Negligence and Causation Issues in Cancer Cases

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Who am I?

- Professor of Oncology-clinical academic & consultant oncologist for last 34 years

- Research programmes in imaging of cancer biology with PET & advanced radiotherapy

- Expert in tumour growth rates and behaviour

- Managerial responsibility in private sector

- Secretariat to UK All Party Parliamentary Group on Radiotherapy

- Founder and chair of national charity Radiotherapy UK

- Founder of the UK #Catch up with cancer campaign

- Co-Founder of the Global Coalition for Radiotherapy

Cancer Facts

- 1 in 2 people get cancer in their lifetime

- 30% increase expected by 2040 (CRUK)

- 1 in 3 people die of their cancer

- Most cancers occur over 75 year of age

- Large body of research in tumour biology

What is Cancer

Basic Biology

- Cells grow uncontrolled and abnormally
  - Abnormalities in genes
  - Production of local growth factors
- Grow to develop a tumour. All tumours are different
- Tumour spreads locally
- Tumour metastases-lymphatics/blood/other

Normal cells   Cells forming a tumour
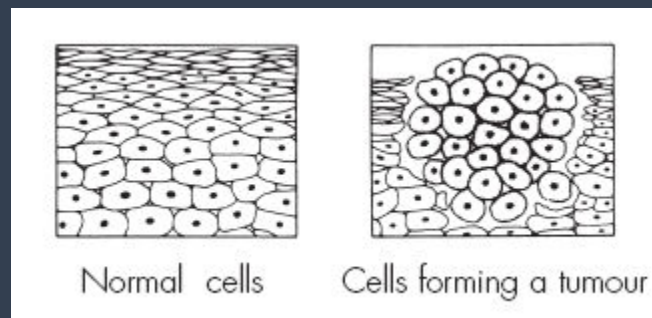
Main arguments in Cancer Cases

- What is stage of the cancer & prognostic factors - treatment & prognosis

- What is the natural history/behaviour/ growth rate of the tumour

- Would treatment and side effects been different?

- Would survival have been extended/Cure?

- All cancers are different

Natural History of Cancer

Pre-malignant → **Malignant-localised** → **Metastatic**

Curable: screening
Cervical: 3-10yrs
Breast: 3-10yrs
Bowel: 5-10yrs
Oesophagus: 2-3yrs

Surgery/adjuvant therapy

Radical radiation

Curable:
Teratoma/Lymphoma

Chemo increase survival
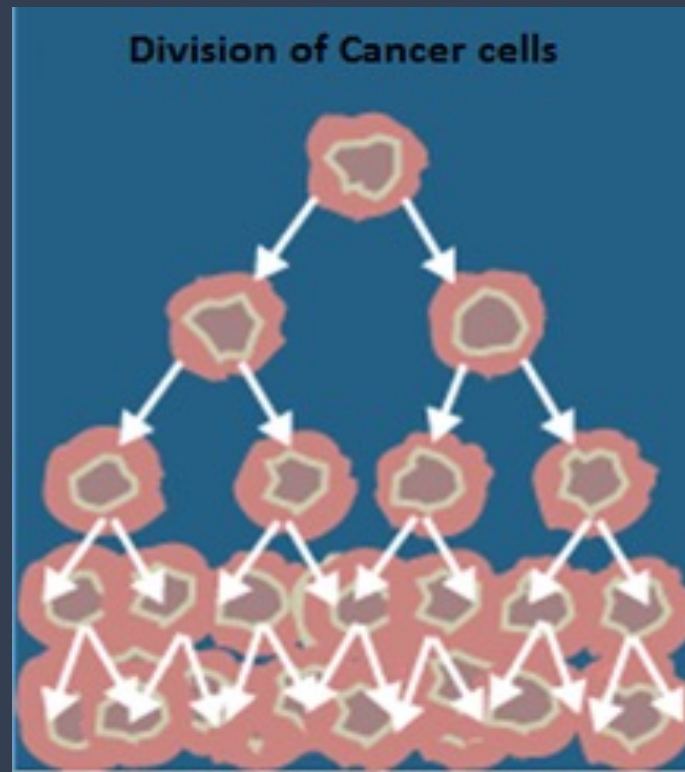Lung: 2months
Colon 3.7+ months
Gastric: 3months
Ovary: years

Chemo given early increase survival: ???

Premalignant stage

-screening programmes
-cervical/mammograms/colonic
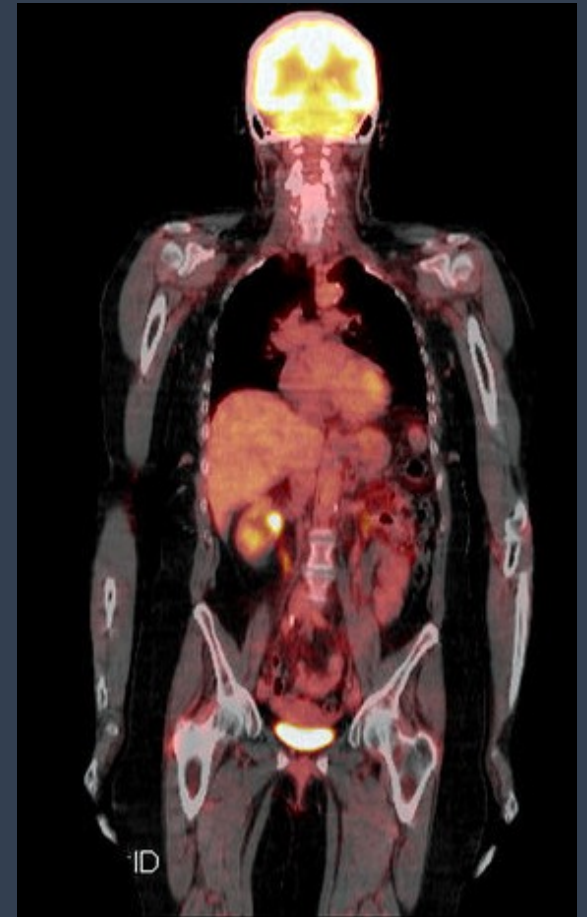-national vs individual

Tumour cell growth

Staging of Cancer TNM

- Primary Tumour T (1-4)

- Regional Lymph nodes N (0-3)

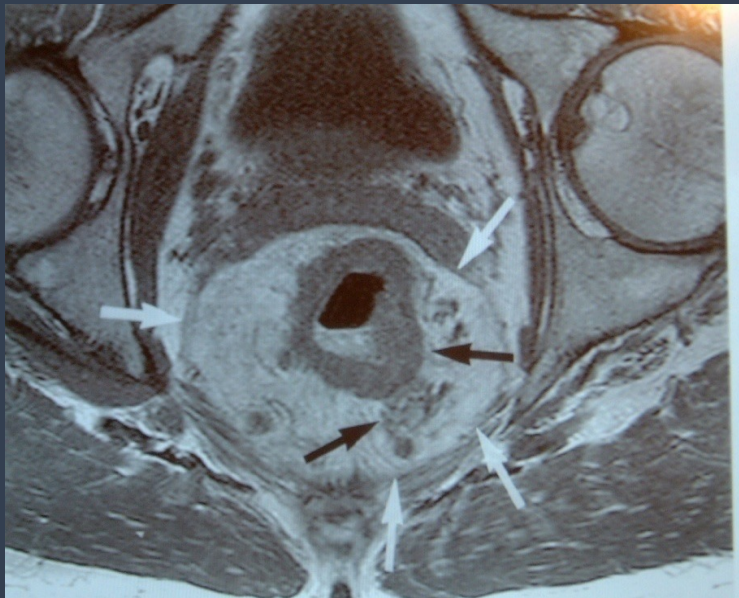- Blood borne spread M (0-1)
  - a/b/c
  - Some alternatives

Staging of cancer

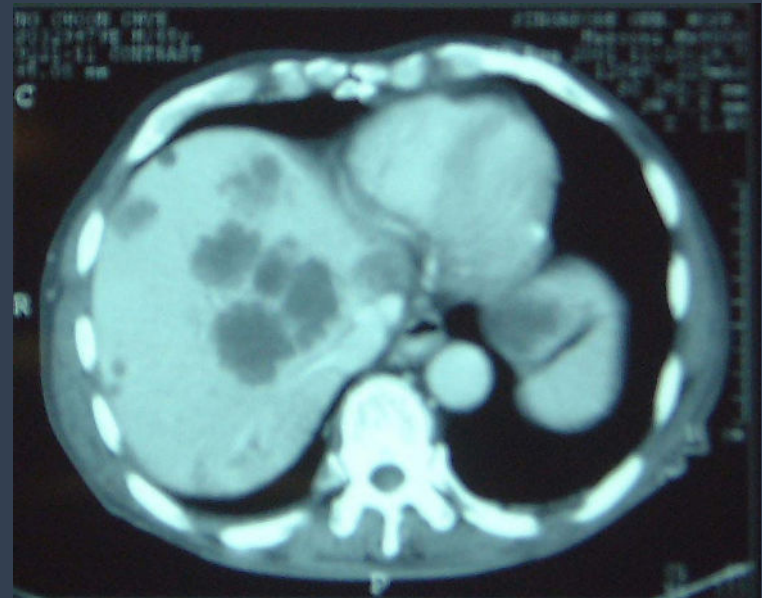TNM UICC classification 8th edition

- Absolute definition

- Clinical vs pathological vs post treatment

- Stage Determines treatment and prognosis

Clinical Staging of Tumours

- Assess
  - Local cancer spread /Distant metastatic spread
  - Decide on treatment at MDT meeting
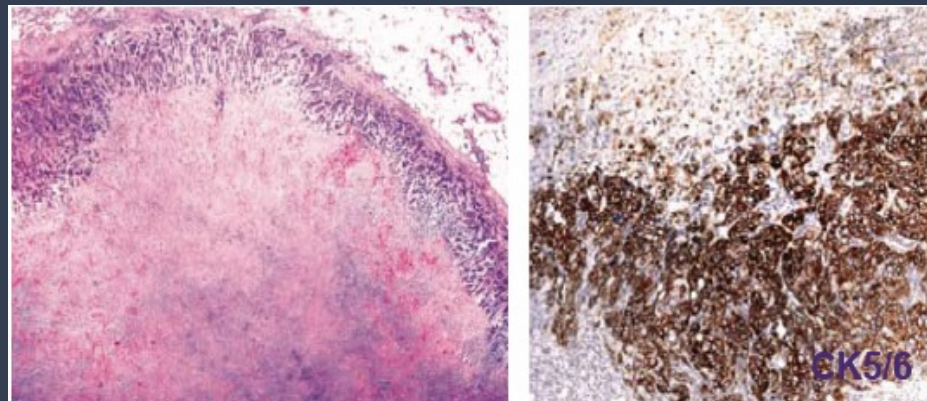

MRI: Rectal cancer

CT: Liver metastases

Histopathology

Cancer under the microscope

- — Prognosis and treatment

- -Pathological staging: pTNM

- -Grading: G1/2/3

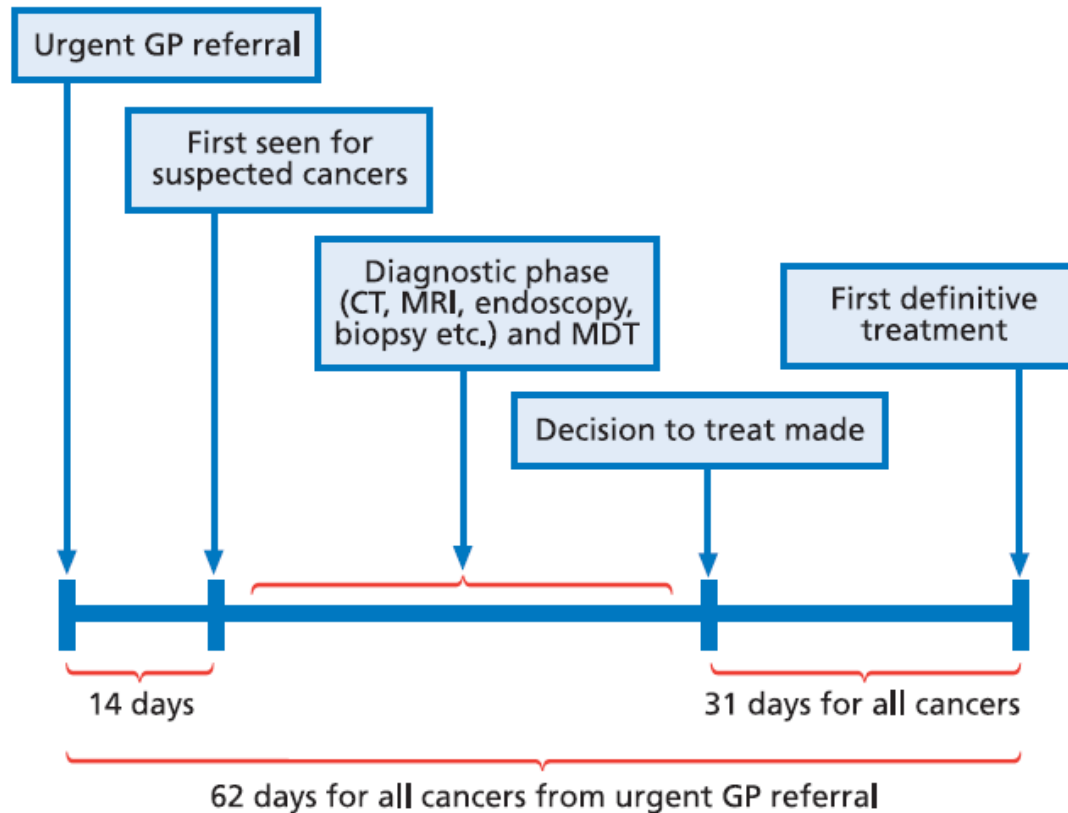- -Immunohistochemistry: specific biology/genes

Diagnosis & Management plan

Multidisciplinary Team Meeting

- MDT clinicians present
- TNM staging
- Histology
- Treatment plan
- Time to Treatment: TTT-31 days

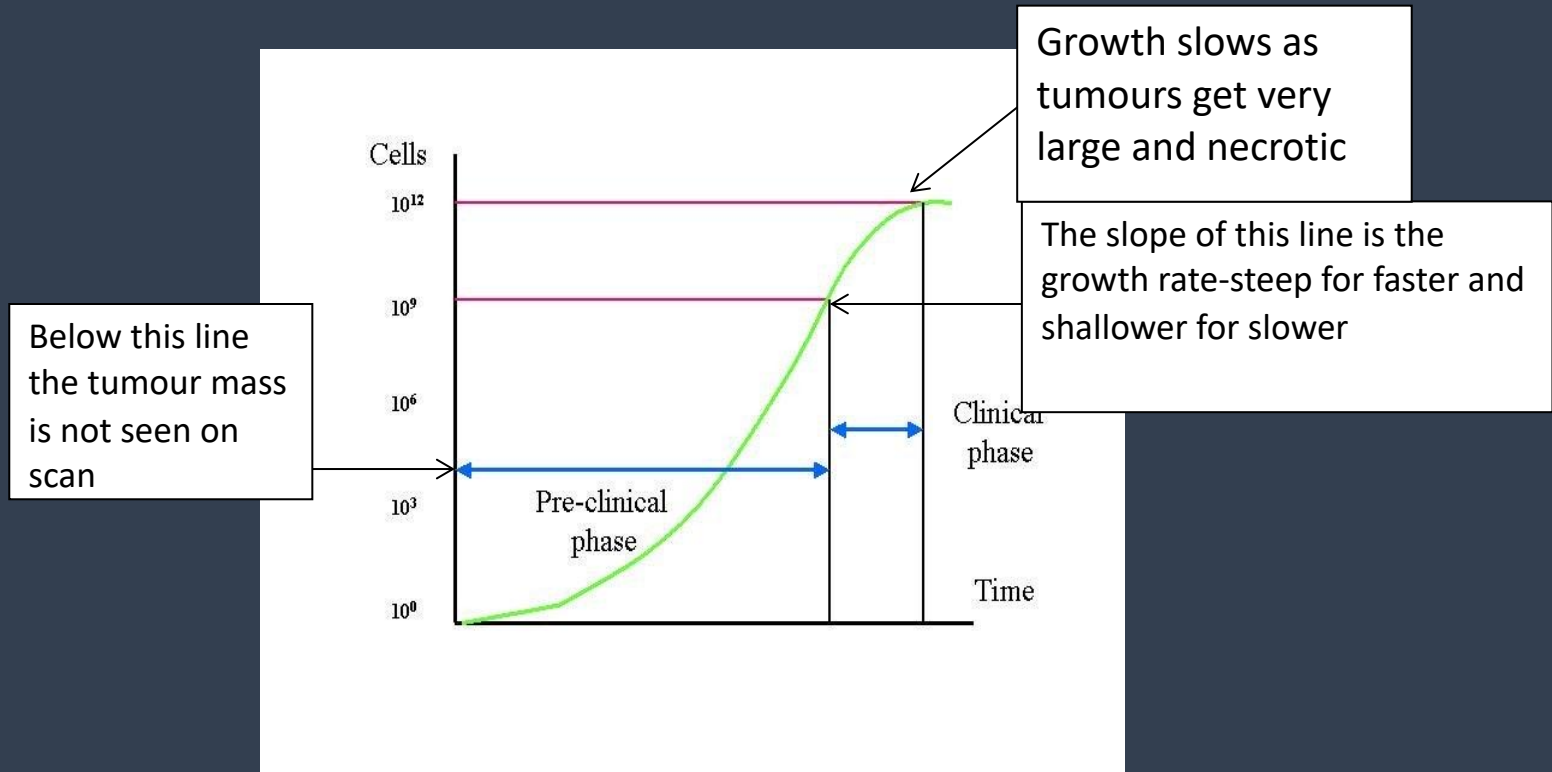# Treatment Targets

Source: Department of Health 2008

Case Studies
Methodology used

- Stage/size of the tumour earlier?

- Were there subclinical metastases earlier?

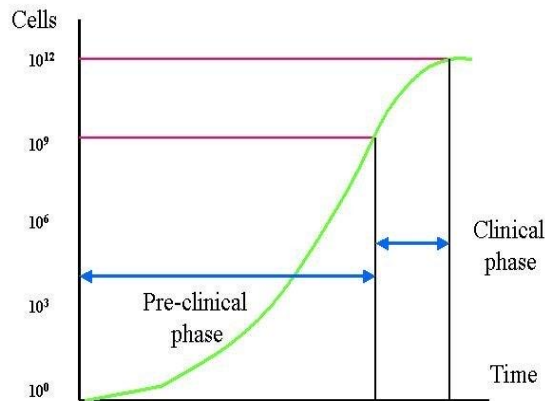- What is the survival and any Loss of life expectancy?

1. Tumour growth rate assessment
Basis of Back extrapolation methodology

Growth slows as tumours get very large and necrotic

The slope of this line is the growth rate-steep for faster and shallower for slower

Below this line the tumour mass is not seen on scan

Cells

10^{12}

10^{9}

10^{6}

10^{3}

10^{0}

Clinical phase

Pre-clinical phase

Time

Back extrapolation calculation

Equation for Doubling time = $T_i \times \log2 / 3 \times \log(D_i/D_o)$ or $(\ln2 \times T_i)/(\ln(V_i/V_o)$

- O T_i = interval time
- O D_i = initial diameter
- O D_o = final diameter
- O V_i = initial volume
- O V_o = final volume

Volume doubling time: Literature average or individual serial measurements.
Plus reality check

Half empty glass

Natural History of Growth

Doublings	Cells	Diameter	
0	1	10 um	microscopic
20	1×10^6	1 mm	microscopic
30	1×10^9	1 cm	Detectable XR
35	$1 \times 10^{10.5}$	3 cm	Average Diagnosis
40	1×10^{12}	10 cm	Death
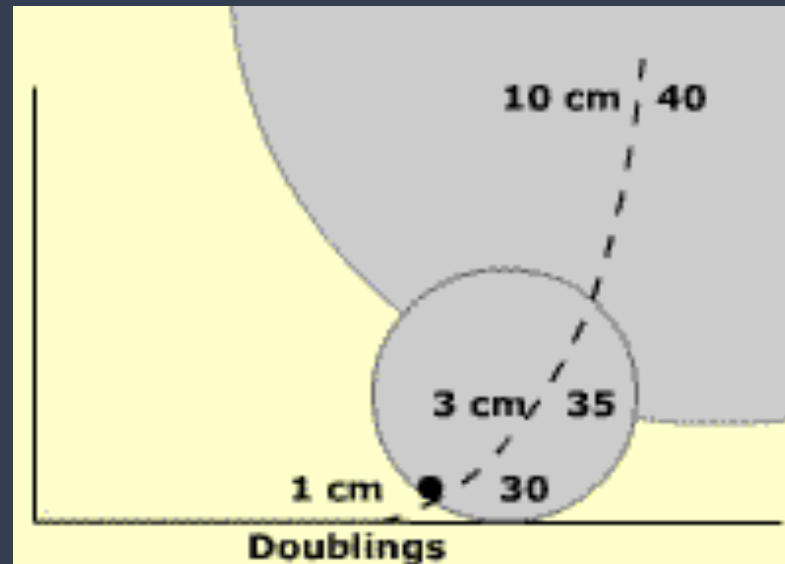
Volume doubling time

Based on literature based assessments

Table 3. Tumor Volume Doubling Time of Primary Breast Cancer According to Age

Age at diagnosis (yr)	Geometric mean in days (95% confidence limits)	68% range*
< 50	80 (44–147)	24–273
50–70	157 (121–204)	46–533
> 70	188 (120–295)	55–640

Likelihood ratio test: $P = 0.06$

* Sixty-eight percent of the tumor volume doubling times are between the presented limits: 16% is smaller than the lower limit, 16% is larger than the upper limit.

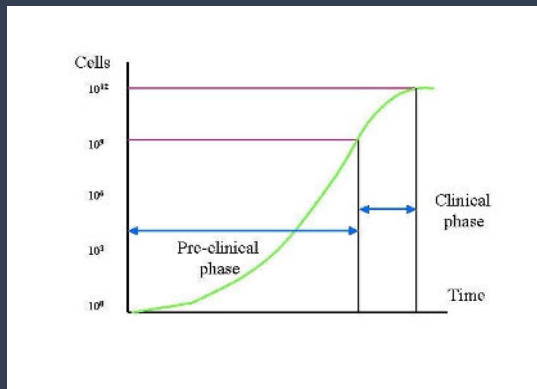or serial clinical measurements with no intervening treatment

2. Asessment of earlier Metastatic disease

- Often extent of clinical metastatic disease can be underestimated
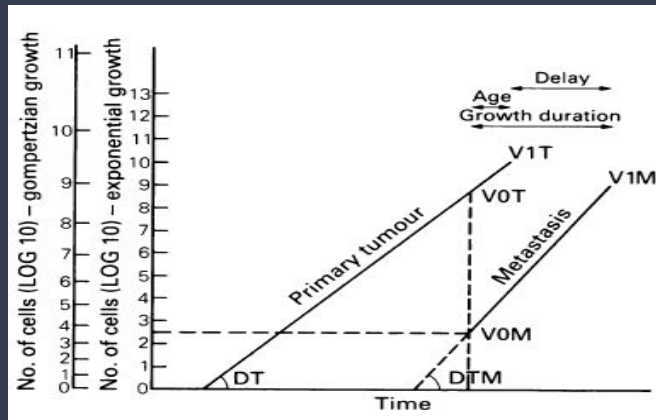
- Important to consider subclinical disease

Growth rate of metastases

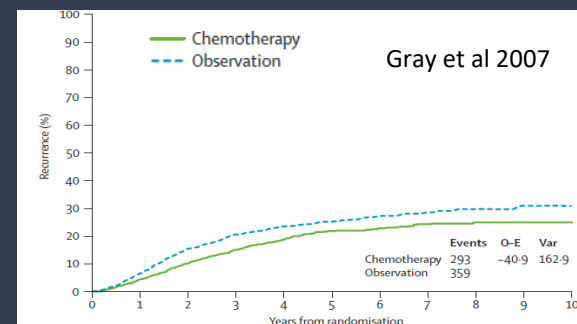- **Back extrapolation technique**

Using known or literature based-only go so far
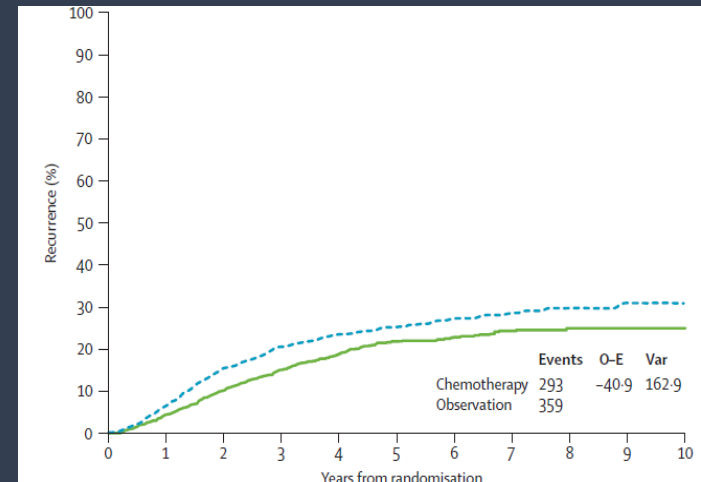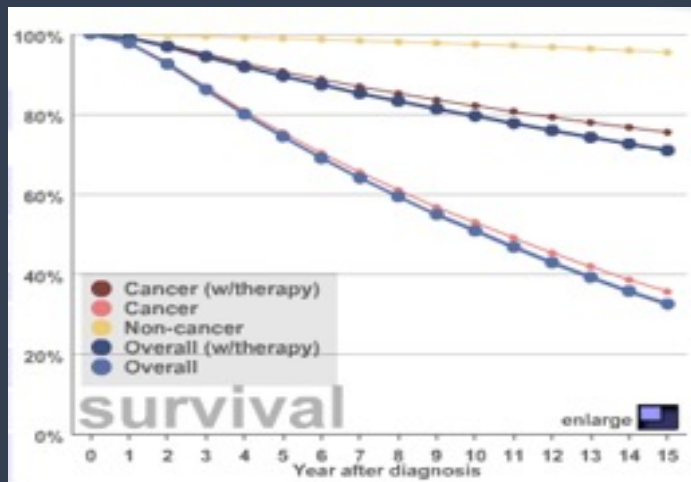

Unknown use x2 primary growth rate

- **Disease free interval**

Time to image metastases following resection
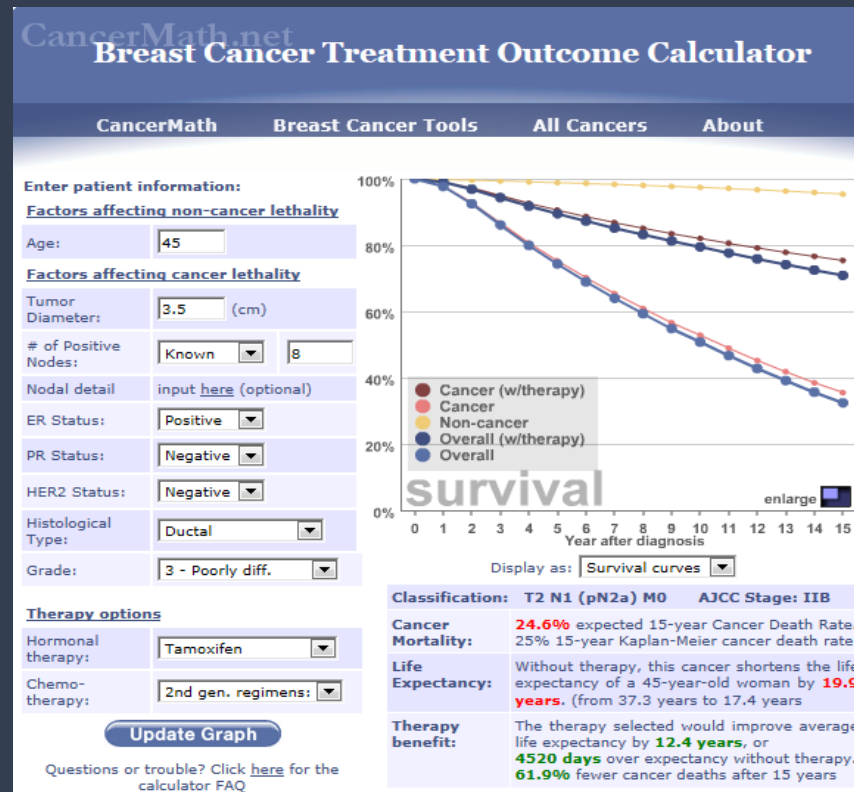= growth rate of subclinical disease

Gray et al 2007

3. Survival and Conditional survival

- Prognosis at diagnosis vs prognosis at a later time

- Assess when most recurrences occur

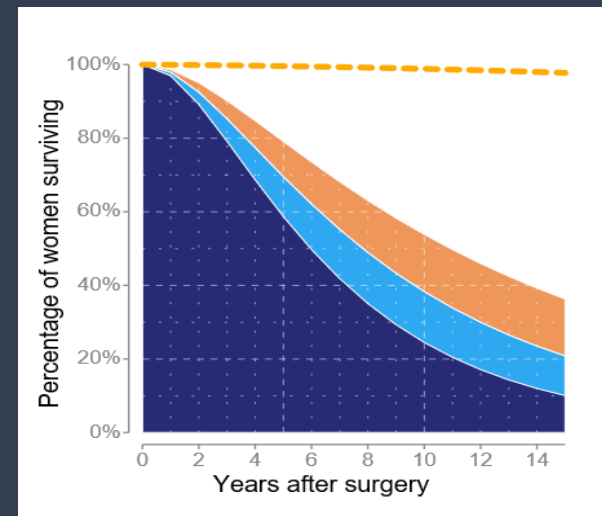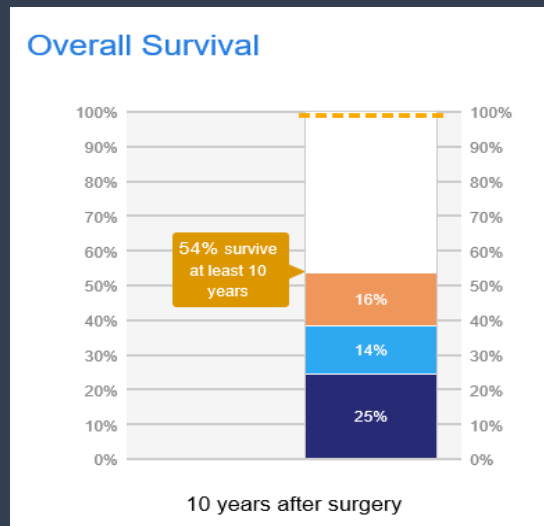- Loss of LE may disappear over time

Life Expectancy
Individual or statistical

Also useful for change in average LE
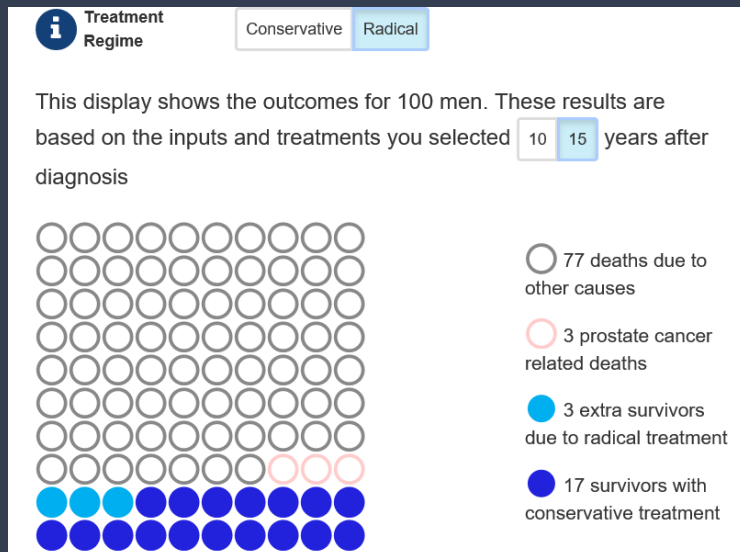JD vs Mather 2012 EWHC 3063 (QB)

Use of Predict : Breast cancer

- http://predict.nhs.uk/

10 year survival 54% so cured

-but 75% have subclinical metastases and adjuvant therapy not cure >50%

15 year survival 36%

Prostate Predict

The Covid-19 problem

- March 16th 2020-suspension of cancer screening, deferral routine diagnostics and outpatients.

- Wuhan data/lack of PPE/anticipated ITU admissions

- NICE guidance on therapy-delay and avoid-redeploy

- 2 week waits dropped by up to 80%

- Cancer services not back to 100% by October 2020

- 2nd wave hit cancer surgery worse

- Lack of effective cancer recovery plan: baked in lack of capacity and underinvestment

- January 2023; 7000 pt a month miss 62 day target

Result of the Covid Cancer Problem

- Cancer treatment backlog growing
- Every 4 week delay=6-13% increase in risk of death
- Predicated 35,000 avoidable deaths at least in year 1
- 210,000 delayed cancer treatments since start of Covid
- Will take 5-10 years to get NHS services fully up and running
- Maximum capacity 75-80%. One survey 89% front line cancer staff thinking of leaving profession.
- OECD-UK started pandemic bottom of HIC in survival

Price et al Lancet Oncology 2022
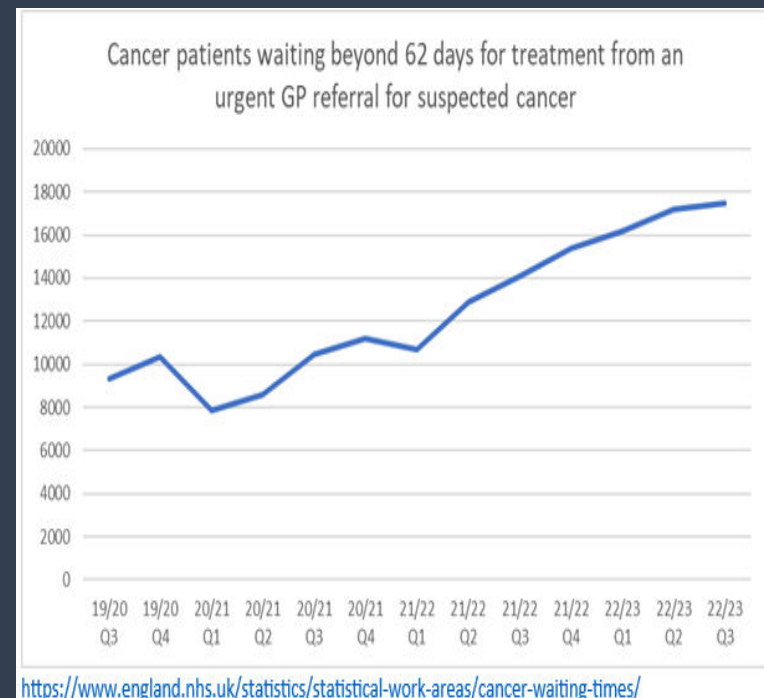
Essay

UK cancer care: a watershed moment and the need for urgent intervention

Figure 2: Organisation for Economic Co-operation and Development cancer incidence (2020) and cancer mortality (2019)⁴

Cancer patients waiting beyond 62 days for treatment from an urgent GP referral for suspected cancer

https://www.england.nhs.uk/statistics/statistical-work-areas/cancer-waiting-times/

Medico-legal implications of Covid-19 cancer care disruption

Claims: During first lockdown

- What was acceptable in Covid and when did it start not being acceptable?
  - Consent to delay or substitute treatment?
  - Is it a breach that the NHS simply cannot provide treatment in a pandemic?
- How to deal with small value/volume of claims?
- Patients quite understanding
- Wuhan variant and no vaccination
- Earlier; not had awful isolated time in hospital

Medico-legal implications of Covid-19 cancer disruption

Claims: end 2020 onward

- Breakdown of clinical pathway

- Poor communication

- Backlog and delays in diagnosis and treatment

- 4 in 10 now waiting more than 62 days for treatment.

- Non selected appointment cancellation

- Chaos of moving to EPR

Medico-legal implications of Covid-19 cancer disruption

Challenges : medicolegal land scape

- Disruption to Legal practices

- Medical record availability

- Expert availability

- What is good: video conferences!

References

Donations to Radiotherapy UK

www. Appg-RT.co.uk/cancer summit 2021

Treatment of Cancer: Price & Sikora 7th edition

Catchup With Cancer | Radiotherapy4Life

Price et al Lancet Oncology November 2022

Current and future challenges facing medico-legal experts – An expert's view. 2018 https://doi.org/10.1177/2516043518772707