Why collect pathology data? Some data less equal than others?

Murali Varma

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RCPath 2017

Pathology report: Basis of all cancer management

THIS IS A COPY REPORT CLINICAL DETAILS: Right WLE and ANC - Grade 3 breast cancer - cores St Josephs.

MACRO:

A: BREAST LUMP (WIDE EXCISION) - right Right local wide excision specimen weighing 80gms and measuring 65 x 55 x 30mm. The specimen inked in 6 colours. Slicing reveals and ill defined tumour. Representative blocks taken. A1, A2 large blocks soft tumour, A3-A4 anterior margin, A5-A7 deep margin, A8-A9 lateral margin.

B: BREAST AXILLARY NODE CLEARANCE ONLY - RIGHT Axillary node clearance specimen measuring 95 x 50 x 25mm containing multiple lymph nodes. Blocks taken in 18 cassettes. RB.

MICRO:

BREAST CARCINOMA PROFORMA REPORT

Lab No S,11.0008550.

INSITU CARCINOMA - DCIS PRESENT DCIS grade(s) - HIGH, DCIS growth pattern(s) - COMEDO NECROSIS PRESENT

INVASIVE CARCINOMA Invasive size - 47 mm Whole size (Inv and Insitu) - 47 mm Invasive type - No special type (ductal NST) Invasive grade - 3 (T3 M3 P3) Tumour extent - Localised Vascular invasion - Present, very extensive.

Excision margins - Reaches circumferential margin INFERIOR and LATERAL margins: involved by invasive tumou DEEP margin: 1mm

Axillary nodes - Total Number = 34 Number +ve = 6

Nottingham prognostic index = 6.94 (Poor prognosis group)

Oestrogen receptor status : Positive (weak, score 3-4) on biopsy HER2 status : Not known

Diagnosis

Prognosis

Choice of Rx

 Prediction of response to therapy

Completeness of excision



A critical review of pathology data collection

Prostate biopsy report

B) (Left lobe) 6 cores of prostate are seen of which 4 are infiltrated by acinar invasive prostate adenocarcinoma of Gleason patterns 3 and 4. Gleason sum 3 + 4 = 7. Gleason pattern 4 accounts for 25%. WHO Grade Group 2. Background multifocal PIN.

The dimension of the tumour and the volume of tumour (given as a %) in each core is as follows: 2mm (12%), 0.2mm (1%), 0.2mm (1%), 3mm (16%).

- Why do we collect data?
- Who do we collect data for?
- What data do we collect?
- How do we collect data?
- How do we report data?

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1. Patient management

2. Clinical Trials entry/exclusion

- **1. Patient management**
- 2. Clinical Trials entry/exclusion
- 3. Epidemiology
 - Cancer registration
 - Incidence and survival comparison
 - •

- **1. Patient management**
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- **3. Epidemiology**
- 4. Current research
- 5. Potential future research

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- **1. Patient management**
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- 3. Epidemiology
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- 5. Potential future research
- 6. Audit of surgeons performance
- 7. "Part of complete pathology report"
 - Dimensions of fallopian tube/spermatic cord

Pathologists

- Macroscopic description
- Block key
- Microscopic description?

Pathologists

Clinicians

- Diagnosis
- Prognostic data
- Predictive data

- Pathologists
- Clinicians
- Epidemiologists
- Cancer registries
- MDT coordinators

SNOMED codes

- Pathologists
- Clinicians
- Epidemiologists
- Cancer registries
- MDT coordinators
- Researchers

SNOMED codes

Pathology data collection

- Different purposes
- For different users
- With very different requirements

Tumour grading

Why do we grade tumours?

Why grade tumours?

Individual patient

- Prognosis
- Management

Why grade tumours?

Individual patient

- Prognosis
- Management

Groups of patients

- Clinical trials
 - Groups have to be comparable

Survival analysis

• Surgeons, Areas (eg. England vs. Wales)

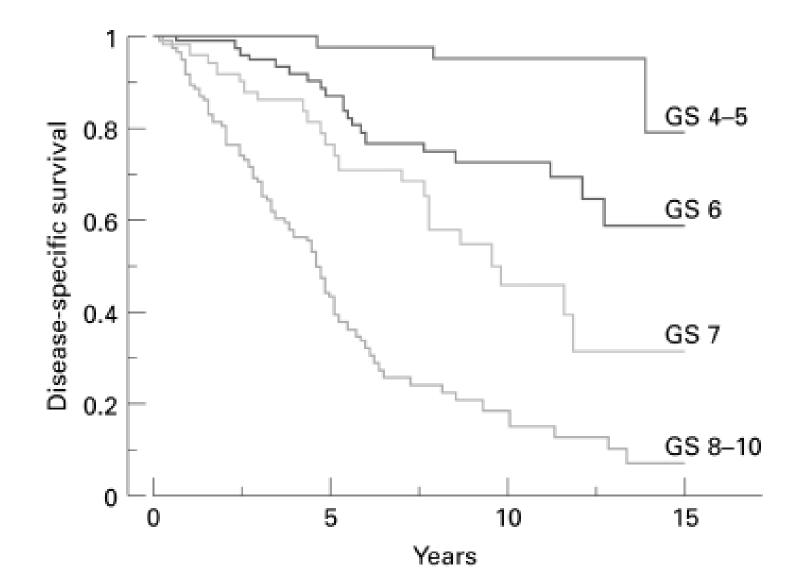
Groups of patients

 All published studies based on group analysis

Prognostic value of the Gleason score in prostate cancer

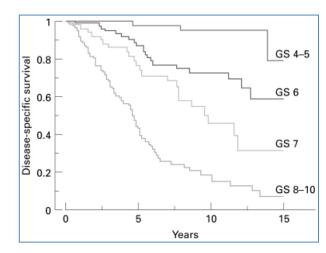
L. EGEVAD, T. GRANFORS*, L. KARLBERG*, A. BERGH[†] and P. STATTIN[‡]

BJU International (2002), 89, 538-542



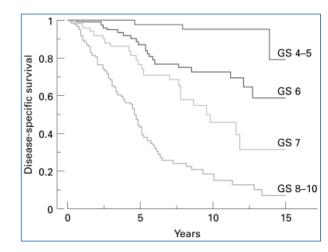
Groups of patients

 Borderline grades cancel each other as randomly distributed across adjacent grades



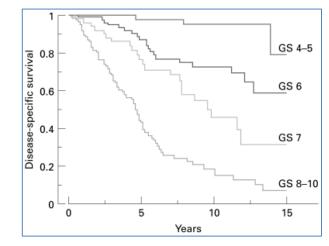
Groups of patients

- Borderline grades cancel each other as randomly distributed across adjacent grades
- Inter-observer reproducibility less important

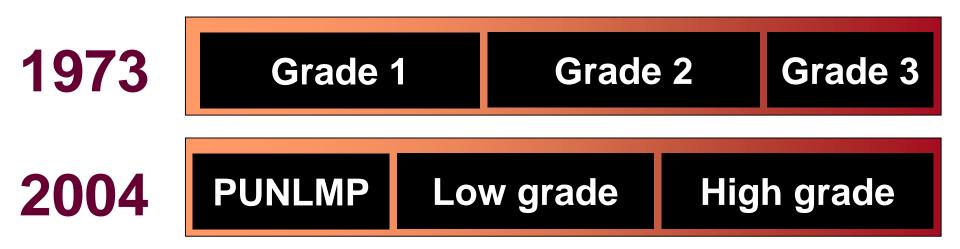


Groups of patients

- Borderline grades cancel each other as randomly distributed across adjacent grades
- Inter-observer reproducibility less important
- Fewer tiers the better?
 - More cases in each group
 - Easier statistics



Grading bladder cancer



Groups of patients

- Borderline grades cancel each other
- Inter-observer reproducibility less important
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Individual patient

Arbitrary lines in continuum

Gleason score 3 + 4 = 7

- Morphological continuum
- Clinical continuum

Pattern 3Pattern 4Pattern 5

Medicine is not Mathematics!

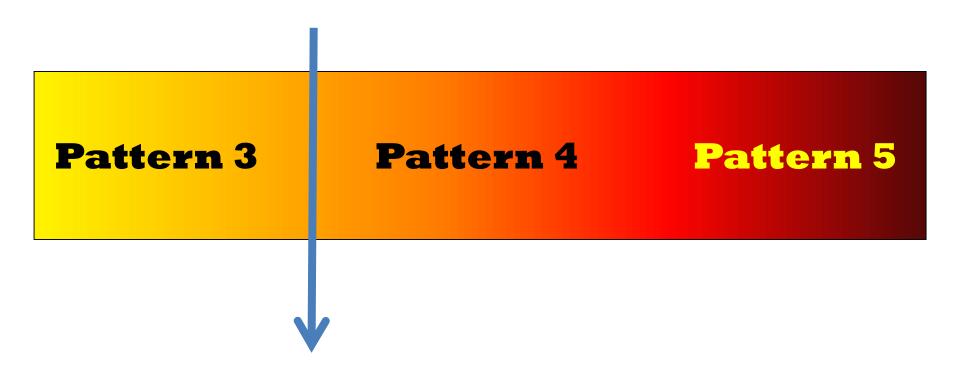
- Gleason score 6: AS
- Gleason score 7: Radical Rx

Medicine is not Mathematics!

- Gleason score 6: AS
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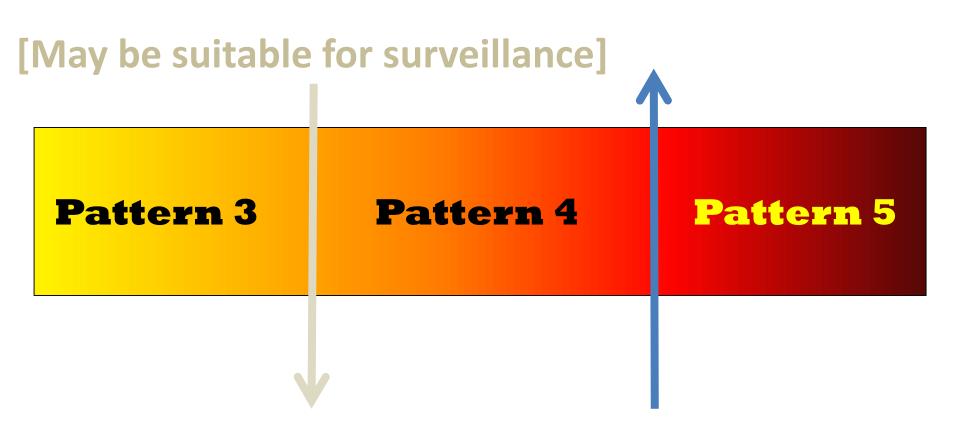
All Gleason 7 tumours are not the same

Gleason score 3 + 4 = 7



[May be suitable for surveillance]

Pattern 3	Pattern 4	Pattern 5



[NOT suitable for surveillance]

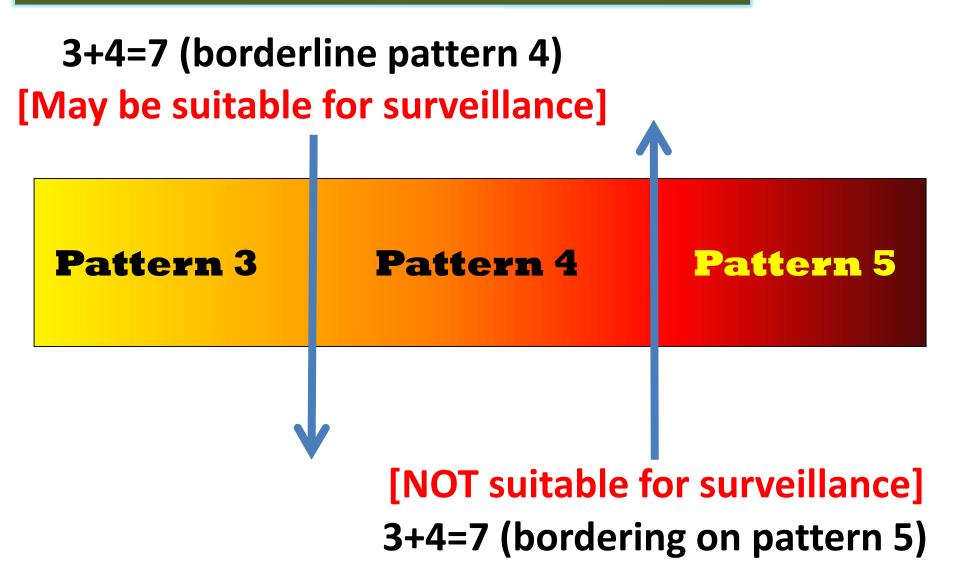
- Incomplete information
- Does not indicate where in the clinical spectrum

Pattern 3	Pattern 4	Pattern 5
I diferii o		

- Incomplete information
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Pattern 3	Pattern 4	Pattern 5

- Analogous to reporting RCC as pT2 without indicating tumour size
 - 71mm
 - 150mm?



Grading tumours

Groups of patients

- Borderline grades cancel each other
- Inter-observer reproducibility less important
- Fewer tiers the better?

Individual patient

- Arbitrary lines in continuum
- Inter-observer reproducibility critical

Grading tumours

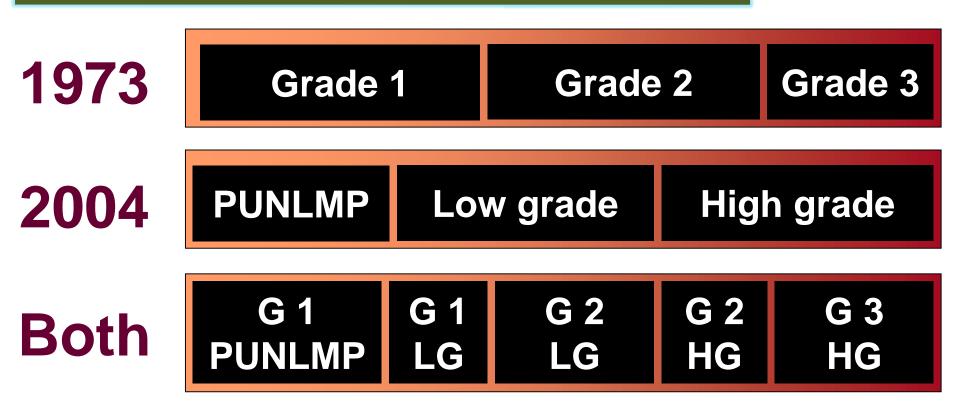
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Individual patient

- Arbitrary lines in continuum
- Inter-observer reproducibility critical
- More tiers the better?

Use both WHO 1973 and WHO 2004?



Using both 1973 and 2004 provides better stratification

Grading: one size fits all

- Individual patient (Treating clinicians)
 - Prognosis
 - Management

Groups of patients (Academics)

- Research/Clinical trials
- Survival analysis

Most grading and staging cut-offs are arbitrary

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 - "Gleason 3+4 and 4+3 are different diseases"

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 - "Gleason 3+4 and 4+3 are different diseases"
 - Only at extremes
 - Tumours do not recognise 50% (Gleason) or 7cm (RCC)

- Most grading and staging cut-offs are arbitrary
- Cut-offs work best for groups not individuals
 - Research, guidelines

- Most grading and staging cut-offs are arbitrary
- Cut-offs work best for groups not individuals
- Cannot replace clinical judgement



Prostatectomy

Accuracy of prostate biopsies for predicting Gleason score in radical prostatectomy specimens: nationwide trends 2000–2012

Daniela Danneman^{*}, Linda Drevin[†], Brett Delahunt[‡], Hemamali Samaratunga^{§1}, David Robinson^{**}, Ola Bratt^{††‡‡}, Stacy Loeb^{§§}, Pär Stattin^{¶1***} and Lars Egevad^{*†††}

Correlation of Gleason Grading of Biopsies and Radical Prostatectomy Specimens 2000-2012. A Registry Study of 15 598 Men. Lars Egevad, Daniela Danneman, Pär Stattin, Linda Drevin Karolinska Institutet, Stockholm, Sweden; Uppsala University Hospital, Uppsala, Sweden; Memorial Stock-Kettering Cancer Center, New York, NY							
ISUP grade, biopsy							
ISUP grade, RP	2-6	3+4	4+3	4+4	9-10		
2-6	65	17	7	5	2		
3+4	28	61	30	17	7		
4+3	5	18	50	33	19		
4+4	1	2	8	33	8		
9-10	1	1	5	12	64		
All	100	100	100	100	100		

United States and Canadian Academy of Pathology annual meeting 2015

[819] Gleason Scores 3+5=8 and 5+3=8 at Biopsy Exhibit a Wide Spectrum of Gleason Scores at Prostatectomy

Alexander Baras, Jonathan I Epstein. Johns Hopkins, Baltimore, MD

Biopsy											
	3+3=6	3+4=7	4+3=7	3+5=8	5+3=8	4+4=8	GS 9,10				
3+3=6	72%	21%	9%	4%	5%	3%	1%	4609			
3+4=7	22%	56%	32%	36%	30%	11%	7%	2968			
4+3=7	4%	18%	40%	36%	20%	26%	10%	1246			
3+5=8	0%	1%	1%	13%	10%	1%	4%	86			
5+3=8	0%	0%	0%	0%	15%	0%	2%	18			
4+4=8	1%	1%	9%	2%	0%	38%	8%	364			
GS 9,10	1%	2%	9%	9%	20%	21%	67%	520			
	5610	2216	1136	55	20	436	338	9811			

Bx: 4 + 4 = 8



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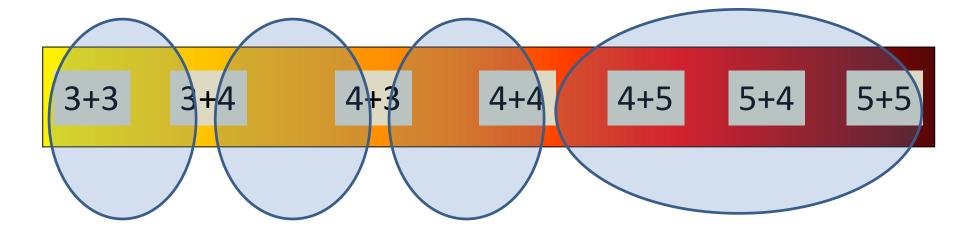
Bx: 4 + 4 = 8 Radical: ≈50% overgraded (≈20% primary pattern 3)

Prostatectomy

Estimation of tumour grade within a morphological and clinical continuum



Estimation of tumour grade within a morphological and clinical continuum



Perfect precision neither possible nor necessary

Pathology data

- Why do we collect data?
- Who do we collect data for?
- What data do we collect?
- How do we collect data?

Pathologists' psyche

- Obsessive Compulsive Disorder
- Paranoia

Pathology data collection

- Record everything that <u>could</u> be useful
- Fear of missing data
 - That could be retrospectively identified

Clinical data collection

- Clinicians would not do complete neurological examination of every patient
 - Would identify clinically significant disease
 - Not cost-effective: would increase consultation time and waiting lists

Data collection Focussed approach

- Collect less data
- Collect this better

Evidence based medicine

Needs evidence

Evidence based medicine

Needs evidence

Evidence based medicine

- Needs evidence
- Needs good quality evidence
- Critically appraised

How do we collect data?

- Same data in all cases
 - One size fits all

RCPath

Data categorisation

Core (mandatory)

- "Required for cancer staging, optimal patient management and prognosis"
- "Supported by robust published evidence"

Non-core (recommended)

RCPath

Data categorisation: core/non-core

 A data item is either core or non-core in all specimens and in any clinical scenario

RCPath

Data categorisation: core/non-core

- A data item is either core or non-core in all specimens and in any clinical scenario
- However a core data item may be critical, important or irrelevant depending on clinical scenario

Diagnosis of prostate cancer in needle biopsy

Critical?

1mm Gleason 3 + 3 prostate cancer in a needle bx

1mm Gleason 3 + 3 prostate cancer in a needle bx

Man with raised PSA

Critical

1mm Gleason 3 + 3 prostate cancer in a needle bx

- Man with raised PSA
 - Critical

Man on active surveillance

Irrelevant

Prostatectomy prognostic data

- Tumour grade
- Tumour volume
- Extraprostatic extension
 - Extent of EPE
- Lymphovascular invasion
- Margin status
 - Extent of margin positivity
 - Grade at positive margin

Prostatectomy prognostic data Clinically less important

Serum PSA excellent tool for monitoring for early recurrence post-radical Prostatectomy prognostic data Clinically less important

- Serum PSA excellent tool for monitoring for early recurrence post-radical
 - Identifies recurrence before clinical/radiology
 - Unlike colon/breast cancer: mets identified only when clinically/radiologically apparent

Prostatectomy prognostic data Clinically less important

- Serum PSA excellent tool for monitoring for early recurrence post-radical
 - Identifies recurrence before clinical/radiology
 - Unlike colon/breast cancer: mets identified only when clinically/radiologically apparent
 - Less reliance on pathology to identify high-risk patients for adjuvant therapy

Prostatectomy prognostic data

- Tumour grade
- Tumour volume
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 - Extent of EPE
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Is all this really necessary?

Pathology data

All data are equal but some data are sometimes **less** equal

How do we report data?

- Same data in all cases
 - One size fits all
 - Vascular invasion in patients with distant mets!!

Proforma reporting One size fits all (scenarios)

Antithesis of personalised medicine?

How do we collect data?

- Same data in all cases
 - One size fits all
 - Vascular invasion in patients with distant mets!!

Precise data

• Lengths and percentages

Pathology measurements: examples

Lengths

- Specimen size
- Tumour size (Macro and Micro)
- Distance to margins

Percentages

- % tumour in prostate biopsy, TURP or prostatectomy
- % tumour components: bladder, testis ...
- % necrosis in RCC
- % sarcomatoid change in RCC

Prostate biopsy report

B) (Left lobe) 6 cores of prostate are seen of which 4 are infiltrated by acinar invasive prostate adenocarcinoma of Gleason patterns 3 and 4. Gleason sum 3 + 4 = 7. Gleason pattern 4 accounts for 25%. WHO Grade Group 2. Background multifocal PIN.

The dimension of the tumour and the volume of tumour (given as a %) in each core is as follows: 2mm (12%), 0.2mm (1%), 0.2mm (1%), 3mm (16%).

Is percentage estimation logical?

% tumour in needle core/organ

- More benign tissue makes tumour better?
- 6mm tumour in 10mm core not more aggressive than 4mm tumour in 5mm core

Is percentage estimation logical?

% tumour in needle core/organ

- More benign tissue makes tumour better?
- 6mm tumour in 10mm core not more aggressive than 4mm tumour in 5mm core
- % tumour components, necrosis, sarcomatoid change etc
 - Depends on sampling protocol
 - % will depend on number of sections taken from areas of necrosis, fleshy white areas etc

How do we collect data?

- Same data in all cases
 - One size fits all
 - Vascular invasion in patients with distant mets!!

Precise data

- *mm or %*
 - amount of tumour, tumour components etc

Prostate biopsy report Tumour extent

B) (Left lobe) 6 cores of prostate are seen of which 4 are infiltrated by acinar invasive prostate adenocarcinoma of Gleason patterns 3 and 4. Gleason sum 3 + 4 = 7. Gleason pattern 4 accounts for 25%. WHO Grade Group 2. Background multifocal PIN.

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Precise data

- *mm or %*
 - amount of tumour, tumour components etc
- Pseudo-precision?

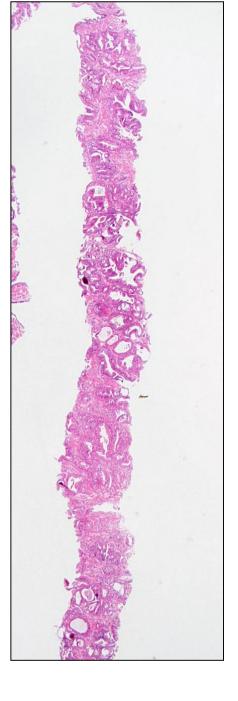
Tumour extent in biopsy

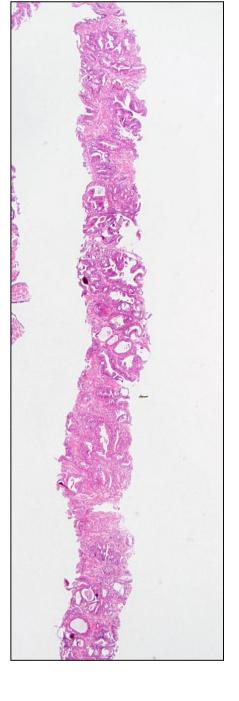
- In view of the marked sampling error of needle biopsies, only a rough estimate of extent is required
 - % core involvement: "eyeball" estimate to nearest 10% (or <10%)
 - Tumour length: to the nearest mm (or <1mm)

Measurements: perfect precision not required

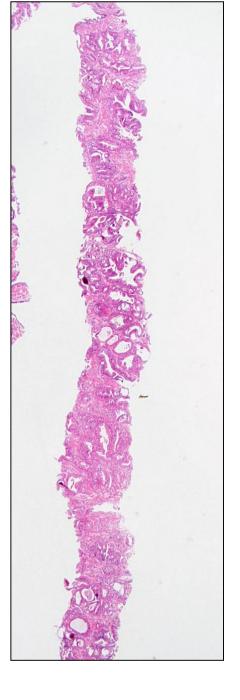
Size/distances (mm)

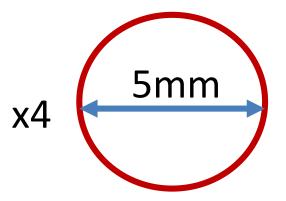
- To nearest mm (or <1mm)
 - "2.1mm" is meaningless
 - May be different in other levels or blocks
 - Cannot eyeball distinguish 2.1 for 2.3mm so would require measuring multiple levels/blocks!

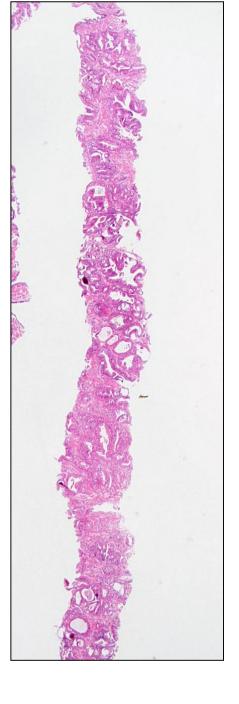


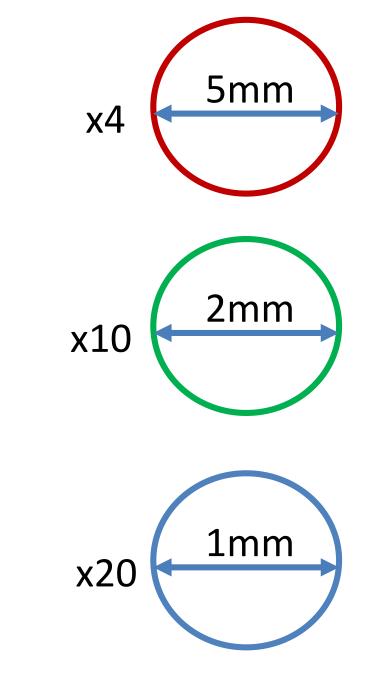


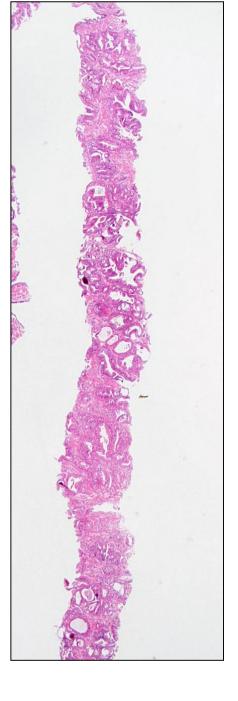
x4

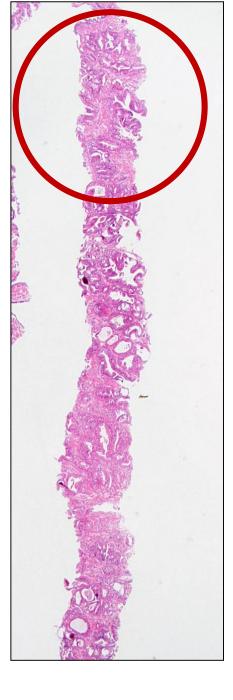


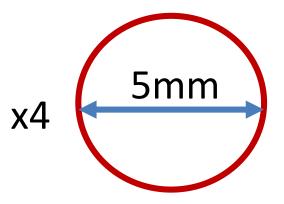




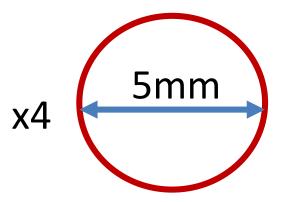


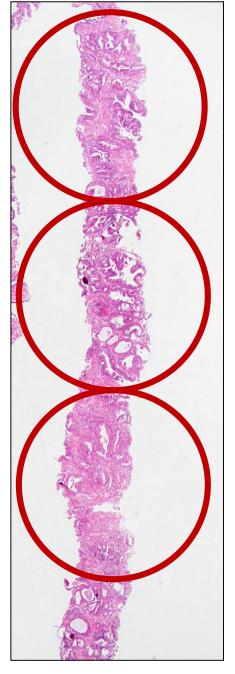


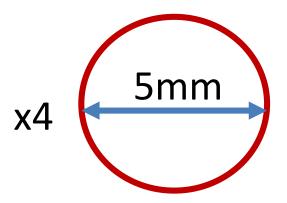


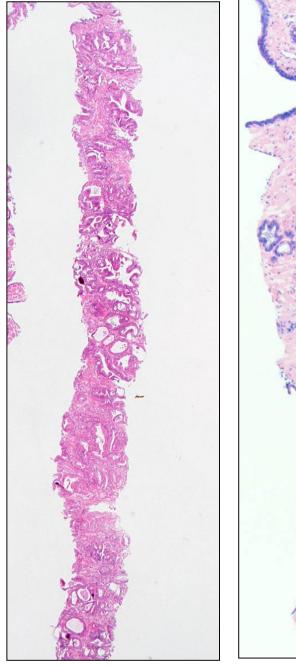


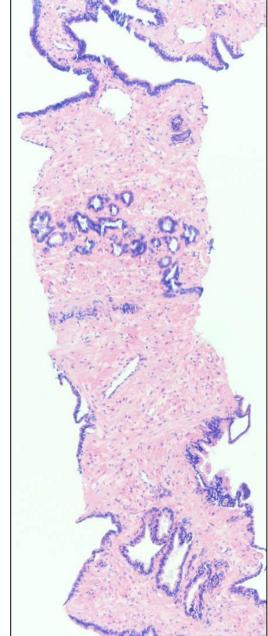


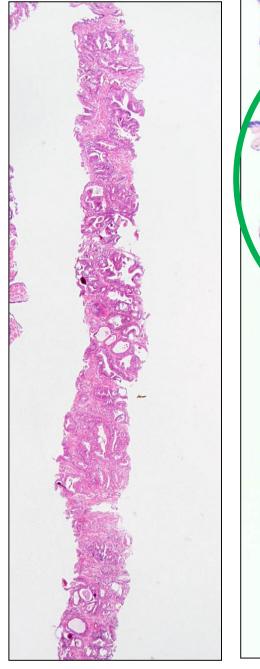


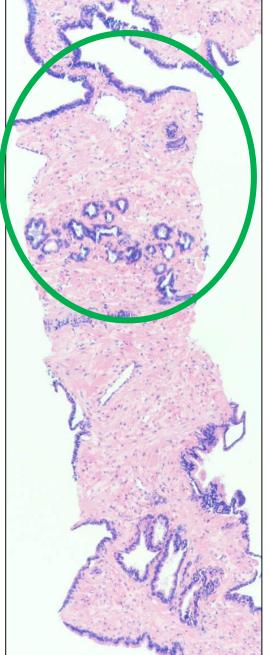


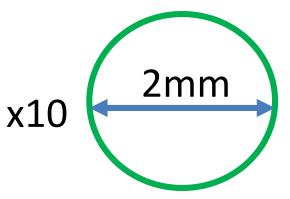


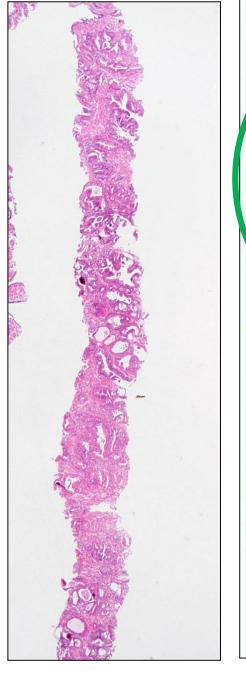


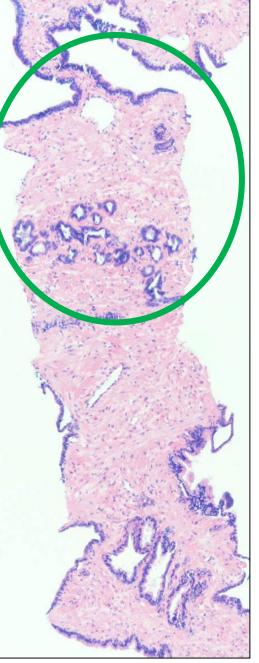


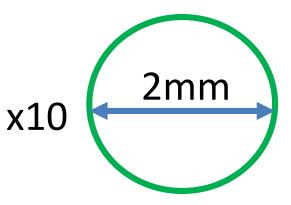












Pseudo-precision Diagnostic criteria Diagnostic criteria for Intraductal cancer Guo and Epstein 2006

- Solid intraductal proliferation
- Dense cribriform intraductal proliferation

OR

- Loose cribriform / micropapillary with
 - Marked atypia (≥ 6x nuclear enlargement)

or

• Non-focal comedonecrosis

Guo and Epstein: "nuclear size ≥ 6x normal" How does one define "nuclear <u>size</u>"?

Guo and Epstein: "nuclear size ≥ 6x normal" How does one define "nuclear <u>size</u>"?

- Nuclear $area \ge 6x$ normal?
- Nuclear *diameter* ≥ 6x normal?

"≥ 6x nuclear enlargement"

Area =
$$\Pi r^2$$

6x **area** = 2.5x diameter

6x **diameter** = 36x area

6x diameter





*

Intraductal Carcinoma of Prostate (IDCP) Reporting Practice:



A Survey of Expert European Uropathologists

Varma M, et al. J Clin Pathol 2016;0:1–6. doi:10.1136/jclinpath-2016-203658

23 experts from 11 countries

5

4

3

2

2

2

United Kingdom:
Germany:
France:
Portugal:
Austria:
Ireland:

1

1

1

1

- Spain:
- Sweden:
- Italy:
- Switzerland:

Guo and Epstein: "nuclear size ≥ 6x normal" How would you define "nuclear <u>size</u>"?

74%

5%

- Nuclear area ≥ 6x normal:
- Nuclear diameter ≥ 6x normal: 21%
- Unsure:

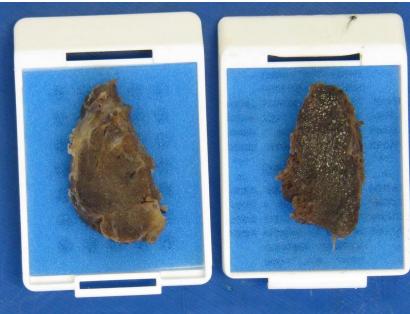
Varma M, et al. J Clin Pathol 2016;0:1–6. doi:10.1136/jclinpath-2016-203658

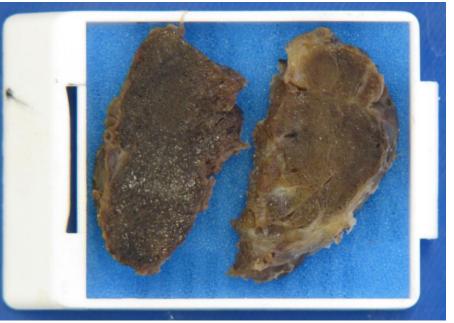
Total thyroidectomy for Graves "2 blocks from each lobe"



"2 blocks from each lobe" What is a block?







Re-define as "x cm² tissue per cm max diameter?

Re-define as "x cm² tissue per cm max diameter?

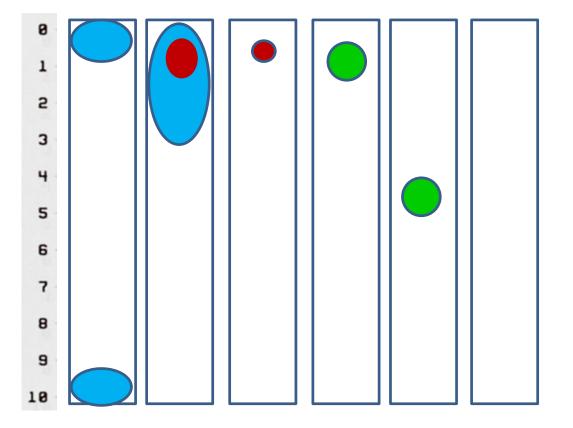
Number of blocks too simplistic?

- Sampling macroscopically different areas more important than number of blocks
- Need fewer blocks for grossly homogeneous tumours?

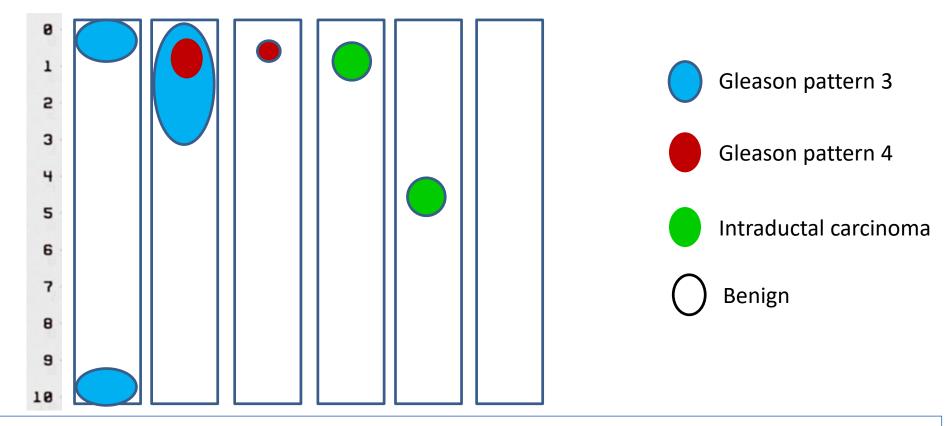
- Re-define as "x cm² tissue per cm max diameter?
- Number of blocks too simplistic?
- Are such requirements pertinent for cystic lesions
 - Size of cystic lesion depends on amount of fluid

Second Second Second Second Einstein's definition of insanity

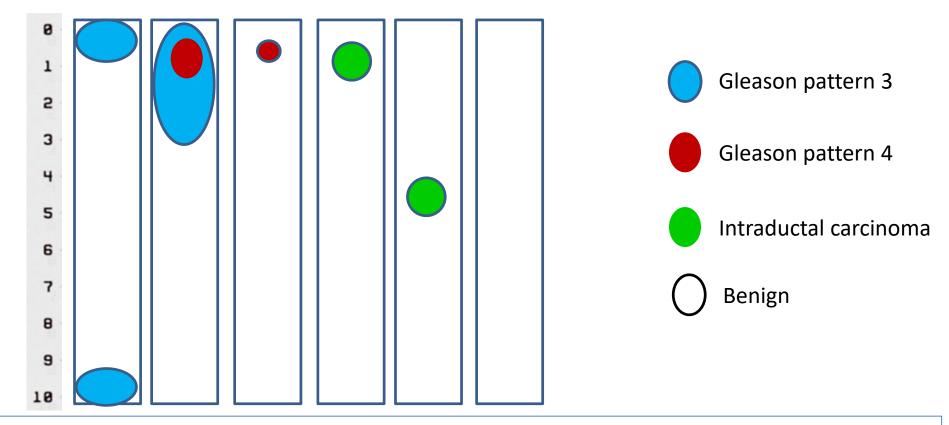
Doing something very differently and expecting the *same* result!







3/6 cores, max 3mm/30%, Gleason 3+4=7 (ISUP Grade: 2) IDC-P not included in tumour extent, Intervening benign excluded, Global Gleason



3/6 cores, max 3mm/30%, Gleason 3+4=7 (ISUP Grade: 2)

IDC-P not included in tumour extent,

Intervening benign excluded, Global Gleason

5/6 cores, max 10mm/100%, Gleason 4+4=8 (ISUP Grade: 4) IDC-P included in tumour extent, Intervening benign included, Worst Gleason,

Pathology data

- Why do we collect data?
- Who do we collect data for?
- How do we collect data?
- Why do we need to change?
- How do we change?

Ever increasing workload

NICE National Institute for	NICE	NICE	Standards	Evidence	Sign in
Health and Care Excellence	Pathways	Guidance	and indicators	services	
NICE Health and Care Excellence					Sign in

Home > NICE Guidance > Conditions and diseases > Genetic conditions > Genetic conditions: general and other

Molecular testing strategies for Lynch syndrome in people with colorectal cancer

1 Recommendations



1.1 Offer testing to all people with colorectal cancer, when first diagnosed, using immunohistochemistry for mismatch repair proteins or microsatellite instability testing to identify tumours with deficient DNA mismatch repair, and to guide further sequential testing for Lynch syndrome (see 1.2 and 1.3). Do not wait for the results before starting treatment.

- Ever increasing workload
- Ever lengthening cancer datasets

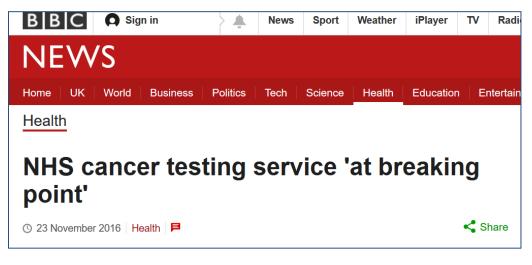
- Ever increasing workload
- Ever lengthening cancer datasets
- Increasing other commitments
 - Management, EQA, Appraisal, revalidation

- Ever increasing workload
- Ever lengthening cancer datasets
- Increasing other commitments
- No increase in resources
 - Manpower, finance

*TESTING TIMES TO COME? AN EVALUATION OF PATHOLOGY CAPACITY ACROSS THE UK

NOVEMBER 2016





Risks of current practice

Waste of resources

• Time and money

Information overload

- Significant findings missed by clinicians
- Stressed pathologist

Risk of errors

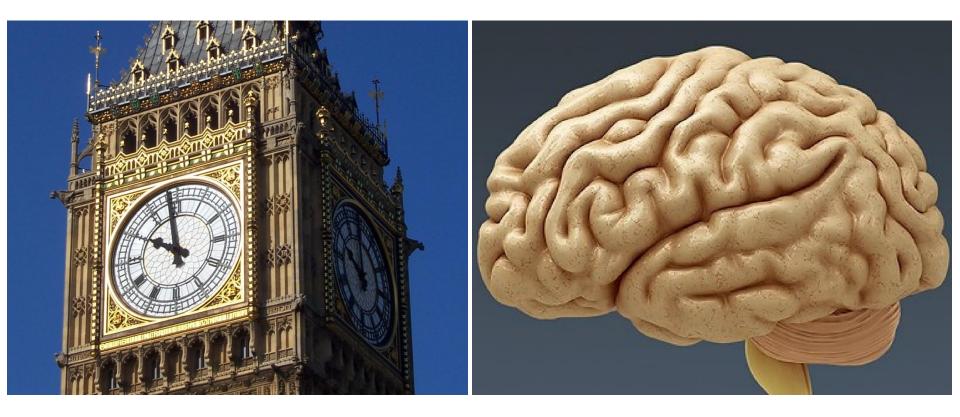
• Missing data due to excess redundant data

Man vs Machine



Human constraints

Time Concentration span



Risks of current practice

- Waste of resources
 - Time and money
- Information overload
 - Significant findings missed by clinicians
- Stressed pathologist
- Risk of errors
 - Missing data due to excess redundant data

B. (Left lobe). Six cores and tissue fragments are seen of which three are infiltrated by invasive prostate adenocarcinoma of Gleason sum 3 + 4 = 7. The vast majority is pattern 3 with a small amount of pattern 4. The dimension of the tumour and the volume the tumour given as a %) in each core is as follows: 8mm 47% 8mm 67% 3 mm (19%). Focal perineural invasion is seen but no ovidence of extraprostatic extension or lymphovascular invasion is present. The greatest percentage of cancer in any core is 67%) The greatest focus of cancer in any cores measures 8mm The total percentage of cancer in the entire tissue of the left lobe is 24%. Associated high grade cribriform PIN is noted.

CONCLUSION:

Α.	PROSTATE,		- FOCUS SUSPICIOUS OF HIGH GRADE PIN. - NO EVIDENCE OF MALIGNANCY.
Β.	PROSTATE,	-	ADENOCARCINOMA, GLEASON 3 + 3. 3/6 CORES INVOLVED. GREATEST PERCENTAGE OF CANCER 67%. GREATEST FOCUS OF CANCER 8MM.

Total: 9 measurements in text + 2 in Conclusion

Risks of current practice

- Waste of resources
 - Time and money
- Information overload
 - Significant findings missed by clinicians
- Stressed pathologist
- Risk of errors
 - Missing data due to excess redundant data
 - Transcription error missed in unduly long report

Information overload? Typo missed

B. (Left lobe). Six cores and tissue fragments are seen of which three are infiltrated by invasive prostate adenocarcinoma of Gleason sum 3 + 4 = 7. The vast majority is pattern 3 with a small amount of pattern 4. The dimension of the tumour and the volume of the tumour (given as a %) in each core is as follows: 8mm (47%), 8mm (67%), 3mm (19%). Focal perineural invasion is seen but no evidence of extraprostatic extension or lymphovascular invasion is present. The greatest percentage of cancer in any core is 67%. The greatest focus of cancer in any cores measures 8mm. The total percentage of cancer in the entire tissue of the left lobe is 24%. Associated high grade cribriform PIN is noted.

CONCLUSION:

A. PROSTATE, RIGHT LOBE - FOCUS SUSPICIOUS OF HIGH GRADE PIN.
- NO EVIDENCE OF MALIGNANCY
B. PROSTATE, LEFT LOBE - ADENOCARCINOMA, GLEASON 3 + 3.
- 3/6 CORES INVOLVED.
- GREATEST PERCENTAGE OF CANCER 67%.
- GREATEST FOCUS OF CANCER 8MM.

Pathology data

- Why do we collect data?
- Who do we collect data for?
- How do we collect data?
- Why do we need to change?
- How do we change?

How do we change?

Consider patient management

- All differentials are not equally important
- All dataset items not equally important

More focussed approach

- Focus on clinically important data items
- <u>While still meeting RCPath requirements</u>
 - RCPath requirements need to change?

Provide more guidance

- Clinical utility of pathology data
- What is important when and why
- How to collect data?
 - Degree of precision required

- Provide more guidance
- More scrutiny of recommended data items
 - Especially non-core data items

- Provide more guidance
- More scrutiny of recommended data items
- Change the way we audit data?
 - Focus on accuracy rather than completeness
 - Evalaute clinical significance of missing data
 - Vascular invasion missing in patients with known LN metastasis may be less important