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Critical illness – Do you need a surgeon or a physician?

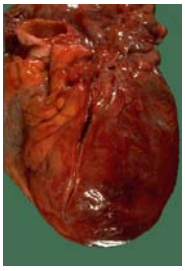
Ian Cox
CMO Gen Re Life Health
CMO Prudential UK

My role(s)

CI definitions - SoBP

- Clarity
- Objective:
  - 'All model wordings should be as robust as possible in differentiating between what is, and is not, covered…'
- Generic terms
- Reduce need for changes in future
- Severity basis for all conditions

Heart Attack



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Clarity?
Heart attack – *of specified severity*

Death of heart muscle, due to inadequate blood supply, that has resulted in all of the following evidence of acute myocardial infarction:

- Typical clinical symptoms (for example, characteristic chest pain).
- New characteristic electrocardiographic changes.
- The characteristic rise of cardiac enzymes or Troponins recorded at the following levels or higher;
  - Troponin T > 1.0 ng/ml
  - AccuTnI > 0.5 ng/ml or equivalent threshold with other Troponin I methods.

The evidence must show a definite acute myocardial infarction.

For the above definition, the following are not covered:

- Other acute coronary syndromes including but not limited to angina.

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BRITISH CARDIAC SOCIETY

British Cardiac Society Working Group on the definition of myocardial infarction

K A A Fox, J Birkhead, R Wilcox, C Knight, J Barth

Heart 2004;90:603–609. doi: 10.1136/hrt.2004.038679

The remit of the British Cardiac Society Working Group on MI is:

- To establish a nomenclature for acute coronary syndromes to meet current treatment and prognostic needs of patients
- To recommend a diagnostic threshold to distinguish patients with MI from patients with acute coronary syndromes with minor but prognostically important increases of troponin concentrations
- To recommend a strategy for establishing a reference standard for troponin assays.

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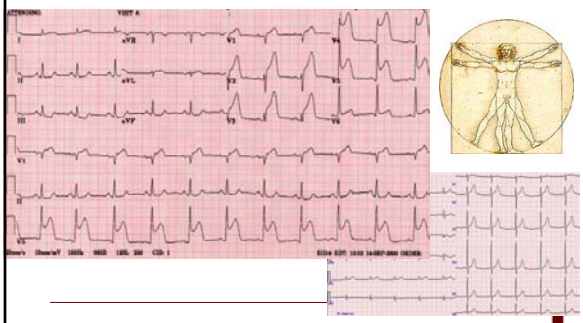
Myocardial infarction - ECG



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Cardiac Biomarkers

Biomarker	Time to Initial Elevation	Time to Peak Elevation	Time to Return to Normal
CK-MB	4-8 hours	12-24 hours	72-96 hours
CK-MB isoforms	2-6 hours	18 hours	<24 hours
Myoglobin	2-4 hours	8-10 hours	24 hours
LD-I	10-12 hours	48-72 hours	7-10 days
cTnI	4-6 hours	12 hours	3-10 days
cTnT	4-6 hours	12-48 hours	7-10 days

CK-MB, MB isoenzyme of creatine kinase; LD-I, lactate dehydrogenase isoenzyme; cTnI, cardiac troponin I; cTnT, cardiac troponin T

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Troponin: Biochemistry

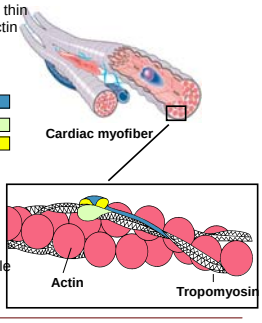
The troponin complex is a component of the thin filaments in striated muscle complexed to actin

There are three types of troponins:

- **Troponin T (Tropomyosin binding)**
- **Troponin I (inhibitory protein)**
- **Troponin C (Calcium Binding)**

The troponins are three different proteins structurally not related with each other

Cardiac troponin T and I differ significantly from troponin T and I found in skeletal muscle



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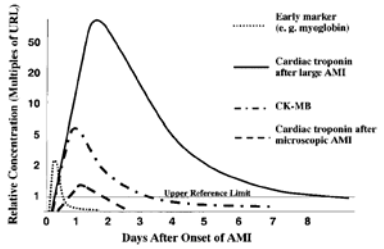
Troponins – rise & fall



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Spectrum of Acute Coronary Syndrome

ACS with unstable angina	ACS with myocyte necrosis	ACS with clinical myocardial infarction
Marker: Tn and CK-MB undetectable	Troponon elevated Tn T < 1.0 ng/ml	Tn T > 1.0 ng/ml +/– CK-MB↑ or AccuTn I > 0.5 ng/ml
ECG: ST↓ or T↓ or transient ST↑ or normal		ST↑ or ST↓ or T inversion: may evolve Q waves
Risk of death*: 5–8%	8–12%	12–15%
Pathology: plaque disruption, intra-coronary thrombus, micro-emboli partial coronary occlusion ◄		► complete coronary occlusion
LV function: no measurable dysfunction ◄		► systolic dysfunction, LV dilatation

Heart 2004;90:603–609.

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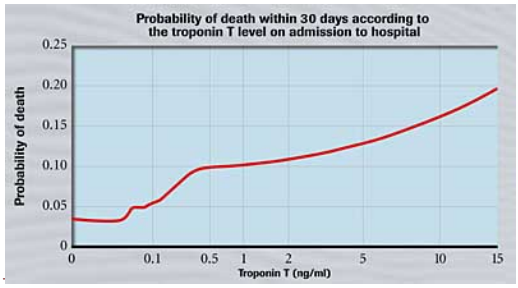
Importance of Troponins



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Ohmann, EM. etal N-Engl-J-Med. 1996; 335:1333

Troponin measurement

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Other causes raised troponins

- Myocarditis
- Coronary emboli caused by endocarditis,
- Angioplasty
- Pulmonary emboli
- Prosthetic valves
- Inflammatory processes, including viral infections such as with coxsackie B
- Radiation-induced coronary stenosis
- congenital abnormalities in a coronary artery
- Cocaine abuse
- Hurler's syndrome, homocystinuria, rheumatoid arthritis, and systemic lupus erythematosus
- Extreme exercise
- Renal Failure

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bmj.com

Editorials

Was it a heart attack?
Troponin positive acute coronary syndrome versus myocardial infarction

Charles J McKenna
J Colin Forfar

BMJ 2002;324:377- 378 16 February

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Prudential FPP – explicitly severity based Heart attack

Severity Level A:

- Heart attack resulting in an ejection fraction of 29% or less, measured at least one month after the heart attack on Optimal Therapy

Severity Level B:

- Heart attack resulting in an ejection fraction of between 30% and 39% measured at least one month after the heart attack on Optimal Therapy

Severity Level C:

- Heart Attack

Severity D,E, F……

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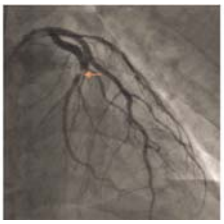
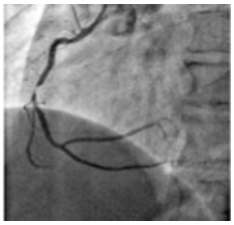
Coronary Artery Stenosis





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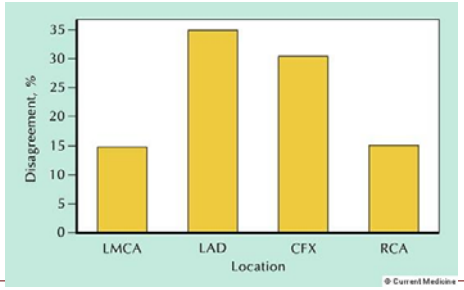
Inter-observer variability on coronary stenosis



Zir LM, Miller SW, Dinsmore RE, *et al.* Interobserver variability in coronary angiography. *Circulation*. 1976;53:627-632

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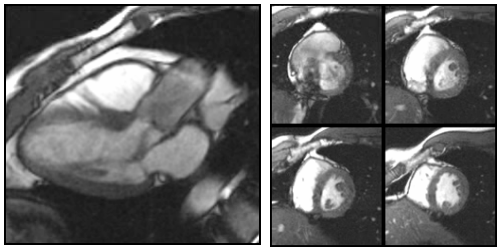
Echocardiography



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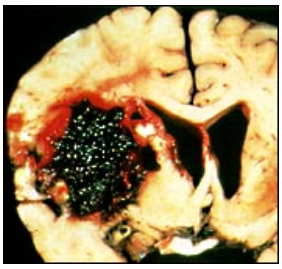
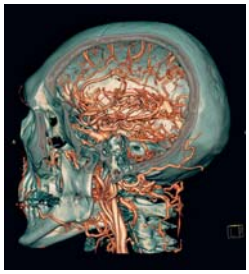
Stroke





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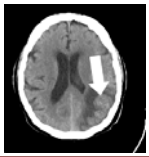
Stroke –
resulting in permanent symptoms

Death of brain tissue due to inadequate blood supply or haemorrhage within the skull resulting in *permanent neurological deficit with persisting clinical symptoms*.

For the above definition, the following are not covered:

- Transient ischaemic attack.
- Traumatic injury to brain tissue or blood vessels.



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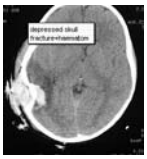
Traumatic head injury – ***resulting in permanent symptoms***

- Death of brain tissue due to traumatic injury resulting in *permanent neurological deficit with persisting clinical symptoms*.



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Coma – *resulting in permanent symptoms*

A state of unconsciousness with no reaction to external stimuli or internal needs which:

- requires the use of life support systems for a continuous period of at least 96 hours; and
- results in *permanent neurological deficit with persisting clinical symptoms.*

For the above definition, the following is not covered:

- Coma secondary to alcohol or drug abuse.

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Benign brain tumour
– resulting in permanent symptoms

A non-malignant tumour or cyst in the brain, cranial nerves or meninges within the skull, resulting in *permanent neurological deficit with persisting clinical symptoms.*

For the above definition, the following are not covered:

- Tumours in the pituitary gland.
- Angiomas.

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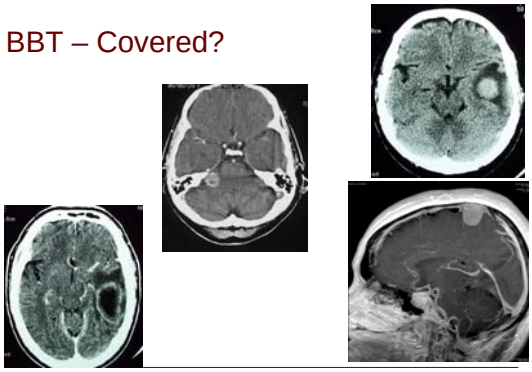
BBT – Covered?



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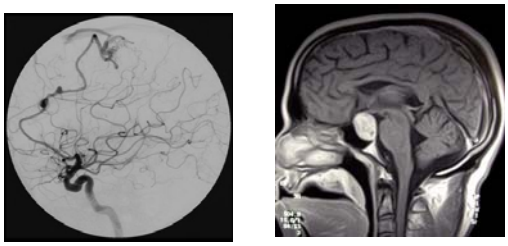
Cerebral aneurysms, A-V malformation & pituitary tumour - excluded



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Permanent neurological deficit with persisting clinical symptoms

Symptoms of dysfunction in the nervous system that are present on clinical examination and expected to last throughout the insured person's life.

Symptoms that are covered **include** numbness, hyperaesthesia (increased sensitivity), paralysis, localised weakness, dysarthria (difficulty with speech), aphasia (inability to speak), *dysphagia* (difficulty in swallowing), visual impairment, difficulty in walking, lack of coordination, tremor, seizures, lethargy, dementia, delirium and coma.

The following are not covered:

- An abnormality seen on brain or other scans without definite related clinical symptoms
- Neurological signs occurring without symptomatic abnormality, e.g. brisk reflexes without other symptoms
- Symptoms of psychological or psychiatric origin.

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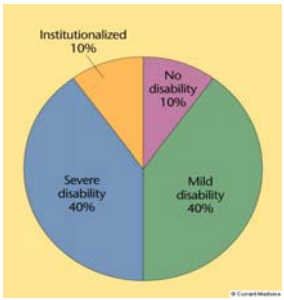
Risk Disability after stroke



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Prudential FPP - Stroke

PRUDENTIAL

Severity Level A:

- A Stroke with a residual deficit measuring 4 or above on the Modified Rankin Scale.
- Any Neurological Disease causing the Permanent and Irreversible inability to perform four out of six Functional Activity Tests
- Loss of Speech
- Quadriplegia
- Paralysis/paraplegia
- Hemiplegia

Severity Level B:

- A Stroke with a residual deficit measuring at least 3 on the Modified Rankin Scale.
- or any Neurological Disease causing the Permanent and Irreversible inability to perform three out of six Functional Activity Tests
- or Permanent Bilateral Hemianopia

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Multiple sclerosis – *with persisting symptoms*

- A definite diagnosis of Multiple Sclerosis by a Consultant Neurologist. There must be current clinical impairment of motor or sensory function, which must have persisted for a continuous period of at least 6 months.

NB: No permanent neurological deficit

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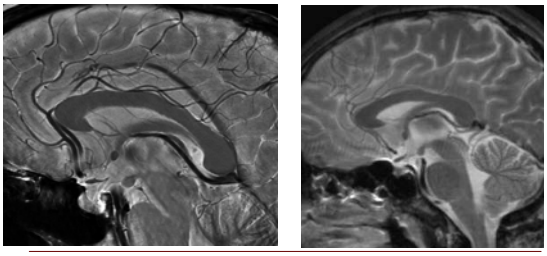
Future changes in neurological imaging
7T vs 1.5T MRI scan



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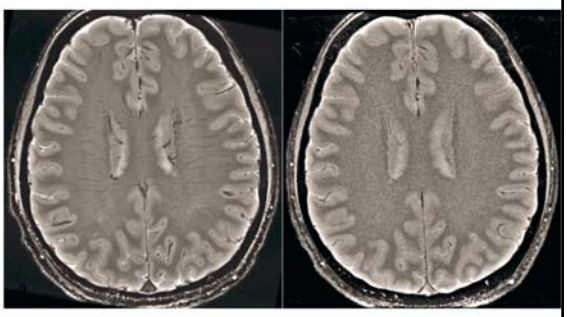
Teslar MRI scan Vs 3 Teslar scan



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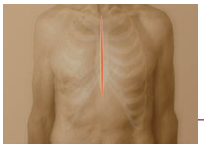
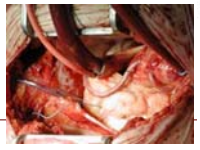
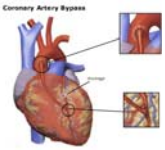
Truly Critical illness?
Coronary artery by-pass grafts – *with surgery to divide the breastbone*

The undergoing of surgery requiring median sternotomy (surgery to divide the breastbone) on the advice of a Consultant Cardiologist to correct narrowing or blockage of one or more coronary arteries with by-pass grafts.







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Cancer – *excluding less advanced cases*

Any malignant tumour positively diagnosed with *histological confirmation* and characterised by the uncontrolled growth of malignant cells and invasion of tissue.

The term malignant tumour includes leukaemia, lymphoma and sarcoma.

For the above definition, the following are not covered:

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Cancer exclusion - ?problem?

All cancers which are histologically classified as any of the following:

- pre-malignant, for example essential thrombocythaemia and polycythaemia rubra vera;
- non-invasive;
- cancer in situ;
- having either borderline malignancy; or
- having low malignant potential.

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Cancer exclusions pt 2

- All tumours of the prostate unless histologically classified as having a Gleason score greater than 6 or having progressed to at least clinical TNM classification T2N0M0.
- Chronic lymphocytic leukaemia unless histologically classified as having progressed to at least Binet Stage A.
- Any skin cancer other than malignant melanoma that has been histologically classified as having caused invasion beyond the epidermis (outer layer of skin).

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Cancers - Stage and Grade

- Stage cancer – think distance train travelled
  - Complicated by T stage and group stage
- Grade cancer – think speed train.
- More useful for 'solid tumours'

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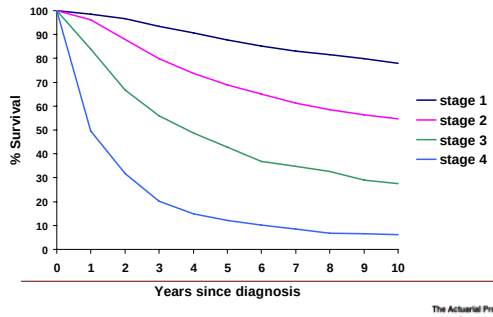
Survival with Breast Cancer



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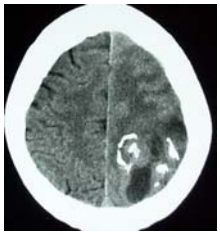
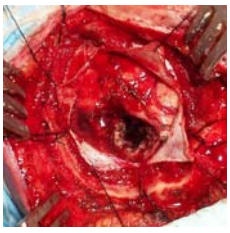
Brain Tumours





Histology not always available

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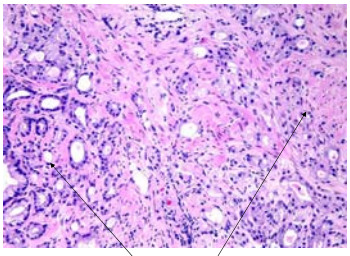
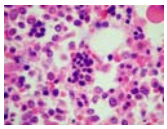
Gleason Score Prostate cancer

Appearance of cancer cells, ranked according to the Gleason Grade.

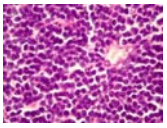


Gleason 3 + 4 = 7

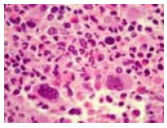
Bone Marrow and Peripheral blood in Leukaemias



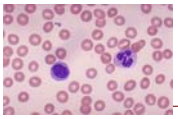
Normal

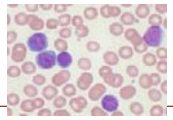


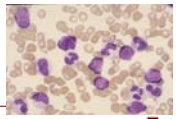
Chronic Lymphatic Leukaemia



Chronic Myeloid Leukaemia







Binet stage in CLL

Clinical stage A

- Clinical stage A CLL is characterized by no anemia or thrombocytopenia and fewer than 3 areas of lymphoid involvement (Rai stages 0, I, and II).

Clinical stage B

- Clinical stage B CLL is characterized by no anemia or thrombocytopenia with 3 or more areas of lymphoid involvement (Rai stages I and II).

Clinical stage C

- Clinical stage C CLL is characterized by anemia and/or thrombocytopenia regardless of the number of areas of lymphoid enlargement (Rai stages III and IV).

Binet and RAI staging in CLL

		Frequency (%)	Median survival
Binet stage:			
A		63	>10 years
B		30	5 years
C		7	1.53 years
Rai stage:			
0	Low	30	>10 years
I II	Intermediate	60	7 years
III IV	High	10	1.5 years

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New markers of CLL –especially prognosis

- Aberrations in chromosomes 13 (13q–), 11 (11q–) and 17 (17p–)
- Cytoplasmic ZAP70 in CLL cells
- Expression of CD38 on CLL cells
- Lymphocyte doubling time
- Serum ß2-microglobulin concentration
- Serum levels of soluble CD23
- Serum thymidine kinase activity
- Somatic hyper-mutations of the immunoglobulin VH-gene region

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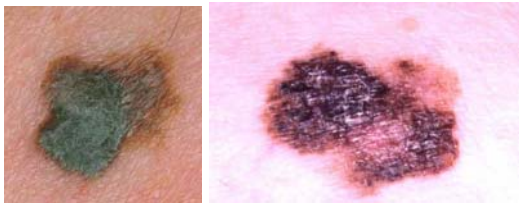
Melanoma



A- asymmetry, B – border, C- colour,

D – diameter>6mm, E - elevation

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Melanoma penetrating dermis

Any skin cancer other than malignant melanoma that has been histologically classified as having caused invasion beyond the epidermis (outer layer of skin).

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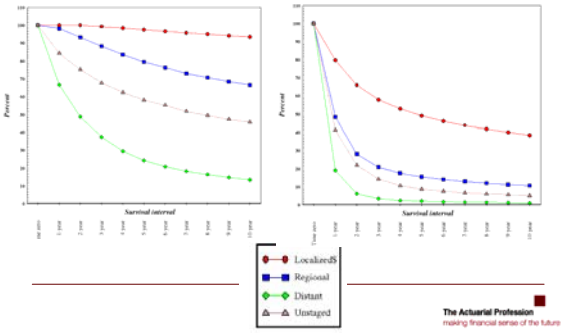
2 cancers – same benefit?



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Virgin Cancer cover

- not a critical illness policy

Type 3 cancer (advanced cancer)

- Type 3 cancer (advanced cancer) includes any malignant tumour characterised by the uncontrolled growth of malignant cells and invasion of tissue that has either:
- originated in the brain, gall bladder, liver, lung, oesophagus, pancreas or stomach, or spread beyond its site of origin in that it has spread to regional lymph nodes, invaded into adjacent structures and/or has distant metastases, …….

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Prudential FPP – Cancer severity A

- Tumours classified as TNM Stage III or above
- Hodgkin's Disease classified as Ann-Arbor Stage III or above
- Non-Hodgkin's Lymphoma classified as Ann-Arbor Stage III or above
- Acute Myeloid Leukaemia
- Chronic Lymphocytic Leukaemia Binet C
- Chronic Myeloid Leukaemia
- Acute Lymphoblastic Leukaemia
- Advanced Aplastic Anaemia

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Prudential FPP - Cancer severity Level C

- TNM Stage II Tumours
- Hodgkin's Disease Ann-Arbor Stage II
- Non-Hodgkin's Lymphoma Ann-Arbor Stage II
- Multiple Myeloma
- Myelodysplasia classified as Intermediate 1 under the International Prognostic Scoring system described in Provision 1 a) i above.

- Stage D – Stage 1 tumours

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Reactive definitions - always

We cannot control medical developments

- Angioplasty
- Prostate cancer
- Leukaemia
- Screening
- Cancer treatments
- Proteomic markers for diagnosis

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doi:10.1093/brain/awf279 Brain (2006) 129, 3042–3050

Proteome-based plasma biomarkers for Alzheimer's disease

A. Hye,[1] S. Lynham,[1] M. Thambisetty,[1] M. Causevic,[1] J. Campbell,[3] H. L. Byers,[3] C. Hooper,[1] F. Rijsdijk,[2] S. J. Tabrizi,[4] S. Banner,[1] C. E. Shaw,[1] C. Foy,[1] M. Poppe,[1] N. Archer,[1] G. Hamilton,[1] J. Powell,[1] R. G. Brown,[1] P. Sham,[2] M. Ward[3] and S. Lovestone[1]

[1]King's College London, MRC Centre for Neurodegeneration Research, [2]King's College London, MRC Social, Genetic and Developmental Psychiatry Centre, [3]Proteome Sciences Plc, Institute of Psychiatry and [4]University College London, Institute of Neurology, London, UK

'*analysis of the protein distribution of the gels alone identifies disease cases with 56% sensitivity and 80% specificity.'*

Research

- How much does each company do?
- Who does this research?
- Rely on reinsurers?
- Trust/sense check

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"Critical Illness – MOT or Cosmetic Surgery?"

Are these the only alternatives on offer?

You need a doctor!

- Product design
- Understanding health care
- Discussing cases with other doctors
- Talking to actuaries!
- However doctors have training needs as well
  - In insurance medicine
  - Statistics –
  - Latest technology and treatment

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The future –Not surgery but 'talking therapy'

- Customer support – explaining definitions
- Develop consensus with SIGs
- Develop communication with Doctors/Societies
- ABI, FOS
- Appeals committee?

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Critical illness – Do you need a surgeon or a physician?

Ian Cox
CMO Gen Re Life Health
CMO Prudential UK