at patients' homes.

Apart from the digitizer, only a PC with an 80286 CPU or above, and optionally a printer, are required. The software allows the adoption of most usual questionnaires; a CAD software that allows for comfortable digitising and editing of self-made printed questionnaire templates is available. There is comprehensive documentation for the system.

### **3.3 The QL-Recorder featuring AnyQuest for Windows**

The Quality-of-Life-Recorder featuring AnyQuest for Windows can use a variety of input devices, and Microsoft Windows or compatible graphical operating environments. So - depending on the target patient population and upon the available budget - electronic questionnaires can be presented on older PCs running Windows 3.1 just as well as on large touch-screens, or on modern, portable mini-pen-computers. Even when your hardware changes, software and questionnaire definition files can remain usable without any changes.

AnyQuest for Windows includes functions to create or edit questionnaire definition files. Questionnaires may contain images (e.g., smiling or crying faces or photos to be checked) and sampled audio files. Discrete answer fields and visual analog scales can be displayed; free text input can be asked for. Interactive questionnaires or the automatic presentation of questionnaire modules depending upon given answers are possible. AnyQuest can perform sophisticated calculations to obtain results, including logical decisions and application of rules regarding individual missing answers. Numeric or text based answers can be processed. Special functions support the development and validation of questionnaires.

The Quality-of-Life-Recorder using AnyQuest for Windows, can be configured to offer a variety of sets of questionnaires, in a way that allows staff to present the right set of questionnaires for a given patient or a given examination just by selecting a respective menu-entry or icon.

The system is completely documented. Among other resources, there is a comprehensive electronic help file, including Quick-Guides for users and designers of electronic questionnaires. A Quality-of-Life-Recorder CD-ROM contains a copy of the respective WWW-site, including the software together with application examples and additional introductory video clips.

## 4 Examples for practical configurations using AnyQuest for Windows

### 4.1 Different hardware platforms

If the patients you want to address can use a mouse, any older PC with Windows 3.1, a mouse and a printer can be used to implement a working routine Quality-of-Life measurement. As these devices are available anywhere (and usually, not used for other purposes any more), no investment in hardware may be needed at all.

If the patients you want to address are not used to handling a mouse, this input device may be replaced by a Trackball for about 40,- Euro. Alternatively, there are touch-screens which can be added to any existing display available; they cost about 150,- to 250,- Euro. If dedicated touch-screens shall be used, maybe even on large flat-panel-displays, costs from 750,- to 5.000,- Euro may be expected.

When the acquisition of new hardware is considered, a mini-notebooks with a touch-screen and/or a pen, together with a simple laser or ink-jet printer with an infrared interface are recommended. The investment to be expected for this is between 1.300,- and 4.000,- Euro. Questionnaires can be administered on the notebook at any place, and even independently from the printer.

No matter which hardware is used, the printed result of a questionnaire administration can be used immediately in the following consultation; collected data are available for advanced evaluation. Examples for possible configurations, including drawings and comprehensive explanations, are available in the WWW and on the QL-Recorder information CD-ROM.

### 4.2 Connection to LANs or to the Internet

If the QL-Recorder is integrated into existing Local Area Networks (LANs) inside a clinic or a practice, recorded data can be stored on a central server, and printouts can be redirected to any available network printer. For example, a patient can fill in a questionnaire on a mini-notebook in the waiting room, and later on, a physician can look at the results on her personal computer in her own consultation room, with no necessity to generate or carry around (!) paper printouts.

As data are recorded as ASCII files, they can be transmitted to central servers via the Internet. It is clearly recommended to encrypt them for this purpose. Within local networks, as well, data security should be taken care for. Several reasons (including specialists societies' recommendations) suggest the use of the freely available operating system Linux instead of commercially available alternatives.

### 4.3 Wireless networks

Wireless LAN technology allows the QL-Recorder to be moved around completely freely. A patient can fill in an electronic questionnaire at any place inside the hospital, maybe in a waiting room or in her bed. Without a cable connection, results are stored on a central server, displayed at a physician's workstation, and/or printed on a network printer. Once installed, wireless LAN infrastructure can also be used for other applications inside a practice or hospital information system.

Prices for wireless LAN infrastructure appear relatively high at first glance, but it must be kept in mind that it makes any technical, financial and logistic efforts for installation of cables obsolete. Technical issues like avoidance of interferences with medical equipment, data security on-air and manufacturer independent standards have been solved in the meantime.

### 4.4 Sterility

If any concerns should arise because of handing an electronic device over to an especially sensible or infectious patient, a mini-pen-computer can be put inside a transparent plastic bag. It remains well usable inside; if a wireless LAN is used, not a single limitation regarding functionality needs to arise from this approach.

## 4.5 Pre-configured software packages

For several questionnaires, specifically customised QL-Recorder software packages exist, e.g. the eIBSQOL prepared for Glaxo Wellcome plc. Some of this software is available free of charge, and can be used immediately, causing no efforts for configuration at all.

## 4.6 Logical integration of the QL-Recorder

The QL-Recorder focuses on the improvement of the interface between the patient and the electronic questionnaire. Its capability to produce result printouts from the individual session as well as for the patient's course over time, is a comfortable add on; the same is the simple tool AnyQuery which lets you search recorded data files and display them again. Primarily, AnyQuest delivers a self-explaining, clearly readable, and completely documented ASCII file as the result of each questionnaire administration. The format of this file is capable to contain data from most thinkable questionnaires.

In order to export data, AnyQuest can convert its result files into tables, which can be imported and processed further by programs like SAS, SPSS, Spida, Excel, Lotus, Access, ... This continues to work even when different questionnaires or different language versions or revisions of the same questionnaire have been used.

By these mechanisms, results from questionnaire administrations using AnyQuest, can be imported into arbitrary working environments. The main keys lie in the simple data format and in the available, open documentation: result files can be transported using common network protocols and applications<sup>1</sup>. Third party applications (e.g. hospital information systems, tumor documentation systems) can receive data from the QL-Recorder. Interfaces have already been created for several systems (AKQUASI, TREG, FEBROSKRIPT). A more universal interface to the SQL database Interbase and the prototype of a WWW client to this database are being developed (January 2000).

Third party applications can generate configuration files for AnyQuest, and thereby control the program (questionnaire definition files which shall be loaded, display options, location to store collected data and so on) from outside. This may be used for example, to interactively put together modules from a questionnaire library using a WWW based application, and then have AnyQuest present the resulting questionnaire.

# 5 Some experiences from real projects

## 5.1 Routine patient assessment in clinic and practice

### 5.1.1 Examination of out-patients in the Medical Clinic of the University of Ulm

In 1993, the QL-Recorder was used at the Medical Clinic of the University of Ulm for the first time. Patients were asked to fill in a paper version of the SF-36, and, afterwards, an electronic version of the QLQ-C30. Out of 624 patients, to whom the electronic system was shown, 622 filled in the electronic questionnaire successfully.

However, only a limited proportion of the patients visiting the clinic during this study was invited to the study at all. This shows, that staff compliance is an important factor when high quality QL-data are to be collected. Patients, on the other hand, could definitely use the system without any difficulties and were happily ready to do so (Sigle).

In 1994, during 4 weeks, all out-patients of the Medical Clinic of the University of Ulm should be examined using the QLQ-C30. In a dedicated room, 6 QL-Recorders, a file server and a printer were set up as a network. During 19 days, 1181 eligible patients visited the clinic according to the hospital information system, and 1133 could be invited to the study. Of these, 1120 agreed to participate (94.8% of the target group). The data were complete by 99.98%, no data were lost at all, but individual patients could not answer a single question (because they felt it was inappropriate for them or they did not understand it). Thus, the collected data are representative for the examined population. The age distribution of participating patients resembled the one of the German population between about 10 to about 90 years; patient profiles from individual specialties

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<sup>1</sup>For example, it took only an hour to write a few scripts transferring printouts generated by AnyQuest from a Windows 95 machine via ftp to a Linux box automatically, entering them into a queue, and displaying them one by one using Ghostscript. This readily replaced a missing printer during an exhibition, requiring only a minimum of resources.

matched clinical expectations very well. For the clinic, there were beneficial findings which would not have been researched for without this study.

The results of this study prove the feasibility of routine questionnaire administration to patients using the QL-Recorder, the readiness of patients to participate, and the clinical importance of such an assessment. The recorded Quality-of-Life data are of an outstandingly high quality, not previously (or since) matched by anything reported in literature (Sigle, Sigle & Porzsolt).

### **5.1.2 Examination of in-patients in the Medical Clinic of the University of Ulm**

In 1996, health related Quality-of-Life was assessed using the QLQ-C30+3 at multiple points in time in 352 hematologic or oncologic in-patients.

Here, too, integration of the assessment in clinical routine work proved crucial for data quality. Patients' readiness to participate in the assessment independently from sex, diagnosis or goal of their therapy (curative/palliative); from 80-90% at 65 years or below, it sank continually to around 40% at 90 years. It remains unclear, whether age itself, or restrictions in Quality-of-Life found in several dimensions, are responsible for this. This observation, however, should be kept in mind, whenever Quality-of-Life is compared between groups differing in the proportion of included patients over 65 years (Holch).

### **5.1.3 Routine examination of out-patients in a practice and out-patient-clinic**

Since 1994, oncologic patients of the Praxis und Tagesklinik E. Rethfeld have been assessed routinely in regular intervals using the QLQ-C30 inside a model project.

This routine assessment proved to be feasible. Recorded data could be used to demonstrate that using a holistic therapeutic approach, patients' Quality-of-Life remains good until towards the end of the course of their disease (Rudolf van Leendert<sup>2</sup>).

### **5.1.4 Routine examination of in-patients**

Since 1995, in-patients of the Bio-Med Kliniken have been examined using the QLQ-C30 routinely at admission to and release from hospital.

This routine assessment proved to be feasible. Relations between baseline Quality-of-Life and remaining survival time could be demonstrated as well as an improvement in Quality-of-Life during the hospital stay in several dimensions (Dirk Höhmann<sup>3</sup>).

## **5.2 Integration with a tumor documentation system**

Since 1995, oncologic patients of the Fachklinik Donaustauf are regularly examined with the QLQ-C30. Recorded data are imported in the tumor documentation system TREG, which has been developed there. Inside this system, interactive statistical evaluations can be performed immediately (Friedrich von Bültzingslöwen<sup>4</sup>).

## **5.3 Use in a clinical study**

In a randomised, controlled therapy study performed at the Kantonsspital Chur and the University of Würzburg, in addition to extensive morphologic examinations, patients' Quality-of-Life is examined before and after the intervention. As Quality-of-Life-Recorder, a mini-pen-computer under AnyQuest for Windows is used.

Quality-of-Life measurement was possible without practical difficulties. Costs to obtain QL-data may have been about 1000 times less than costs to obtain morphological data. The study has not been completed yet, so further information cannot be given yet (Doris Wagner<sup>5</sup> et al.).

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## 5.4 Use in questionnaire development and validation

### 5.4.1 Development of an instrument to assess QL in children

Since 1998, a questionnaire to assess Quality-of-Life in children has been developed at the Childrens' Clinic of the University of Ulm. In the current validation phase, both children and parents fill in electronic versions of the respective questionnaires on a QL-Recorder which is implemented using a mini-pen-computer. For both children and parents, a specific configuration has been prepared: the clinical data manager (a student) can start the respective questionnaire administration by clicking at the respective icon on the desktop.

This solution is accepted very well by both children and parents, even children at the age of 8 years do not have any difficulties to handle the QL-Recorder (Lutz Goldbeck<sup>6</sup>, Reiner Braun).

### 5.4.2 Development of an instrument to assess QL in very old patients

The Geriatriezentrum am Wienerwald (GZW) develops instruments to assess Quality-of-Life in geriatric patients with dementia. Data required for validation and factor analyses were collected with two QL-Recorders (mini-pen-computers). In this project, the GZW cooperates with colleagues from the University of Graz, the University of Umeå and the University of Ulm. For both nurses and physicians, individual configurations, each including a specific battery of questionnaires, have been prepared, which can be selected and presented by clicking at the respective icon on the desktop.

Because patients with dementia are studied here, nurses and physicians carry out a proxy rating and so, use the Quality-of-Life recorder themselves. Here, too, in 670 ratings, each including about 100 items, a perceived substantial simplification of data collection could be demonstrated. No technical problems regarding the use of the QL-Recorders occurred (Marina Kojer<sup>7</sup> et al.).

## 5.5 User specific packages

In 1999, a package was prepared for Glaxo Wellcome plc., including two indication specific questionnaires in 10 languages. This package can be installed directly from CD-ROM; afterwards the functionality of the electronic questionnaire is available immediately. A booklet contains an introduction; additional scientific background information is included on the CD-ROM (Timm Volmer<sup>8</sup>).

This package is an example for a user specific solution. The software is designed in a way which represents the customer and the product. Similar solutions can be imagined, if an institution or a project coordinator want to distribute one or multiple questionnaires as user-friendly as possible among a larger number of users.

## 6 Data protection

### 6.1 Theoretical issues

It is very remarkable that, as soon as anyone starts to use electronic tools for data collection, all those sleeping beauties arise, who otherwise fail to notice in their beautiful dreams all these openly accessible file-trolleys and x-ray-pockets lingering throughout the wards of most known clinics.

European or national law regarding data protection, require special measures, before anyone starts to record patient related data (even using paper). Rules applicable to the scientific utilization of data can differ from those applicable to routine patient treatment. In any case, one should try to make an electronic system for questionnaire administration to patients at least as secure, as a paper based one<sup>9</sup>. This does not only include protection from unauthorised access to data, from data being stolen or being destroyed, but also protecting the availability of recorded data. It may be required by law, and it may be reasonable, too, to contact a person

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<sup>9</sup>However, generally, one should refrain from artificially making an electronic system as INsecure, as paper based systems have always been.

responsible for data protection, employed either by ones own institution or by the public. Qualified members of the local IT department, or external consultants, can also assist. Comprehensive material regarding this topic is available in the WWW<sup>10</sup>.

## 6.2 Practical issues

In Germany, it is generally required, to inform a person responsible for data protection about the contents of data which will be stored. Data revealing the identity of the patient to whom they are related, are termed “patient data”, and must be protected especially well. Formally, anonymous data are not “patient data”.

Thus, it may be reasonable, to record only a coded patient identification together with each questionnaire, which protects the patient from the possibility, that anyone could know his identity when getting hold of questionnaire data, without also having necessary additional tools (e.g., an index list which is kept separately in a safe place). This approach may cause additional work at a later point in time, especially if the collection of all necessary information and the final merging of all components has not been designed carefully in advance.

In any case, the device used for data storage (e.g., a mini-pen-computer) should be protected from abuse. This can be achieved by physical measures, e.g., locking the device away, when it is not used, or keeping it in a clearly visible area during recharging, or installing passwords at multiple places. Security should be taken into account when the operating system is chosen - and some commercially available systems may turn out to be neither the most stable nor the most secure ones. Whenever recorded data are communicated, they should be encrypted adequately.

The chance that one treats one’s patients’ data correctly, gets higher together with one’s knowledge about data protection in IT environment and about national law. To use one’s time economically, one should receive some consultation from people who read the appropriate newlists and publications regularly.

## 7 Practical hints regarding the use of the QL-Recorder

For both staff and patients, an electronic QL-Recorder should be at least as easy to handle, as a paper questionnaire. Nowadays, available technology enables us to implement any imaginable idea, and to comply with any requirement - however, lowest possible costs and the possibility to communicate collected data well are important goals.

If an electronic system requires a substantial introduction or training of the patient, this may nowadays be considered a sign of a sub-optimal user interface.

At least in configurations using a touch-screen or a pen-computer, patients can use AnyQuest as easily as paper and pencil. The system can be configured in a way that staff only need to click at one icon to select a questionnaire or a prepared battery for a certain patient group. There are templates for comprehensive, illustrated manuals describing the technical steps (like powering the system on or off), and instructive video clips as well.

Apart from the preparation of technical infrastructure, comprehensive staff training including clear information regarding the importance of Quality-of-Life data, is essential. When staff have understood, why QL or patient satisfaction are studied, they will support these activities: afterwards, QL-measurement becomes just another examination, which is just as important, and just as normal as taking a blood sample.

The electronic questionnaire can be located at a special place, which can be surveyed by staff, but which is not especially exposed. Alternatively, solutions using a mini-pen-computer may be presented to the patient anywhere, but this may require special sensitivity in involved staff, to avoid for example, that a new, anxious patient, is pressed to fill in a questionnaire in a loud environment making him feel uneasy.

Each patient should be invited to fill in a questionnaire at standardised points in time, e.g. while waiting for his consultation, using a standardised invitation, e.g.: “We have prepared a questionnaire for you, because we would like to learn how you feel according to your own opinion - and not merely according to your doctor’s.” As soon as patients hear that - really and explicitly - someone asks them for their own opinion, they agree almost without exception to fill in a questionnaire.

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<sup>10</sup>...this abbreviation refers to the World-Wide-Web, which many individuals think to be the “Internet”, but which is just one of its many applications.

Afterwards, the patient should be asked for his name and date of birth (if these data are collected, and not known anyway). The person presenting the questionnaire, should enter these data into the system in front of the patient. This assures, first, that these data are collected reliably<sup>11</sup>, and second, the patient can see how the actual hardware (e.g. the stylus or the finger<sup>12</sup>) is used.

Afterwards, the QL-recorder is handed over to the patient. The person presenting the questionnaire informs him that he may call for help in case of difficulties or questions, or if answers should be corrected, or if the patient feels he cannot or does not want to answer a question<sup>13</sup>.

The patient is asked to return the QL-Recorder after completion of the questionnaires. Staff puts the resulting printout into the patient's file, and the physician uses the results from the Quality-of-Life measurement during the consultation (e.g., the course of fatigue, pain, or emotional function).

When routine Quality-of-Life measurement is introduced, extensive training (role plays) among staff can help to reduce uncertainty and to identify possibilities to optimize the process. Sustaining the analogy to taking a blood sample: Uncertainty can result from a lack of understanding of the importance of the examination, from a lack of practice, but also from a deficient education. Independently from its causes, uncertainty is felt by a patient immediately, and leads to unsatisfactory results.

## 8 Further Information

In the World-Wide-Web, <http://www.ql-recorder.com> offers further information regarding the QL-Recorder. In addition to a current evaluation version of the QL-Recorder software and a library of questionnaire definition files, you can find information about its availability, practical guides, documentation, publications, and a literature reference.

A copy of the site can be made available on CD-ROM upon request. It contains additional video clips, which for example show a mini-pen-computer. This can give an impression of the easy handling of the solution in everyday use.

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<sup>11</sup>And in a standardised way, e.g. if initials or an encrypted patient identification code are collected.

<sup>12</sup>A pen works more precisely on small screens or for individuals with large hands - and, especially, leaves fewer fingerprints on the screen.

<sup>13</sup>Respective options could be displayed on the screen as well, where the patient could access them on his own without asking for staff assistance. However, this would make the screen display and the introduction a little bit more complex, and it would probably render more patients browsing through the questionnaires, giving less spontaneous answers, or refraining from answering individual questions more easily.



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