Supplementary Web Appendix Methods and Results

1. METHODS

1.1 Intended Form and Content

The intention of the OECI Quality Standards was to adopt a form which conforms to best international standard-setting practice¹, in that they consist of a specific and objective indicative statement, the compliance to which can be scored (in a graded system according to the Deming cycle²) as a self-assessment by centres, and the same standards are subsequently externally scored by independent evaluators within a peer review visit.

The intent was also that each Standard should be based on internationally-accepted best practices from Cancer Centres, and where possible should be based on evidence of efficacy. Two examples are:

- (A) Multidisciplinary team (MDT) working chapter 4 of the Quality Standards³. The principles of the benefits of MDT working on the quality of cancer care across tumour types are well established and documented, including the professional disciplines which should be present in the MDT meetings, and the modus operandi^{4,5,6}.
- (B) The importance within Centres of having mechanisms to translate research into clinical practice chapter 8 of the Quality Standards⁷. These mechanisms are multifaceted and generally capitalise on the benefits of co-location, and include: programmes and funding to give clinicians protected time for translation research; a knowledge transfer programme including colloquia where research projects and findings are disseminated; and support for innovation and technology transfer^{8,9,10,11}.

1.2 Comparative Review and Gap Analysis

a. The starting point for the Standards revising process was the existing Standards of OECI's Manual Version 2.0 and the suggestions and issues that had been raised during the implementation of these standards by the participating cancer centres and the peer review teams.

- b. The set of standards was reviewed against other published quality standards, namely Qmentum¹²; Joint Commission International¹³; the German Cancer Society¹⁴, Institut National du Cancer¹⁵; National Institute for Health and Care Excellence¹⁶, the ASCO QOPI certification program¹⁷, and the International Society for Quality in Healthcare (ISQua)¹⁸. This review was conducted by the Netherlands Comprehensive Cancer Organisation (IKNL)¹⁹ using a screening methodology based on: (i) Relevance/potential for improving patient outcomes in cancer; (ii) Feasibility in the majority of cancer institutes and centres in Europe; (iii) capability of objective self-assessment and external review, and (iv) applicability to almost all cancers within an overall centre-based approach.
- c. The recommendations of ISQua, following their review and accreditation of the OECI Manual 2.0 standards, were implemented. This entailed OECI introducing processes to analyse the results and recommendations of other related certifications which contribute to the whole cancer pathways (for instance: national accreditations, ISO certifications of nuclear medicine, radiotherapy, pathology and biobanking, JACIE²⁰ accreditation of haematopoietic stem cell transplantation and cellular therapy departments), and avoiding duplication with these.
- d. The OECI Accreditation and Designation Board, comprising cancer centre directors from across Europe (named below), decided that new standards were required around molecular pathology, nuclear medicine, radiology, radiotherapy and surgical oncology, and that quality standards on prevention services, patient-centred care, patient involvement and survivorship should be strengthened. The input from acknowledged experts in these fields, and of patient groups, was obtained, to inform the stages of decision-making.
- e. Integral of this whole process was the decision about which of the standards in each chapter were absolutely core to the quality programme, defined as: "fundamental to good quality of care or research, requiring structural evidence of compliance during the peer review at every 5 year re-accreditation". This also had the objective of facilitating a lighter administrative burden during re-accreditation exercises. The selection of the Core Set was made by formal decisions of the Accreditation Board, based on consensus, at each stage of the process, and validated by the Expert Societies and Patient Groups in 1.3 below.

1.3 Input from Expert Societies and Patient Groups

- a. An expert meeting was held on 10 April 2019 in Brussels with participants from 10 European Societies and Patient Groups including ECCO, ESTRO, EORTC, EONS, ECPC, ECL, ESMO, CCE, CPE, EACS, and OECI peer review teams. Particular foci for discussions were: patient involvement and empowerment; multidisciplinarity; supportive and palliative care; research; clinical research and education; governance and organisation of cancer centres.
- b. The resulting output from the meeting was sent for review to 94 OECI cancer centres for comment and input. Detailed feedback was received from 14 OECI Centre members.
- c. The Revised Standards were presented at the OECI Annual Oncology Days on 13 June 2019 in Bari, Italy, and further input was taken from the assembly.

Decision Process

Throughout the process the decision-making body was the Editorial Board, the OECI Accreditation Board, whose members are named below. Final approval to the new Standards was given by the OECI Board in June 2019. The definition of the core set was a separate decision of the OECI Accreditation Board after going through the whole process of revision and adaptation.

The whole set of revised Quality Standards and Indicators in Manual 3.0 have recently been published^{21,22}. The resulting set of 100 Core Standards presented below (representing 27% of the full set of standards) are integral to Manual 3.0 which OECI has implemented in the Accreditation Programme from 1 January 2020.

2. RESULTS

The 100 Core Quality Standards decided upon through the methods outlined above fall into nine chapters. These are:

1. Governance of the cancer centre

- 2. Organisation of quality systems
- 3. Patient involvement and empowerment
- 4. Multidisciplinarity
- 5. Prevention and Early Detection
- 6. Diagnosis
- 7. Treatment and Care
- 8. Research
- 9. Education and Training

100 CORE QUALITY STANDARDS

Chapter 1: Governance of the cancer centre

Structure of the cancer centre - identifiable entity

The cancer centre has an identifiable governing entity (board of directors/executive committee) with accountability for:

- strategic plan for cancer care
- strategic plan for research
- quality and safety
- budget

Structure of the cancer centre - quality management

There is an identifiable director who has quality and risk management as his/her responsibility.

Strategy and quality cycle of the cancer centre

There is a written strategic plan for the cancer centre which covers at least three years, and which is formally endorsed by the board.

According to the planning and control cycle the centre produces a (multi-)annual report which results in a quality improvement plan.

Co-operation with universities

Written co-operation agreements exist with at least one university for training and postgraduate education activities.

Written co-operation agreements exist with at least one university for research activities.

Co-operation with external partners

There are written agreements or regulations, which are currently implemented, with other hospitals and cancer centres, setting out the goals for cooperation, the division of responsibilities and tasks.

Chapter 2: Organisation of quality systems

Integrated quality, risk and safety management

There is a quality management system based upon continuous quality improvement and risk-based thinking, promoted by the line management.
There is a dedicated unit or department responsible for administering the quality
system.

There is a quality, risk and safety dashboard with standardised indicators (including overall survival, patient satisfaction, patient quality of life, MDT activities). The line management of the cancer centre are responsible for implementing

improvements after analysing results of quality and risk and safety factors.

Quality assurance

There is an internal audit system following an annual plan covering all departments.

Cancer data registration (institutional level)

The number of newly diagnosed patients and treated patients by tumour type in the cancer centre are available annually at the cancer centre level.

The outcome data of cancer patients by tumour type are known at the cancer centre and MDT level and are used by management for strategic planning or policy decisions.

Waiting and throughput times

Maximum waiting times are defined for critical stages in the diagnosis and care process. If the defined maximum waiting times are exceeded, improvement actions are defined promptly.

Complications registry

The cancer centre has a comprehensive system for reporting, registration and assessing Serious Adverse Events.

Human Resources Management – appraisal policy

Regular appraisal of all staff (medical, nursing, supportive disciplines, technicians, administrative) is part of the human resources management of the cancer centre.

Privacy, protection of and access to personal data

Personal data protection is guaranteed for patients according to the General Data Protection EU Regulation (GDPR) 2016/679.

There are policies on informed consent for diagnostics, treatment and research, that meet national laws and regulations.

Chapter 3: Patient involvement and empowerment

Patient involvement

The cancer centre involves patients and patients' voluntary organisations and support groups in the planning and organisation of services.

Patient education programmes

There are patient education programmes that aim to improve patients' understanding of their illness and diagnosis, including information on self-care and how to manage multiple aspects of their illness.

An information and support centre is available in the cancer centre and easily accessible for staff, patients, family members and caregivers.

Patient information

The cancer centre provides information material that is readable, up-to-date, appropriate and available in languages commonly spoken by the population served.

Informing patients about their care

There are procedures in place which specify how and by whom patients are informed about their diagnostic results, treatment options, follow-up, and survivorship support, which involve shared decision-making.

All patients are given contact information of clinical staff in case of emergency.

Discharge procedure and follow-up

There is a defined discharge procedure including giving information on further treatment, follow-up, re-admission and home care.

Patient satisfaction/experience

The cancer centre has methods regularly to gather patients' experiences during outpatient and inpatient care.

Satisfaction surveys are analysed, reported and acted upon in an administrative and organisational setting.

System for receiving and managing complaints

The cancer centre has a clearly identified complaints officer or a complaints office.

Chapter 4: Multidisciplinarity

Patient Pathways¹

There is a written patient pathway for each tumour (sub) type treated in the cancer centre which charts the process from patient admission up to the end of follow-up of care.

Patient Pathways: coordination of patients on the pathways

For every patient there is an identified coordinator or manager of their pathway from admission until the end of follow-up, to ensure their continuity of care.

Implementation of guidelines

For each type of cancer, it is formally agreed which clinical guidelines (institutional/local/regional/national/international) are used for diagnostics, treatment and follow-up.

Electronic Patient Record

Each patient has an Electronic Patient Record which enables all relevant disciplines along the patient pathway to access all relevant information concerning the patient.

Process of multidisciplinary meetings

The centre has Multidisciplinary Teams (MDTs) covering every tumour type which follow Standard Operating Procedures (SOPs).

The SOPs specify core and extended attendance from all relevant diagnostic and therapeutic disciplines, including oncology nursing and supportive care.

The SOPs state for each MDT whether all patients are fully discussed or listed according to standard patient pathways following definitive diagnosis.

MDT review

Every MDT meets at least twice a year in a learning event to review outcomes, quality of procedures, patient pathways and indicators, for quality improvement and future research.

¹ A patient pathway (sometimes called a "care pathway" or "clinical pathway") is a plan for decision-making and organisation of diagnostic and care processes for a well-defined group of patients in well-defined stages, beginning with first suspicion of cancer to survivorship/follow-up or end of life. This is distinct from a "care plan" which is personal to an individual patient.

Chapter 5: Prevention and early detection

Oncogenetic service

An oncogenetic clinic is available and accessible to all appropriate patients.

Cancer risk reducing strategies in the cancer centre

Information is available in the cancer centre on overall healthy living in the fields of: diet, smoking, alcohol, exercise, spotting signs and symptoms.

There is a non-smoking policy in the cancer centre.

Support is provided to patients to quit smoking.

Chapter 6: Diagnosis

Molecular diagnostics

The cancer centre has a molecular diagnostics programme for the use of all tumour sub-types that are clinically validated.

Medical Imaging - Radiology and Nuclear Medicine

Staffing levels of key disciplines in the departments are planned so as to ensure safety, accuracy and high quality care.

Quality control of all equipment used for imaging is routinely performed, according to the relevant national protocols and/or European guidelines.

Radiology and Nuclear Medicine reporting

The radiologist's written report is available to the attending doctors at the latest 72 hours after the examination.

Pathology

The pathology laboratory/institute has sufficient Board-certified pathologists available to fulfil the requirements of each specialty served by an MDT in the centre.

The laboratory has Standard Operating Procedures covering the collection, preanalytical and analytical phases, reporting and storage of specimens of all kinds which follow international standards.

Pathology reporting

Pathologists' reports for routine histology and immuno-histochemistry are provided within five working days of reception of the specimen.

Chapter 7: Treatment and Care

24/7 access to specialist care

There are arrangements in place to provide all relevant specialist care for patients 24 hours a day, every day.

There is an acute oncology assessment unit (emergency unit) particularly for patients with toxicities which operates according to Standard Operating Procedures.

Surgical oncology

Minimum surgical volumes per cancer surgeon are defined for each tumour type.
There is 24-hour availability of surgical oncologists in all major specialties including at
weekends and on public holidays.

Reconstructive surgery

There is a full range of reconstructive surgery, immediate or delayed, including aesthetic and functional restoration surgery for all body regions.

Ra	ndiotherapy
	Staffing levels of key disciplines are planned so as to ensure safety and high quality
	care.
	The centre has a 24-hour on-call radiotherapy service outside working hours (including
	weekends and public holidays), if necessary through co-operation agreements.
	The radiotherapy department has a written contingency plan.

Radiotherapy equipment	
The radiotherapy department has at least two megavoltage linear accelerators.	
The radiotherapy department of the centre has sufficient linear accelerators to meet the demands of providing radiotherapy to all its patients.	
Medical devices used for radiotherapy treatment are periodically certified by an authorised body.	

Medical oncology (oncology and haemato-oncology) Staffing levels of key disciplines are planned so as to ensure safety and high quality care. There are sufficient chairs and beds to manage patient numbers for systemic therapies.

Medical oncology, anti-cancer drugs: prescription and pharmacy preparation	
There is a quality-assured digital system for the prescription, preparation and	
administration of anti-cancer drugs.	
There is a Standard Operating Procedure (SOP) for the prescribing of anti-cancer	
drugs.	
A validation procedure for the whole process, including prescription, preparation and	
distribution, is implemented.	

Medical oncology, anti-cancer drugs: administration	
	There are SOPs for the administration of anti-cancer drugs.
	Anti-cancer drugs are administered by nurses, who have completed a specific training programme for chemotherapy administration.
	Each patient has a medical consultation prior to the commencement of systemic therapy.

Pain service	
	There is systematic screening of pain with validated assessment tools through the whole pathway of the patient.
	A defined pain team, or pain specialists as part of the palliative care team, is available to both inpatients and outpatients.

Referral to supportive disciplines There are guidelines which define the indications for referral and the types of intervention from supportive disciplines.

Psycho	Psycho-oncology	
	There is a psycho-oncology service with competence in oncology psychiatry and/or clinical psychology.	
	Structured screening with validated assessment tools is systematically used.	

Rehabilitation

There is timely access to rehabilitation services with multidisciplinary interventions for cancer patients.

Social counselling

Social counselling, including social benefits advice, employment rights and housing needs. is organised according to guidelines and is accessible for all cancer patients.

Survivorship support

Advice and support are given to patients and caregivers on prevention of recurrence and overall healthy living in the fields of: diet; exercise; spotting signs and symptoms.

Palliative² care

The cancer centre has a written policy which defines when and how patients are referred to specialised palliative care services as part of their care pathway.

End of life care

End of Life care is appropriately and sensitively arranged according to patients' needs and wishes.

There is a policy for ascertaining the wishes and preferences of patients and relatives for End of Life care.

Chapter 8: Research

Strategic planning for oncology research There is a regularly updated research strategic plan covering at least three years, which is integrated into the overall strategy of the cancer centre. The cancer centre research performance/ activity is regularly evaluated and communicated in a scientific report.

The centre has research groups and output covering translational and clinical research.

Research - organisational structure

There is a defined organisational structure specifically for research and innovation related to cancer.

Means for conducting research activities

The cancer research budget covering both external and internal funding for the cancer centre is defined each year.

The cancer centre provides access to shared technological platforms for research activities.

Periodical external site visit/review

An external Scientific Advisory Board (SAB) meets at regular intervals and advises the cancer centre on its cancer research strategy, organisation, infrastructure and overall performance.

The performance of each research group is externally or internally reviewed at regular intervals.

Scientific interaction and integration

Regular briefings on research activities, results and new opportunities are organised through information sharing and meetings for laboratory researchers and clinicians.

There are funding mechanisms and/or programmes to give clinicians protected time for clinical and/or translational research.

² Palliative care is an approach that improves the quality of life of patients and their families facing the problem associated with life-threatening illness, through the prevention and relief of suffering by means of early identification, assessment and treatment of pain and other problems, physical, psychosocial and spiritual.

Scientific dissemination programme

There is a structured, documented and up-to-date scientific programme in the cancer centre through colloquia, seminars and theme-specific conferences.

Grant proposals

The cancer centre has training programmes and supportive services for grant applicants.

Organisation of clinical research

There is a Research Ethical Committee (internal or external) or Institutional Review Board (IRB) which evaluates ethical aspects of all research proposals on human subjects or material.

There is an institutional clinical research management unit dedicated to cancer clinical trials.

The cancer centre keeps and publishes an up-to-date database of clinical trials, including the actual accrual of patients.

Biobank

There are SOPs defining the patient information, informed consent, collection, storage, registration, recovery and use of the biological samples.

There is a centralised biobank database which provides linking to detailed clinical data.

Chapter 9: Education and training

Analysing and providing for oncology training needs

Relevant training is provided to all staff according to individual needs, institutional requirements, and regulatory requirements, including Good Clinical Practice.

Undergraduate academic education in oncology

The cancer centre provides oncology education for undergraduate degrees for medical and nursing students.

Postgraduate academic education in oncology

The cancer centre provides postgraduate oncology education for physicians.

The cancer centre provides postgraduate oncology education for nurses (including palliative care).

Editorial Board (the Accreditation and Designation Board of OECI (2018-19))

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Abbreviations:

ECCO European CanCer Organisation

ESTRO European Society for Radiotherapy and Oncology

EORTC European Organisation for Research and Treatment of Cancer

EONS European Oncology Nursing Society
ECPC European Cancer Patient Coalition

ECL European Cancer Leagues

ESMO European Society for Medical Oncology

CCE Cancer Core Europe
CPE Cancer Prevention Europe

EACS European Academy of Cancer Sciences

¹ https://www.nice.org.uk/standards-and-indicators/how-to-use-quality-standards

² https://improvement.nhs.uk/documents/2142/plan-do-study-act.pdf

³ https://www.oeci.eu/Accreditation/Attachments/OECI A&D MANUAL 3.0.2019 DEF.pdf, Appendix II, Chapter 4, pp 13-14

⁴ Kaasa et al Lancet Oncology, 2018, Nov 19 e 588

⁵ Selby P Am J Clin Oncology Educ Book 2019, Jan, 39, 332-340

⁶ Marsden et al Br J Hosp Med 2019, Dec 80, 696-6989.

⁷ https://www.oeci.eu/Accreditation/Attachments/OECI A&D MANUAL 3.0.2019 DEF.pdf, Appendix II, Chapter 8, pp24-27

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¹² https://accreditation.ca/intl-en/accreditation/qmentum/

¹³ https://www.jointcommissioninternational.org/pathway/

¹⁴ http://www.ecc-cert.org/certification-system/document-collection/ and Kowalski et al BMC Cancer 2017;

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¹⁵ https://en.e-cancer.fr/

¹⁶ https://www.nice.org.uk/guidance/published?type=qs&title=Cancer

¹⁷ https://practice.asco.org/quality-improvement/quality-programs/qopi-certification-program

¹⁸ https://www.isqua.org/external-evaluation.html

¹⁹ https://www.iknl.nl/en/about-iknl

²⁰ https://www.ebmt.org/jacie-accreditation

²¹ https://www.oeci.eu/Accreditation/ReadNews.aspx?id=28

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