The Quality-of-Life-Recorder: a quick overview

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1 Aims & History

- Aims 1993: To make QL-measurement in routine care as easy as blood pressure measurement.

- To improve data quality & data availability.

- To reduce workload.

- To make data generally shareable and processable, obeying industry standards and making it possible to fulfill requirements defined by GCP and FDA standards.

- Questionnaire independency, questionnaire library.

- 2001: Provide basic built in analysis tools.

- 2001: Provide a uniquely feasible tool to carry out advanced outcome research projects (DMP, Quality assurance) in the routine medical care setting by provision of the xDT/BDT/GDT interface and its possibility to conveniently collect patient satisfaction data and outcome data in the same data as routine administrative and medical data of almost any practice management system used in Germany.

- 2002/2003: Additional Java version: complete platform independence, functionality also available through WWW-browsers or standalone Java-application.

2 Users, Projects, Results

2.1 Original QL-Recorder, QLQ-C30

- Sigle, Porzsolt, 1993, 620+ patients & measurements:
  QL-Recorder well accepted, patient management / staff compliance crucial.

- Sigle, Porzsolt, 1994, 1.200+ patients & measurements:
  Routine assessment feasible, compliance > 98,5%, completeness > 99,99%,
  data clinically valid, routine measurement can stimulate improvements.

- van Leendert, since 1994, 600+ patients, 12.000+ measurements:
  QL improved through combined classical and alternative approach. Model practice.

- Höhmann, since 1994, 2.000+ patients, 5.000+ measurements:
  QL improved during stay, QL prognostic for survival.

- von Bültzingslöwen, since 1995, 170+ patients, 170..500+ measurements:
  QL-Recorder data can be integrated in computer based Tumor-Documentation- / Interactive-Statistical Analysis system. Routine assessment feasible; staff training crucial.

- Holch, Schaeffler, Porzsolt, 1997: 200+ patients, 400+ measurements:
  evaluation pending.

- Bernhard, SIAK, 1999: support processing of multicenter paper forms.

- Additional projects: status unknown / planned but never used.

2.2 QL-Recorder with AnyQuest for Windows, QLQ-C30

- Eisemann, Uni Umea, 1999: Swedish QLQ-C30 V 2.0, Swedish BC

- Höhmann, 1999: QLQ-C30, HADS. 130+ measurements, 100+ patients:
  (No touch screen) - Feasible even for patients unfamiliar with mouse.

- Kleef, 2000: QLQ-C30 V 2.0, within a clinical study (which was aborted because of too restrictive inclusion criteria and too little patient recruitment)

- Eberhardt, 2000: QLQ-C30 V 2.0, QL-Recorder link to a computer-based Tumor-Documentation - / Interactive statistical analysis system (TREG) - few measurements.

- Woernle et al, 2001/2002: QLQ-C30 V 3.0, routine application in patients of an anthroposophically oriented clinic, 700+ measurements.

- Kleef, 2002: QLQ-C30 V 3.0, routine application in patients undergoing moderate whole body hyperthermia as described by Heckel, repeated before every therapy cycle, 600+ measurements.

- Sigle, 2002: QLQ-C30 V 3.0, on-demand application in patients of a general practitioner setting, bi-directional integration of QL-Recorder with electronic medical record of the locally used practice management software Quincy PCnet via GDT interface, 200+ measurements.

Until 1999, using the original and the new QL-Recorder, about 20.000 measurements with the QLQ-C30 were completed. No technical problems and no acceptance problems occured.

2.3   Other questionnaires

- White, Florida: Free Christian counseling: MOCI, MRT

- Hawkes: (US, Hospital based research, nutrition disorders?)

- Novartis, Dept. Clinical Economics: SF-36 used for training / exhibitions.

- Sigle, Porzsolt: Routine course evaluation in EBM / CE courses for colleagues & student education.

- Sigle, Herrmann, Kordy, FOST: 30+ qnrs / modules: integration in AKQUASI, FoxPro-based quality-assurance database-application, preferred over scanner-interface for practical reasons.

- Heisterborg, 1999, qnr?: Routine use on old pen-computer feasible, very well accepted. Current status?

- Goldbeck, 1999, Children Hospital Uni Ulm + Hospital Wangen:
  own questionnaire for children & parents, development / validation:
  100+ patients, 130+ measurements. acceptance extremely fine, no tech problems.

- Wagner, 1999, Chur: Minnesota living with heart failure qnr:
  20 patients, 40+ measurements.

- Kleef, 1999: Green climacteric symptom checklist. Pharmaceutic trial with QL as endpoint. Project initiated.

- Kojer, Eisemann, Greimel, Sigle, Porzsolt, 1999/2000, GZW Vienna: Spitzer Index, Barthel Index, Global deterioration scale,...: development / validation of QL in geriatric patients w/ dementia: 600+ measurements.

- Glaxo Wellcome, 1999: eIBSQOL - package: primary aim reached.

- Goldbeck, 1999, Children Hospital Uni Ulm: development of additional questionnaires with link to external database.

- Glaxo Wellcome, 2000: Advanced development of the eIBSQOL: additional languages, including Greek.

- Sigle, 2000/2001: Enhancement of questionnaire library in several languages: SAQLI, SGRQ, MRF-28, Epworth scale, QSQ, new talking SF-36, new HADS, Quality-of-Wellbeing-Scale.

- Fraunhofer Gesellschaft AIO, 2001: Application of questionnaires related to patient opinions in market research in the medical area in a leading German clinic: 300 patients.

- *Goldbeck, 2002, Children Hospital Uni Ulm, co-operating hospitals in Munich and Stuttgart: Awarded the Lilly Quality-of-Life Prize 2002 for the project that uses the QL-Recorder as central element. Project abstract is available on the CD-ROM/WWW-site.*

- Rush, 2002/2003 (ongoing): Screening of psycho-oncologic patients.

3 Available technology

The QL-Recorder is readily available and offers the following functions and features:

- Editor, Librarian, Presenter, Interpreter, Calculator, Printer, MiniDatabase, MiniQuery, MiniStatistics, Collector, Exporter

- Many kinds of data / question types / free text, supports development / validation

- Supports almost any questionnaire, including interactive multimedia.
  Sets for different studies / patient populations / raters can be prepared.

- Supports any hardware, requires almost none:
  Depending on your budget and setting, start with any old Windows 3.1 PC or
  use small, portable pen-computers in a wireless network throughout your hospital.

- OS: Win 3.1, 95, 98, ME, NT 3.51, NT 4.0, 2000, XP, Linux/Wine, Linux/VMware, ...

- Uniform output, open formats, automatically combines different qnr sources. Data from different studies can be stored in different locations on one system. Data from different centers can be kept identifiable and easily separable even when merged automatically.

- SQL database interfaces available (e.g. FoxPro, Interbase) / easy to generate.
  Import into AKQUASI exists, TREG exists, Gießener TDS being developed.

- Results can be transferred to central server, via any network or the Internet, and entered into any database, automatically.

- Otherwise Internet ready, too: Java version started. Interactive WWW-based query under development; using free, safe and stable platform obeying standards.

- Bi-directional Interface according to the xDT/BDT/GDT standard: the patient identification can be received from an external software, e.g. a practice managment system or a HIS; computed questionnaire results can be transceived to the external software, e.g. to ultimately display it in the patient's lab's results page.

- Fully documented. Online-Help with index, reference and quick-guides for users and for developers

- Supports qnr copyright / history info, personalization, source site info

- Can communicate sponsor / content provider identity

- Can be customized - cannot be reproduced easily

- Open license - available for free (credits: Glaxo Wellcome plc.)

4 Available Know-How

- Author of QL-Recorder has know-how in: IT (general, operating systems, programming, databases, communication, medical documentation, medical administration), medicine, clinical trials, outcome measurement, Evidence-Based Medicine.

- AG Klinische Ökonomik under Prof. Franz Porzsolt has additional know-how and ressources.

5   Recent implementation examples

- eIBSQOL: booklet + CD-ROM, with indication specific QL-questionnaire in 10 languages, produced to be a freely available tool for physicians in routine practice, introduced with launch of a new product by GlaxoWellcome plc.

- Implementation study: QLQ-C30 Version 3.0 - a European QL-questionnaire, 20 of 36 languages now available on the QL-Recorder, incentive for an early discussion about future co-operation with the EORTC QL study group.

Both of these versions come with logos of the sponsoring or related organisation. Both come in a ready-to use setup for most clinical users. But still they offer all advanced QL-Recorder functionality to more advanced users.

6   Recent development

- Ressources to aid the design, implementation and support of projects by third parties have been produced:

  - configuration examples and -tutorials, reference set-ups,
  - comfortable tutorials for users and questionnaire designers,
  - templates for project design, project applications, staff education are available (derived from real-life projects and applications).
  - ANQ to Borland Interbase SQL Perl sample application and xDT interface tools were made available on the WWW-site.
  - For documentation in future Diabetes Mellitus Disease Management Projects according to the 4. Änderungsverordnung zur RSAV, a protoype was developed which allows a user to collect data from the German health insurance card, and afterwards to enter all data required for the base documentation via AnyQuest. This prototype demonstrates both data acquisition from an external source (card reader and software) and automatic post-processing (production of a text file with results according to attachment 2a of the available version of the draft legislation).

- Heckel Medizintechnik, Esslingen, design a standardised terminal based upon the QL-Recorder.

- A special cooperation will take place with the University of Göttingen with regard to data collection and analysis at general practitioners using the xDT interface.

- First contatcs were established with commercial partners.

7   The Lilly QoL Prize 2002 - a QL-Recorder user's experience!

Dr. Goldbeck and colleagues at the Uni Ulm developed a questionnaire for patients with cystic fibrosis routinely administered with the QL-Recorder. Resulting ANQ-files are further processed in an MS Excel based worksheet and can immediately be used for clinical decision making. Several co-operating hospitals have now adopted this approach.

Dr. Goldbeck has informed me that this project is awarded the Lilly Quality-of-Life Research Prize 2002 - Congratulations!