

PDD- Why do we need a HTA funded randomised trial?

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PDD- Diagnostic tool or Treatment?

Better diagnosis rarely changes outcomes

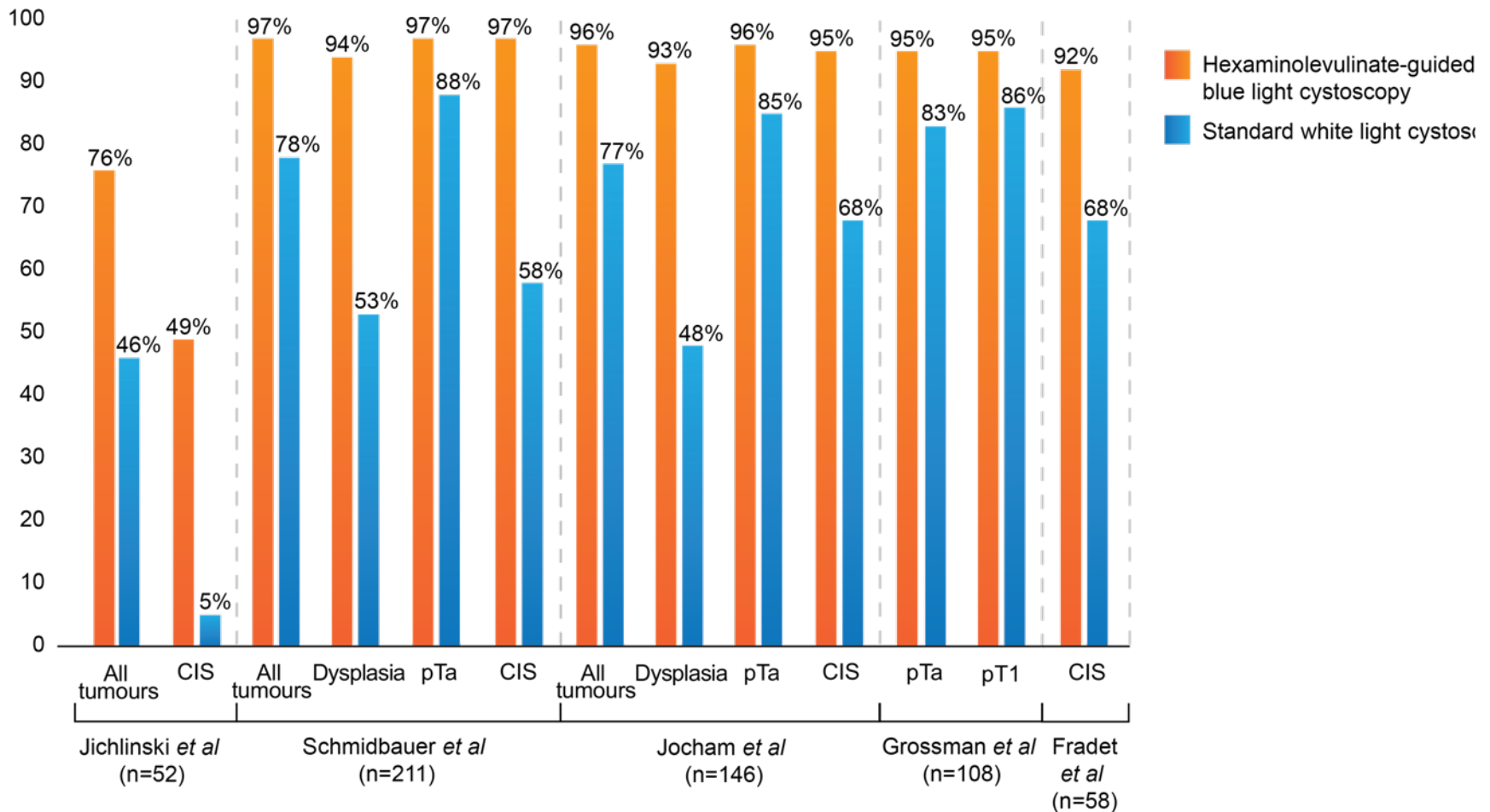


Surgical treatment complex and difficult to measure

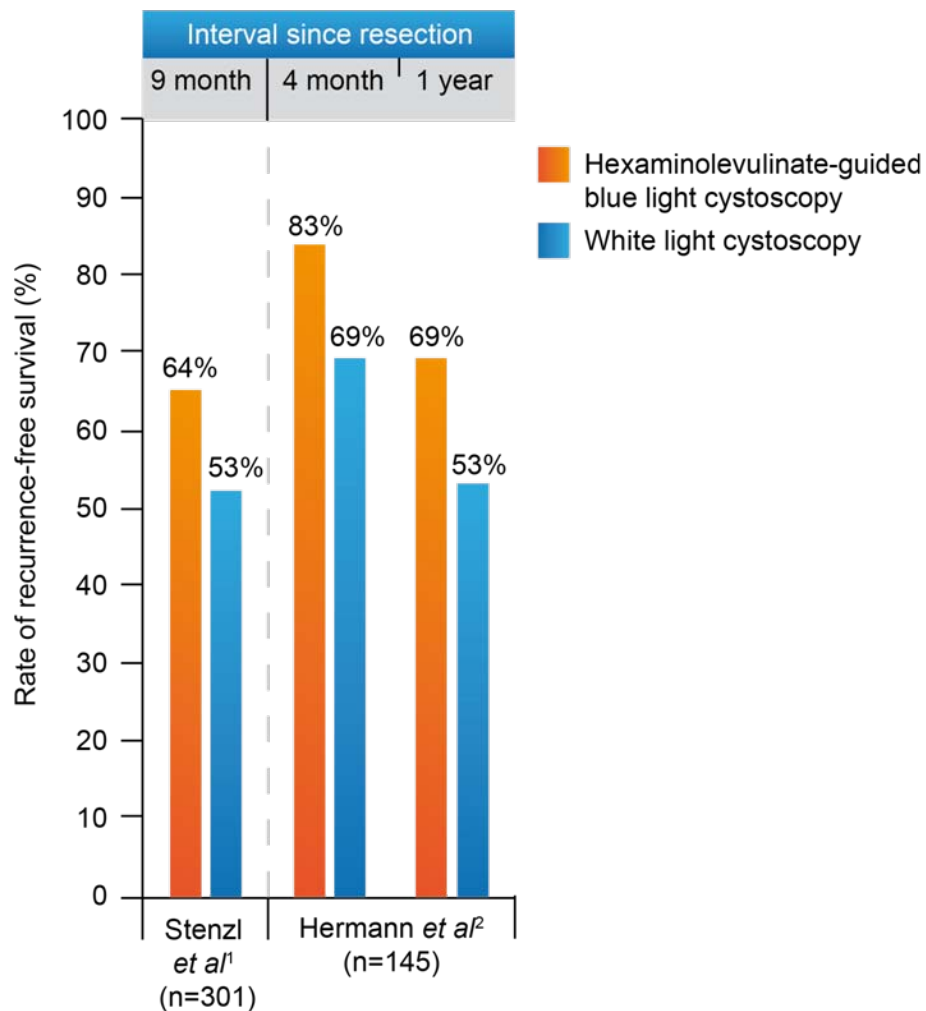


Is there enough current evidence
to implement/ditch PDD?

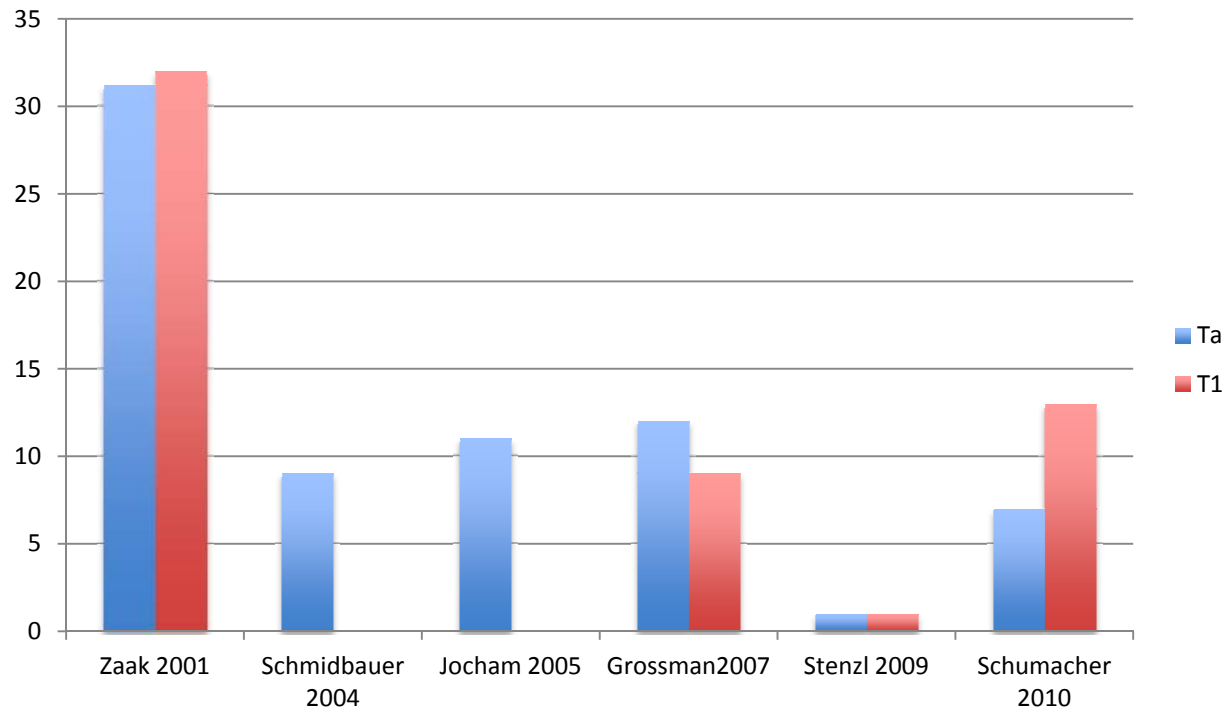
Tumour detection rate for cystoscopy under blue light versus white light



Recurrence-free survival after resection guided by blue light or white light cystoscopy^{1,2}



Additional Papillary tumour detection rates



The Narrowing Gap

- Blinding
- Use of immediate MMC
- (5-ALA)
- Improved TURBT technique
- Ratio of T_a/T_1

A prospective randomised trial of Hexylaminolevulinate (Hexvix) assisted transurethral resection (TURBT) plus single shot intravesical mitomycin (MMC) versus conventional white light TURBT plus single shot MMC in newly presenting bladder cancer

O'Brien, T.S. et al.

249 pts

Although photodynamic diagnosis offers a more accurate diagnostic assessment of a bladder tumour, in this trial we have not shown that this reduces recurrence.

Systematic review of the clinical effectiveness and cost-effectiveness of photodynamic diagnosis and urine biomarkers (FISH, ImmunoCyt, NMP22) and cytology for the detection and follow-up of bladder cancer

G Mowatt, S Zhu, M Kilonzo,
C Boachie, C Fraser, TRL Griffiths,
J N'Dow, G Nabi, J Cook and L Vale

Conclusions: The advantages of PDD's higher sensitivity in detecting bladder cancer have to be weighed against the disadvantages of a higher false-positive rate. Taking into account the assumptions made in the model, strategies involving biomarkers and/or

PDD provide additional benefits at a cost that society might be willing to pay. Strategies replacing WLC with PDD provide more life-years but it is unclear whether they are worth the extra cost.

Further research is required in the following areas:

- RCTs including economic evaluations comparing PDD with rigid WLC at TURBT plus adjuvant immediate single-dose intravesical chemotherapy in patients diagnosed with bladder tumours at CSC.

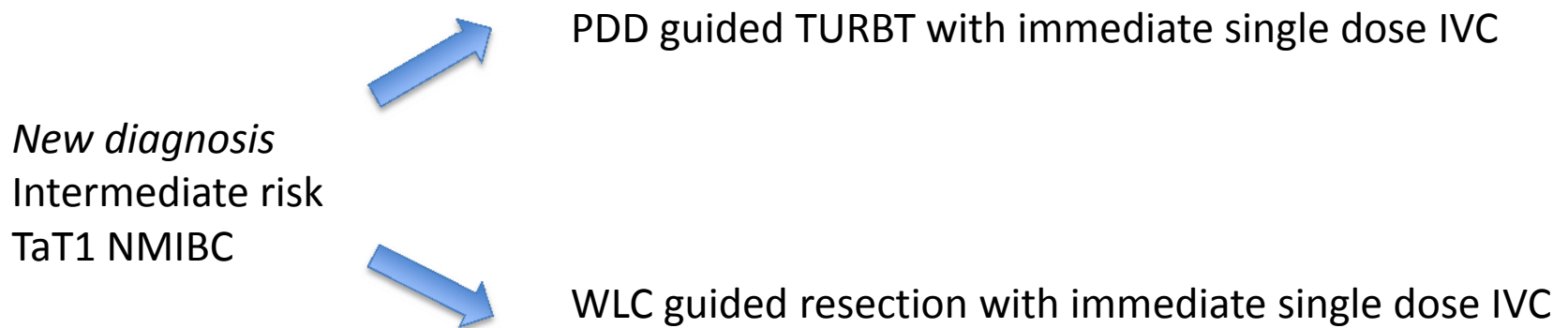
The HTA programme

- ‘Costs and broader impact... for those who manage or develop policy for the NHS’
- ‘A pressing need within the NHS’
- Multidisciplinary
- HR-QOL
- Costs

HTA Diagnostics and Imaging Evaluations

- Effect on pt **management** and **outcomes** (where changes in management → **benefits**)
- Improvements in accuracy **not important *per se***.
- Justify how accuracy is **relevant**
- Changes in other **resources/subsequent therapies**

Does the use of PDD guided TURBT improve treatment outcomes for newly diagnosed patients with bladder cancer?

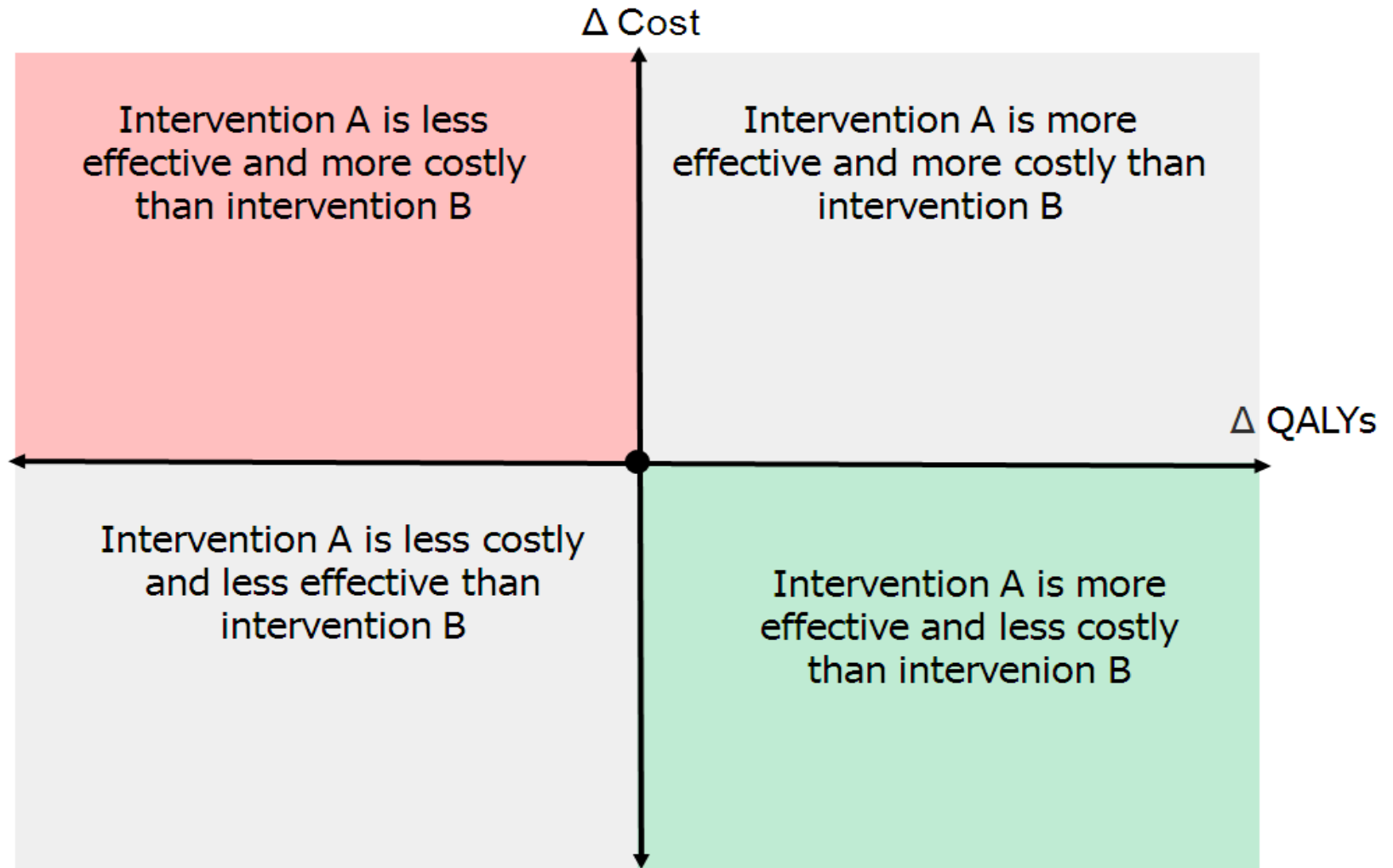


- Clinical and cost-effectiveness of PDD
- Account for learning curve affecting outcomes
- Full assessment of the costs
- Investigate safe monitoring frequency

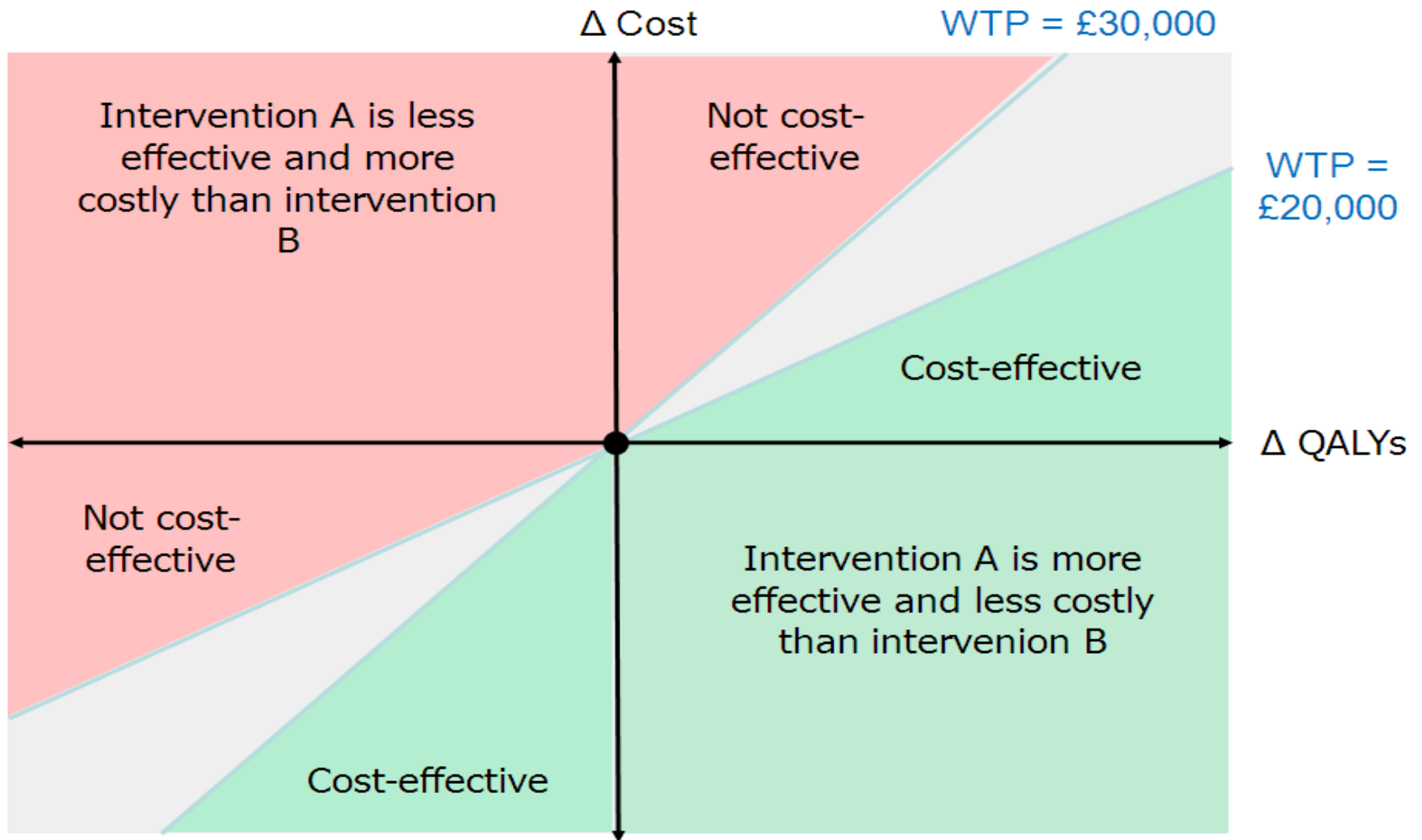
Whats the big deal?

- Total cost of Hexvix for ~ 5000 new NMIBC/yr = £2m (Trial cost £3.6M)
- Total cost of Rx and f/up for 5 years is ~ £65m
- Not diagnosis RCT but investigate ↓ surveillance

Interpreting cost-effectiveness

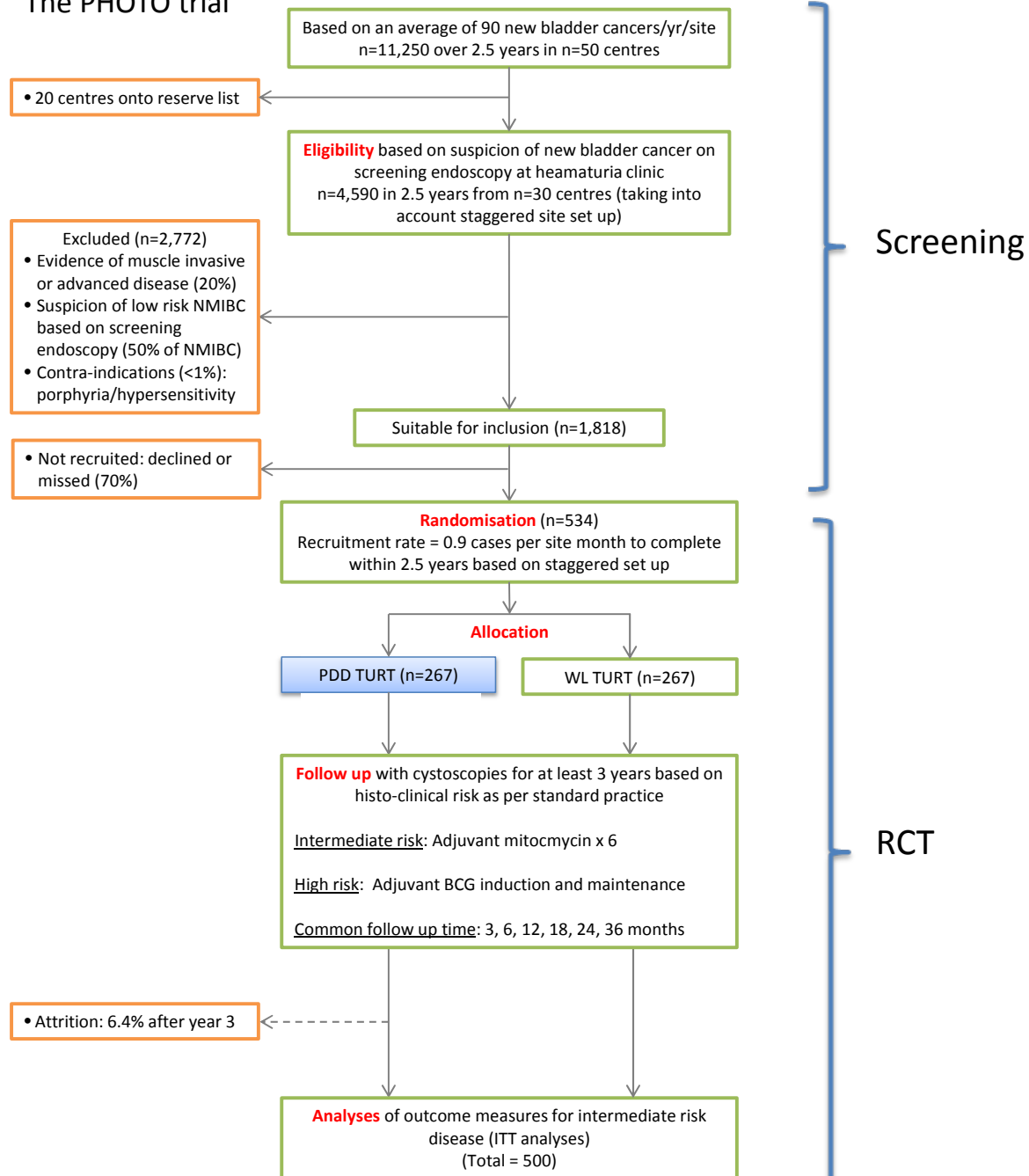


Cost-effectiveness plane: willingness to pay

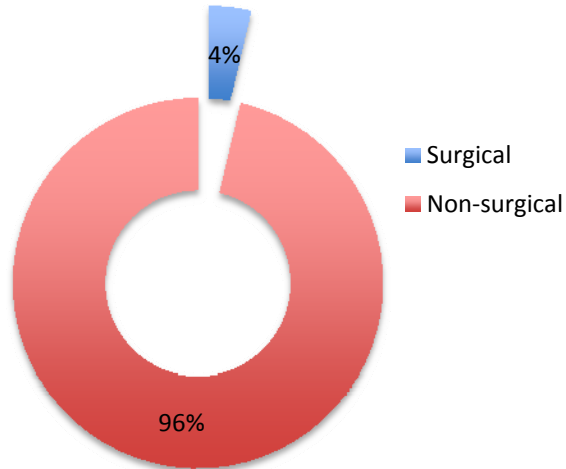


- Bladder cancer overtaken by breast cancer as most expensive cancer to Rx
- Herceptin costs £1m per life saved

The PHOTO trial



Why urology needs a HTA-funded RCT



106/2831 NCRI awards



- PDD improves the accuracy of NMIBC Dx
- Effect on management, outcomes and benefits less clear
- PDD – The NHS needs a HTA-funded randomised trial