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Quality of life in (haemato)oncology

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EORTC QOL Group Member

Marseille, 28/03/2017

#EBMT17

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- No financial conflict of interest.
- Active member of the European Organisation of Research and Treatment of Cancer (EORTC) Quality of Life Group.





- 1. Quality of Life/ Patient-reported outcomes
 - a. Definition
 - b. Assessment
 - c. Areas of application (clinical trials, routine clinical care)
- 2. Quality of Life in haematology/haematooncology
- 3. Outlook and perspective of Quality of Life assessment

Measures of treatment evaluation

 →QOL have become an important outcome supplemental to clinical parameters (e.g., survival, toxicity ratings, costs)
 →second in importance to survival (ASCO, 1996)

QOL is a multidimensional construct

"HRQOL is a multi-domain concept referring to the effect of an illness and its therapy upon a patient's physical, psychological and social wellbeing, as perceived by the patients themselves. In clinical research, HRQOL measures can provide a means of capturing the personal and social context of the disease experience."

(EMA 2012) pain nausea/vomiting dyspnea fatigue depression anxiety family/ social life work/ leisure vopean Society for Blood and

QOL is a patient-reported outcome

"A patient-reported outcome (PRO) is any **report of the status of a patient's health condition that comes directly from the patient**, without interpretation of the patient's response by a clinician or anyone else." (FDA 2006)

PROs

- are standard tools for eliciting patient experience
- provide a patient-centered description of toxicity (e.g. of hematopoietic cell transplantation), complementary to information reported by clinicians
- include reports of disease symptoms (eg. nausea, fatigue, pain), treatment adverse effects, functional status and quality of life (QOL)



ASCO ANNUAL MEETING

ASCO DA

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THE FUTURE OF PATIENT-CENTERED CARE AND RESEARCH

HEALTH SERVICES RESEARCH AND QUALITY OF CAR

The Rise of Patient-Reported Outcomes in Oncology

MAY 26, 2016

By Ethan Basch, MD, MSc

Article Highlights

- · Patient-reported outcomes (PROs) are reflections of how patients feel and function and are measured via questionnaires.
- Electronic "ePRO" software enables patients to self-report via the Internet, automated telephone systems, or downloadable applications.
- Multiple studies have been conducted that tested whether it is feasible to integrate PROs into routine cancer care (it is), and whether outcomes are improved as a result (they are).
- ASCO has a PRO committee that is developing and testing PRO measures, which, in the future, may be used to assess quality within ASCO's Quality Oncology Practice Initiative.

Just a few years ago, few had heard of the term "patient-reported outcome" or "PRO." Now, PROs seem to come up frequently in discussions about almost every aspect of oncology—in clinical care delivery, clinical trials, quality assessment, and comparative effectiveness research (Fig. 1 shows uses and benefits of PROs in each of these contexts).

PROs are reflections of how patients feel and function—for example, symptoms related to disease or toxicities, physical functioning, or quality of life. They are measured via questionnaires that are rigorously developed and tested to assure that the questions are clear, that they are measuring what we think they are measuring, that they are reliable, and that scores change as we might expect.



Click to Expand.

PROs in Clinical Trials

Drug development trials are perhaps the most well-traveled context in which PROs have been used in nocloagy. Many Fig. 2. of the PRO questionnaires in use today were developed for use in clinical trials. The U.S. Food and Drug Administration (FDA) has provided guidance on methods for developing and using PROs in product development and has indicated that benefits in PROs can be the basis for full drug approval and that PRO endpoints can be an essential adjunct in trials with progression-free survival primary outcomes or non-interiority development.

Recently, the FDA has encouraged the use of PROs to assess three complementary but distinct areas in cancer clinical trials specifically: disease-related symptoms (e.g., pain related to metastases), physical functioning (e.g., the ability to conduct activities of daily life), and symptomatic adverse events (e.g., measured by the National Cancer Institutie's new PRO version of the Common Terminology Criteria for Adverse Events). The June 6 Education Session "Integrating Patient-Reported Outcomes Into Cancer Clinical Trials and Regulatory Review" will highlight these efforts (visit the ASCO IPlanner on the Attendee Resource Center [am asco orgitar;] for session time and location information].

I Inderstanding natiogte' cumptors and physical functioning experience is vital to appreciating the properties of cancer



PROs in Routine Cancer Care



Interest is burgeoning to integrate systematic collection of symptoms from patients during routine cancer clinical care. This is generally done using electronic "ePRO" software that enables patients to self-report via the internet, automated telephone systems, or downloadable applications. Patients can report during visits via iPads or self-service computer kosks, and between visits using their own devices. Reports showing longitudinal symptom trajectories in tables or graphs can be viewed by clinicians at visits, and email alerts can be triggered in real-time to nurses anytime a severe or worsening symptom is self-reported.

Most of the major electronic health record (EHR) vendors can support this function to some extent. Although most systems are still rudimentary, they are advancing with each software update. Most commonly, ePROs are collected through the EHR's patient portal, which can push email invitations to patients asking them to complete online questionnaires, and don't provide intuitive ways for clinicians to view the PRO information in the medical record. However, local customizations are possible to improve these functions, or a third-party ePRO system can be licensed to avoid these limitations. It is expected that all of these EHR functions will rapidly improve.

Multiple studies have been conducted (see references below) that tested whether it is feasible to integrate PROs into routine cancer care (it is), and whether outcomes are improved as a result (they are).

Click to Expand.

Feasibility: In general, when patients receiving active cancer treatment or following cancer surgery are offered an

PROs in Quality Assessment

An area of rapid development is the use of PROs to measure quality of care delivery. Other specialties are ahead of oncology. In orthopedics, for example, pain, mobility and physical functioning are increasingly assessed via PROs postoperatively to assess performance at the practice or provider level. Most PRO-based quality metrics assess control of symptoms or physical functioning, which differentiates them from patient satisfaction or experiential questionnaires that assess processes such as timely returning of telephone calls by clinicians.

ASCO has a PRO committee that is developing and testing PRO measures, which, in the future, may be used to assess quality within ASCO's Quality Oncology Practic Initiative (QOPI®), ASCO is following standards for PRO-based quality measures established by the National Quality Forum and is drawing from ongoing outside initiat For example, PRO measures to assess quality of oncology care are currently being piloted across the state of Minnesota, and ASCO is a pather in these efforts.

An example of a PRO-based quality measure is the proportion of patients in a practice with metastatic disease receiving systemic therapy who experience moderate or worse pain. Similar measures might be used for other symptoms, such as nausea or constipation. Key considerations when developing PRO-based quality measures include meaningfulness to patients and responsiveness to changes in clinician behavior ("actionability").

PROs in Comparative Effectiveness Research

Studies designed to understand treatment benefits and harms in real-world contexts often aim to understand the patient experience via PROs. Registries and pragmat trials increasingly integrate PROs, and PROs have been strongly encouraged by the major U.S. funder of comparative effectiveness research (CER), the Patient-Center Outcomes Research Institute. For example, arthralgias with aromatase inhibitors (and resulting drug discontinuation) and urinary/sexual symptoms following monotated num have been characterized through proceeding radiative trials.

PROs in Routine Cancer Care

How to assess QOL in oncology

- Karnofsky Performance Status used to assess patient's health status
- Since 1990s: multidimensional QoL assessment instruments have been developed
 - Generic instruments: SF-36
 - Cancer specific: e.g., EORTC QLQ-C30 (Aaronson et al.), FACT-G (Cella et al.): core questionnaire and site specific modules

→ Always use a VALIDATED questionnaire (operationalised, standardised, comparable across languages and cultures)

How to assess QOL in oncology

EORTC QLQ-C30: QOL questionnaire developed by



The foture of cancer therapy

6 Functioning Scales

- Physical Functioning
- Emotional Functioning
- Social Functioning
- Role Functioning
- Cognitive Functioning
- Global QOL

30 questions

9 Symptome Scales

- Fatigue
- Pain
- Nausea/Vomiting
- Dyspnea
- Gastrointestinal Problems
- Pain
- Appetite Loss
- Sleep disturbances
- Financial impact

EORTC QLQ-C30 (version 3)

We are interested in some things about you and your health. Please answer all of the questions yourself by circling the number that best applies to you. There are no "right" or "wrong" answers. The information that you provide will remain strictly confidential.

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3.	Do you have any trou	ble taking a <u>short</u> wall	c outside of the house?	1	2	3	4
4.	Do you need to stay i	n bed or a chair during	the day?	1	2	3	4
5.	Do you need help wit yourself or using the	th eating, dressing, was toilet?	shing	1	2012	3	41
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7.	Were you limited in I leisure time activities	oursuing your hobbies ?	or other	1 201	2	N 3	4
8.	Were you short of bro	eath?		1	2	3	4

Physical Functioning

Role Functioning Dyspnea

ssessment

How to assess QOL in oncology

modular approach:

- core questionnaire (QLQ-C30)



modules specific to tumour site, treatment modality or a QOL dimension (e.g. EORTC QLQ-HighDoseChemotherapy29, MY20)

For example:

EORTC QLQ-HDC29 for the assessment of issues relevant for patients undergoing high-dose myeloablative treatment with haemotological stem cell transplantation.

- 6 multi-item scales (Gastrointestinal Side Effects, Body Image, Impact on Family, Sexuality, Issues During Hospital Stay, Worries/Anxiety)
- 8 single-items (Skin Problems, Fever, Aches in Bones, Urine Frequency, Ability to Finish Things, Taking Regular Drugs, Fertility, Spirituality)



How to assess QOL in oncology

General recommendation:

perform data collection electronically (ePRO) whenever possible:

- reduces need of human resources for data collection and work load
- increases data quality compared to paper-based systems (less missing data, CAT)
- can be linked to clinical and administrative databases (eHealth records)
- can easily extend QOL/ symptom assessment beyond the hospital (web-based)
- patients are more likely to report sensitive information via electronic interfaces (e.g. impaired sexual functioning, depression, incontinence)



How to assess QOL in oncology

Needs adequate, flexible and user-friendly QOL data collection systems (IT, infrastructure)

Example: CHES (Computer-based Health Evaluation System)

- Software solution for real-time collection, calculation and presentation of QOL/ PRO data
- Collaboration with EORTC QLG since 2009, EBMT since 2015 (providing IT-infrastructure for the GVHD registry of the German-Austrian-Swiss GVHD Consortium)
- Complementing Austrian Myeloma Registry with QOL data

1. QOL/PRO

b. Assessment

EBA European Society for Blood and Marrow Transplantation

Dashboard

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Patient clinical data

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CHES .GVHD Patientenliste + Patientendaten - Daten Management -1652 Sie befinden sich hier: Patientendaten / Basisdaten MED-A (EBMT Register) 1st diagnosis of aGvHD Maximum Severity Sociodemographics/ patient data HSCT-treatment Donor information (for up to 3 donors) Diagnosis Last diagnosis before 23.12.2014 787 Treatment: Patient (ID): Myeloproliferative neopla Multiple donors or this treatment. different sources of Centre in which this Patient (IDAA): 1652 stem cells: University Interval from last treatment was given: transplant (days): Total number of UPN Hospital ID: 1652 Country of the centre: Germany products: Diagnosis date: 01.04.2014 mehr Editieren meh GvHD-reported in EBMT-database Other treatments: DLIs, cell therapies Relapse and Survival Date of treatment: Assessment at last Chronic graft versus V 02.04.2015 follow up: host disease (cGvHD): Other cell therapy (non Disease status (at last HSCT): Extent of cGvHD: FU): Donor lymphocyte V Relapse or progression Assessment date: infusion (DLI): after transplant: mehr Impressum Terms of Use Info

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GvHD severity ratings

b. Assessmer

JOL/PR

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QOL data – graphical presentation

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b. Assessment

QOL/PRO

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Areas of application of PRO assessments

1. QOL in clinical trials and CER:

as primary/ secondary end-point; "labeling claims" (FDA, EMA); treatment safety studies (AE reporting)

2. QOL in routine cancer care: screening/ monitoring, continuity of care

3. QOL in cost effectiveness research: as a utility measure (health economics, HTA analysis)

4. QOL for quality assessment : benchmarking, registries (certifications!)

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Why assess QOL/PRO in clinical trials

- to evaluate overall treatment effectiveness, treatment toxicity, patient's QOL
- to compare multiple treatment options with similar survival outcome (e.g. de Wreede et al. 2013)
- to generate a risk-benefit profile in drug development (in early phase trials, QOL can reflect tolerability and inform decision about dosing)
- to evaluate a new therapeutic strategy in real-world context (registries!)
- → in trials with progression-free survival as primary outcome (e.g. trials on cGvHC, Wood 2013)

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Why assess QOL/PRO in clinical trials

Improved relapse-free survival after autologous stem cell transplantation does not translate into better quality of life in chronic lymphocytic leukemia: Lessons from the randomized European Society for Blood and Marrow Transplantation-Intergroup study

Liesbeth C. de Wreede,¹ Maggie Watson,² Marleen van Os,¹ Donald Milligan,³ Michel van Gelder,⁴ Mauricette Michallet,⁵ Peter Dreger,⁶ Claire E. Dearden,² Janis Homewood,⁷ Jehan Dupuis,⁸ Michel Leporrier,⁹ Michal Karas,¹⁰ Bernadette Corront,¹¹ Gabriela M. Baerlocher,¹² Wolfgang Herr,¹³ Sylvain Choquet,¹⁴ Dietger W. Niederwieser,¹⁵ Laurent Sutton,¹⁶ Nicolaus Kröger,¹⁷ Theo M. de Witte,¹⁸ and Johannes Schetelig¹⁹ on behalf of the Chronic Malignancies Working Party of the EBMT, and the UK Medical Research Council

Randomized EMBT trial (2014):

- High-dose chemo with ASCT to observation in first or second remission of CLL
- Report on QOL of first 3 years following randomisation (n=186)
- Significant improvement of relapse-free survival but no survival advantage with ASCT

"Long-term consequences of different treatment approaches on QOL are particularly relevant in chronic diseases (such as CLL) that cause relatively few short-term complaints, where strategic choices have to be made between more or less aggressive treatments and their respective timing and sequences."

QOL/P

AE reporting in clinical trials

- Top priority within oncological treatment evaluation: detection and tracking of adverse events (AEs)
- Standard classification system for symptome monitoring (e.g., chemotherapy) and AE reporting in clinical trials: Common Toxicity Terminology for Adverse Events (CTCAE)
- Method of data collection is clinician-based.
- Process is complex with multiple steps of information transfer vulnerable to errors (e.g. misinterpretation, omission).

Application

Clinician-based symptom reporting: possible caveats

- clinician ratings underestimate frequency and intensity of symptoms
- patients identify symptoms earlier than clinicians' do or even capture side effects that clinicians' completely miss
- higher discrepancy between patient and clinician ratings of subjective/ less observable symptoms (e.g. fatigue, dyspnea)
- Limitations of CTCAE: lack of formal validation, no standardised recording/ training, differences between raters (Bruner et al. 2007)
 - \rightarrow due to logistic or interpersonal reasons (e.g. communication, social desireability)

(Sneeuw et al. 1999, Savage et al. 2002, Coombes et al. 2003, Pakhomov et al. 2008, Basch et al. 2006, 2009, Snyder et al. 2009, Ruhstaller et al. 2009, Oberguggenberger et al. 2011, Efficace et al. 2014, Gravis et al. 2014, Letellier et al. 2016)

European Society for Blood an

QOL/PRO in clinical trials - example

Is the toxicity of adjuvant aromatase inhibitor therapy underestimated? Complementary information from patient-reported outcomes (PROs). Oberguggenberger, Hubalek, Sztankay et al. *Breast Cancer Res Treat.* 2011 Jul;128(2):553-61.

- Prevalence and severity of patient-reported physical side-effects and psychosocial burden (PRO-BETh) related to adjuvant AI therapy compared with prevalence derived from pivotal phase IV trials (ATAC 2005, BIG1-98 2005).
- Overall, PROs resulted in significantly higher prevalence rates as compared to proxy ratings for all symptoms published in pivotal clinical trials except vaginal bleeding and nausea.

QOL/PRO in clinical trials - benefits

→ systematic assessment of QOL/PRO can provide data to complement clinician reporting (FDA 2006)

- more reflective of underlying health status than clinician reporting
- improves accuracy and efficiency of subjective AE data collection
- predicts meaningful clinical outcomes including survival: predictive value of physical functioning before HCT (Wood et al. 2016), fatigue (Efficace et al. 2015), nausea and vomiting (Quinten et al. 2012)
- patient self-reports of symptomatic adverse drug reactions provide a more comprehensive picture of properties of the drug (Anderson, Krska, Murphy, & Avery, 2011; Avery et al., 2011; de Langen, van Hunsel, Passier, de Jong-van den Berg, & van Grootheest, 2008; Inch, Watson, & Anakwe-Umeh, 2012; van Hunsel, Harmark, Pal, Olsson, & van Grootheest, 2012).

Nonetheless: CTCAE have higher predictive value for critical clinical events!

QOL/PRO in clinical routine

Clinical/ medical interview

- collection of non-standardised, subjective information
- aimed at formulating diagnosis
- not sensitive for monitoring change or assessment of outcomes

Patient Reported Outcomes Measures - PROs

- additional, quantitative information on patient's health status (functioning, symptoms)
- standardised longitudinal data assessment, detects changes over time
- Developed for outcome assessment

Purpose

Benefits

- screening of physical and psychosocial symptoms
- monitoring of treatment process and PROs/ QOL

standardised data for research and quality assurance

- improve symptom management
- enhance patient-doctor communication
- · facilitate patient involvement in care process and decision making
- improve patient empowerment (foster self-management)
- support multidisciplinary care

QOL/PRO

pplication

... to help patients track their symptoms

e.g. Paroxysmal Nocturnal Haemoglobinuria:

- "Patients should be encouraged to report: fatigue, pain, headaches, sexuality and sexual functioning, weakness, shortness of breath, trouble swallowing ..." (subjective!)
- "Early detection of signs and symptoms can aid the healthcare team to provide optimal care in a timely manner to avoid more serious complications."
- \rightarrow online reporting by patients with validated questionnaires
- → integration of QOL data with electronic patient records
 - self-management tools

Monitoring

- In PNH-positive patients with small PNH clones, monitoring is essential because clone size can rapidly increase over a period of several months¹
- High-risk patients should be tested and continually monitored with highsensitivity flow cytometry, performed on peripheral blood (not bone marrow)^{2,3}

It is useful to askpatients to keep a record of their symptoms and bring it to their appointments. A patient diary and symptomtracker exists as a separate resource for you to give to your patients.

> of Hematologi, Determiter 1013, 2011, Sen Diego, D.A. Attasted: 1033 2. Sorowitz (NJ et al. Qotometry S Clin Cytom 2010; 78(4): 211-230 8. Parker C et al. Blood 2006; 106(12): 3686-3709.

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... to enable self-monitoring and -management

Home Information -Fragebogen Werte Lebensqualität

PERSÖNLICHER GESUNDHEITSSTATUS

SYMPTOME

LEBENS QUALITÄTS PORTAL

() Vorbereitung

(5) Vor dem Termin

() Unterstützungsange-

Was Sie tun können

Körperliche Beein-

() Beeinträchtigung in

Freizeit und Arbeit

Soziale Beeinträchtigung

() Emotionale Beeinträch-

(S) Kognitive Beeinträchti-

() Müdigkeit/Fatigue (5) Übelkeit & Erbrechen

() Atemübungen bei Kurzatmiakeit

() Schlafstörungen () Appetitverlust

() Finanzielle Schwieriokeiten

() Obstipation () Durchfall/Diarrhoe

tigung

gung

() Schmerz

trächtigung

() Im Gespräch

bote

Information -

Körperliche Beeinträchtigung

Regelmäßige Bewegung kann in vielerlei Hinsicht einen positiven Einfluss auf Wohlbefinden haben, Indem sie:

- Ihr Energielevel, Ihre Ausdauer und Belastbarkeit erhöht,
- Ibren Schlaf verhessert

Home

- sich positiv auf ihre Stimmung und Aufmerksamkeit auswirkt.
- Fatigue (andauernde Müdigkeit ohne vorherige Anstrengung) reduziert.
- Muskelabbau, -schwäche und steifen Gelenken vorbeugt.
- · eine gute Balance und Koordinationsfähigkeit unterstützt,
- · Übelkeit verringert, zu Ihrer Entspannung beiträgt und
- Ihren Appetit und Ihre Verdauung anregt

Abmelden

Besonders bei chronischen Schmerzen oder Schmerzen im Zuge einer Krebserkrankung ist es wichtig, sich zu bewegen, damit die vorhandenen Muskeln genutzt und trainiert werden und die Gelenke geschmeidig bleiben, um zusätzlichen Schmerzen vorzubeugen. Machen Sie so viel körperliche Bewegung, wie Sie können, achten Sie ledoch auf Ihre Grenzen und machen Sie nicht mehr, als ihnen gut tut. Lassen Sie sich im Vorfeld am besten vo Ihrem Behandlungsteam beraten.

Lebensqualität Fragebogen Werte Aktiv werden

CHE	CKBOX: KÖRPERLICHE BEWEGUNG	Eb.
WELCHE?	WIE INTENSIV UND OFT?	BEACHTEN SIE!
Spazieren gehen, Radfahren, Schwimmen, leichte Gymnastik, Yoga, Tai Chi, Meditation, auf einer Linie balancieren, u. a.	optimal: 3-4 Mal pro Woche	Es braucht Zeit, bis man sich neue Gewohnheiten angeeignet hatt Auch wenn Sie es nicht immer gleich gut schaffen, aktiv zu sein, versuchen Sie es immer wieder.
Haushalts- und Gartentätigkeiten: Staubsaugen, Putzen, Aufräumen, Pflanzen schneiden, Rasenmähen, Unkraut jähten, u. a.	optimal: 30 Minuten pro Tag, auch aufgeteilt auf kürzere Einheiten (bspw. 3 Mal 10 Minuten)	Alarmzeichen: Sie fühlen sich schwach, schwindlig, erschöpft und sind außer Atem. Machen Sie unbedingt eine

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Benefits of QOL/PRO in oncology

improved communication with HCPs ✓ increased symptom management ✓ involvement in clinical decision making ✓ increase patient satisfaction with care ✓ patient empowerment ✓ (self-management tools)

Patient

real world data ✓ (efficacy, safety) cost effectiveness studies ✓ market share development√ Research Pharma quantitative, comprehensive information on patient's subjective health status (change over time, early detection)

- support for clinical decision making
 - focussing of communication during patient appointment

continuity of care

multidisciplinary care

 quality assurance, benchmarking
 patient satisfaction
 patient safety (remote monitoring via patient portal)
 less use of health ressources

(Abernethy et al., 2009; Basch et al., 2005; Detmar, Muller, Schornagel, Wever, & Aaronson, 2002a, 2002b; Efficace et al., 2012; Greenhalgh & Meadows, 1999; Luckett, Butow, & King, 2009; Montazeri, 2009; Snyder et al., 2012; Snyder et al., 2010; Taenzer et al., 2000; Velikova et al., 2004; Velikova et al., 2010).

Physician

Payer

QOL assessment in haematooncology

- in contrast to the large number of studies in patients with solid tumours, relatively few studies have reported QOL in patients with haematological malignancies (Efficace et al. 2008, Hotlick et al. 2014)
- frequent assessment of symptoms and QOL in the post-transplantation period has not been explored extensively (although associated with serious long-term effects)
- offers several potential advantages for the study of transplantation-related toxicity and to complement performance-based and clinician-reported outcomes when evaluating the effects in HCT:
 - characterizing and differentiating the patient-reported impact of discrete conditioning regimens
 exploring the relationship between symptoms and early QOL as possible mediator of long-term QOL impairment
 - informing use of strategies (e.g. exercise, supportive care interventions) for QOL improvement
 - identifying early patient-reported predictors of long-term mortality, morbidity and decreased QOL

Quality of life in long-term survivors of haematopoietic transplantation

Innsbruck Medical University

- BMT and PBSCT survivors listed in the database of the Dept. of Internal Medicine V (Haematology and Oncology)
- QOL and symptom burden assessed: - EORTC QLQ-C30/+HDC29
 - QLQ-C30 data compared with data of ageand gender-matched healthy controls (Holzner et al. 2004)
- Mail survey (**2002**, **2008**, **2016**) (Pallua et al. Bone Marrow Transplant. 2010)
- Time since diagnosis: 9.4 (SD 6.6) years [1-33 yrs]

Patients suffering from chronic GvHD:

- deteriorated role functioning, global QOL
- increased fatigue, dyspnea, worries/anxiety, gastrointestinal side effects, and skin problems (PBSCT leading to more severe impairments)

Compared to healthy controls:

- **In 2008:** large difference (>20 points) for role functioning, dyspnoea and financial impact
- **in 2016:** moderate differences (10-20 points) for physical, role and social functioning, fatigue and dyspnoea; highest for financial impact.
- → QLQ did not change significantly over time → even up to decades after transplantation, patients do not recover to a normal level

QOL assessment: outlook and perspective

Patient-reported QOL is an important outcome measure in medicine (besides survival, disease-free survival, costs) → ASH, EMBT, NCI, FDA, EMA, NHI

RESEARCH Establish PRO as essential component of:

treatment studies(phase III, IV; FDA, EMA)

- drug safety monitoring
- pharmacovigilance
- HTA analyses (cost-utility assessment)

ROUTINE CARE

Comprehensive integration of standardised ePRO assessment for:

- screening for physical and psychological symtome burden
- long-term symptom monitoring
- individual treatment evaluation for clinical decision making
- web-based PRO reporting

3. Outlook and perspective

24" ANNUAL CONFERENCE 18-21 October 2017 Philadelphia, Pennsylvania UNITED STATES

ISOQOL 24th Annual Conference

ISOQOL 24th Annual Conference

Quality of Life and Cancer Clinical Trials Conference 20 & 21 April 2017 Crowne Plaza Brussels - Le Palace, Belgium

Thank you for your attention!

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The Future of cancer therapy

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