



IVD's & Evidence – Use & Risk Model

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Date

IVD's and Evidence – Use and Risk Model

Key Points

- IVD's \neq Pharmaceuticals
- IVD's = Aid to diagnosis
- IVD's = Complexity of use
- IVD's = Clinical value
- IVD's = Risk

IVD's

- WHO uses them?
- WHAT are they used for?
- WHEN are they used?
- WHERE are they used?
- HOW are they used?

WHO uses IVD's

- Professional - BMS, Clinician, Nurse
- Retail - Pharmacy, Drug Store, Supermarket
- Public/Patient - DTC, OTC, Rx
- Other - Ambulance, Health Screening companies

WHAT are IVD's used for?

- Rule in condition (+ clinical observation)
- Rule out condition (+ clinical observation)
- Inform worried well and worried sick

WHEN are IVD's used?

- Aid to diagnosis - HbA1c, PSA, BNP
- Screening - Lipids, Bowel Cancer
- Monitoring - SBGM
- Staging - Cancer RA
- Targeting Therapy - Companion Diagnostics

WHERE are IVD's used?

- Hospitals - Path Lab, OR, ER, ICU etc
- Primary Care - GP, Practice Nurse, Public Health
- Community - Almost anywhere!

HOW are IVD's used?

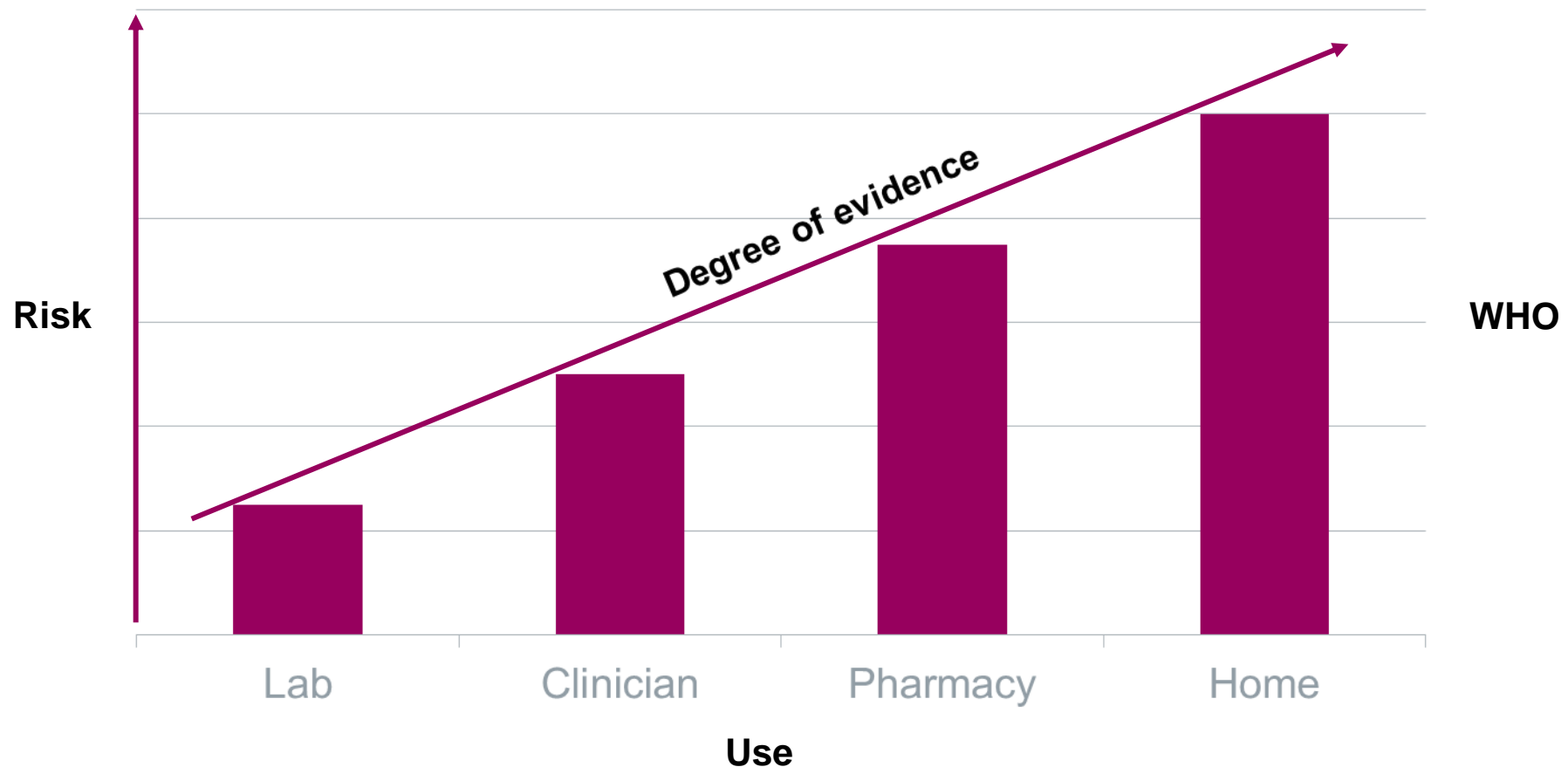
- As a back up test
- As a front line test
- In combination with clinical scoring (e.g. Wells Score)

IVD Evidence should...

- Relate to the risk
- Relate to the use

Risk, Use & Evidence

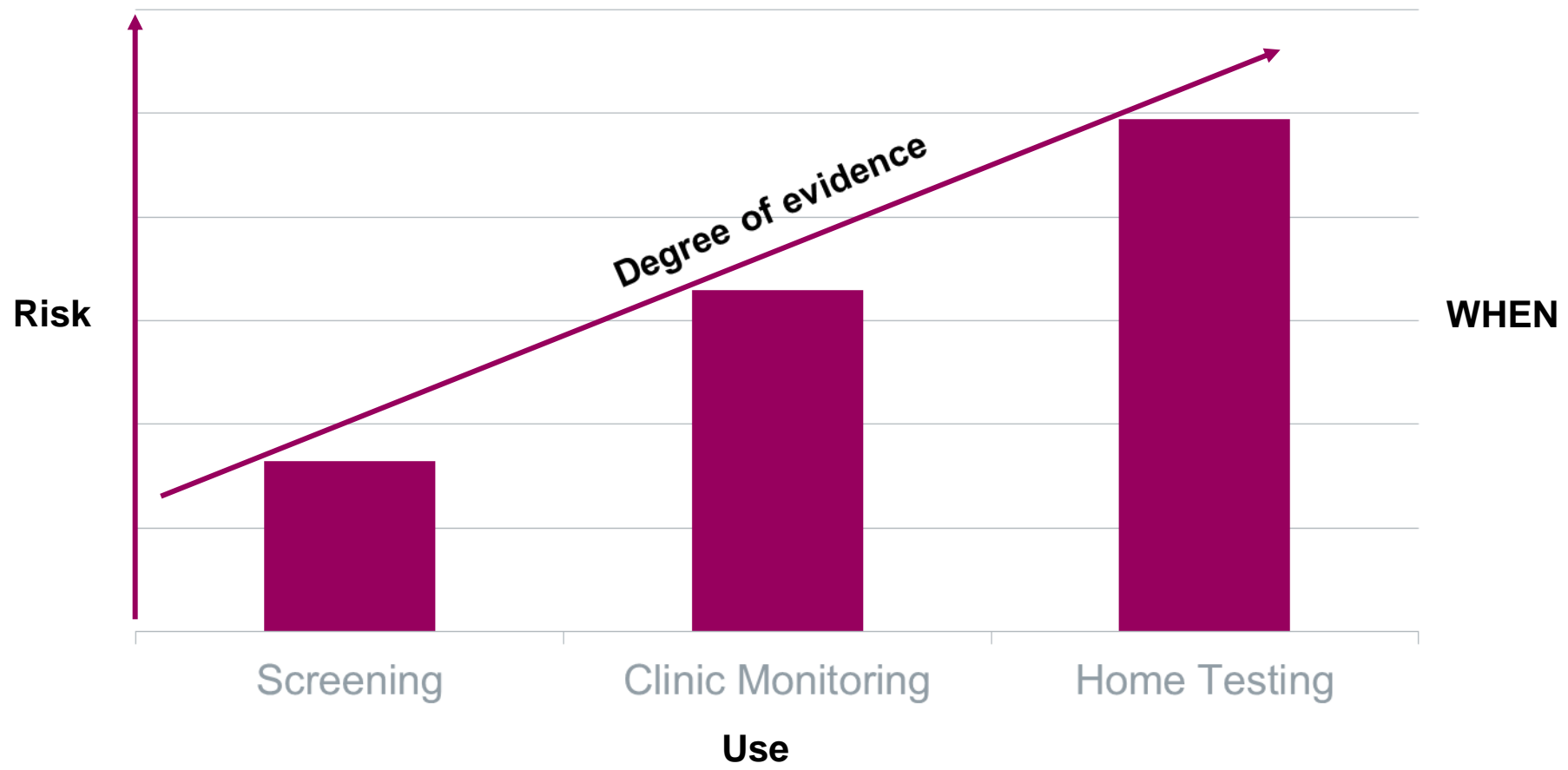
Pregnancy Test



WHO

Risk, Use & Evidence

Blood Glucose



IVD Evidence should also ...

- Relate to manufacturers claims/constraints
- Not just be about technical comparisons
- Be compared to a relevant (not always gold!) standard
- Relate to the clinical benefits (good enough)
- Relate to the patient benefits
- Relate to the health economic impact (NHS data freely available)
- Be accessible to SMEs (low cost)

In conclusion

- Risk and use relative to evidence needed
- Easy access to (ideally) single evaluation organisation for IVD's
- IVD value much more than technical
- Health economic data should be made simpler and available to all (simple software model)

Finally

- Industry also needs to improve its ability to generate evidence (IVD Clinical trials support)

Thank you – Any Questions?