SACRO CUORE DON CALABRIA
I R C C S

MEMBER OF ECI
Organisation of European Cancer Institutes - EEIG

1° Evento Alumni della Scuola

Patient Reported Outcomes

Linee guida per la raccolta,
l'analisi e il *reporting* delle evidenze
patient-reported

Giovanni L. PAPPAGALLO

SPIRIT-PRO Extension explanation and elaboration: guidelines for inclusion of patient-reported outcomes in protocols of clinical trials

Melanie Calvert ,[1,2,3,4,5]
Olalekan Aiyegbusi,[1,3] Dere
Jill Bell,[10] Antonia Bennett
Andrew Bottomley,[15] Julia
Joseph C Cappelleri,[19] He
Lori Frank,[23] Robert M Gol
Amanda Hunn ,[27] Bellin
Thomas Morel,[30] Linda Ne
Michael Palmer,[33] Donald
Ameeta Retzer,[1] Dennis Re
Grace Turner ,[1,4] Antoni
Anita Walker,[1] Lari Wenzel

BMJ Open 2021;**11**:e045

16-item checklist which aims to improve the content and quality of aspects of clinical trial protocols relating to PRO data collection to minimise research waste, and ultimately better inform patient-centred care

da uno spunto di Francesco Sparano

ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centered outcomes and comparative effectiveness research

Bryce B. Reeve · Kathleen W. Wyrwich · Albert W. Wu · Galina Velikova · Caroline B. Terwee · Claire F. Snyder · Carolyn Schwartz · Dennis A. Revicki · Carol M. Moinpour · Lori D. McLeod · Jessica C. Lyons · William R. Lenderking · Pamela S. Hinds · Ron D. Hays · Joanne Greenhalgh · Richard Gershon · David Feeny · Peter M. Fayers · David Cella · Michael Brundage · Sara Ahmed · Neil K. Aaronson · Zeeshan Butt

Qual Life Res (2013) 22:1889–1905

to promote the appropriate use of PRO measures to inform PCOR and CER, which in turn can improve the effectiveness and efficiency of healthcare delivery

da uno spunto di Francesco Sparano

Analysing data from patient-reported outcome and quality of life endpoints for cancer clinical trials: a start in setting international standards

Andrew Bottomley, Madeline Pe, Jeff Sloan, Ethan Basch, Franck Bonnetain, Melanie Calvert, Alicyn Campbell, Charles Cleeland, Kim Cocks, Laurence Collette, Amylou C Dueck, Nancy Devlin, Hans-Henning Flechtner, Carolyn Gotay, Eva Greimel, Ingolf Griebsch, Mogens Groenvold, Jean-Francois Hamel, Madeleine King, Paul G Kluetz, Michael Koller, Daniel C Malone, Francesca Martinelli, Sandra A Mitchell, Carol M Moinpour, Jammbe Musoro, Daniel O'Connor, Kathy Oliver, Elisabeth Piault-Louis, Martine Piccart, Francisco L Pimentel, Chantal Quinten, Jaap C Reijneveld, Christoph Schürmann, Ashley Wilder Smith, Katherine M Soltys, Martin J B Taphoorn, Galina Velikova, and Corneel Coens, for the Setting International Standards in Analyzing Patient-Reported Outcomes and Quality of Life Endpoints Data (SISAQOL) consortium

***Lancet Oncol* 2016; 17: e510–14**

to provide recommendations on how to standardise the analysis of HRQOL and other patient-reported outcomes data in cancer randomised trials

da uno spunto di Francesco Sparano

Reporting of Patient-Reported Outcomes in Randomized Trials

The CONSORT PRO Extension

JAMA. 2013;309(8):814-822

Melanie Calvert, PhD | Douglas G. Altman, DSc | David Moher, PhD
Jane Blazeby, MD | Dennis A. Revicki, PhD | Michael D. Brundage, MD

Five CONSORT PRO checklist items are recommended for RCTs in which PROs are primary or important secondary end points. These recommendations urge that the PROs be identified as a primary or secondary outcome in the abstract, that a description of the hypothesis of the PROs and relevant domains be provided (ie, if a multidimensional PRO tool has been used), that evidence of the PRO instrument's validity and reliability be provided or cited, that the statistical approaches for dealing with missing data be explicitly stated, and that PRO–specific limitations of study findings and generalizability of results to other populations and clinical practice be discussed.

da uno spunto di Francesco Sparano

Clinician's Checklist for Reading and Using an Article About Patient-Reported Outcomes

Albert W. Wu, MD, MPH, FACP; Anna N. Bradford, PhD, MSW, LCSW; Vic Velanovich, MD; Mirjam A.G. Sprangers, PhD; Michael Brundage, MD, FRCP, MSc; and Claire Snyder, PhD

Mayo Clin Proc. 2014;89(5):653-661

can help clinicians systematically evaluate PRO studies by determining whether the study design was appropriate and whether the measurement approach was adequate and properly executed as well as by assisting in the interpretation and application of the results to a specific patient population

da uno spunto di Francesco Sparano

ESMO GOOD SCIENCE BETTER MEDICINE BEST PRACTICE

ANNALS OF ONCOLOGY driving innovation in oncology

SPECIAL ARTICLE

The role of patient-reported outcome measures in the continuum of cancer clinical care: ESMO Clinical Practice Guideline☆

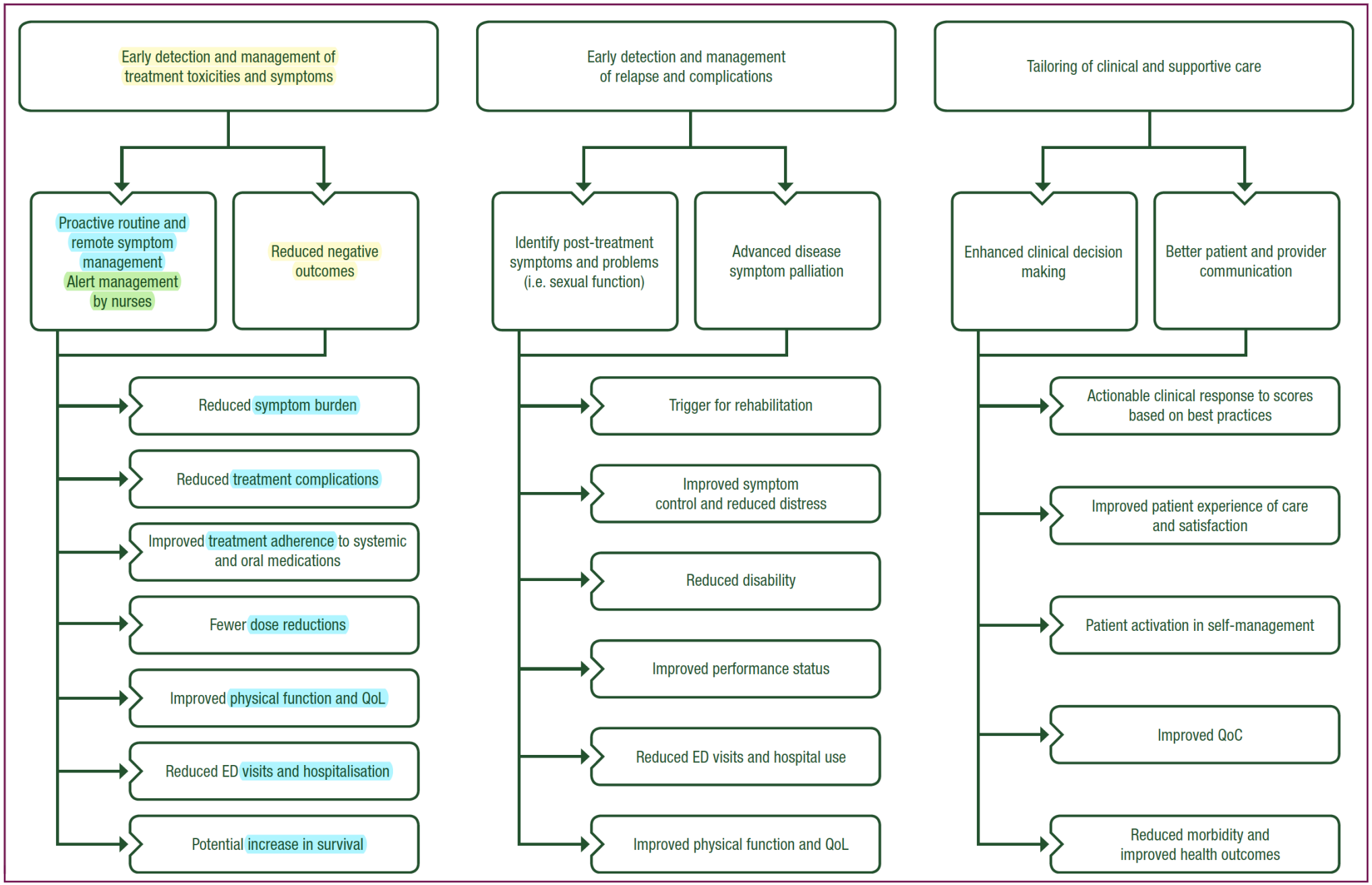
M. Di Maio[1], E. Basch[2], F. Denis[3,4], L. J. Fallowfield[5], P. A. Ganz[6], D. Howell[7], C. Kowalski[8], F. Perrone[9], A. M. Stover[2,10], P. Sundaresan[11,12], L. Warrington[13], L. Zhang[14], K. Apostolidis[15], J. Freeman-Daily[16], C. I. Ripamonti[17] & D. Santini[18], on behalf of the ESMO Guidelines Committee*

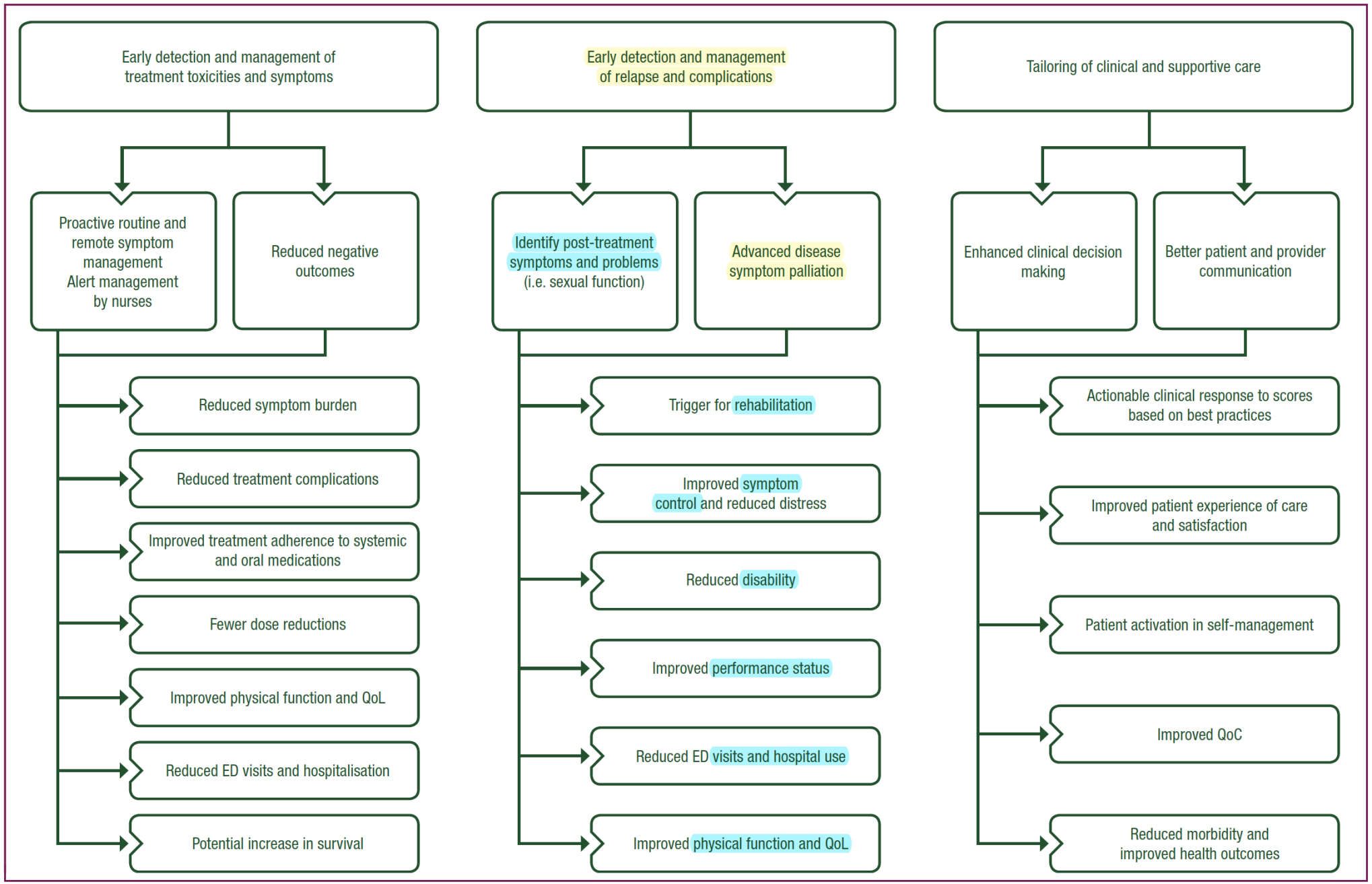
[1]Department of Oncology, University of Turin, at A.O. Ordine Mauriziano Hospital, Turin, Italy; [2]Lineberger Comprehensive Cancer Center, University of North Carolina, Chapel Hill, USA; [3]Institut Inter-régional de Cancérologie Jean Bernard (ELSAN), Le Mans; [4]Faculté de Santé, Université de Paris, Paris, France; [5]Sussex Health Outcomes Research & Education in Cancer, Brighton & Sussex Medical School, University of Sussex, Falmer, Brighton, UK; [6]Jonsson Comprehensive Cancer Center, University of California, Los Angeles (UCLA), USA; [7]Department of Supportive Care, Princess Margaret Cancer Centre Research Institute, Toronto, Ontario, Canada; [8]Department of Certification – Health Services Research, German Cancer Society, Berlin, Germany; [9]Clinical Trial Unit, National Cancer Institute IRCCS G. Pascale Foundation, Naples, Italy; [10]Department of Health Policy and Management, University of North Carolina at Chapel Hill, Chapel Hill, USA; [11]Sydney West Radiation Oncology Network, Westmead Hospital, Westmead; [12]Sydney Medical School, The University of Sydney, Sydney, Australia; [13]Leeds Institute of Medical Research at St James's, University of Leeds, St James's University Hospital, Leeds, UK; [14]Department of Medical Oncology, Sun Yat-Sen University Cancer Center, Guangzhou, China; [15]European Cancer Patient Coalition, Brussels, Belgium; [16]The ROS1ders, Sacramento, USA; [17]Oncology - Supportive Care in Cancer Unit, Department Oncology-Haematology, Fondazione IRCCS Istituto Nazionale dei Tumori Milano, Milan; [18]Medical Oncology Department, University Campus Bio-Medico, Rome, Italy

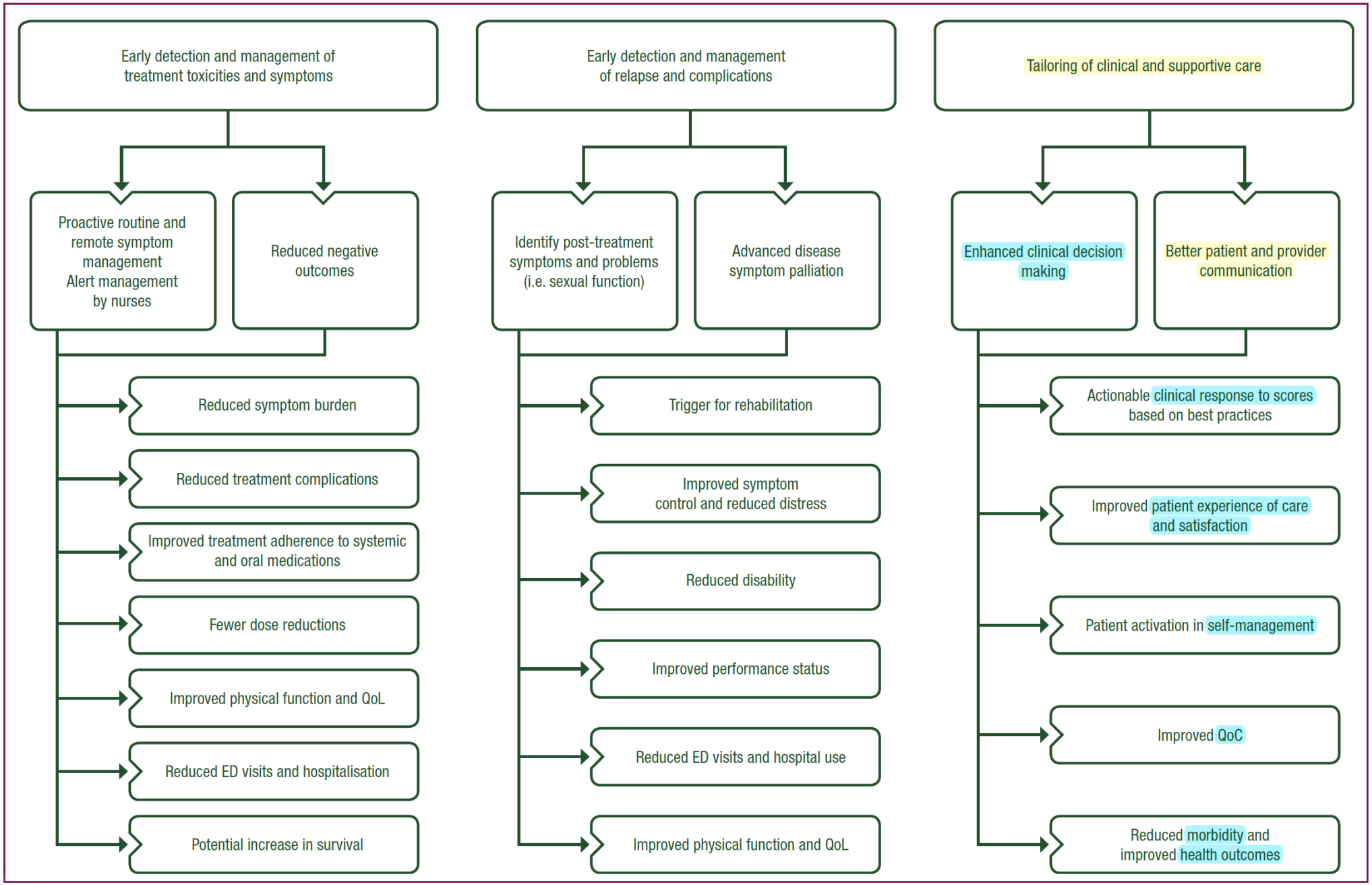
CHECK FOR UPDATES

Available online 21 April 2022

Key words: PROs, PROMs, clinical practice, cancer, PROM implementation


Early detection and management of treatment toxicities and symptoms
Proactive routine and remote symptom management Alert management by nurses
Reduced negative outcomes
Reduced symptom burden
Reduced treatment complications
Improved treatment adherence to systemic and oral medications
Fewer dose reductions
Improved physical function and QoL
Reduced ED visits and hospitalisation
Potential increase in survival
Early detection and management of relapse and complications
Identify post-treatment symptoms and problems (i.e. sexual function)
Advanced disease symptom palliation
Trigger for rehabilitation
Improved symptom control and reduced distress
Reduced disability
Improved performance status
Reduced ED visits and hospital use
Improved physical function and QoL
Tailoring of clinical and supportive care
Enhanced clinical decision making
Better patient and provider communication
Actionable clinical response to scores based on best practices
Improved patient experience of care and satisfaction
Patient activation in self-management
Improved QoC
Reduced morbidity and improved health outcomes


Early detection and management of treatment toxicities and symptoms
Proactive routine and remote symptom management Alert management by nurses
Reduced negative outcomes
Reduced symptom burden
Reduced treatment complications
Improved treatment adherence to systemic and oral medications
Fewer dose reductions
Improved physical function and QoL
Reduced ED visits and hospitalisation
Potential increase in survival
Early detection and management of relapse and complications
Identify post-treatment symptoms and problems (i.e. sexual function)
Advanced disease symptom palliation
Trigger for rehabilitation
Improved symptom control and reduced distress
Reduced disability
Improved performance status
Reduced ED visits and hospital use
Improved physical function and QoL
Tailoring of clinical and supportive care
Enhanced clinical decision making
Better patient and provider communication
Actionable clinical response to scores based on best practices
Improved patient experience of care and satisfaction
Patient activation in self-management
Improved QoC
Reduced morbidity and improved health outcomes


Early detection and management of treatment toxicities and symptoms
Proactive routine and remote symptom management Alert management by nurses
Reduced negative outcomes
Reduced symptom burden
Reduced treatment complications
Improved treatment adherence to systemic and oral medications
Fewer dose reductions
Improved physical function and QoL
Reduced ED visits and hospitalisation
Potential increase in survival
Early detection and management of relapse and complications
Identify post-treatment symptoms and problems (i.e. sexual function)
Advanced disease symptom palliation
Trigger for rehabilitation
Improved symptom control and reduced distress
Reduced disability
Improved performance status
Reduced ED visits and hospital use
Improved physical function and QoL
Tailoring of clinical and supportive care
Enhanced clinical decision making
Better patient and provider communication
Actionable clinical response to scores based on best practices
Improved patient experience of care and satisfaction
Patient activation in self-management
Improved QoC
Reduced morbidity and improved health outcomes

The role of patient-reported outcome measures in the continuum of cancer clinical care: ESMO Clinical Practice Guideline☆

M. Di Maio[1], E. Basch[2], F. Denis[3,4], L. J. Fallowfield[5], P. A. Ganz[6], D. Howell[7], C. Kowalski[8], F. Perrone[9], A. M. Stover[2,10], P. Sundaresan[11,12], L. Warrington[13], L. Zhang[14], K. Apostolidis[15], J. Freeman-Daily[16], C. I. Ripamonti[17] & D. Santini[18], on behalf of the ESMO Guidelines Committee*

Use of PROMs in patients undergoing active treatment

- Digital symptom monitoring with PROMs in routine clinical care during systemic cancer treatment is recommended, based on evidence of benefits on communication, satisfaction, treatment adherence, symptom control, QoL, emergency room and hospital admissions and survival [I, A].

https://doi.org/10.1016/j.annonc.2022.04.007 Volume 33 ■ Issue 9 ■ 2022

The role of patient-reported outcome measures in the continuum of cancer clinical care: ESMO Clinical Practice Guideline☆

M. Di Maio[1], E. Basch[2], F. Denis[3,4], L. J. Fallowfield[5], P. A. Ganz[6], D. Howell[7], C. Kowalski[8], F. Perrone[9], A. M. Stover[2,10], P. Sundaresan[11,12], L. Warrington[13], L. Zhang[14], K. Apostolidis[15], J. Freeman-Daily[16], C. I. Ripamonti[17] & D. Santini[18], on behalf of the ESMO Guidelines Committee*

Responding to PROMs data and remote monitoring alerts

- Clinical personnel at sites routinely collecting PROMs should receive training on the review and interpretation of PROMs data [I, A].
- Provider organisations and clinical teams should clarify personnel roles and responsibilities and redesign workflows to ensure PROMs data are reviewed and acted upon [I, A].

https://doi.org/10.1016/j.annonc.2022.04.007 Volume 33 ■ Issue 9 ■ 2022

The role of patient-reported outcome measures in the continuum of cancer clinical care: ESMO Clinical Practice Guideline☆

M. Di Maio[1], E. Basch[2], F. Denis[3,4], L. J. Fallowfield[5], P. A. Ganz[6], D. Howell[7], C. Kowalski[8], F. Perrone[9], A. M. Stover[2,10], P. Sundaresan[11,12], L. Warrington[13], L. Zhang[14], K. Apostolidis[15], J. Freeman-Daily[16], C. I. Ripamonti[17] & D. Santini[18], on behalf of the ESMO Guidelines Committee*

Responding to PROMs data and remote monitoring alerts

- Oncology nurses or other allied health support (e.g. social workers) with appropriate training should serve as first responders to PRO alerts [I, A].

https://doi.org/10.1016/j.annonc.2022.04.007 Volume 33 ■ Issue 9 ■ 2022

The role of patient-reported outcome measures in the continuum of cancer clinical care: ESMO Clinical Practice Guideline☆

M. Di Maio[1], E. Basch[2], F. Denis[3,4], L. J. Fallowfield[5], P. A. Ganz[6], D. Howell[7], C. Kowalski[8], F. Perrone[9], A. M. Stover[2,10], P. Sundaresan[11,12], L. Warrington[13], L. Zhang[14], K. Apostolidis[15], J. Freeman-Daily[16], C. I. Ripamonti[17] & D. Santini[18], on behalf of the ESMO Guidelines Committee*

Applicability and limitations

- The allocation of funds for validated software reimbursement, dedicated resources (nurses, physicians, etc.) and systematic evaluation of PRO implementation programmes in oncology clinics is recommended [V, A].

https://doi.org/10.1016/j.annonc.2022.04.007 Volume 33 ■ Issue 9 ■ 2022