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Assessing the Value of Diagnostic Tests: Advances in methodology

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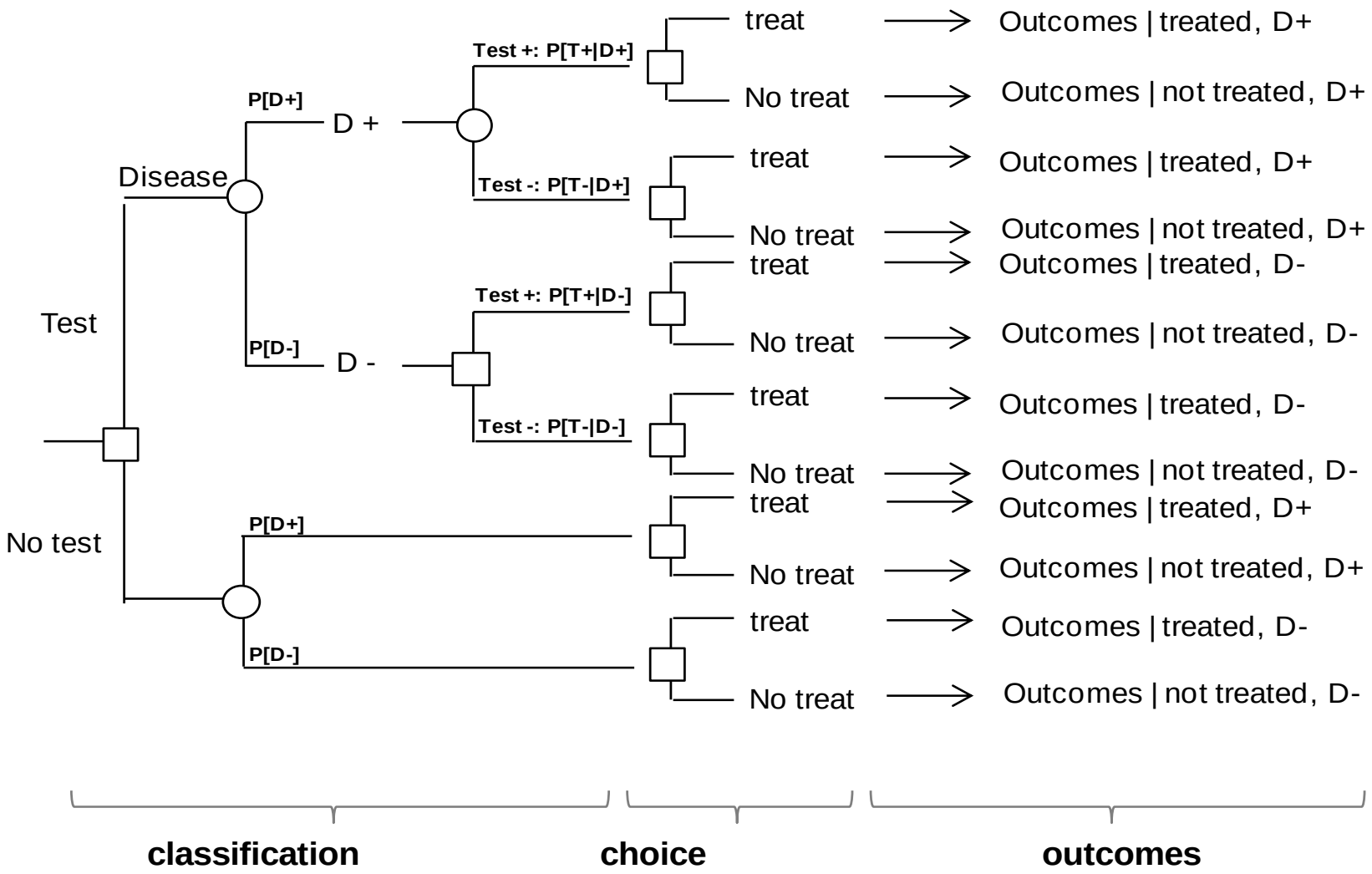
Outline

- A framework for assessment
- A case study assessing colposcopy
  - Using accuracy results for decisions that are not dichotomous
  - Choice with additional classification evidence
- Conclusions

A Framework for Assessment



Adjunctive Colposcopy Technologies

- Colposcopy used to visualize the cervix to identify precancerous cells, CIN1-CIN3.
- A mathematical model was developed
  - Patients were classified based on the SN and SP reported in the literature
  - Treatment decisions were based on reasons for referral and colposcopy results
  - Outcomes were based on the patients underlying health state and treatment

Modelling binary classification

- Clinical accuracy studies reported SN and SP at the CIN2+ cut-off
- Clinicians suggested that treatment decision would be based on whether a patient was identified as,
  - Clear
  - CIN1
  - CIN2/3
  - Cancer

Sensitivities and Specificities

Diagnostic device	Sensitivity	Specificity
Colposcopy alone	0.519	0.817
DySIS	0.648	0.702
DySIS + colposcopy	0.796	0.626

- Louwers et al. *BJOG*, 2011

Probabilities to convert Sensitivities and Specificities

True health state	Result based on CIN2+ cut-off	Diagnosis based on colposcopy or new technology	Probability
Cancer	False-negative	Clear	0.333
		CIN1	0.667
	True-positive	CIN2/3	0.077
		Cancer	0.923

- Gallwas et al. *Lasers Surg Med*, 2011

Choices based on all classifications

- The value of the diagnostic is determined by the ability to inform the correct treatment choice
- This depends on the additional information the diagnostic provides when all of the other information used to make the treatment decision is considered
- Does the diagnostic provide information on a characteristic already considered, or is this a new characteristic?

Reason for referral	Colposcopy or new technology results	Treatment possibilities	Guidelines and clinical advice (%)	Gateshead data (%)
Moderate dyskaryosis	Normal	Discharge and return to normal screening	0	8.6
		Follow-up	100	28.6
		Immediate treatment – excision biopsy	0	8.6
		Biopsy, no curative intent (punch or small excision)	0	54.3
	Low grade	Discharge and return to normal screening	0	0.0
		Follow-up	0	7.1
		Immediate treatment – excision biopsy	0	11.1
		Biopsy, no curative intent (punch or small excision)	100	81.7
	High grade	Discharge and return to normal screening	0	1.3
		Follow-up	0	5.4
		Immediate treatment – excision biopsy	80	84.9
		Biopsy, no curative intent (punch or small excision)	20	8.4
	Cancer (I–IV)	Discharge and return to normal screening	0	0.0
		Follow-up	0	0.0
		Immediate treatment – excision biopsy	90	100.0
		Biopsy, no curative intent (punch or small excision)	10	0.0

Conclusions

- The methods for modelling diagnostics are not very different from other health technologies, although additional information is needed
- The framework for assessment may help understand the decision problem and needed information
- The issues I have discussed in the case study could have been resolved by reporting the appropriate information