To the standardisation of pathology protocols

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To the standardisation of pathology protocols

introduction

- ‘Clinicians are from Mars and pathologists are from Venus’ (*Powsner SM Arch Pathol Lab Med 2000;124:1040-1046*)

  –30% discordance between pathologists’ intended meanings and interpretation by surgeons (open-book-examination-style questionnaire of pathology reports)

  –‘Clinicians and pathologists need to improve medical communication’

  –First efforts to standardize pathology reports in 1970’s (Am J Clin Pathol 1973;60:789-798)

  –The ‘communication gap’ still exists in 2011

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- ‘Quality indicators in breast cancer care’
  (*Rosselli Del Turco M et al. Eur J Cancer 46(2010) 2344-2356*)
  - Eusoma workshop: QI on diagnosis, surgery and loco-regional treatment, systemic treatment & staging, counselling, follow-up and rehabilitation
  - QI 4: ‘completeness of prognostic/predictive characterisation’
  - Target standard: >98%
  - Main motivation: optimal patient-tailored treatment planning based on prognostic and predictive histopathological data

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- 'European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed.' : '**pathology labs should be accredited according to national standards**'

- In Belgium: **ISO 15189:2007** necessary for predictive-factor testing & reporting (ER, HER2, …)
  ('Medical laboratories – Particular requirements for quality and competence')

- **ISO 15189:2007 requirements** concerning reporting of results (chapter 5.8):
  - The format of the report form should be determined **in discussion with the user**
  - The laboratory management shares responsibility with the requester for ensuring that reports are received by the appropriate individuals within an agreed-upon time interval
  - Results shall be **legible**, without mistake in transcription *(+ elements listed)*
  - The report shall indicate if the quality of the sample received was unsuitable or could have compromised the result ***(disclaimer-strategy)***
  - **Archive** such that prompt retrieval of information is possible

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aims of standardisation

- To increase the **quality** of the pathology report: 'fit for purpose' (TAT!)

report	content	format	Multi-disciplinary discussion	interface
Complete/accurate	++		+	
Uniform	+	+		
Clear/usable		++	++	+
Data transfer to national registry, tissue bank,…		++		++
Statistical analysis		++		++
Implementation of international scoring sytems, grading, …	+		++	
Suitable for auditing		++		+

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standard request form

- Accurate pathology report not possible without knowledge of clinical/imaging information:
  - Often no standardisation of clinical/imaging information in medical patient records: quadrant location?
  - Often no standardised format op pre-operative multidisciplinary meeting report: metastatic disease? previous surgery?
  - Some information should be readily accessible during intra-operative pathological assessment

- Standard request form:
  - Recommended in publications related to standard pathology reporting
  - Format: ticking boxes + free text space
  - Content:
    surgical procedure
    tumour characteristics (size, multi-focal?, palpable?, pre-op diagnosis, position in specimen)
    orientation of specimen / multiple specimens
    time of excision / fixation (pre-analytical conditions!)

- Flemish Society of Obstetrics and Gynaecology (VVOG)-initiative

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standard request form

Patient identification: Name: First name: Gender: Date of birth: Address: Insurance company: Registration number:	**Identification of prescribing physician** Name: First name: Address: RIZIV nr.: Date of prescription: Signature: Send copy of report to:
☐FNAC ☐CNB ☐VACNB ☐wide local excision ☐additional excision ☐mastectomy ☐sentinel lymph node n=.... ☐additional lymph nodes ☐axillary clearance ☐other:	☐ **Intra-operative examination:** **Tel. nr. operating room:** Specific question:
Request for immunohistochemical examination: ☐ER ☐PR ☐HER2/neu ☐ Ki-67	

Date of biopsy/excision: ..... ☐ **Fixed: ..... h** **(note starting time of formalin fixation)**

or

Time of biopsy/excision: ..... h ☐ **Unfixed:** **deliver specimen promptly to lab!**

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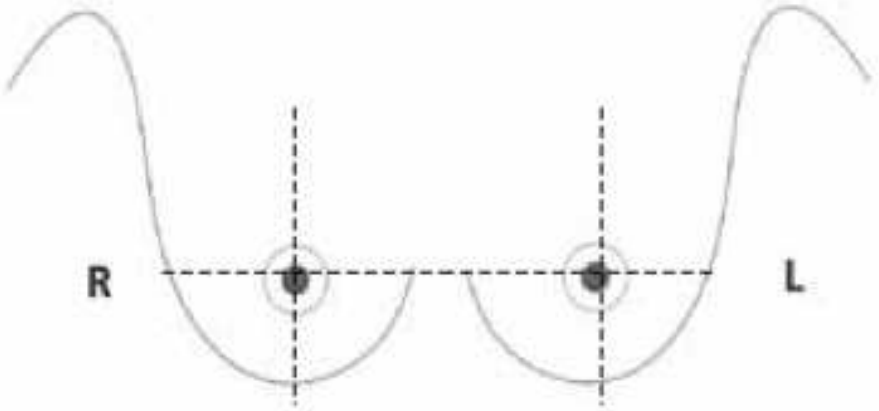
Anatomical localisation and clinical information:

Draw position of the tumour(s) on the scheme!



Numbering of containers:

Orientation of specimen:

Maximal tumour diameter: .....mm ☐clinically ☐imaging

multifocal? ☐yes ☐no microcalcifications? ☐yes ☐no

palpable? ☐yes ☐no wire guided? ☐yes ☐no

specimen radiography? ☐yes ☐no

preoperative tumour diagnosis? ☐yes ☐no histology: ..... lab reference:

preoperative axillary FNAC? ☐yes ☐no cytology: ..... lab reference:

previous surgery of the breast? ☐yes ☐no :.....

previous radio-/chemotherapy? ☐yes ☐no :.....

clips present? ☐ yes ☐no inflammatory symptoms suggestive of T4d? ☐ yes ☐no

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- Compliance?
  - Complete reporting of pathological information is a shared responsibility of the surgeon and the pathologist
  - dialogue with requester when designing request form
  - latest version available on the intranet site of the hospital
  - audit: interim analyses of compliance
  - feedback to requester
  - complaint registration, error registration and analysis to improve content/format
  - use of disclaimers in pathology report

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standard pathology report

'synoptic report', 'standard proforma', 'pathology checklist', 'pathology data form' <> 'free text'

•'European guidelines for quality assurance in breast cancer screening and diagnosis. 4th ed.' (summary document in 2008, *Ann Oncol*)

- '**Standard histopathology reporting forms should be used**'
- 'specimen European breast pathology data form' in guidelines
- More static (2006-version still valid, 2011-version in press)

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‘synoptic report’, ‘standard proforma’, ‘pathology checklist’, ‘pathology data form’ <> ‘free text’

- ‘College of American Pathologists’
  - electronic Cancer Checklists
  - On www.cap.org
  - More dynamic (frequent updating)

- ‘Commission on Cancer of the American College of Surgeons’ in 2010 / Standard 4.6 ‘guidelines for patient management and treatment’
  - For commendation: ‘90% of the cancer pathology reports include all of the scientifically validated data elements defined by the CAP protocols and 90% use a synoptic format’

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standard pathology report

CAP-checklist

- Includes elements from *AJCC Cancer Staging Manual 7th edition*
- Regularly scheduled updates: 'Invasive breast' updated October 2009
- Education service for optimal implementation in pathology workflow
- Recognized as a 'gold standard' in summary reporting worldwide
- 'work aids' provided:
  - For use at the microscope
  - Formatted on 1 page
  - Contain the minimally required cancer reporting elements
  - Do not contain the additional optional elements of the full electronic checklists
  - Contain a pathological staging key
  - Corresponds to the 'specimen European breast pathology data form'/ 'Breast cancer histopathology minimum dataset report' of the UK-NHS
  - Minimal efforts to extract a standard report

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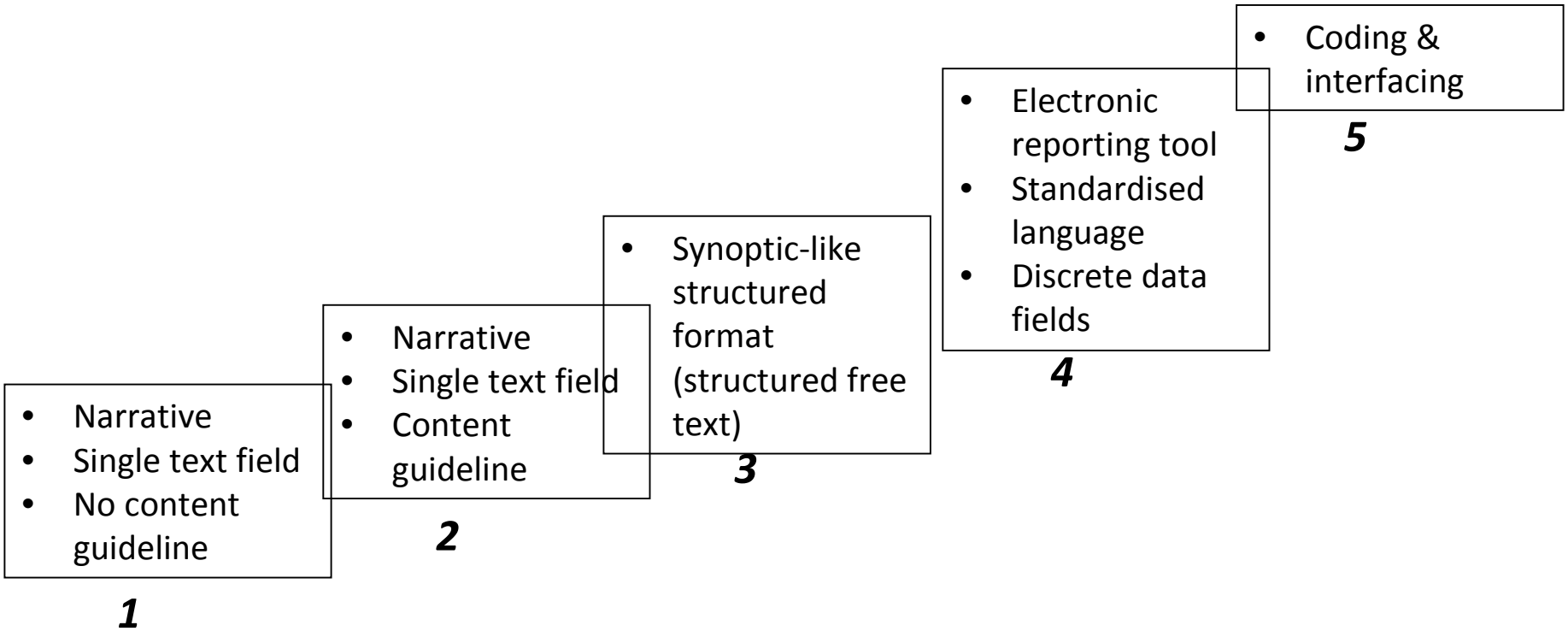
‘Spectrum of cancer pathology reporting’



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Effects of the introduction of standardised synoptic pathology reporting:

Study: Srigley JR *et al.* J Surg Oncol 2009; 99:517-524

•CAP checklist implementation in Ontario in 2005 (Canada): 85 pathology labs: evolution of completeness of reporting.

TABLE III. Changing Rates of Synoptic Reporting

Site	Year	No. of audited reports	Synoptic format (%)
Breast[a]	2005	1,746 (1,652 cases)	86.9
	2006	1,285 (1,113 cases)	95.0

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TABLE IV. Relationship Between Completeness of Cancer Pathology Reporting and Tumor Site, Year, and Format

Site	Year	No. of synoptic	Complete (%)	No. of narrative	Complete (%)
Breast	2005	1518	80.0	228	43.0
	2006	1057	93.0	56	71.4

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TABLE V. Relationship Between Report Format and Completeness Rates by Disease Site (Pooled 2005 and 2006 Data)

Site	Format	No. of reports	Complete (%)
Breast	Synoptic	2,575	85.3
	Narrative	284	48.6

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Effects of the introduction of standardised synoptic pathology reporting:

comparable results in

- Austin R et al. Pathology 2009; 41(4): 361-365
(Australian Cancer Network)

- Idowu MO et al. Arch Pathol Lab Med 2010; 134: 969-974
(CAP-member laboratories in US, Canada, Australia)

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Experienced advantages of standardised synoptic pathology reporting:

- More likely to be complete than narrative reports (no features overlooked, also reporting on the absence of a feature)
- Especially useful for low-volume pathology labs
- Saves time when retrieving information
- More user-friendly
- Better suited for cancer surveillance, epidemiological studies, health resource planners, tissue banking (better implementation of reporting recommendations e.g. TNM)
- More easy to use for quality improvement in the lab/hospital (database linked to input fields: queries possible, e.g. number of sentinel lymph nodes, …)

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Additional information to be added to most synoptic pathology report models available today:

•Paraffin-blocks: coding and content

•Pre-analytical information influencing the quality of analyses (e.g. ER-, HER2-immunohistochemistry / RNA-expression analysis): cold ischemia time, time to fixation

•Disclaimer statements if pre-analytical requirements are not fullfilled

•Specific data-fields related to breast surgery following neo-adjuvant treatment and related to inflammatory breast cancer (T4d)

•Electronic validation statement (date/time/pathologist) linked to the laboratory information system

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Critical remarks:

•Monitoring/auditing system for completeness (10-15% still inadequate)

•Be aware of forced choices (‘drop down menus’): complete but also accurate?

•Ticking boxes: can be error-prone (format-issue)

•Some data forms are too detailed: define ‘required’ & ‘optional’ elements

•Needs to be carefully reviewed before validation

•Design principles: use of diagnostic headlines for key points, layout continuity, optimization of information density, reduction of unnecessary information *(Valenstein PN, Arch Pathol Lab Med 2008; 132: 84-94)*

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conclusions

- Standard reporting of breast pathology is recommended by Eusoma & CAP and leads to high quality (‘fit for purpose’) pathology reports
- Data forms / checklist are available and are being updated when necessary
- Checklist with tick boxes and minimal need for free text are the preferred format (‘drop down menus’, ‘standardized language’)
- In Flanders: few labs have adopted standard reporting (pathologists ‘addicted’ to narration)
- Large-scale implementation only feasible if the standard report replaces/shortens the free text report.
- Pathologists-in-training should be instructed to use standard synoptic reports
- The use of standard pathology reports should be a requirement for obtaining accreditation (Eusoma, ISO, …)
- Standard pathology request forms & reports improve communication between clinicians and pathologists and thus the quality of care.