

Electronically assisted Outcome Measurement*

Dr. med. Jörg Sigle†

19th May 2001

* A more comprehensive version of this document is available in the WWW at <http://www.q1-recorder.com/documents>
† Im Vogelsang 2, 75438 Freudenstein, Germany, joerg.sigle@jsigle.com, <http://www.jsigle.com>

Summary

Whoever evaluates results of diagnostic or therapeutic measures, performs Outcome Measurement. To be useful, measures must either improve the time or the quality of survival of patients. If valid instruments for Outcome Measurement are applied correctly, their results belong to the strongest parameters with the highest prognostic importance in medical research.

Expenses for patient assessments using questionnaires can be reduced by means of information technology. At the same time, they improve data quality and data availability. They enable physicians to incorporate computed test results into consultations immediately after the assessment. Analyses of data from multiple centers can be carried out years after the original assessments without any special preparations, even when this was not originally planned. These possibilities are rendered by a generic tool for data collection, the Quality-of-Life-Recorder.

Electronically collected data can be used and communicated in a variety of ways. Technical solutions can implement almost anything desired, but they have to be tuned exactly to match each specific task. To do this, and also to protect collected data appropriately, special knowledge is required. Good staff training is absolutely necessary for all tasks in the area of Outcome Measurement - for study design as well as for performing assessments or for evaluation of published studies. Some other non-technical requirements must be met as well.

Using currently available tools, routine Outcome Measurement, one possibility of doing research within routine care, can be implemented on a high level immediately. Its results would be very valuable for physicians, patients and society, and would satisfy an actual and urgent requirement: they alone enable us to allocate the limited resources of our healthcare system to a selection of measures with proven benefit for patients.

It is now within the responsibility of political and administrative authorities to request data supporting the benefit of applied medical measures from those who apply them, and to provide required resources for routine Outcome Measurement, and to support respective activities.

1 Introduction

Asking patients to assess their own health related quality of life (QL), has been shown to be a valuable tool to assess results of medical measures (Outcome Measurement). The method is of similar interest for both smaller or multicenter studies. However, merely at a few locations, quality of life is currently measured routinely, thereby integrating outcome research into routine patient care. This is due to a lack of knowledge about its value, and due to practical obstacles, like a lack of infrastructure and funding [5]. Currently available tools can help in overcoming these obstacles [8].

This text explains how modern technology can enable its users to carry out QL-measurements with high data quality and data availability. It shows criteria which should be met by an electronic questionnaire - and which are actually met by the provided example of the Quality-of-Life-Recorder using AnyQuest for Windows. The text may serve either to improve your understanding of existing systems, or as a checklist for future projects.

Following this part, readers with less interest in technical details will find non-technical requirements for reasonable collection of high quality and useful data. Just as anywhere else, valuable information to be acquired from patient assessment must be paid for. Expenses, however, are relatively small in comparison with other medical areas; costs are caused mainly by the acquisition of technical equipment and know-how. Time is required for staff training, collection and evaluation of data, and for discussion of results. An important precondition to meet all non-technical requirements is a change of attitudes - away from waiting for external pressure, and towards one's own creative activity.

Beginning with the current situation, looking at technical possibilities, and finally suggesting to use them reasonably, this text describes the way towards feasible, widely available Outcome Measurement by means of presenting electronic questionnaires to patients.

Basic information about Outcome Measurement can be found in [2, 3, 4, 5, 6, 8, 9, 7]. In the [11], you can find the working software of the QL-Recorder, a questionnaire library, drafted project designs, users'

and service providers' addresses, and literature, including a more comprehensive version of this text [14], which also discusses different technical approaches.

2 Why e-Outcome Measurement? - and how?

Conventionally, patients are presented paper questionnaires. Not before such a questionnaire has been returned, staff can verify the readability, completeness and content related correctness of given answers. If the patient does not remain to be available, identified errors cannot be corrected anymore. Any manual data entry into data processing system should be carried out twice, to identify - regularly occurring - typing errors. Only afterwards, technical systems can assist in evaluating the answers. Within this process, many tasks require concentrated working. This fact limits the capacity available for patient assessments by questionnaires, causes relatively high costs and makes it difficult or impossible to use the routine, widespread use of patient assessments by questionnaires in research and medical practice. Respective studies additionally show only a moderate data quality - either, because questionnaires can't be evaluated partially, because questions have been overlooked, or because questionnaires from individual patients are missing completely.

Easier, everything would be, if a patient could fill in an electronic questionnaire by himself without any assistance. The tool should check given answers for completeness and formal correctness, calculate results and provide them for further processing. All of these steps should occur invisibly, automatically, fast and reliably. The final product - high quality data inside an electronic system, completely processed and, optionally, printed out - should be available immediately after a questionnaire administration. Such a system would enable its users to administer questionnaires to patients in routine care; results could even be used in the directly following consultation.

There are two approaches towards an electronically supported patient assessment with questionnaires:

Off-line-methods: The patient completes the usual paper questionnaire. Staff takes care of its further handling; answers are, usually at another place and later on, fed into an electronic system. This process can run automatically or semi-automatically (e.g. via scanner, fax, digitizer...). Because of this, data quality cannot be ensured immediately and completely automatically. Such methods are especially apt to widespread or multicentric data collections, when technical infrastructure is limited, and restrictions regarding data quality and the speed of data availability are accepted.

On-line-methods: The patient completes the questionnaire directly at the electronic system. Only on-line-methods can avoid any expenses for handling questionnaires. Only they enable interactive and multi-media-questionnaires, can record data regarding the place, the time and the duration of the assessment automatically, and make available recorded data in automatically ensured quality immediately for any further processing. These advantages are essential, when questionnaire results shall be used in an immediately following consultation. Only such a system can also provide the information, whether an individual patient has been assessed at all, at any given time. Only by this information can it be ensured that, for example, every patient within a follow-up program completes a questionnaire during each visit - and does this reliably, before he has left the clinic again.

Finally, it has been shown that electronic questionnaires are well accepted by patients, and that they can collect data more completely and better than paper questionnaires or even interviews (literature in [8]).

An ideal electronic tool should be able to work with a variety of questionnaires. A library of electronic questionnaires should already exist. Persons with basic IT related knowledge should be able to transfer paper questionnaires onto the system. Data from arbitrary questionnaires should be provided in a persistent format via open, well documented interfaces. If possible, one should be able to configure the system for specific projects without technical specialists' knowledge. It should be possible to distribute existing configurations to multiple users easily. Specific requirements regarding hard- and software-infrastructure should be small, existing equipment should be supported as good as possible. From the beginning to a completed application, including the evaluation of data, cost should remain as small as

possible - and, most important: should be clearly defined - including one-time-investments, operating costs and staff working time.

As smaller steps are usually taken more easily, it would finally be fine, if the same system could be introduced in a simple, autonomously working version, and could be integrated in existing IT environments for more complex projects later on.

Focussing, and the modular approach. An electronic questionnaire may focus on the collection of data through the man-machine-interface, and on providing collected data. Tools for statistical evaluation, visualisation, storage and organisation inside of data-bases, encryption, transmission through electronic networks including the internet, even for automatic presentation of an existing questionnaire according to a specific schedule, are available as required already. In no case, it is necessary to re-implement a functionality available in standard applications already - to include staff positions for IT experts in publicly funded projects for this purpose, does not constitute any scientific achievement, but is at least questionable. A modular approach which uses externally available components leads to faster development, better stability, longer lasting usability, more flexibility and openness for third party systems.

Generation and maintenance of electronic questionnaires. Users with general IT knowledge should be able to transfer their own questionnaires onto the electronic system, and should receive usable results from questionnaire administrations fast. For this purpose, questionnaire primers with good layout should be available. The process of generating and editing questionnaire definitions should be clearly documented. Of course, it should be possible to edit existing questionnaire definitions later on, either within a dedicated editing environment, or using external programs - or using both of these tools. The generation of versions for different languages out of an existing electronic questionnaire should be possible efficiently. It should be possible to combine layouts and individual parts of existing questionnaires, and to recycle them. When paper questionnaires are transferred to the system, it should be possible to use available resources, for example files generated with a wordprocessor or available in the PDF format, in order to avoid the necessity of typing them again or of copying them word-by-word or sentence-by-sentence. In the other direction, it should also be possible to export the contents of an electronic questionnaire in a format which is simple, text-based, and self-documenting.

Closed systems, where questionnaire definitions only exist as entries in specifically prepared data-bases and fixed evaluation algorithms, which can only be understood and edited by experts, will in the long term probably lead to high costs and dependence from one supplier, or to impossibility of maintenance and ongoing development of the system. This can hardly be one of the expected long-term consequences of the public funding of scientific research.

Documentation and user support. Each tool for electronic patient assessment by questionnaires should be documented completely. If a data-base system is used, documentation must cover this system as well. It must describe, which software under which operating system may be required to access data later on, and how any tables ("relations") used for data storage are organised. Tutorials, videos and similar material should support local users in learning how to use the system. These tutorials should mention basic aspects of patient assessment (no interference, while a patient selects answers!) and general aspects of data collection (data protection!), and should facilitate the access to more specific sources of information. For advanced or specifically qualified users, the system should be easily integratable into existing IT environments. Some person should be there to help in case of questions, to participate in the implementation of advanced projects, or to recommend third party support.

Most simple handling - and special possibilities. Patients should be able to complete electronic questionnaires on their own. Neither an introduction nor formal training should be necessary. These requirements call for an extremely simple man-machine-interface. A user-interface alike the more or less interactive forms, which are commonly used in contemporary software or in the WWW, is not something easy to use for persons without experiences in computer use. The same is true for devices with a display with limited readability, or offering a number of buttons with different functions to be understood and used. Depending on the target population, study design and budget, a variety of solutions are available, which are described in [8] and [14]. Additionally, some hints regarding hardware selection are included

there. In this text, features and possibilities of the current QL-Recorder using AnyQuest for Windows are described, which make this tool especially easy to handle and very universally usable.

The graphical user-interface of the system resembles the handling paper and pencil very closely. One question is presented at any one time, it offers answer fields or analog scales, or images which can be checked. The behaviour of answer fields can be determined in a variety of ways, for example to allow or to prohibit multiple selections. Question layout can be designed freely, but it is recommended to keep it simple and to use large fonts. Colours, images, audio signals or voice (and music) recordings can be integrated. Free text entries can be processed.

The following selection of already implemented possibilities shows special requirements learnt from practical use: hiding of all control elements which are not required by patients; step-wise reduction of available menus by configuration; answering of a question by only clicking at an answer field or a point on an analog scale once; simple possibility for correction; optionally displayable fields for “can-not-answer”/“don’t want to answer”; additionally appearing questions asking for the reasons for this; special processing of shortly following clicks, to compensate for touch-screens delivering noisy signals without puzzling patients; configurable option to automatically position the pointer to a standardised position, to avoid a tendency towards the position of the last answer; configurable option for patients to go forward or backward within loaded questionnaires, or alternatively, automatic proceeding to the next question after each given answer; interactive presentation or omission of questions or modules, also including the link-in of external programs at any point in time and communication with those; provision of various different configurations available on a single hardware system, which can store data in separate places; support of language specific character sets (for example, Greek, Kyrillic); configurable colours, fonts, display of images (also as background); support of talking questionnaires or background music; automatic adjustment of questionnaire elements according to the used screen size; support of arbitrary input- and pointing-devices.

Electronic questionnaires which a user of this system can generate on his own, by simply defining their contents, automatically inherit all these possibilities.

Beware of dead-ends! A new electronic system must not, as the paper questionnaire which it shall replace, constitute a dead-end for data. Instead, it should provide collected data in an open way and be able to communicate with other systems. At the beginning, an immediate, practically useful applicability can promote its acceptance by physicians and patients. A QL-Recorder, for example, can calculate the results of a questionnaire administration on its own and generate a printout, including a graphical presentation of the patient’s course over time in each assessed dimension. This can immediately be used to evaluate the success of a treatment in the individual case, and to improve the doctor-patient communication.

On the opposite, however, it also can bring together data collected by arbitrary researchers at arbitrary points in time, by “pressing a single button”, and bring them into a format appropriate for statistical analysis (for example using SAS, SPSS, Excel...), and export them. Finally, it can be integrated seamlessly: An external program can define via an ASCII-configuration-file, which questionnaires shall be loaded for a session, and which configuration settings are to be used for it. During the recording of the patient identification, during calculations of conditional branching formulas and questionnaire results, and after the session has been completed, AnyQuest can call arbitrary external programs, exchange data, and use their results. This enables you, to verify, complete, or reject an entered partial patient identification using an external data-base. Or, to retrieve it from a chip-card completely. The process through a questionnaire presentation can be changed according to answers just given as well as after looking up earlier results. Collected data can be transferred to external programs, which may carry out arbitrary computations; AnyQuest can include their results into its questionnaire results. Immediately after a questionnaire administration has been completed, an external program can be notified and asked to process the newly available results. It may process them in any way, transmit them, enter them into a data-base - for example the one providing your electronic patient file or your tumor documentation system and so on.

AnyQuest itself, however, does not require a data-base: it stores data as ASCII/ANSI text files, which are clearly human readable, self-documenting, and can be transferred to arbitrary platforms using arbitrary communication protocols (through the Internet, as well)¹. The format supports arbitrary questionnaires,

¹The XML-format is currently getting en-vogue according to some similar characteristics.

allows for future expansions, and contains some features which simplify later data processing with external tools. For programmers, it is very simple to transfer such a file into any given target format, if required, for example into the HL-7-, the BDT- or the XDT-format.

Available services of the operating system or external software can be used transparently to implement access control, on-the-fly-encryption on disk- or file-level, or storage and provision of collected data over local or wide area networks.

Using this approach, each step after the data collection itself, which implies data transfer or data processing, can be left out or occur in a delayed fashion, which can be especially desirable for de-central data collection and non-persistent communication links to central servers. In a simple configuration, the system can be installed completely without any knowledge or infrastructure from the area of data-bases, and immediately be used in a productive fashion. In the other extreme, it can receive questionnaires, multimedia elements and configurations from any existing data-base system, and exchange raw data, decisions, and calculated questionnaire results. To integrate it into future projects, only the smallest links between external systems and the QL-Recorder software must be prepared. As it communicates completely by exchanging data files and calling external programs, there is no dependence from special functions of a simple operating system environment or certain networking protocols. The on-line-help includes the documentation of all file formats used by AnyQuest, of its communication abilities, and hints regarding automatic or manual transmission of data as well as their processing by other software. Example programs are available upon request.

Contents to be stored. For each questionnaire session, the following data should be stored: Source software and version; place and/or institution of assessment, and/or investigator; time of assessment; patient identification, type and level of detail according to individual requirements. Moreover, for each questionnaire used within an assessment, the following data should be stored: Language; version; other meta-data; raw-data from the assessment; computed results; other data.

Multicenter data collection and meta-analyses. For meta-analyses and inter-study evaluations, it would often be helpful to be able to access original data of various authors after some years. Projects of this type must fail, if original data are not available any more, or only in files with too little documentation, which can only be read with specific software (which may not be available any more). The format which AnyQuest for Windows uses for its files, enables you at any point in time, to join arbitrary files from arbitrary questionnaire administrations where arbitrary questionnaires were used completely automatically to a single table, just by choosing one menu option. This table can afterwards be used for statistical analyses (for example, meta-analyses, cross-validations...) and can be imported by arbitrary evaluation software. In this process, all desired types of information are automatically transferred from the original questionnaire result files into the generated table.

Communication of collected data. Should a communication or central storage and evaluation of de-centrally collected data be desired, at least the following ways could be used: Sending them on physical media, for example floppy disks; direct communication link with the central server; transmission via the Internet; administration of the questionnaire over the Internet with immediate data storage on a central Server. In this process, all Internet or LAN protocols can be used (including ftp or e-mail). Simple, open standards should of course be preferred over proprietary protocols. When patient data are sent over public networks, they must be encrypted. Alternatively, Virtual Private Networks can be implemented over public lines.

In any case, the preparation of data for transfer and the transfer itself, including encryption and the connection to a central collecting site, can either run manually or automatically. Larger expenses for user training² or for setting up an automatically working structure (and testing it thoroughly) are only justified, when a project involves regular transfer of data. For a single or rarely occurring data transmission to a study center, manual copying of data onto a disk and manual mailing as a registered letter may not be the currently most en vogue, but probably the most simple and thus the best way. Should the

²...for whom it is usually more than trivial, to export a few records from a data-base and/or to pack a few files using ARJ or WinZIP and a password for encryption, and who usually do not even know what a "directory" is and where their packed data have finally been stored...

QL-Recorder have no disk drive, data can be transmitted via the infrared-port, for example to another laptop, or wireless networking cards can be used. In any case, incoming data from arbitrary sources can be processed on a target server automatically, and, if required, be provided to the outside again. The chosen concept should be designed or reviewed by a person who has some competent theoretical knowledge as well as practical experience and knows up-to-date sources of information regarding security in information technology[23].

AnyQuest for Windows offers flexible options for communication which will still be usable in the future, because it only generates clearly readable ASCII/ANSI files and it can call arbitrary external programs or scripts for their processing.

Data protection and patient identification. Data protection includes both, protection against unauthorised access, and ensuring availability. Thus, electronic Outcome Measurement has to be accompanied by a backup strategy³. Data protection regulations do not apply to electronic data processing environments alone. In paper based environments, they are just regularly grossly violated, for example in the typical trolley used in ward-rounds.

According to applicable law, patient data are medical data, which can be associated with the individual to whom they are related immediately. If files are generated to store data related to individuals, this may be obligatory to be reported in advance. Details can be found in the respective data protection regulations of individual countries and in European regulations. Files resulting from the collection of patient identification data together with outcome data, are probably patient data related to individuals. One should carefully consider in advance, which patient identification should be available directly connected to outcome data. An anonymised patient identification code, which is connected to a patient only by an externally locked-up list, may constitute a rather secure approach. If the printout showing results of the QL measurement shall be collected inside the patient's file, initials and date of birth or a special identification code, known only inside the hospital, are usually sufficient. On the other hand, it may be necessary to collect the full name and date of birth, as external lists are not feasible. Or, a special identification code may be needed which is of guaranteed long-term specificity for an individual patient. It may be useful to design a reasonable solution together with competent specialists, for example the local person in charge of data protection issues. It may be useful or recommended to have patients express their agreement with data storage and document this in writing.

Selection and configuration of the operating system. Without license costs, the free operating system Linux offers stability, data security and reliable, efficient configurability. Microsoft Windows applications can, for example, run under WINE, when the required know-how is available and local hardware (for example, a touch-screen), is supported. If a sufficient budget is available, Windows NT or Windows 2000 can also offer relatively secure and relatively stable environments.

A restricted account should be defined for patient assessment. Another account may be provided for supporting staff; an account with administrative rights should not be in reach of anyone without expert knowledge of the system. Even a system with Windows 9x or Windows 3.x can be secured: With suitable tools (for example, X-teq X-Setup) or by manual entries in the system registry, access to drives and directories is restricted, the Active Desktop is switched off, certain entries in the Start-Menu are removed. As the usual login dialogs in Windows 9x can be surpassed by pressing ESC without any password, the desktop and Start-Menu of the account which is reached then must be restricted as far as possible, too. A floppy disk drive can be removed or deactivated, an infrared-port should - depending on local requirements - be deactivated generally or inside the patients' account. Icons for system configuration through the Task-Bar should also be removed. If an extreme level of security is desired, or Windows 3.x is used, all files that might be used to display data, can be deleted (for example, any editor, any word processor and so on), but this also restricts the usability of the system for other purposes, should be well planned and well documented. As the QL-Recorder allows to enter patient identification at the screen, usually pen-computers without a keyboard can be used, further reducing the room left for abuse.

Especially when mini-pen-computers are used for patient assessment, precaution should be taken against results of a lost device. For this purpose, data can either be stored immediately on a central network server, or they can be transferred to another device manually after every few sessions. If a QL-Recorder

³...as only with our modern tools, sooo many sooo valuable data can be destroyed sooo fast and sooo easily.

shall be integrated into a clinic network, for example, to use a network printer or a fileserver, this connection can and may only be made in co-operation with locally responsible IT staff. They can also assist in obtaining required operating system licenses at the lowest cost, depending upon local licensing policy and available licenses. In wireless networks, encrypted connections should be used⁴. Configuration examples are available on the WWW-site of the QL-Recorder.

If a system cannot be configured with minimal security, nobody should be granted access to this system without careful supervision.

Future platforms. In the future, questionnaires may be available, which are for example displayed through a mobile phone with a little screen and limited computing power. Currently available devices, however, cannot be used by patients of any age, even with limited visual capabilities, or without any training. If solutions are newly designed on such platforms, the implementation should use as general standards as possible (Java as programming language, ASCII/ANSI files for data storage and exchange, Postscript for printing and graphics, data storage compatible with existing systems). An implementation of AnyQuest for Java was already started with the aim to make available questionnaire definition files usable on future platforms, where collected data can be stored through an encrypted SSL link directly on the server from which the questionnaire was received - both questionnaire definition files and result files use the same format as with AnyQuest for Windows.

Copyright and rights to use. Available paper questionnaires are often protected by copyrights; several authors collect user fees. It can be discussed, in how far a copyright extends to electronic versions of paper questionnaires - the electronic version could be regarded as independent work, written in a language of its own - and in how far results of publicly funded research activities should be available for use by the public who paid for it [22]. To allow for a constructive co-operation with authors of scientific questionnaires, however, each user of electronic questionnaires should review the conditions for use of any given scientific instrument, which he intends to use, and obey these conditions. Sources of information can be found at [8] and [12]; a MedLine- or WWW-recherche may also help.

Validation of electronic versions. When a paper questionnaire is transferred to an electronic system, most often, some minor modifications are necessary. For example, the patient might be asked to “select an answer”, instead of “checking” or “encircling” it. Introductory phrases like “During the last week...”, which are printed once for a whole list of questions in a paper questionnaire, can be displayed with each individual question in the electronic version. Numeric codes for individual answers are usually printed in paper questionnaires, to ease their evaluation. Of course, these need not to be visible in electronic questionnaires. Usually, layout and clarity can be improved when a questionnaire is transferred from a paper to an electronic version. Interactivity can contribute to the improval of data quality, and, at the same time, enable us to be more respectful to a patient’s feelings, for example, when a breast cancer patient is asked first, whether she has been sexually active, and only if she answers “yes”, she is asked, whether, as a consequence of her disease, she found this less satisfying. However, these possibilities can generally influence the contents of collected data. Because of this, one should consider carefully, whether a new validation of the electronic version would be necessary, before one includes such functional upgrades. Using the QL-Recorder, I examined results for the QLQ-C30 in the electronic version accordingly, and found no systematic differences compared to the paper version. Clinical validity of the data collected with this system, could be demonstrated easily and impressively [8].

The questionnaire library of the QL-Recorder offers a selection of questionnaire definition files [12]. Each file includes copyright- and literature-references which cannot be deleted.

Electronic versions of the EORTC Quality-of-Life-Questionnaire (QLQ) [17] core and some modules are made available in co-operation with the EORTC Quality-of-Life Group. For the core questionnaire, a collection with reference values exists on CD-ROM [18]. The questionnaire definition files for the

⁴Setting up such a network, is nowadays almost trivial, so if some companies ask for DM 2.500,- per day for each of two staff plus expenses, this seems questionable. Especially, as a computer journal noticed recently, that a *large* clinic in Hannover used a wireless network which was quite open to the outside, due to specific technical features of one of the devices which such a company installed for the above price.

SF-36 [19], a widely used questionnaire for general use, includes an external calculation modules, which implements the algorithms given in the user's guide, including the comparison with a reference population and the computation of normalised scales. To demonstrate technical possibilities, a complete talking version of the SF-36 was generated. The example of the Quality-of-Well-Being-Scale shows, how a quite demanding interview with relatively limited acceptance [20] can be developed into a self administered questionnaire [21], and finally to an easily usable electronic version [12]. The IBSQOL [13] is an indication specific questionnaire, which is provided by GlaxoWellcome plc. as eIBSQOL in currently 19 language versions, including Greek.

3 Non-technical requirements for Outcome Measurement

How do new ideas come into the world? And, why do they sometimes not come at all? The following paragraphs may apply specifically to the situation in Germany: Currently, we do not feel the limits we can reach technically or intellectually, but limits in the creative imagination of potential users, limits between the different worlds in which administrative staff, physicians, patients and politicians live, or limits of budgets which are obstacles to actual synergisms. New ideas and approaches are responded to with: "We have never done it that way!" and "We have always done it this way!"

Modern tools do still appear in hospitals. Slowly, and in the administrative area, first - as the bulge of data generated there enforces their use. At the same time, workload for medical staff rises: as always, treatment is documented for medical purposes on paper, and recently, additionally, for administrative purposes in the electronic way. But alas, examples for better solutions have been there for more than 14 years [15]! But why not everywhere? One possible explanation: As long as the working power of assistant physicians is available in de facto unpaid overtime, the working power of "Physicians in practical training (AiP)" for 2/5 of regular compensation, the working power of trainees in patient care and of civil servants almost and the working power of students in the "practical year (PJ)" and doctoral students completely free of cost, which can be used to locate one or another patient file manually, or to flip through the ICD-10 manually, but no-one of these persons asks for MedLine, well designed IT applications in medicine appear to be superfluous and unable to compete: it remains simply more expensive than the human worker.

Costs + Benefit = Transparency. A special problem are costs which occur in a hidden way: if patient care is sub-optimal because of too tired or deficiently trained staff, or because of missing Outcome Measurement data. They occur immediately, if medical resources are used up without need, and in a delayed fashion, when the results of sub-optimal treatment or consultation appear. To obtain clarification, all resources - including working power - must be accounted for exactly as they are consumed. Thorough studies, asking which medical measures are how effective, but also, how beneficial⁵ [1], and who delivers them in which quality, should be requested, performed, and also paid for.

The neutral (naive? despaired?) patient may wonder, why politicians, payers of expenses, physicians from different specialties and lay healers argue, which measures should be reasonable, approved - and, most important: reimbursable! If costs and benefits would not remain something that may be diffusely felt, but become quantifiable and associable to their specific causes, this could contribute to such politically or financially motivated discussions giving way to scientifically founded therapy decisions. Such a gain in transparency should finally be the motivation for any kind of Outcome Measurement.

The research question. In addition a clear motivation to investigate the benefit of medical measures for patients, a reasonable QL-measurement requires a clearly defined research question. Here are some examples: "How do individual patients' physical function or pain change under their individual therapy?" - Here, QL-measurement is used as an examination in the individual patient to obtain an objectivized parameter for therapy-monitoring, a similar approach to blood-pressure-measurement. Or: "From all our patients, can we isolate subgroups, who show a special benefit with regard to parameters like physical function, pain, overall psychological condition?" - Here, QL-measurement is used to investigate a group of patients in order to evaluate and optimize a therapeutic offer.

⁵After a critical assessment of existing studies, one might often doubt the proven effectiveness for several measures...

Acceptance by patients and medical staff. According to our own experience, the sentence “We would like to ask you, how you feel according to your own opinion, and not only according to your doctor’s opinion.” - luckily and sadly - gives us a patient compliance beyond 90%. Of course, a pre-requirement for this is, that the meaning and importance of Outcome Measurement are communicated to the patient consistently, positively and understandably.

Staff training. Before Outcome Measurement is performed within a project, it is necessary, to train involved staff. The meaning and importance of collected data for the quality of patient care and for the individual patient need to be communicated. And, that QL-measurement is an examination alike any other.

Staff must get experienced in the use of the applied technical tools⁶, no matter whether paper based questionnaires or electronic tools are used. In any case, they should be able to help the patient in a competent way. Before confronting patients with a tool that is a complex thing inside, staff should practice this action in repeated role plays among themselves. Exactly as with taking blood samples, a questionnaire administration must be carried out reliably and in a high technical quality, if it is medically required - be it to assess the course of an individual or to evaluate medical measures within studies. Exactly as with measuring the blood pressure, tools to perform routine QL-measurement are available; and exactly as with measuring the blood pressure, physicians must now learn to use the results in the individual case and for strategic decisions on therapeutic concepts. This requires a longer process of gathering experience and of looking at results of both individuals and clinical studies.

As a beginning of this learning process, the fundamental difference between surrogate parameters (blood pressure et al.) and real outcome parameters (survival time, quality of life) should be communicated and understood among all medical professionals.

Nomination of support who can be reached. Competent people should be ready to answer technical or content related questions, and they should be well known to co-operating staff and well reachable.

Working infrastructure. Before they are used regularly, technical installations should be tested with some simulated and some real patients, also involving real staff, and, if required, should be optimised. For each technical subsystem one should assess, how crucial its function is for the whole system, and in how far it should be tried to ensure its fail-safe operation. Examples for reasonable measures include the provision of multiple redundant workplaces for patients, or the provision of a spare tank for an ink-jet-printer, when printouts are going directly to the patient file.

It may be reasonable, to provide a few copies of the used questionnaire on paper, to be able to collect data on this medium in exceptional situations, independently of the availability of technical equipment at a given place or time.

Good organising and tight feedback. Especially when introducing routine QL-measurement, it is necessary, to support the good quality of data collection by organising measures. These include: exact description of the studied patient population and indications; exact description of available examination methods; design and communication of a schedule with interim goals; early co-ordination of all elements with involved staff; training of all staff; information of patients about reason for and practical aspects of the examination; tight controlling, whether all planned patients are examined; if yes: information of staff about patient registration rates, reactions from patients, quality and contents of results; if no: identification of source and reasons for lost patients and discussion with staff.

If a paper based patient file is used, a result printout placed into it can inform staff whether a patient has already completed a questionnaire. If a complete assessment in all patients is planned, staff can be instructed to send all patients without a printout (and without a notification, that the patient rejected the participation in the study) to the QL-measurement. If patients do not want to or cannot participate in the assessment, reasons must be documented and examined.

⁶“Get experienced” also includes formal training regarding basic principles of using graphical or other locally available user interfaces - administration representatives might want to ask the other end of IT hotlines, on which level of computer knowledge most of the problems and their solutions are sadly located.

As most important reason for missing data, we identified a lack of staff compliance [8, 10]. Missing data result especially: if out-patients visit special examination rooms directly instead of going to a central reception, while peripherally working staff do not know that all (or special) patients should attend one special examination; and if in-patients are released or moved to another ward without sending them to the final QL-measurement before. In both cases, mechanisms and results are identical: a staff member fails to inform a patient about the scheduled examination (whichever reason he may have), the patient is not available anymore for this examination later on, data are lost. As described above, this leads directly to less clear study results, and indirectly to a waste of resources and thus to a lower quality of patient treatment and care.

Budget and society's attitudes. The requirements described above cannot (or only for a very limited duration, if there is a large personal contribution of participating individuals) be met, unless dedicated resources are allocated to Outcome Measurement. In reality, in the short term, (model-)project funds are used, or the board of a clinic expects an advantage from their ability to prove the benefit of their medical offers and finances the necessary investments. In the long term, the examination should be included for reimbursement into existing honorarium- and billing keys.

Accordingly, diagnostic and therapeutic measures with questionable benefit should not be removed from or remain in catalogs of approved measures based upon political decision making, but they should be approved and reimbursed exactly if at the same time, at which such a measure is provided, its benefit for patients is studied using valid instruments. This suggestion is warranted first, because QL-parameters can help to evaluate the course of a disease in an individual, and, second, because when data from long-term studies regarding the outcome of such measures are available, catalogs with approved measures can be changed in a way, which allows to transfer resources from less beneficial measures to more beneficial ones. This transfer, however, will be founded clearly upon data describing the benefit of measures, and no more upon opinions or upon opinions combined with data describing their effectiveness, as nowadays.

The potential offered by the new approach is not exactly tiny: it affects all resources spent by society for our healthcare system.

4 Looking back, and looking forward

Since 1993, several users have performed far more than 20.000 questionnaire administrations with the QL-Recorder. The tool was used for routine measurement of quality of life in a variety of clinics and doctors' offices, in in-patients and out-patients, as part of tumor documentation with data transfer into several documentation systems, in clinical studies, during the development and validation of questionnaires for children and grown-ups, for external assessment of patients by medical staff, for widespread provision of an indication specific electronic questionnaire including automatic result computation within a user-specific software package as a new service in addition to a new drug, and even to present questionnaires to patients to collect data for strategic decisions in the health market. An overview with more detailed information regarding different projects and literature references is given in [14].

In these projects, data were collected, which cannot be found in literature from patient populations of comparable size or with comparable quality. The technical solutions that were used are extremely cost effective and have proven to work reliably. Patients' compliance was superb; patients of any age did not have any difficulties to use the QL-recorder. Doubts regarding the feasibility or sub-optimal compliance in medical staff, instead, appeared to be the primary obstacle. The complete assessment of defined patient groups shows not to be a medical or technical, but an organising problem, which can exclusively be solved by immediate availability of collected data and result calculations provided by an electronic questionnaire. Collected data were, as far as respective evaluations are available, reliable, obviously clinically valid and technically processable. These experiences show, that routine QL-measurement is technically perfectly feasible, accepted well by patients, and delivers meaningful data.

At the moment, a formal co-operation with the EORTC Quality-of-Life Group is initiated, which shall improve the availability and spreading of an electronic version of the questionnaire developed by this group, and ensure the high quality of this version in the long term.

Patient assessment and data evaluation as a professional service. One can imagine, that presenting questionnaires to a patient, planning and preparation of studies, and evaluation of collected data, may be offered as a professional service in the future. In the technically related area of market research, such offers already exist. In the medical field, special consideration is required for data protection, the medical profession's obligation to remain silent about patients' concerns, for obeying standards of Good Clinical Practice where applicable, and for the scientific quality of selected questionnaires used and prepared analyses.

As far as the QL-Recorder is concerned, resources and information are available to enable interested third parties to set up their own offer of professional services anywhere between preparation of infrastructure and complete planning, performing and evaluation of QL-measurements. The WWW-site shows information about users who'd be interested to share their experience with others, and about already available sources of user support.

References

- [1] Die WWW-Site der Cochrane-Collaboration:
<http://hiru.mcmaster.ca/cochrane/cochrane/cc-broch.htm>
- [2] Sacket DL, Richardson WS, Rosenberg W, Haynes RB: Evidence-Based Medicine - How to practice & teach EBM. Churchill Livingstone, New York, Edinburgh, London, Madrid, Melbourne, San Francisco, Tokyo 1997
- [3] in [2], Table 3b3.2, Seite 138
- [4] Australian NHMRC National Breast Cancer Centre: Clinical Practice Guidelines for the Management of Early Breast Cancer; Second Edition, 1999. Im WWW abrufbar unter <http://partners.health.gov.au/hfs/nhmrc/publicat/synopses/wh28syn.htm>
- [5] Osoba, D: Measuring the effect of cancer on quality of life. In: Osoba, D (Hrsg): Effect of cancer on quality of life. CRC Press, Boca Raton, 25-40, 1991
- [6] Porzsolt F: Messung von Lebensqualität - Wie und wozu Sie das Wohlbefinden Ihrer Patienten quantifizieren sollten. Der Allgemeinarzt 18: 610-624, Juni 1996
- [7] Researcher's guide to the Choice of Instruments for Quality-of-Life Assessment in Medicine: Im WWW verfügbar unter <http://www.qlmed.org>
- [8] Sigle J: Praktische Aspekte der Lebensqualitäts-Messung: Routinemäßige Messung der Lebensqualität bei Ambulanzpatienten mit einem elektronischen Lebensqualitäts-Recorder. Promotionsarbeit, Universität Ulm, 1997. Im WWW abrufbar unter <http://www.ql-recorder.com/documents>
- [9] Sigle J, Porzsolt F: Practical aspects of quality-of-life measurement: design and feasibility study of the quality-of-life recorder and the standardized measurement of quality of life in an out-patient clinic. Cancer Treatment Reviews 22 Supplement A: 75-89, January 1996. Textfassung im WWW abrufbar unter <http://www.ql-recorder.com/literat/litsigle>
- [10] Holch S: Routinemäßige Messung der Lebensqualität bei stationären Patienten. Promotionsarbeit, Universität Ulm, voraussichtlich 2000
- [11] Die WWW-Site des Lebensqualitäts-Recorders: <http://www.ql-recorder.com>
- [12] Bibliothek elektronischer Fragebogen für den LQ-Recorder: Im WWW abrufbar unter <http://www.ql-recorder.com/libquestns>
- [13] GlaxoWellcome: IBSQOL - Measuring quality of life in IBS. Introducing a new disease-specific assessment package. Erste Auflage November 1999, zweite Auflage Februar 2000, erste deutsche Auflage August 2000, dritte englische überarbeitete Auflage voraussichtlich November 2000. Kontaktadresse im WWW verfügbar unter <http://www.ql-recorder.com/libquestns>
- [14] Sigle, J: Elektronisch unterstütztes Outcome Measurement (Vortragsfolien und ausführlicher Begleit-text): <http://www.ql-recorder.com/document/general/eomd>
- [15] Sigle J, Porzsolt F: When will we have electronic patient files? ESPO Newsletter 11: 7-10, 1996
- [16] Welickowa G: Automated collection of QoL data: a comparison of paper and touch screen questionnaires. J Clin Oncol 17/3: 998-1007, 1999
- [17] Aaronson NK, Ahmedzai S, Bergman B, The European Organization for Research and Treatment of Cancer: QLQ C-30: a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer Inst 85(5): 365-376, 1993; Weitere Informationen im WWW abrufbar unter <http://www.eortc.be/home/qo1>
- [18] EORTC QLQ-C30 Reference Values CD-ROM, 1999: erhältlich über die EORTC Quality of Life Group; Kontaktadresse und weitere Informationen im WWW abrufbar unter <http://www.eortc.be/home/qo1>

- [19] Ware JE: SF-36: How to Score the Revised MOS Short-Form Health Scale (SF-36). The Health Institute, New England Medical Center, Boston, Massachusetts, 1988; Weitere Informationen im WWW abrufbar unter <http://www.sf-36.com>
- [20] Porzsolt F, Wölpl CP, Rist CE, Kosa R, Büchele G, Gaus W: Comparison of three instruments (QLQ-C30, SF-36, QWB-7) measuring health related quality of life/quality of well-being. *Psycho-Oncology* 5: 103-117, 1996
- [21] Kaplan RM, Sieber WJ, Ganiats TG: The Quality of Well-being Scale: Comparison of the Interviewer-Administered Version with a Self-Administered Questionnaire; Weitere Informationen im WWW unter <http://orpheus-1.ucsd.edu/famed/hoap/index.html>
- [22] Sietmann R: Zirkelspiele - Die wissenschaftliche Literaturversorgung steckt weltweit in der Krise. c't 20/99, 216-231
- [23] Bundesamt für Sicherheit in der Informationstechnik, <http://www.bsi.de>