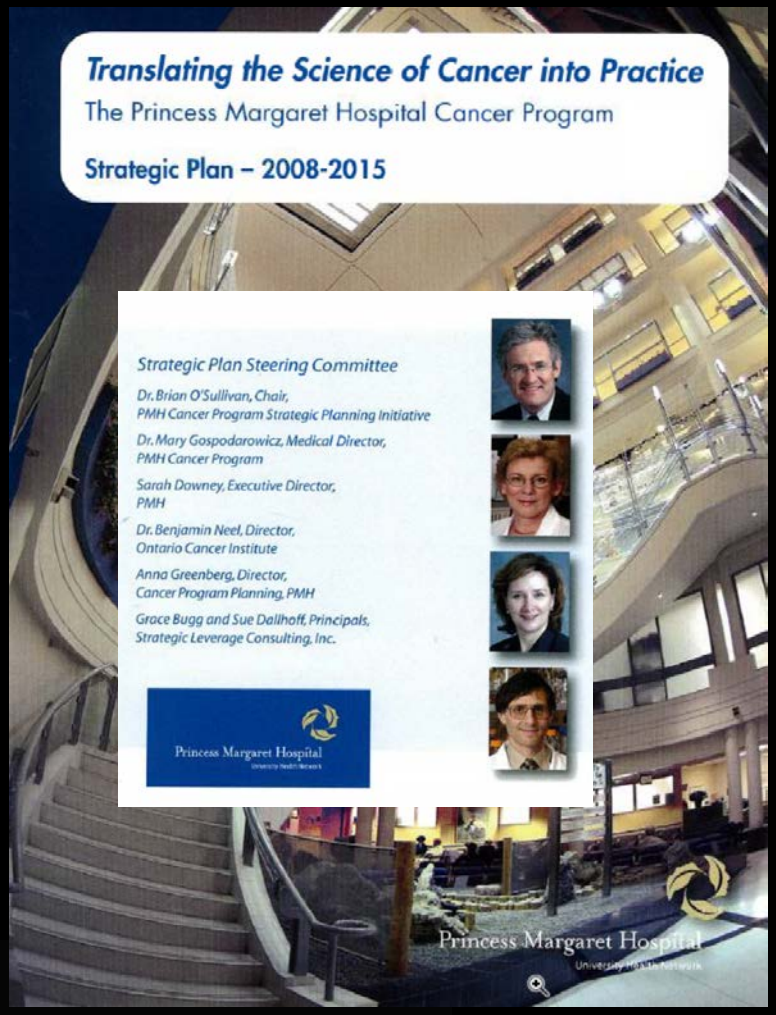
Essential Pillars to Advance Oncology Practice

Brian O'Sullivan
Bartley-Smith / Wharton Chair
Professor, Department of Radiation Oncology
The Princess Margaret / University of Toronto
Radiation Oncology Chair
United States NCI Head and Neck Steering Committee

15:00 ~ 15:25
20 May 2017

Conflict of Interest

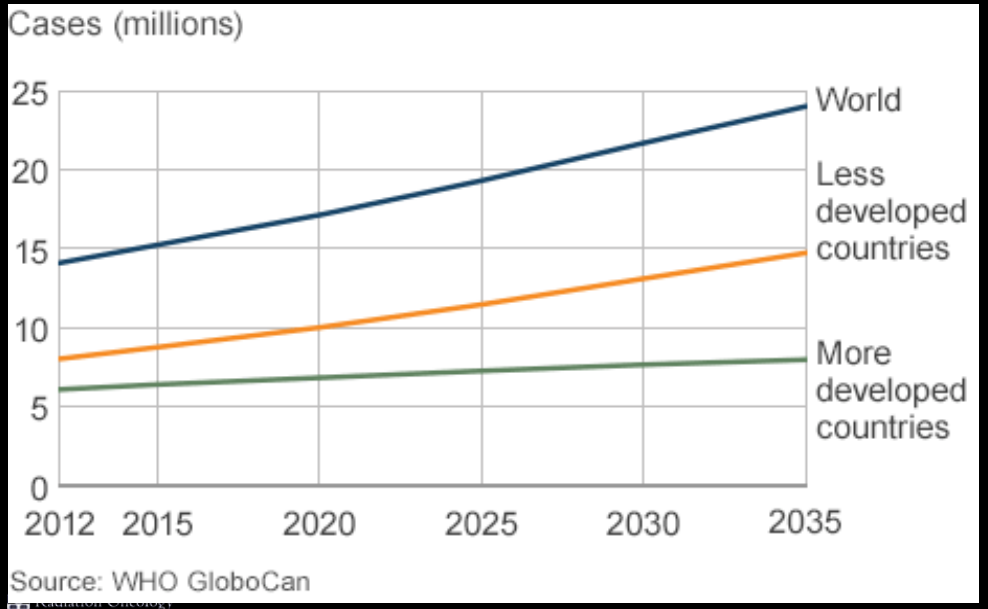
- None



UHN Princess Margaret Cancer Centre

GLOBOCAN 2012

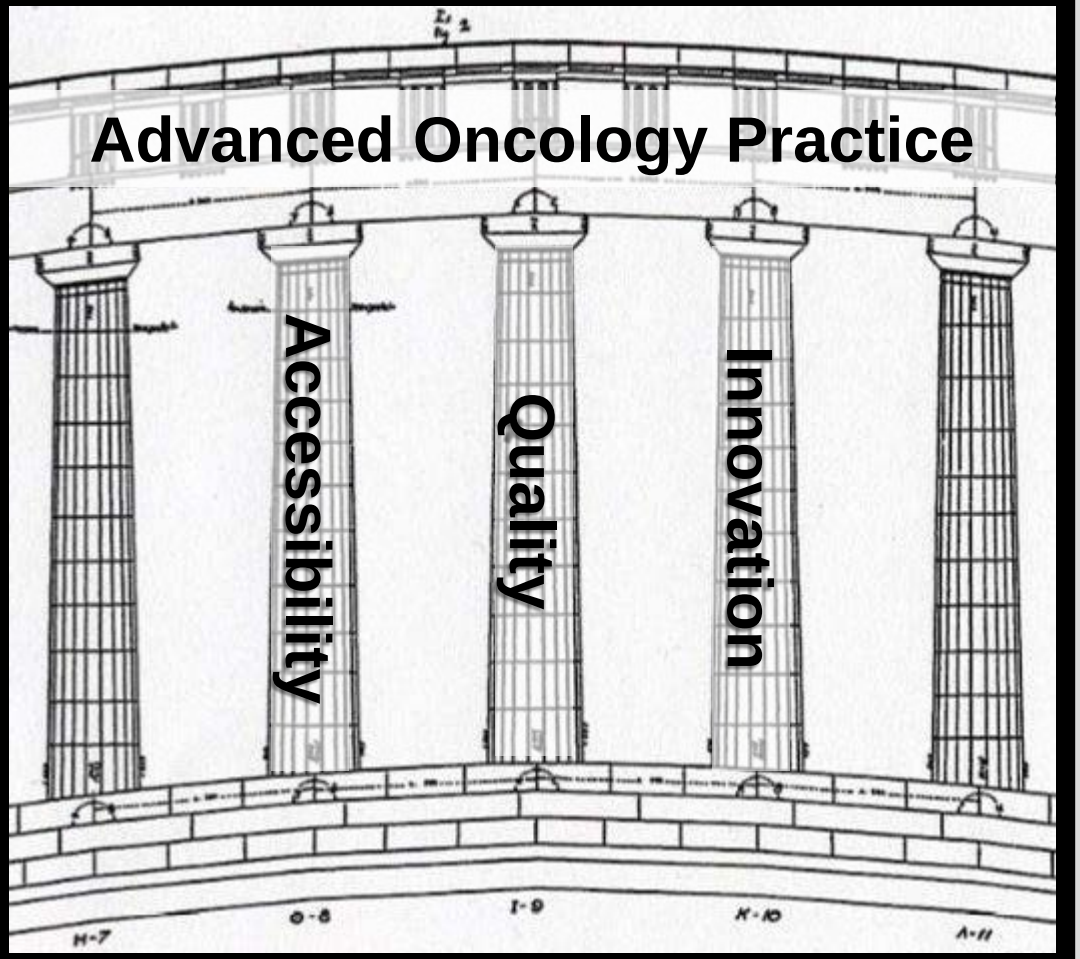
ESTIMATED CANCER INCIDENCE, MORTALITY AND PREVALENCE WORLDWIDE IN 2012



Challenges with cancer care:

- Rising volumes / costs
- Safety and quality
- Shortages of health human resources
- Fragmented systems
- Rising patient expectations

Essential Pillars to Achieve “Advanced Practice”



Stylobate: Fundamental Components of Cancer Care

- Accessibility:
  - Capacity
  - Affordability / Equity
  - Public awareness
- Quality of care:
  - Standards
  - Guidelines
  - Peer-reviewed QA
- Innovation:
  - Gathering information
  - Appraisal of evidence
  - Clinical trials
  - “Disciplined” new approaches

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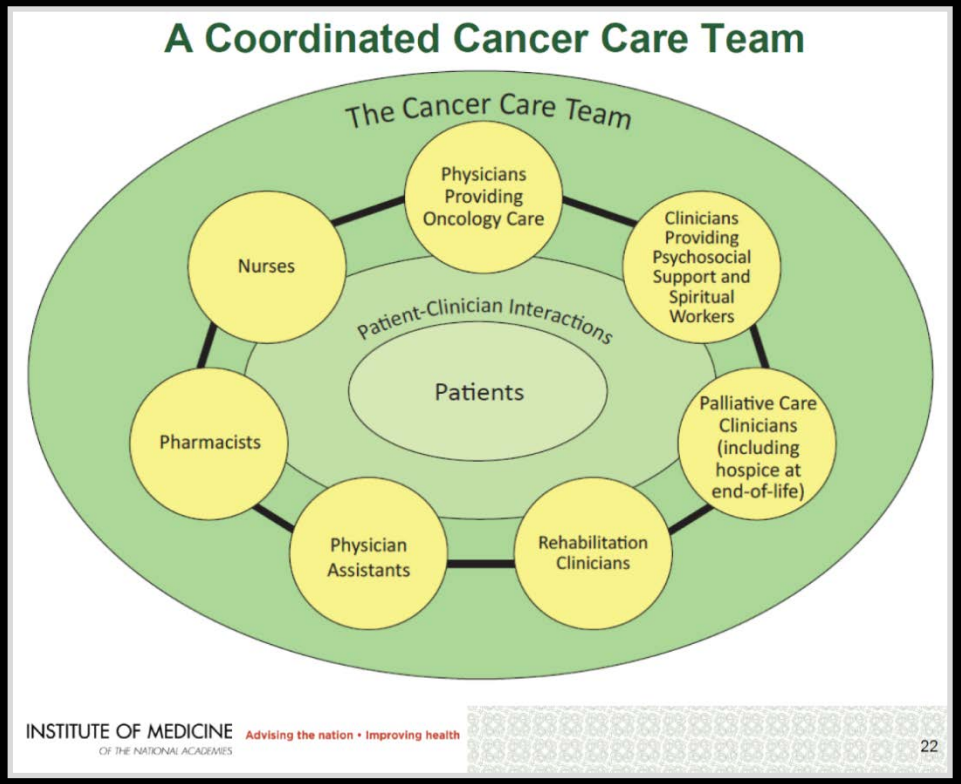
Fundamental Components of Cancer Care

- Diagnostic
  - Laboratory/pathology
  - Imaging
- Surgery
- Radiotherapy
- Chemotherapy
- Supportive care
  - Psychosocial
  - Nutrition
  - Pain management
  - Others



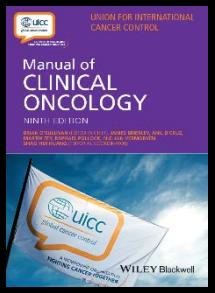
3

Prognosis and classification of cancer

Brian O'Sullivan, James Brierley and Mary Gospodarowicz

Department of Radiation Oncology, The Princess Margaret Cancer Centre, University of Toronto, Toronto, ON, Canada

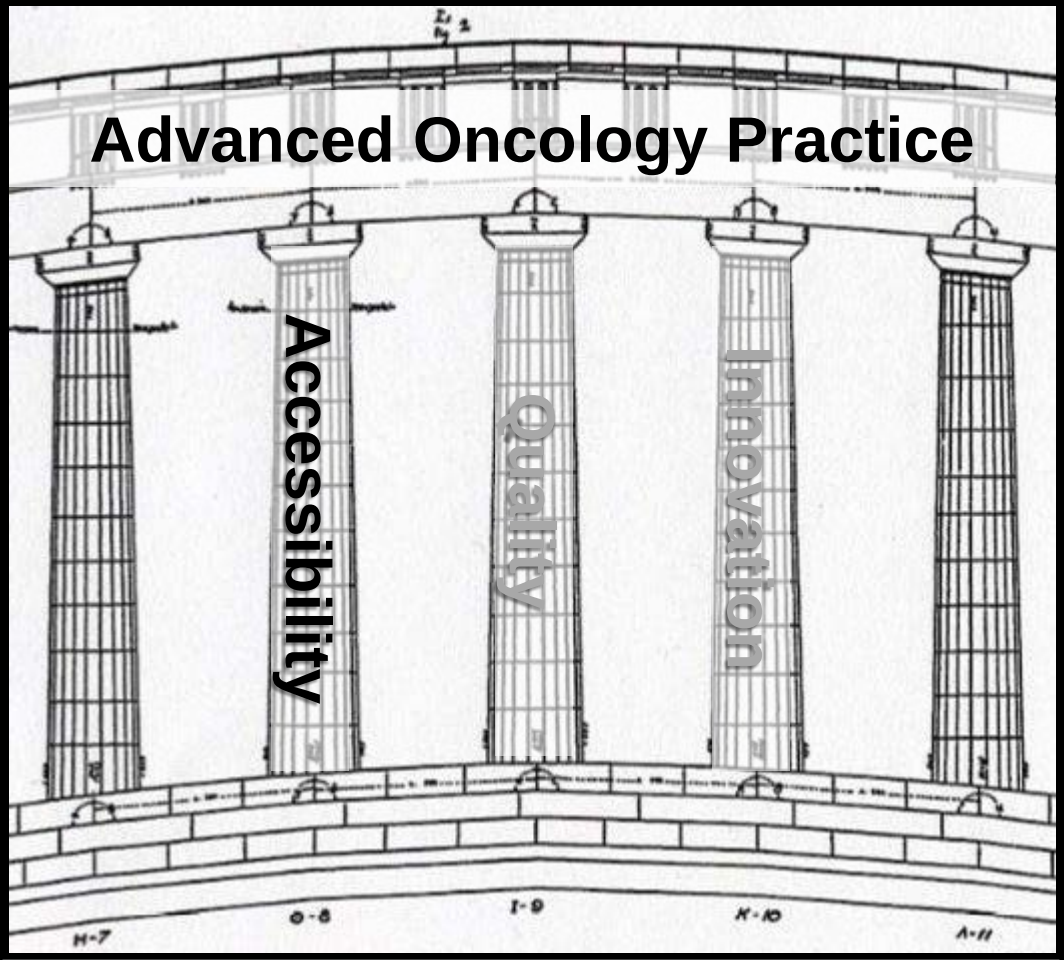
O'Sullivan, Brierley, Gospodarowicz (MCO 9th ed, 2015)



SETTING OR ENVIRONMENT FOR A PATIENT(S)

	Treatment	Education	Quality
Physician	Choice of physician or specialty: • Quality of diagnosis • Accuracy of staging Choice of treatment Expertise of physician: 'narrow experts' Timeliness of treatment Ageism	Ignorance of medical profession Access to internet Knowledge, education of the patient Participation in clinical trials Participation in continuing education	Quality of treatment Skill of the physician Treatment verification
Healthcare system	Access to appropriate diagnostic methods Access to care: • Distance • Waiting lists • Monopoly control of access to care Availability of publicly-funded screening programmes	Continuing medical education Lack of audit of local results Access to internet Development of practice guidelines Dissemination of new knowledge	Quality of equipment Quality management in treatment facility Maintenance of health records Availability of universal health insurance Quality of diagnostic services Implementation of screening programmes Promotion of an error-free environment
Society	Preference for unconventional therapies Socioeconomic status Appropriate geographical distribution of cancer centres Individual payment status Access to transportation, car, etc. Ageism	Literacy Access to information	Access to an affordable health programme Nutritional status of the population

Essential Pillar: Accessibility

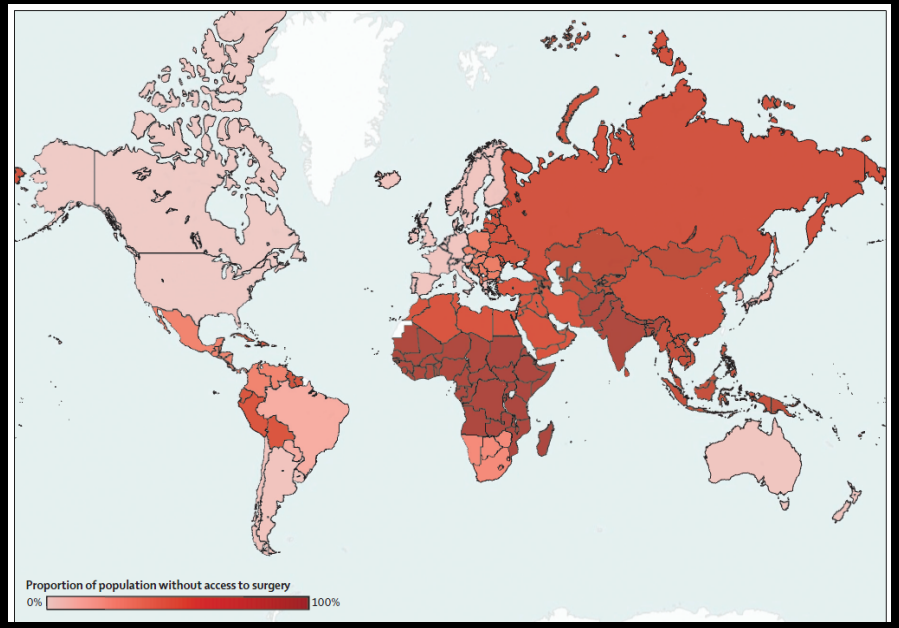


Stylobate: Fundamental Services for Cancer Care

- **Accessibility:**
  - **Capacity**
    - Closing equity gap ?
    - Training, Staffing, Facilities, Equipment
  - **Affordability**
    - Equitable health coverage
    - Good Value Health Care
  - **Public awareness**
    - Early diagnosis
    - Dispel myths
    - Advocacy

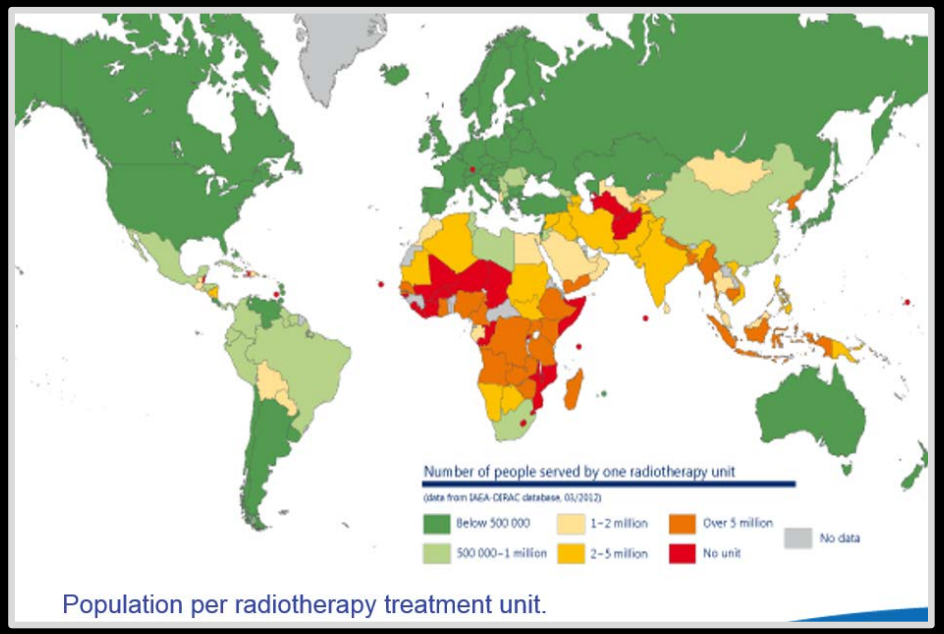
Access to Cancer Care: The Equity Gap

Proportion of Population without Access to Surgery



Meara et al, Lancet 2015

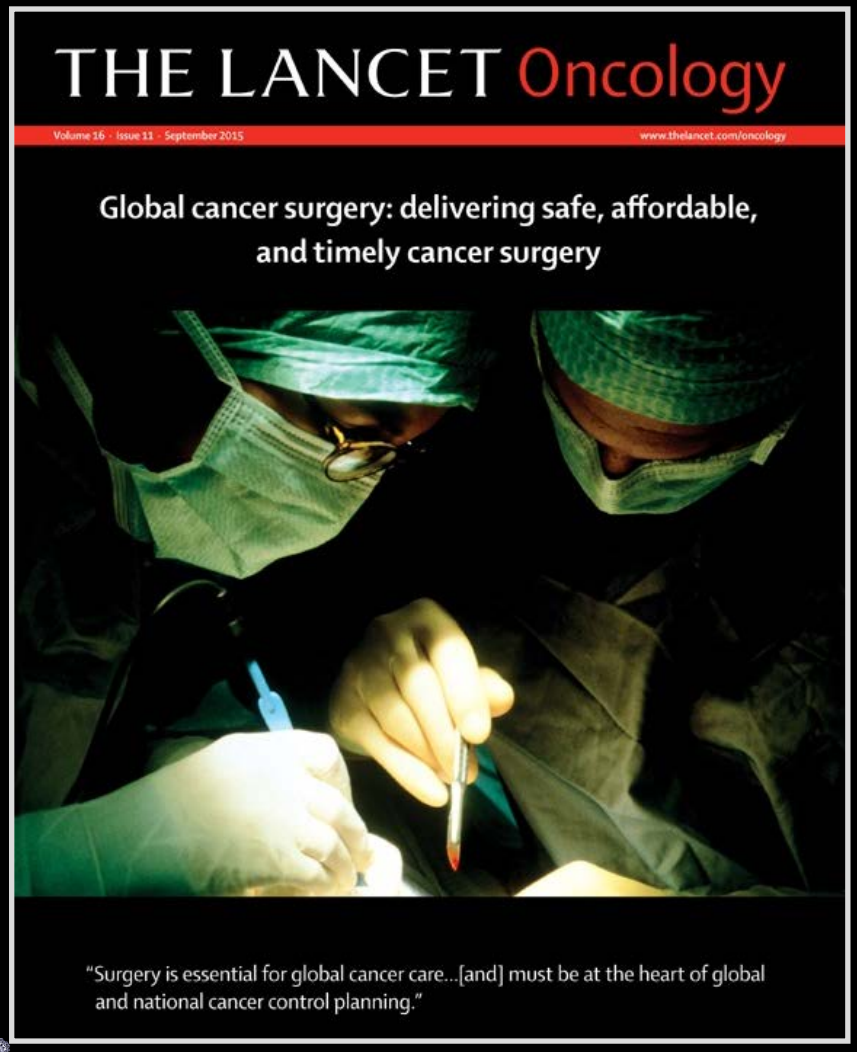
Population per Radiotherapy Treatment Unit



Atun et al, Lancet 2015

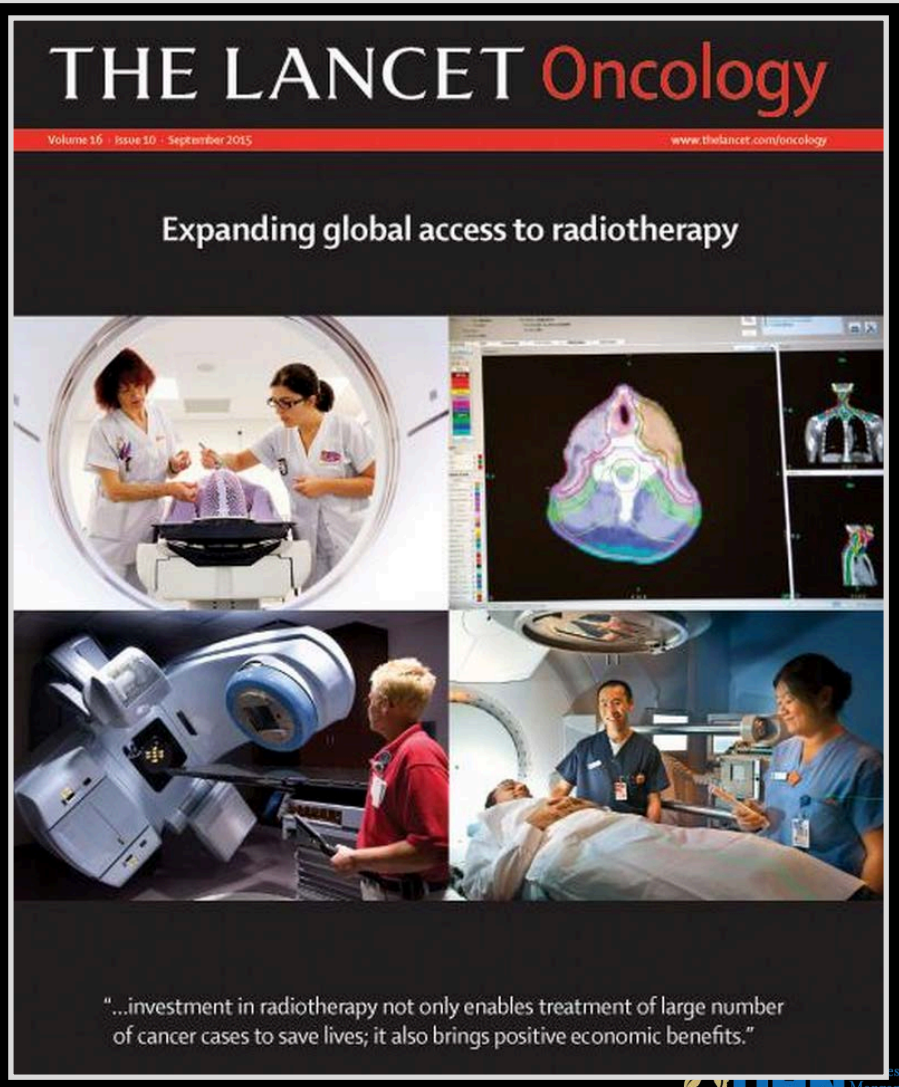
Global cancer surgery: delivering safe, affordable, and timely cancer surgery

Richard Sullivan, Olusegun Isaac Alatise, Benjamin O Anderson, Riccardo Audisio, Philippe Autier, Ajay Aggarwal, Charles Balch, Murray F Brennan, Anna Dare, Anil D'Cruz, Alexander M M Eggermont, Kenneth Fleming, Serigne Magueye Gueye, Lars Hagander, Cristian A Herrera, Hampus Holmer, André M Ilbawi, Anton Jarnheimer, Jia-fu Ji, T Peter Kingham, Jonathan Liberman, Andrew J M Leather, John G Meara, Swagoto Mukhopadhyay, Shilpa S Murthy, Sherif Omar, Groesbeck P Parham, C S Pramesh, Robert Riviello, Danielle Rodin, Luiz Santini, Shailesh V Shrikhande, Mark Shrime, Robert Thomas, Audrey T Tsunoda, Cornelis van de Velde, Umberto Veronesi, Dehannathparambil Kottarathil Vijaykumar, David Watters, Shan Wang, Yi-Long Wu, Moez Zeiton, Arnie Purushotham



Expanding global access to radiotherapy

Rifat Atun, David A Jaffray, Michael B Barton, Freddie Bray, Michael Baumann, Bhadrasain Vikram, Timothy P Hanna, Felicia M Knaul, Yolande Lievens, Tracey Y M Lui, Michael Milosevic, Brian O'Sullivan, Danielle L Rodin, Eduardo Rosenblatt, Jacob Van Dyk, Mei Ling Yap, Eduardo Zubizarreta, Mary Gospodarowicz



Closing the Equity Gap: *Radiotherapy*

The Lancet Oncology Commission

Expanding global access to radiotherapy

Lancet Oncol 2015; 16: 1153–86

Rifat Atun, David A Jaffray, Michael B Barton, Freddie Bray, Michael Baumann, Bhadrasain Vikram, Timothy P Hanna, Felicia M Knaul, Yolande Lievens, Tracey Y M Lui, Michael Milosevic, Brian O'Sullivan, Danielle L Rodin, Eduardo Rosenblatt, Jacob Van Dyk, Mei Ling Yap, Eduardo Zubizarreta, Mary Gospodarowicz

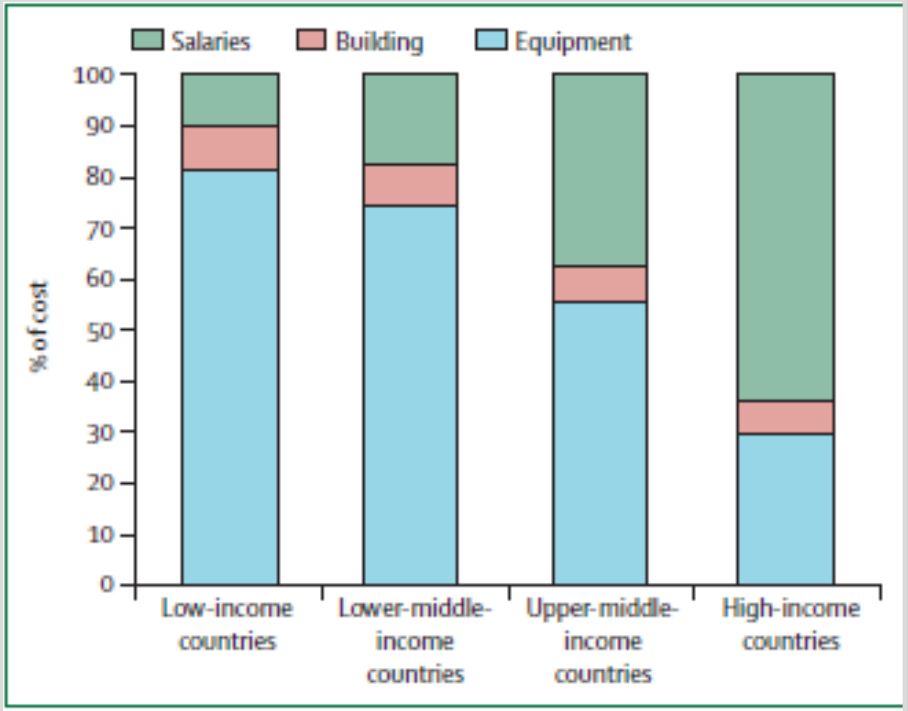


Figure 8: Cost breakdown for salaries, buildings, and equipment needed for radiotherapy, by gross-national-income region

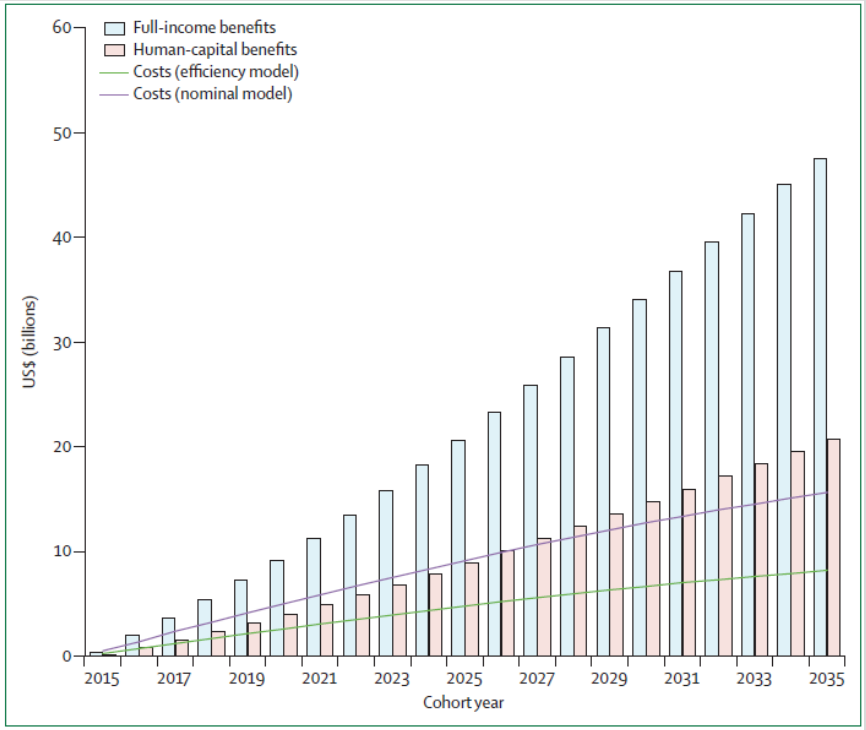


Figure 11: Cost and benefits of investments to scale up radiotherapy services in low-income and middle-income countries, 2015–35
The costing models are described in the text and include both operational and capital costs.

Lancet 2017; 389: 403–76

Essential medicines for universal health coverage

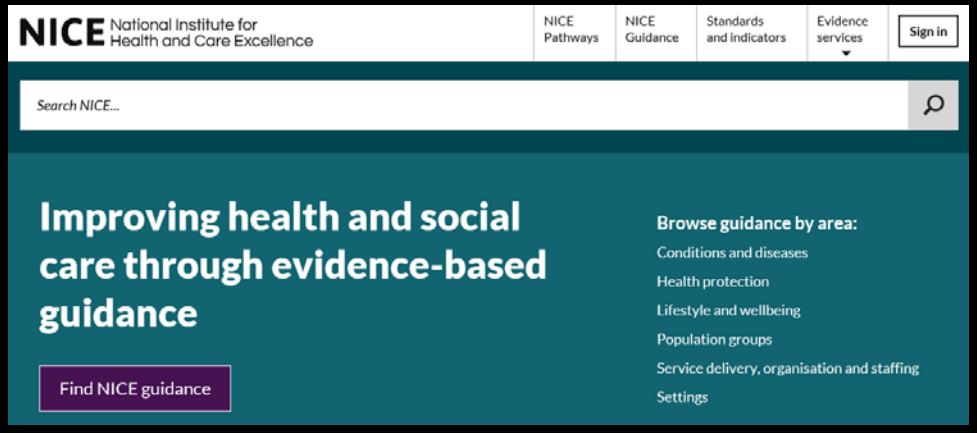
Veronika J Wirtz*, Hans V Hogerzeil*, Andrew L Gray*, Maryam Bigdeli, Cornelis P de Joncheere, Margaret A Ewen, Martha Gyansa-Lutterodt, Sun Jing, Vera L Luiza, Regina M Mbindyo, Helene Möller, Corrina Moucheraud, Bernard Pécoul, Lembit Rägo, Arash Rashidian, Dennis Ross-Degnan, Peter N Stephens, Yot Teerawattananon, Ellen F M 't Hoen, Anita K Wagner, Prashant Yadav, Michael R Reich

- Problems:
  - Overuse
  - Underuse
  - Misuse
  - Unnecessary use of highly priced medicine

Also 'substandard and falsified medicines'

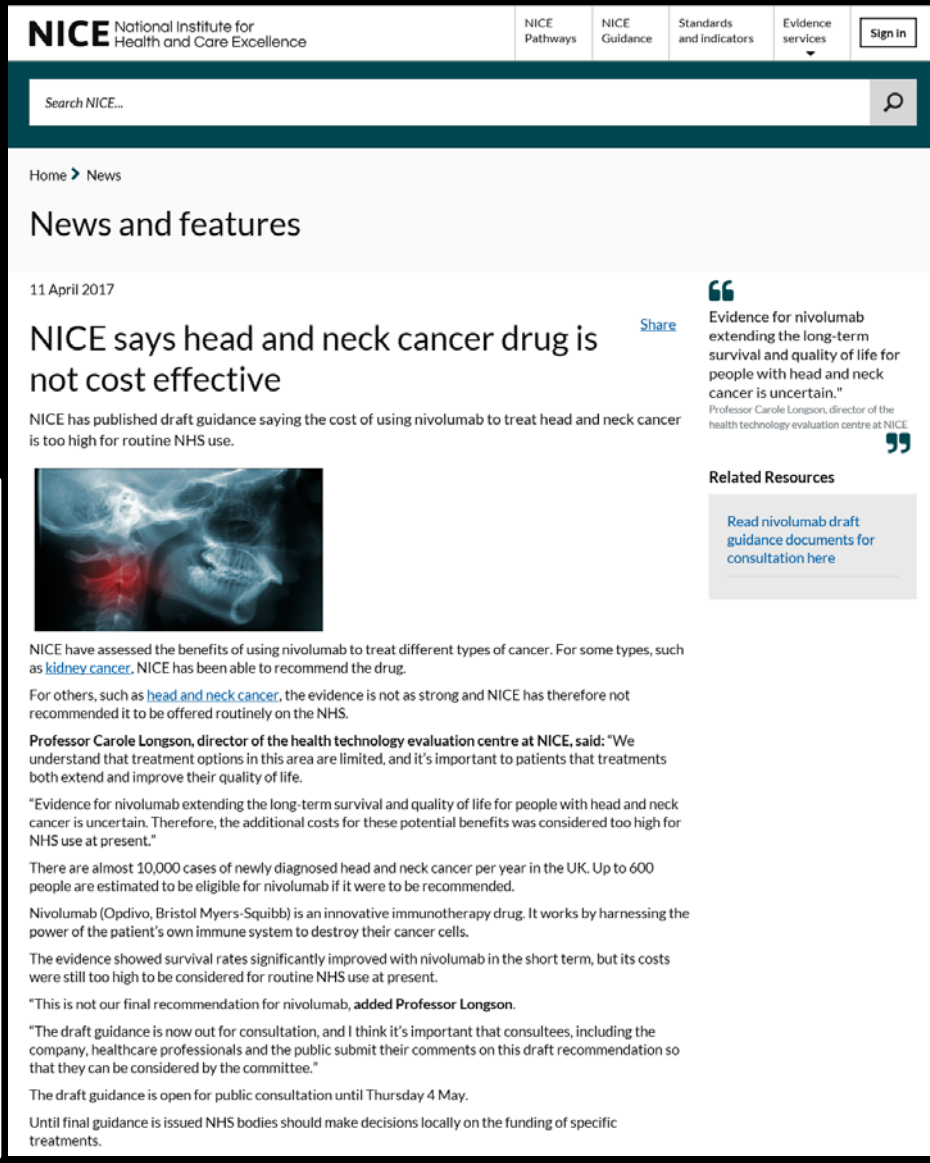
-related correspondence

- Initiatives:
  - Paying for a basket of essential medicines
  - Making essential medicine affordable
  - Promoting quality use of essential medicines
  - Developing missing essential medicines

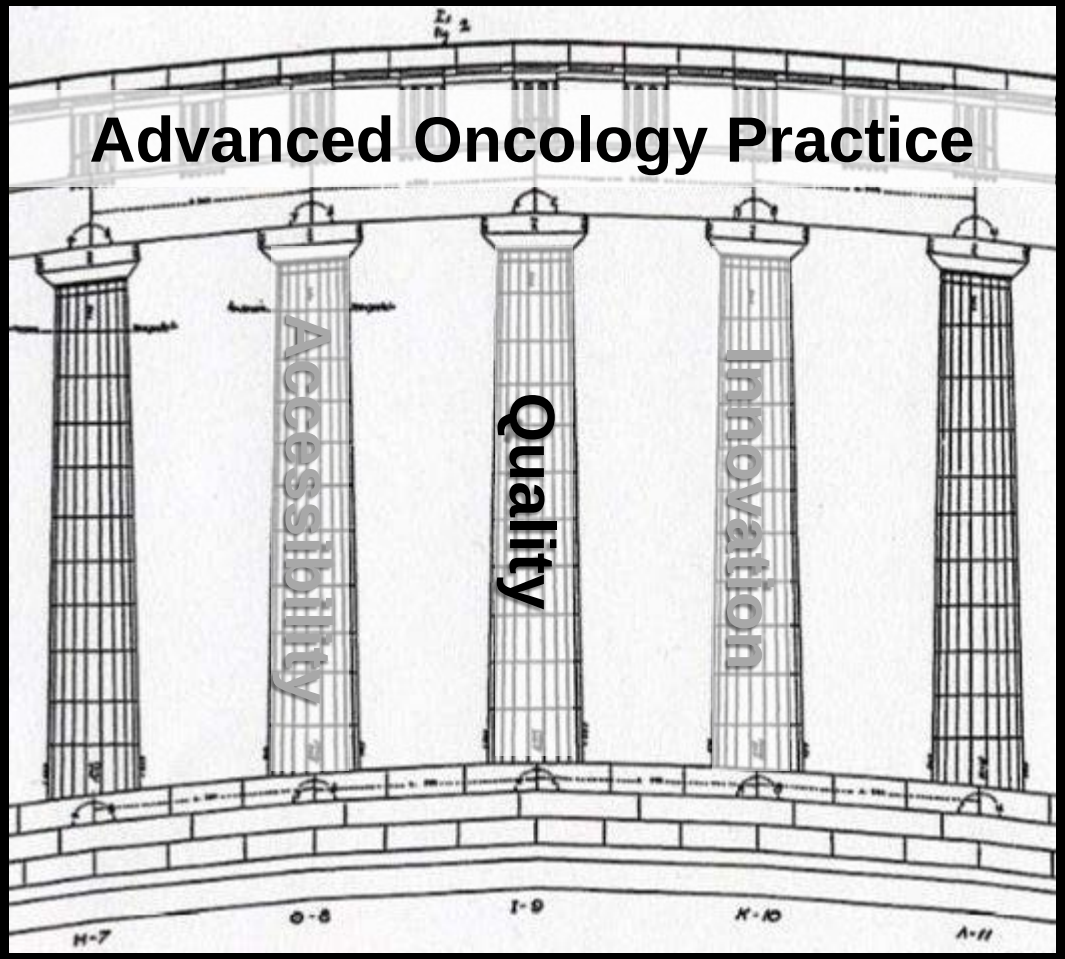


Evidence-based guidance and advice

- Since 1999, we have provided the NHS, and those who rely on it for their care
- range of advice on effective, good value healthcare
- reputation for rigor, independence and objectivity



Essential Pillar: Quality



Stylobate: Fundamental Components of Cancer Care

- Quality:
  - Standards
  - Guidelines
  - Peer-reviewed quality assurance
  - Timely feedback loop

Standards and Guidelines

Standards (things to be accomplished):

- Statements to facilitate performance:
  - Articulate “desirable” levels of performance
  - Describe expected outcomes

Guidelines (ways to do things):

- Statements of principles/procedures to facilitate:
  - Quality in practice (clinical, biomedical research, and health services)
  - Patient care decisions

Cancer Care Ontario
Action Cancer Ontario

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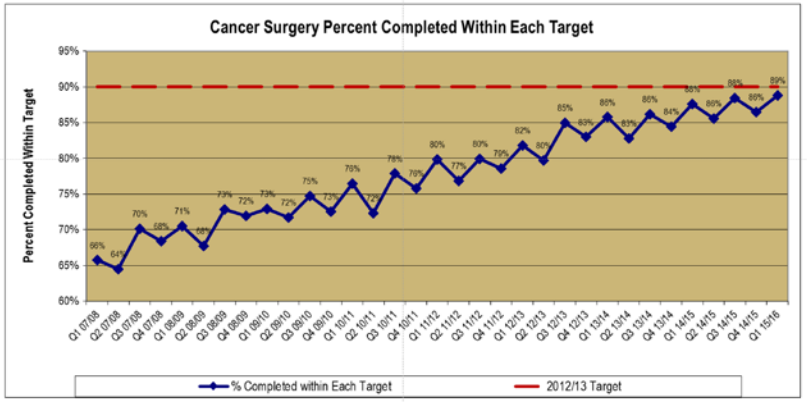
  - Clinical Programs
  - Quality & Performance Improvement
  - Regional Cancer Programs
  - Wait Times
    - Understanding Wait Times
    - Radiation Treatment Wait Times
    - Systemic Treatment Wait Times
    - CCO Wait Time Information Office
    - Wait Times Highlights
    - Surgical and Diagnostic Wait Times Reporting
    - Wait Times Toolkit - Surgery
  - Alternate Level of Care

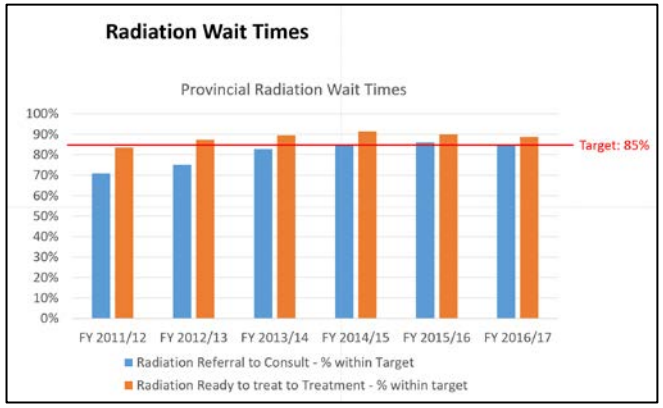
Wait Times Measurement Toolkit and Resources for Cancer Surgery

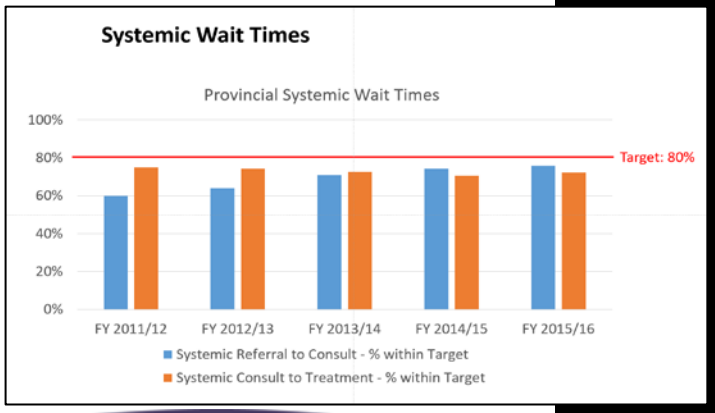
Surgical Wait Times - Decision to Treat to Surgery



Related Resources

- Wait Time Targets for Cancer Treatments: Executive Summary
- Surgical Oncology Program





- Radiotherapy ‘waiting’ has disappeared in Ontario

Ontario
Cancer Care Ontario
Action Cancer Ontario

Radiation Oncology UNIVERSITY OF

UHN Princess Margaret Cancer Centre

VOLUME 28 · NUMBER 18 · JUNE 20 2010

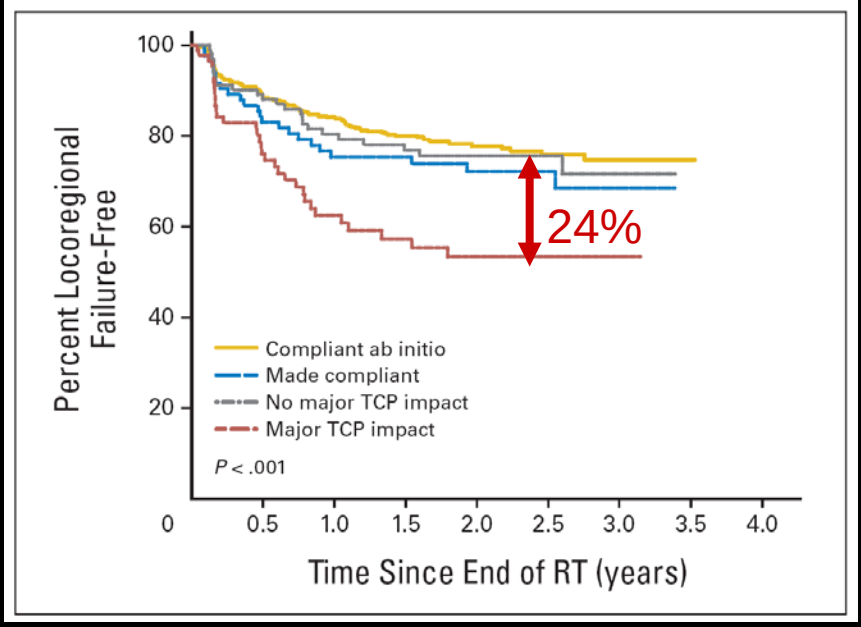
JOURNAL OF CLINICAL ONCOLOGY

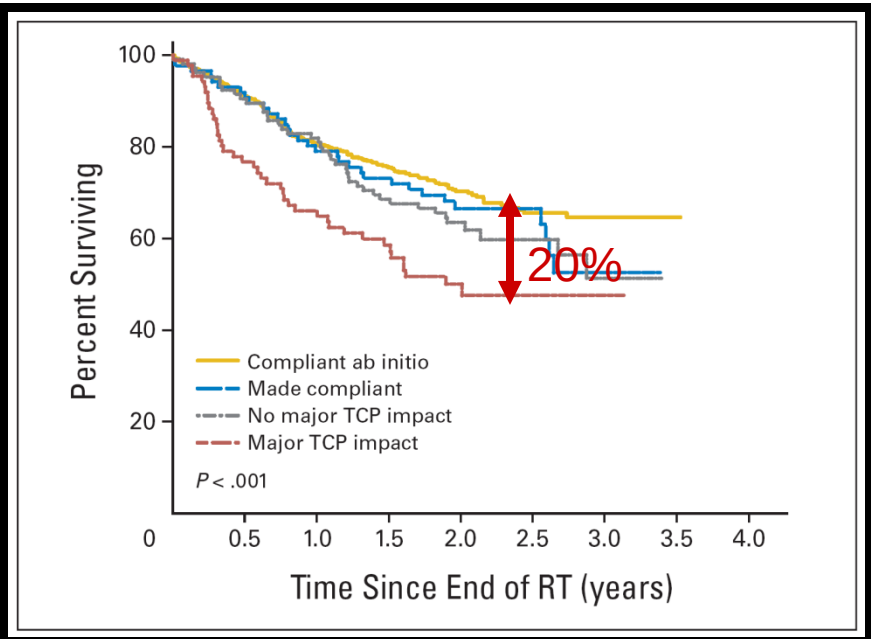
ORIGINAL REPORT

- >800 patients across four Continents
- Influence by center' accrual numbers
- Multivariate adjustment for disease stage

Critical Impact of Radiotherapy Protocol Compliance and Quality in the Treatment of Advanced Head and Neck Cancer: Results From TROG 02.02

Lester J. Peters, Brian O'Sullivan, Jordi Giralt, Thomas J. Fitzgerald, Andy Trotti, Jacques Bernier, Jean Bourhis, Kally Yuen, Richard Fisher, and Danny Rischin





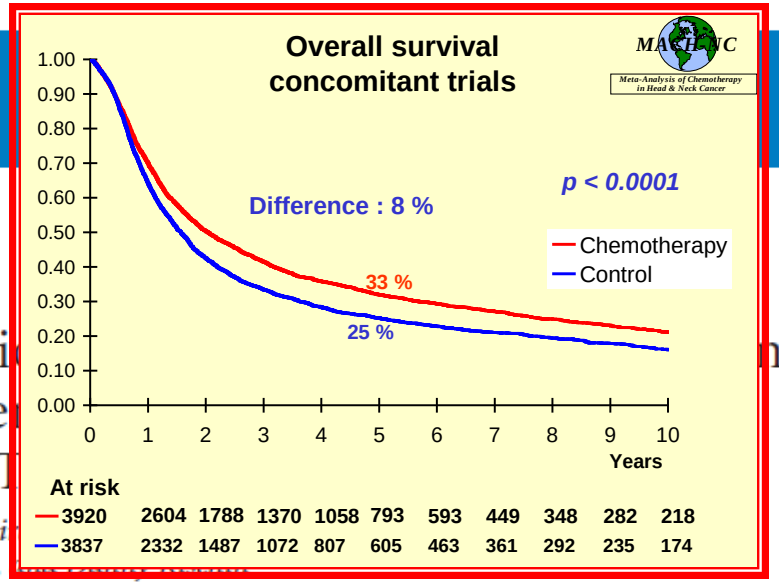
Radiation Quality Matters: Results by deviation status

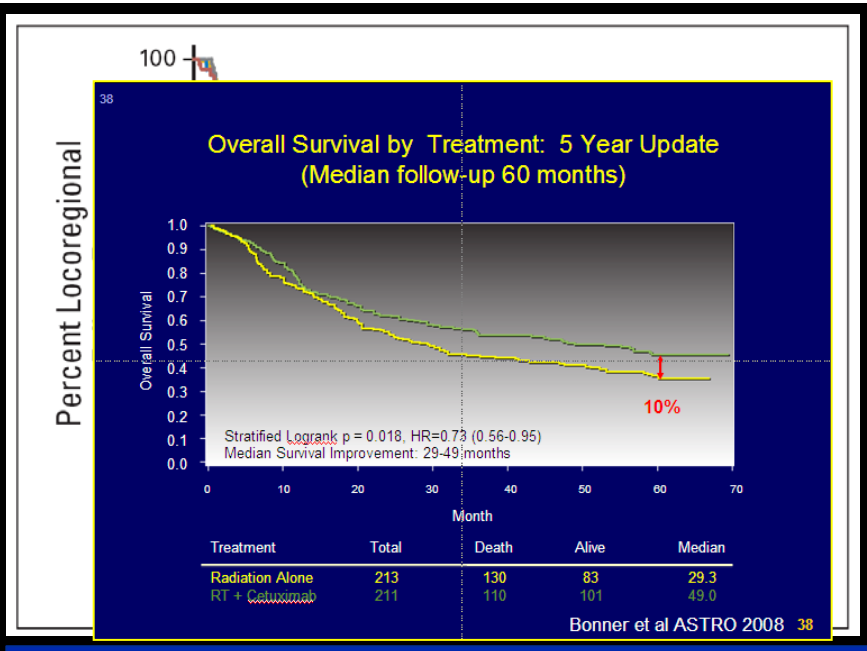
VOLUME 28 · NUMBER 18 · JUNE 20 2010

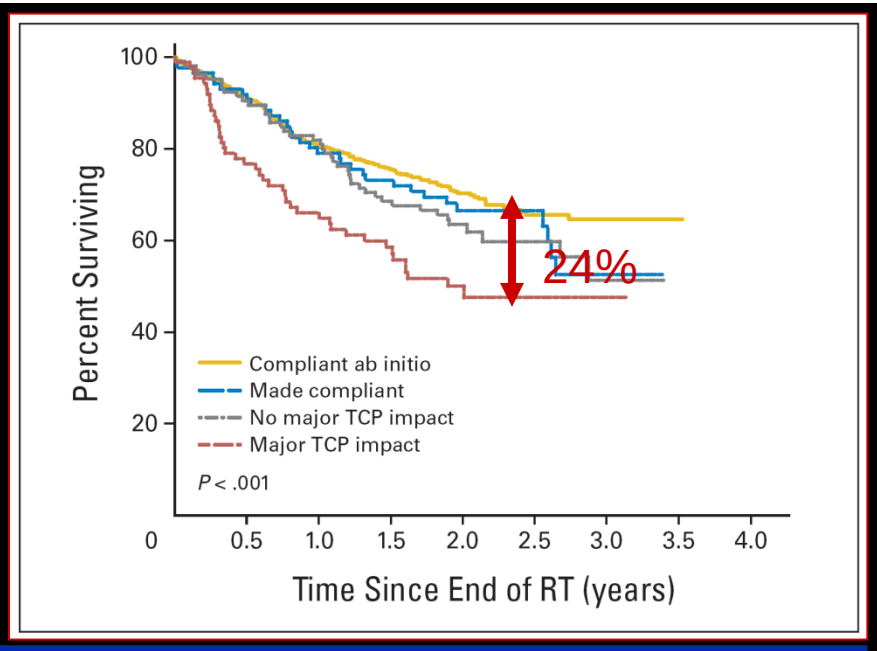
JOURNAL OF CLINICAL ONCOLOGY

Critical Impact of Radi… Quality in the Treatme… Cancer: Results From T…

Lester J. Peters, Brian O'Sullivan, Jordi Gi… Jean Bourhis, Kally Yuen, Richard Fisher, …







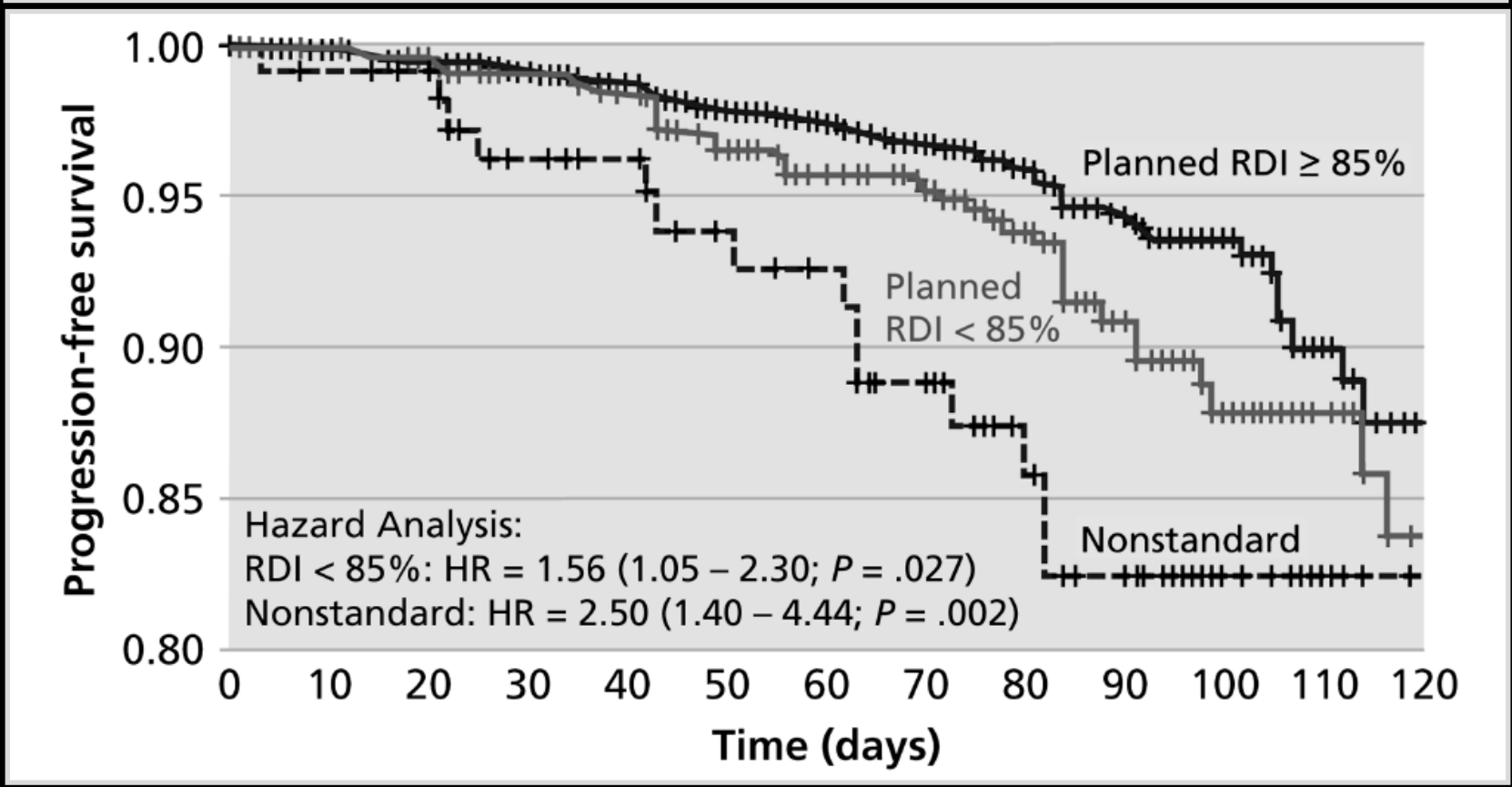
Radiation Quality Greater impact on outcome than new treatment

Impact of Chemotherapy Dose Intensity on Cancer Patient Outcomes

JNCCN The official journal of the National Comprehensive Cancer Network®

(*JNCCN* 2009;7:99–108)

Gary H. Lyman, MD, MPH, FRCP (Edin), *Durham, North Carolina*



RDI: relative dose intensity

Oncologist's Experience Matters: *Surgery*

Original Research—Head and Neck Surgery

AMERICAN ACADEMY OF OTOLARYNGOLOGY–HEAD AND NECK SURGERY FOUNDATION

Transoral Robotic Surgery: A Population-Level Analysis

2014

Michelle M. Chen[1], Sanziana A. Roman, MD[2], Dennis H. Kraus, MD[3], Julie A. Sosa, MD[2], and Benjamin L. Judson, MD[1]

Otolaryngology–Head and Neck Surgery
2014, Vol. 150(6) 968–975

DOI: 10.1177/0194599814525747
http://otojournal.org
SAGE

- NCDB database: 877 patients
- TORS 2010-2011
- High-volume (vs. low-volume) TORS centers had lower rate of positive margins (16% vs 26%, $p<0.001$) and unplanned readmissions (3% vs 6%, $p=0.03$)

RT QA Rounds: Constructive culture without penalty

QA Initiative:
Radiation Medicine

- Needed because we make mistakes
- As treatment complexity increases we are more susceptible to mistakes
- As treatment conformality increases so does the requirement for correct target selection

Why do we need these?

- Once weekly
  - Multidisciplinary among RMP professionals
  - Real time audit
- Case presentation
  - Clinical description
  - Imaging
  - Planning CT with contoured volumes
    - GTV (primary and nodal)
    - HTV (“High Risk” post operative tissues at risk)
    - All associated CTVs

Clinical Investigation

International Journal of Radiation Oncology biology • physics

www.redjournal.org

Prospective Qualitative and Quantitative Analysis of Real-Time Peer Review Quality Assurance Rounds Incorporating Direct Physical Examination for Head and Neck Cancer Radiation Therapy

Carlos E. Cardenas, MS,* Abdallah S.R. Mohamed, MD, MS,†,‡ Randa Tao, MD,† Andrew J.R. Wong, BS,† Mussadiq J. Awan, MD,† Shirly Kuruvila, BS, CMD,† Michalis Aristophanous, PhD,* G. Brandon Gunn, MD,† Jack Phan, MD, PhD,† Beth M. Beadle, MD, PhD,† Steven J. Frank, MD,† Adam S. Garden, MD,† William H. Morrison, MD,† Clifton D. Fuller, MD, PhD,† and David I. Rosenthal, MD†

MDACC Data

Cardenas, Rosenthal et al. IJROBP, 2016 (in-press)

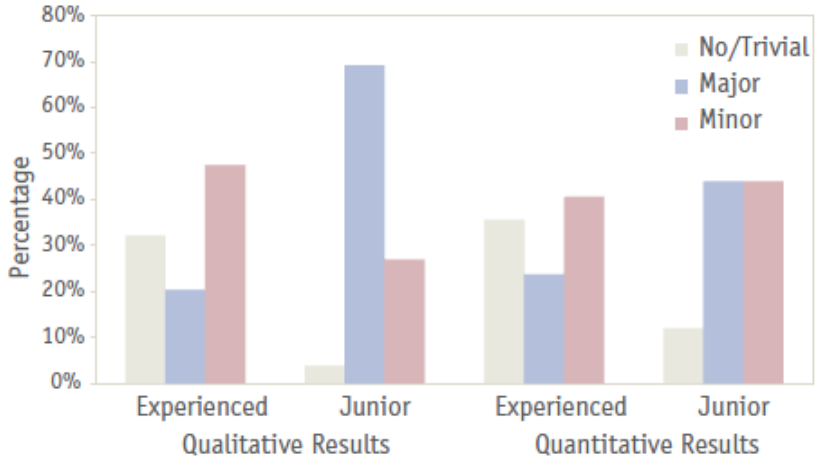


Fig. 2. Percentage for each type of qualitative and quantitative change per physician experience. Quantitative change type was determined according to Dice similarity coefficient classification.

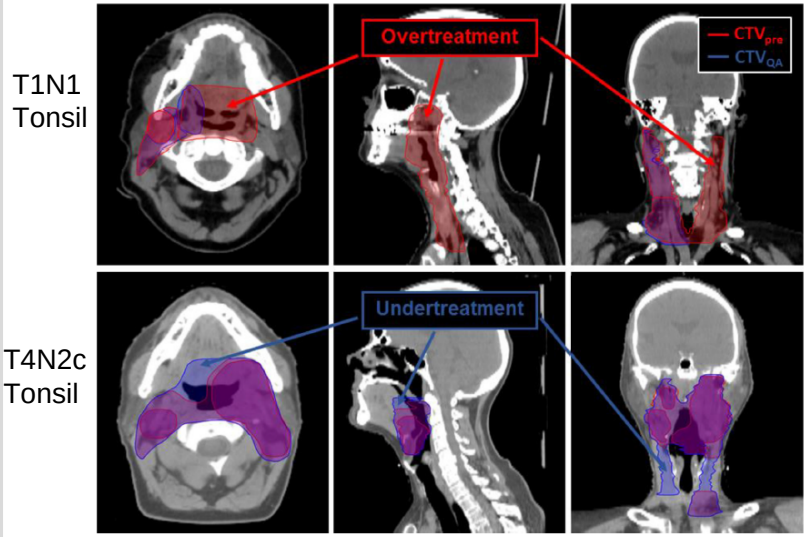


Fig. 1. Patient images showing differences in clinical target volume (CTV) changes and their effect on false-negative Dice (*FND*) and false-positive Dice (*FPD*) metrics. Top row, simulation CT images for a patient with T1N1 cancer of the right tonsil. Differences in contours before (red) and after (blue) quality assurance (QA) are visualized. For this patient, high *FND* and Dice similarity coefficient (overtreatment) values were recorded for CTV1 and CTV3, as can be visually assessed on the axial and coronal images. Bottom row, a patient with T4N2c of the left tonsil who was treated with definitive radiation therapy. CTV volumes after QA (blue) show regions that were added and could be considered potential near misses.

- Data from a major US cancer center: **1/3** patients had major changes after peer-review
- Although junior physicians had more major changes, experienced ones were not immune from major errors

Impact of Guidelines in Cancer Outcomes

Table 5. Local control by size category of RT Margin

RT margin	Total No.	No. controlled	control %
< 1 cm	47	14	30
1–2 cm	110	95	86
> 2 cm	71	67	94
Total	228	176	77

$p < 0.0001$.

ELSEVIER

Int. J. Radiation Oncology Biol. Phys., Vol. 51, No. 2, pp. 332–343, 2001

0360-3016/01/$–see front matter

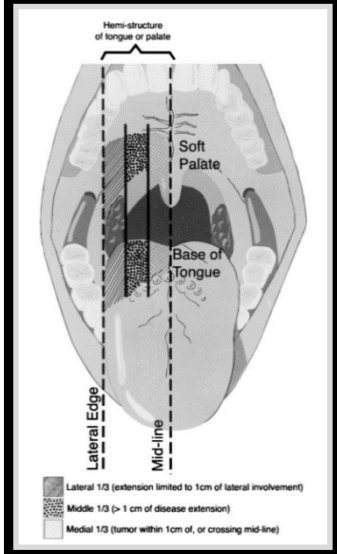
PII S0360-3016(01)01613-3

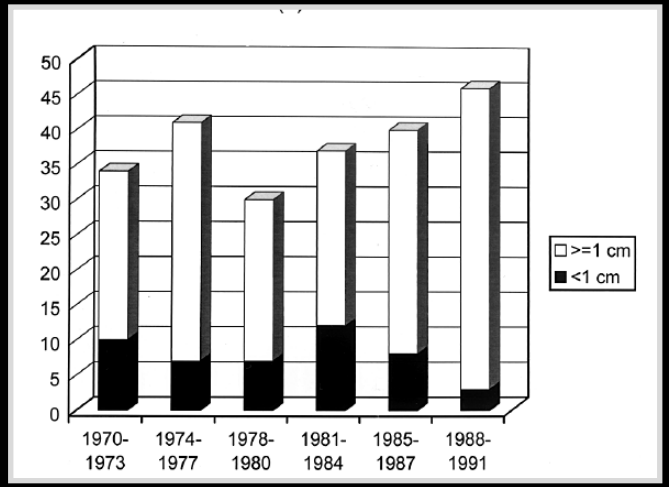
CLINICAL INVESTIGATION Head and Neck

THE BENEFITS AND PITFALLS OF IPSILATERAL RADIOTHERAPY IN CARCINOMA OF THE TONSILLAR REGION

B. O'Sullivan, M.B., F.R.C.P.C.,* P. Warde, M.B., F.R.C.P.C.,* B. Grice, M.R.T.(T),* C. Goh, M.B., F.R.C.S.,† D. Payne, M.D., F.R.C.P.C.,* F-F. Liu, M.D., F.R.C.P.C.,* J. Waldron, M.D., F.R.C.P.C.,* A. Bayley, M.D., F.R.C.P.C.,* J. Irish, M.D., F.R.C.P.C.,† P. Gullane, M.B., F.R.C.S.C.,† and B. Cummings, M.B., F.R.C.P.C.*

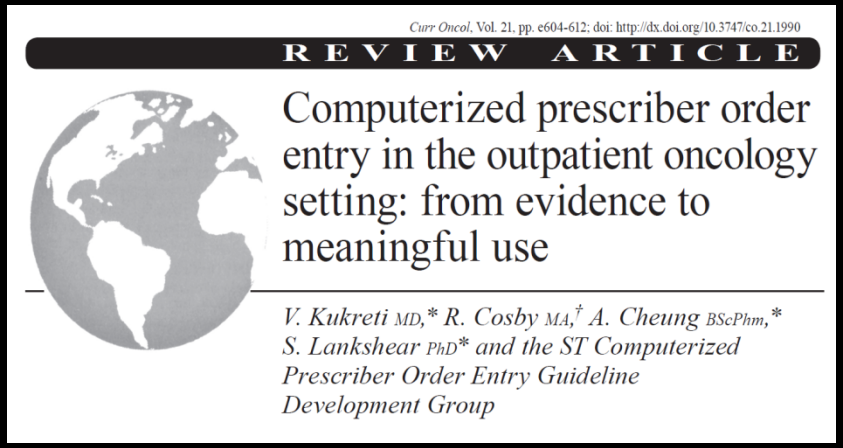
- A change to better coverage of the target volume coincided with the introduction of written policies
  - Policies required 2 cm clinical target volume (CTV) coverage around gross tumor volume (GTV)
  - Planning 3D volumes without CT planning was abandoned at PMH





UHN Princess Margaret Cancer Centre

QA Initiative:
Medical Oncology



Curr Oncol, Vol. 21, pp. e604-612; doi: http://dx.doi.org/10.3747/co.21.1990

REVIEW ARTICLE

Computerized prescriber order entry in the outpatient oncology setting: from evidence to meaningful use

V. Kukreti MD, R. Cosby MA,† A. Cheung BScPhm,* S. Lankshear PhD* and the ST Computerized Prescriber Order Entry Guideline Development Group*

Kukrett et al 2014

- "Computerized prescriber order entry" (CPOE) should be used in outpatient chemotherapy to reduce chemotherapy-related medication errors
- Adoption will be enhanced by CPOE processes that complement current practice and workflow processes

QA Initiative:
Surgical Practice

N Engl J Med 2009;360:491-9.

The NEW ENGLAND JOURNAL of MEDICINE

A Surgical Safety Checklist to Reduce Morbidity and Mortality in a Global Population

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Table 5. Outcomes before and after Checklist Implementation, According to Site.*

Site No.	No. of Patients Enrolled		Surgical-Site Infection		Unplanned Return to the Operating Room		Pneumonia		Death		Any Complication	
	Before	After	Before	After	Before	After	Before	After	Before	After	Before	After
							percent					
1	524	598	**4.0**	**2.0**	**4.6**	**1.8**	0.8	1.2	**1.0**	**0.0**	**11.6**	**7.0**
2	357	351	2.0	1.7	0.6	1.1	3.6	3.7	1.1	0.3	7.8	6.3
3	497	486	5.8	4.3	4.6	2.7	1.6	1.7	0.8	1.4	13.5	9.7
4	520	545	3.1	2.6	2.5	2.2	0.6	0.9	1.0	0.6	7.5	5.5
5	370	330	**20.5**	**3.6**	1.4	1.8	0.3	0.0	**1.4**	**0.0**	**21.4**	**5.5**
6	496	476	4.0	4.0	3.0	3.2	2.0	1.9	3.6	1.7	10.1	9.7
7	525	585	**9.5**	**5.8**	**1.3**	**0.2**	1.0	1.7	2.1	1.7	**12.4**	**8.0**
8	444	584	4.1	2.4	0.5	1.2	0.0	0.0	1.4	0.3	6.1	3.6
Total	3733	3955	**6.2**	**3.4**	**2.4**	**1.8**	1.1	1.3	**1.5**	**0.8**	**11.0**	**7.0**
P value			<0.001		0.047		0.46		0.003		<0.001	

* The most common complications occurring during the first 30 days of hospitalization after the operation are listed. Bold type indicates values that were significantly different (at $P<0.05$) before and after checklist implementation, on the basis of P values calculated by means of the chi-square test or Fisher's exact test. P values are shown for the comparison of the total value after checklist implementation as compared with the total value before implementation.

Contents lists available at ScienceDirect

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journal homepage: www.elsevier.com/locate/clon

Original Article

Laryngeal Cancer Treatment and Survival Differences across Regional Cancer Centres in Ontario, Canada

P.A. Groome *, B. O'Sullivan †, W.J. Mackillop *, J. Irish ‡, K. Schulze *, L.D. Jackson *, R.J. Bissett §, P.F. Dixon §, L.J. Eapen §, S.P. Gulavita §, J.A. Hammond §, D.I. Hodson §, R.G. Mackenzie §, K.M. Schneider §, P.R. Warde †

Multivariate analysis:

- cause-specific survival differences
- not explained by control for case-mix, treatment or waiting times.

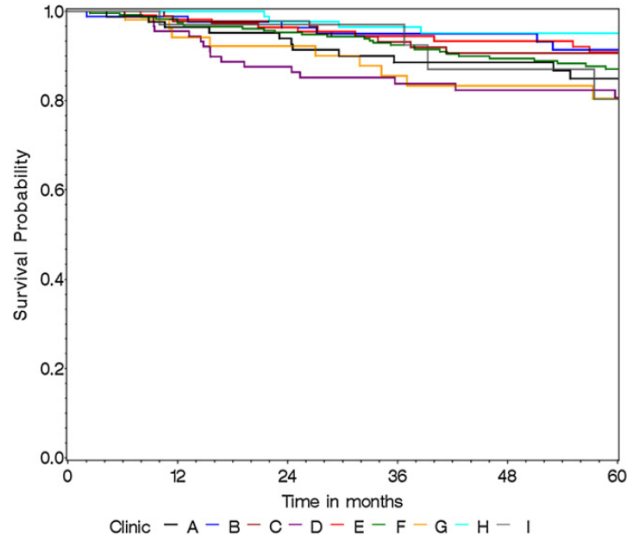


Fig. 1. Stage I and II laryngeal cancer: cause-specific survival by regional cancer centre. (Log-rank $P = 0.06$).

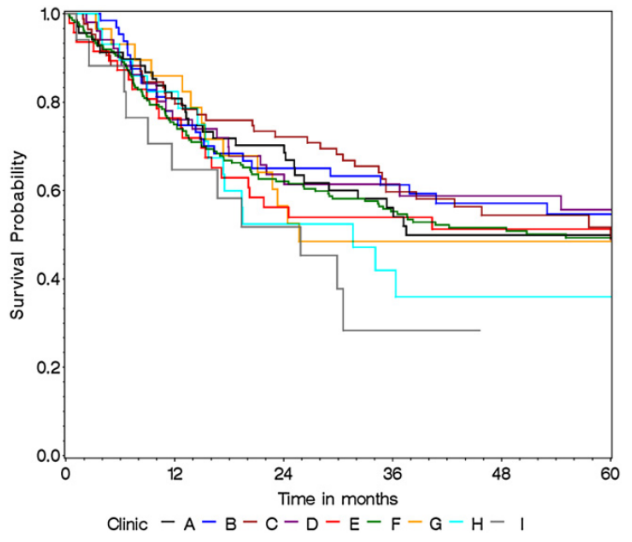


Fig. 2. Stage III and IV laryngeal cancer: cause-specific survival by regional cancer centre (Log-rank $P = 0.58$).

Differences ranged compared with reference (centre A) adjusting for covariates:

- Stage I and II group: 82% risk reduction in one centre (P = 0.008)
- Stage III and IV group: 153% increase in risk (P = 0.02).

cancer care ontario | action cancer ontario
program in evidence-based care | programme de soins fondé sur des preuves

The Management of Head and Neck Cancer in Ontario

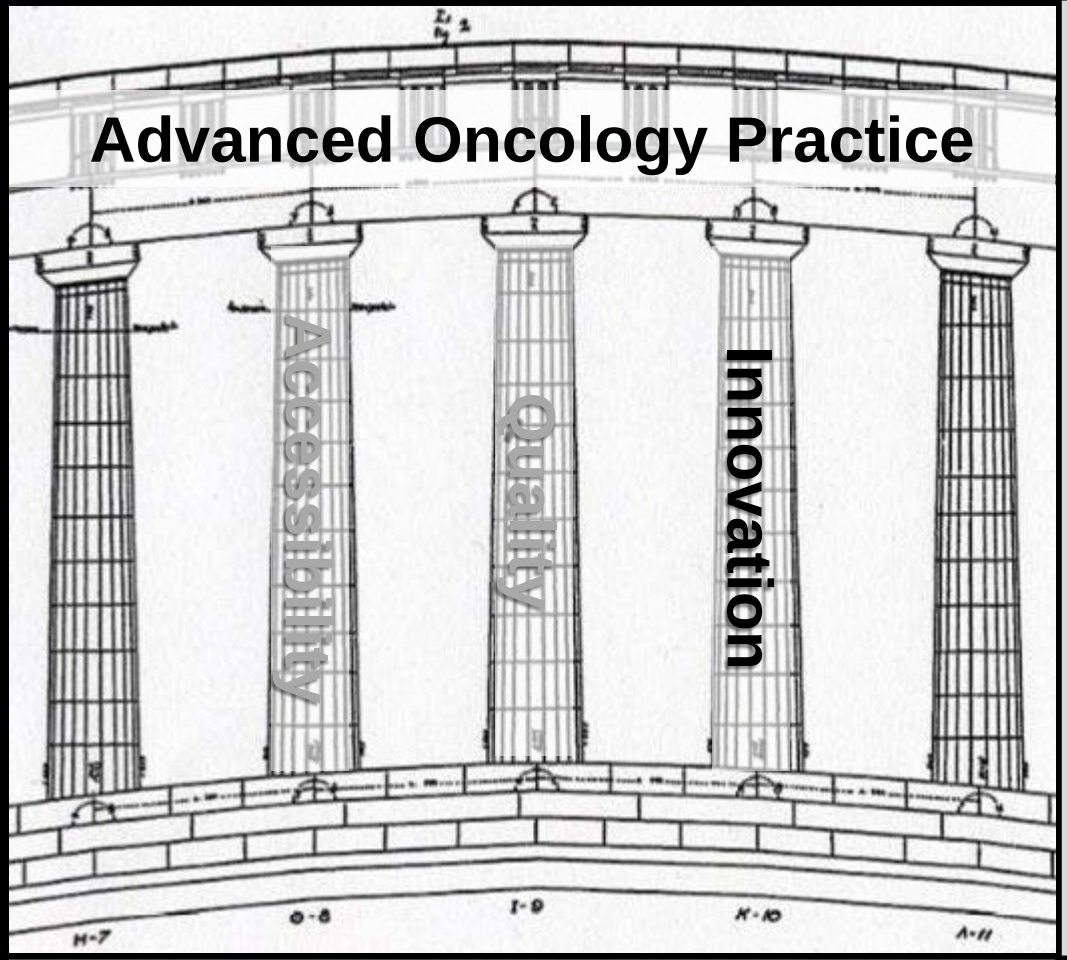
R Gilbert, M Devries-Aboud, E Winquist, J Waldron, M McQuestion, and the Head and Neck Disease Site Group

A Quality Initiative of the
Program in Evidence-Based Care (PEBC), Cancer Care Ontario (CCO)

Report Date: December 15, 2009

Core Team Member	*Recommendations for minimum volumes required*
Surgery/ Oncology	Assess 50 new patients and major surgery* on 40 patients per year *(Source: HNMWG* and NICE)*
Surgery/Reconstructive	20 microsurgery cases annually *(Source: HNMWG*)*
Medical Oncologist	1.0 FTE per 200 head and neck cancer patients seen in consultation and a minimum of 25 patients treated annually *(Source: NICE)*
Radiation Oncologist	1.0 FTE per 150 head and neck cancer patients seen in consultation and a minimum of 50 patients treated annually *(Source: NICE)*
Specialized Oncology Nurse	1.0 FTE per 100 patients seen in consultation per year *(Source: HNMWG*)*
Advanced Practice Nurse	1.0 FTE per H&N site group (especially with larger site groups seeing > 200 patients in consultation per year OR shared across another site group) *(Source: HNMWG*)*
Speech Language Pathologist	1.0 FTE per 150 patients seen in consultation per year *(Source: HNMWG*)*
Registered Dietitian	1.0 FTE per 150 patients seen in consultation per year *(Source: HNMWG*)*
Social Worker	1.0 FTE per 150 patients seen in consultation per year *(Source: HNMWG*)*

Essential Pillar: Innovation



Stylobate: Fundamental Components of Cancer Care

- Innovation:
  - Gathering information
  - Appraisal of evidence
  - Clinical trials
  - “Disciplined” new approaches

From Health Systems to Learning Health Systems

Best Care at Lower Cost

The Path to Continuously Learning Health Care in America

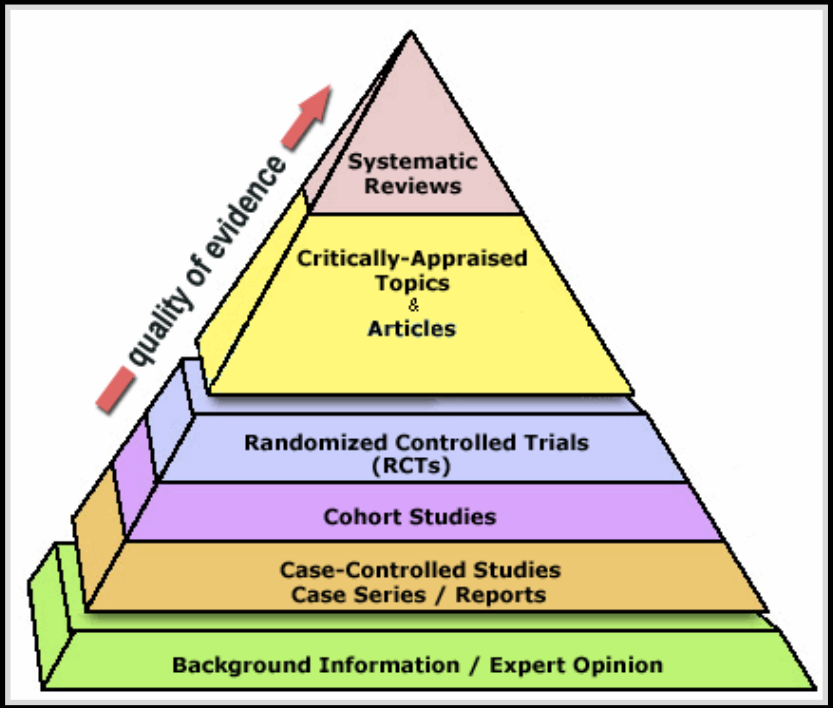
INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

Mark D. Smith, MD, MBA, *Study Chair*

Sources of Evidence

- **Published literature**
  - Various quality: high level of evidence is scant
    - Be aware of publication bias, reporting bias, reviewers' bias, omission bias
- **Official and unofficial communication**
  - Presentations at conference/courses/symposium
    - Subject to bias, especially vendor sponsored symposium
- **Textbooks**
  - Could be out-of-date
- **Guidelines**
  - E.g. NCCN, ASTRO, ASCO, ESTRO, CCO, Institutional
    - Not all guidelines are revised frequently
    - High level of evidence may not always available

The Hierarchy of Published Evidence in Medicine



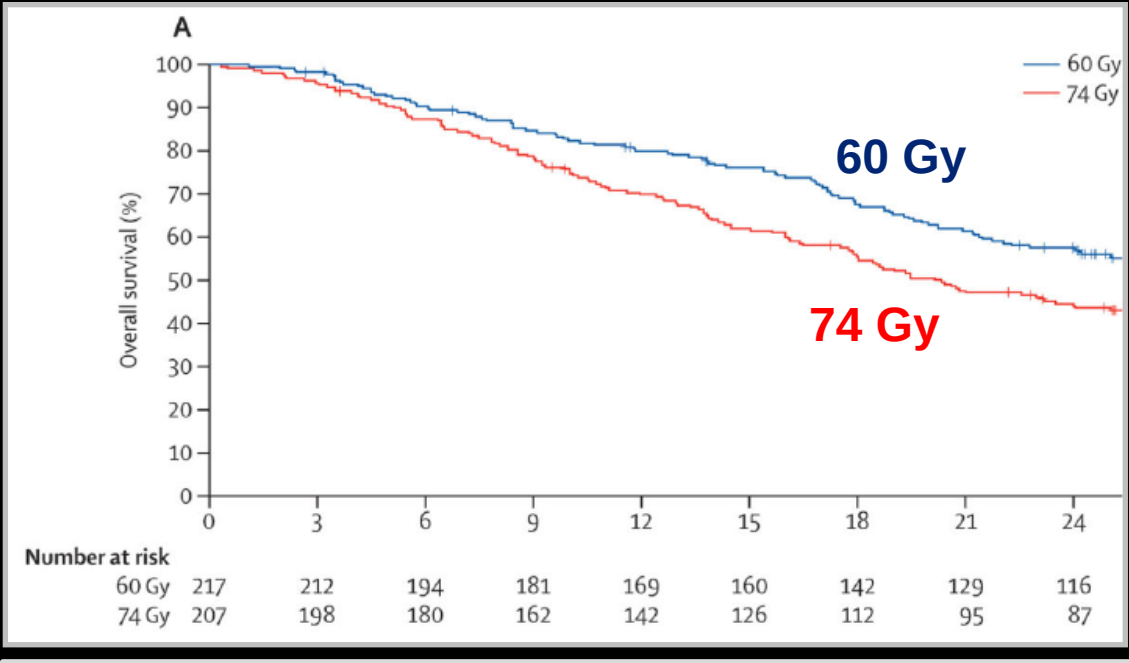
- Major treatment guidelines (e.g. NCCN) making evidence based recommendations
- Strength of recommendations depends on levels of evidence
- Caveats of clinical trials:
  - "*Ideal*" vs "*real*" world
  - Confounding elements

Guyatt et al. JAMA 2000

A '*New*' Approach May Not Always Be Better

Standard-dose versus high-dose conformal radiotherapy with concurrent and consolidation carboplatin plus paclitaxel with or without cetuximab for patients with stage IIIA or IIIB non-small-cell lung cancer (RTOG 0617): a randomised, two-by-two factorial phase 3 study

Jeffrey D Bradley, Rebecca Paulus, Ritsuko Komaki, Gregory Masters, George Blumenschein, Steven Schild, Jeffrey Bogart, Chen Hu, Kenneth Forster, Anthony Magliocco, Vivek Kavadi, Yolanda I Garces, Samir Narayan, Puneeth Iyengar, Cliff Robinson, Raymond B Wynn, Christopher Koprowski, Joanne Meng, Jonathan Beitler, Rakesh Gaur, Walter Curran Jr, Hak Choy

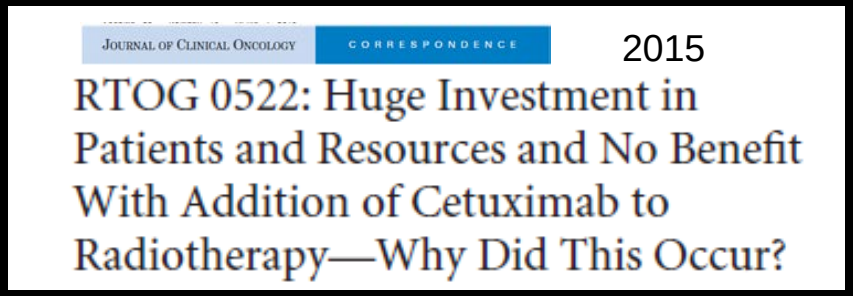


Counter-intuitive result of RTOG 0617

- A planned interim analysis showed:
  - The tested higher RT dose (74 Gy) had lower OS compared with the standard dose of 60 Gy
- On June 17, 2011, two of the four arms in the RTOG 0617 protocol were closed to accrual

Bradley, *et al.*
Lancet Oncol. Feb, 2015

Emphasizes the importance of 'stopping' rules and interim analysis



A large Phase III trial that followed a Phase II trial without preceding Phase I safety data

- Adding cetuximab to cisplatin and accelerated radiation therapy (RT) compared with cisplatin and radiation (CRT) alone:
  - It did not improve outcome
  - It resulted in more interruptions in RT, and more morbidity and treatment-related death
  - "These results are extremely disappointing due to the precipitous study design"
- RTOG 0522 phase III trial was based on a small single centre phase II trial (n=22) that closed early due to adverse events without a prior phase I trial – these investigators had concluded that evaluation of the safety profile was needed
- *My additional comment:*
  - *The standard arm was based on putative superiority of a previous experimental arm but result was not known yet and was never proven.*

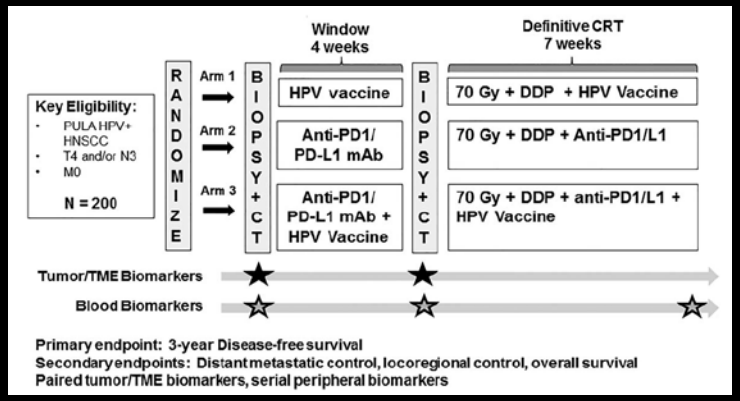
Douglas Adkins, Jessica Ley, Tanya M. Wildes, and Loren Michel
Washington University School of Medicine, St Louis, MO

Communication | NIH NATIONAL CANCER INSTITUTE | Cancer

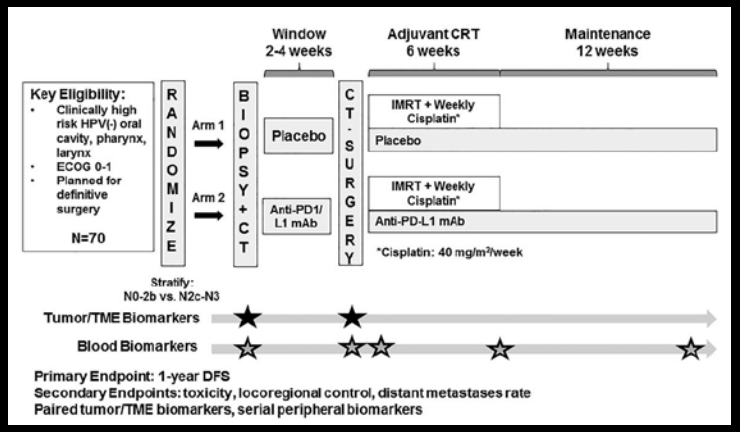
Immunotherapy of Head and Neck Cancer: Emerging Clinical Trials From a National Cancer Institute Head and Neck Cancer Steering Committee Planning Meeting

Julie E. Bauman, MD, MPH[1]; Ezra Cohen, MD[2]; Robert L. Ferris, MD, PhD[3]; David J. Adelstein, MD[4]; David M. Brizel, MD[5]; John A. Ridge, MD, PhD[6]; Brian O'Sullivan, MD[7]; Barbara A. Burtness, MD[8]; Lisa H. Butterfield, PhD[1]; William E. Carson, MD[9]; Mary L. Disis, MD[10]; Bernard A. Fox, PhD[11]; Thomas F. Gajewski, MD, PhD[12]; Maura L. Gillison, MD, PhD[13]; James W. Hodge, PhD, MBA[14]; Quynh-Thu Le, MD[15]; David Raben, MD[16]; Scott E. Strome, MD[17]; Jean Lynn, RN, MPH[18]; and Shakun Malik, MD[18]

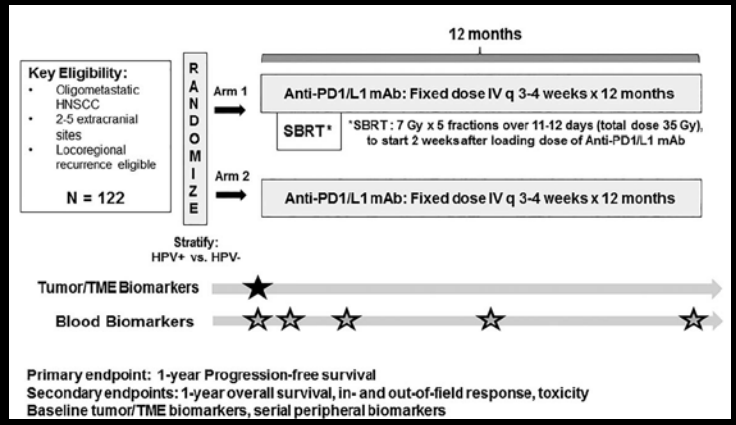
Working Group 1: HPV(+) T4 and N3 Window study: CRT +/- AntiPD1/L1 +/- vaccine



Working Group 2: HPV- Planned for Surgery and Window study: Post-op CRT +/- AntiPD1/L1



Working Group 3: 2-5 extracranial Oligometastases Anti-PD-1/L1 +/- SBRT



Practice evolved: preference for SBRT

Development of “Responsible” New approaches

- Will always exist, underpinned by need to improve:
  - Governed by principles: safety, oversight, regulations
  - Driver is “unmet needs” and shortcomings of existing treatment
    - E.g. problems of compromised management, toxicity, efficiency, cost
- Constant tension governed by:
  - Ethics, innovation, resources, skill-set, culture / tradition, reasonable vs unreasonable expectation
- Many examples (technical/clinical without randomised trials):
  - IMRT, laporoscopic surgery, robotic surgery, imaging (MR / PET)
  - Clinical: “breast conservation”, larynx conservation, limb preservation
- Appropriate principles:
  - Measurement, training, protocols, infrastructure and redundancy

“Only if we identify problems worth solving will we develop solutions worth pursuing”: Azagury D: Stanford Biodesign: “Patient Safety in Surgery” 2014

Summary About Advancing Practice

- Advancing oncology practice requires efforts from all stakeholders:
  - Medical professionals
  - Health care system
  - Society, government, industry
- Essential pillars comprise:
  - Accessibility
    - Building capacity, affordability, public awareness
  - Quality of care
    - Vigilance, monitoring, SOPs
  - Innovation
    - Encouraging “disciplined” novel ideas and generating and interpreting high level of evidence