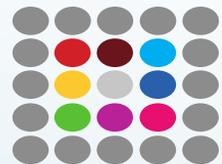


Budget Impact and Resource Implications

What's new in 2017?

Eifiona Wood
Health Economist, AWTC
Senior Research Fellow, Bangor University



AWTTC
All Wales Therapeutics
& Toxicology Centre



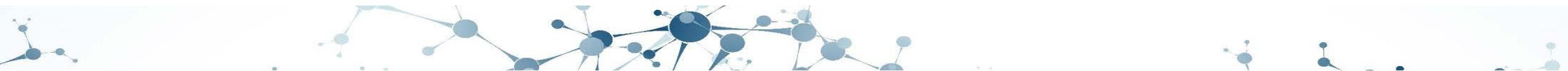
Role of NMG in BI

- NMG appraises the evidence on the clinical effectiveness and cost-effectiveness of the medicine
- The assessment of budget impact falls to the AWMSG

However, now the NMG are expected to 'verify' that the BI section of the ASAR looks reasonable...

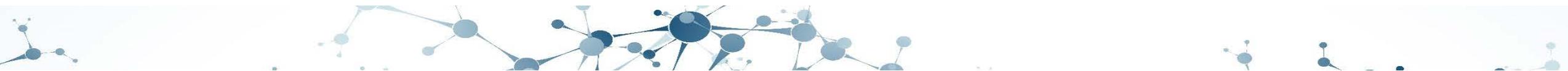
...but only as part of the 'check' when reviewing the ASAR for accuracy/typographical errors...

...to provide an opportunity for any anomalies to be addressed prior to consideration by AWMSG



Budget Impact Model template

Objective:	To add consistency to BI calculations
Action:	Develop a BI template to support company submissions
Output:	Cost-calculator template assessing costs with and without new drug in the treatment mix to provide a credible estimate of the budget impact of approving the drug in Wales over a 5 year time period. The model compares the drug use, and resource use costs separately
Status:	In use





What is the aim of the budget impact analysis?

- assess the *financial consequences* of the introduction of a new technology in the short-term in a specific setting
- *forecasts the associated costs* for the new drug and *changes in rates of use* for the mix of current treatments
- determines by *how much annual budgets are likely to increase (or decrease)* to allow planning for these changes

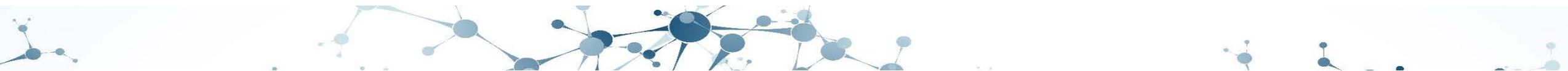
Sullivan SD, Mauskopf JA, Augustovski F, et al. Budget impact analysis- principles of good practice: Report of the ISPOR 2012 budget impact analysis good practice II task force. Value Health. 2014;17(1):5-14.

Mauskopf J, Earnshaw S. A methodological review of US budget-impact models for new drugs. Pharmacoeconomics. 016;34(11):1111-1131.



Cost-effectiveness vs Budget Impact

	Cost-effectiveness	Budget impact
<i>What is the question?</i>	Is it value for money?	Is it affordable?
<i>What is the time frame?</i>	Usually longer-term (e.g. lifetime)	Short-term (1-5 years)
<i>What inputs are considered?</i>	Clinical evidence, resource use, utilities, costs	Patient numbers, resource use, costs
<i>What are the health outcomes</i>	QALYs	Not considered
<i>Decision rules</i>	Yes	No
<i>Value judgements</i>	Minimal	Yes



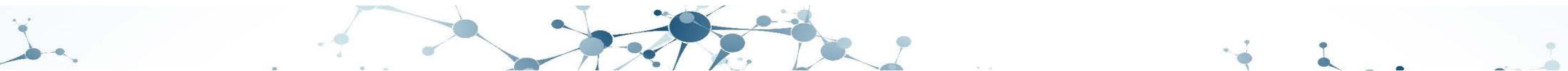
Opportunity Costs

NHS Wales has a *limited budget*



opportunity costs

*Positive recommendations, that have a positive budget impact,
result in savings having to be made elsewhere*



New Treatments Fund Wales

- the **early introduction of the most innovative, high-cost medicines** recommended NICE and AWMSG
- ensuring treatment for **life-limiting and life-threatening diseases** are **immediately and consistently** available across Wales
- make drugs available **no later than two months** from the date of final guidance
- **£80m in funding** allocated for a five-year period
- Compared to England and Scotland, less restrictive, providing funding deemed cost-effective for any conditions published.





What makes a good budget impact analysis?

A model that can provide a credible assessment on the impact to the NHS in Wales of the introduction of a new intervention

- Perspective (budget holder)
- Short time horizon (5 years)
- Key epidemiological and cost inputs
- Marketplace dynamics
- Results
 - cost differences between the new scenario and the current scenario
 - impact on healthcare resources
- Sensitivity analyses

Requires robust data sources that reflect the local epidemiology and costs

Main critique of BI models

- Quality
 - Often **poor** and **inconsistent**
 - **Few** attempt to estimate real **local costs** in a **credible way**
 - Epidemiology and cost data often obtained from **weak sources**, such as foreign estimates, assumptions and/or expert opinion
- Result
 - it is **hard to provide plausible estimates** of a budget impact in a specific environment



AWTTC BI model template: What are the key model inputs?

- **Size and characteristics** of the **eligible population**
- Intervention mix **with and without** new intervention
- **Uptake** of the new intervention
- Costs of interventions
- Costs of condition-related health care services (**resource use**)
- **Alternative values** for uncertainty and scenario analyses

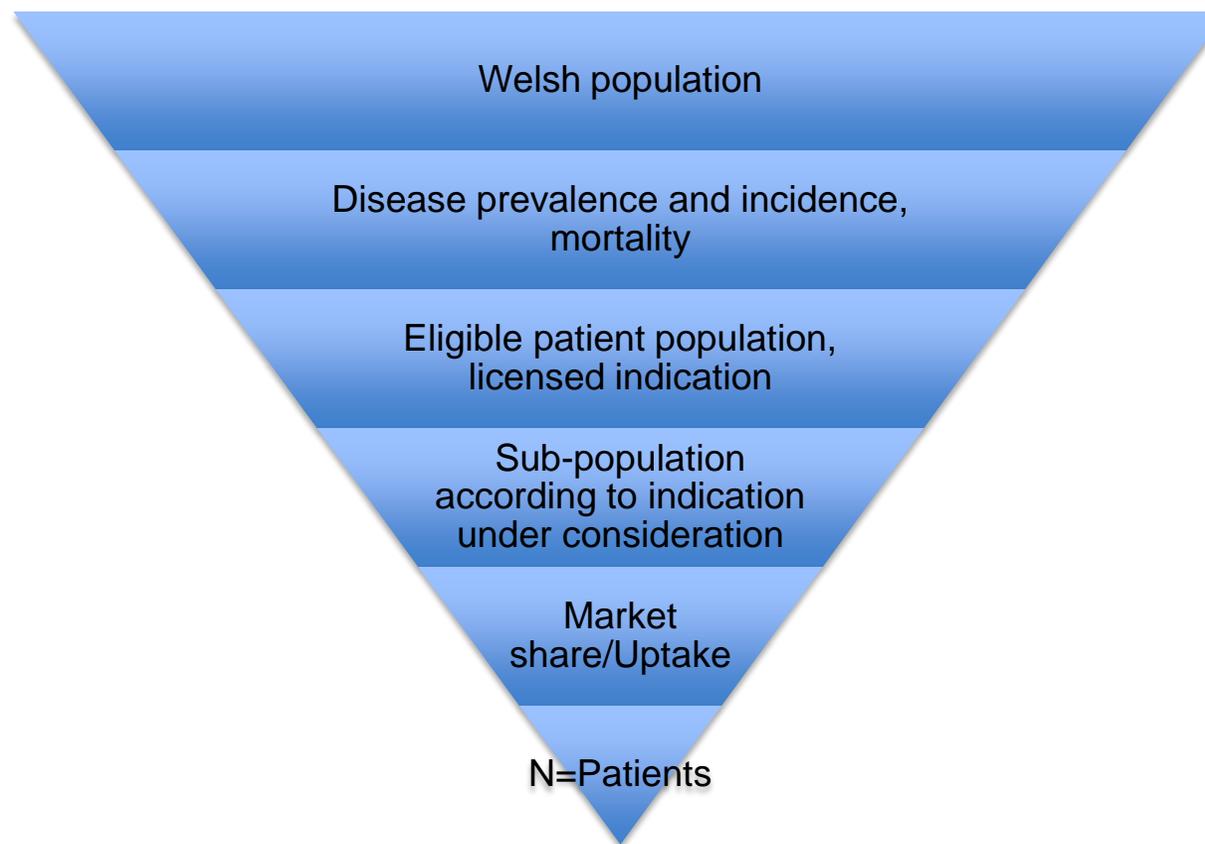
Forecasting is challenging, but should be attempted so long as the assumptions are clear, justifiable and supported by evidence





Key input parameters: epidemiology

Size of eligible population



Robustness of data sources...



Key input parameters: epidemiology

Size of eligible population

- Will the eligible population change with time?
 - Previously untreated patients may now **seek treatment**
 - New treatment may **increase** time on treatment, **slow** disease progression, **reduce** mortality
 - Treated population size may **increase**
 - If not considered, will introduce bias into BI estimates



Key input parameters: market share and uptake: Intervention mix

- Compares current use without new intervention to predicted use with new intervention
- Will any of these estimates change with time?
- How to predict the rate of uptake
- Data sources

Can be a major determinant of budget impact...

However, little data is usually available on which to forecast uptake



Key input parameters: costs

- Which costs are taken into account?
 - **Drug acquisition costs** (resource use and unit costs, PAS if applicable)
 - **Supportive therapy** acquisition costs
- Discounting?
 - **No**, interested in impact at that point in time.
- Source

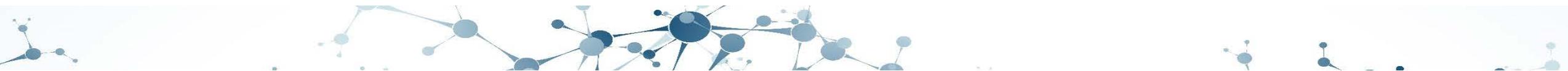
These costs have an immediate effect on budgets increasing costs or be money saving





Key input parameters: healthcare service resource use

- Resource use inputs
 - Administration
 - Diagnostics and monitoring
 - Adverse events
 - Primary and secondary care
 - Personal and social care
- Impact - can be **resource saving** e.g. fewer bed days in hospital.
 - No immediate effect on NHS bottom line and may have no impact at all on the short-term budget, but there is potential that savings may be realised at a future point
 - Still needs to be evaluated - can effect planning and is important for the overall picture
 - Both drugs costs and resource costs are typically identified in the ASAR, *but interpret the bottom line with care...*



Sensitivity analysis

- Uncertainty

- BI requires assessment of the impact of uncertainty on model outcomes

allow budget holders to **understand the impact that changes** in single input parameters may have **on results**

- One way sensitivity and scenario analyses around the input parameters
- Two types of uncertainty – parameter and structural (best-case/worst-case)
- *Data-driven* preferred to arbitrary fixed percentage change
- Estimation of their plausibility



Where to find the new BI template



All Wales Medicines Strategy Group
Grŵp Strategaeth Meddyginiaethau Cymru Gyfan

About AWMSG Appraisals Medicines management

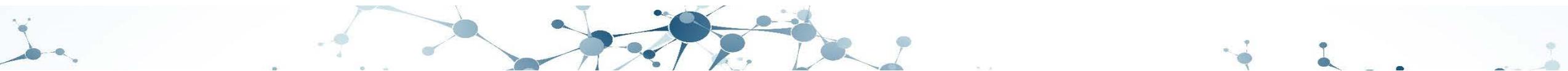
Pharmaceutical industry

○ Appraisal information

- > About
- > Appraisal process
- > Wales Patient Access Scheme
- > AWMSG in relation to NICE
- > Orphan, ultra-orphan and rare diseases
- > All appraisal documents

All appraisal documents

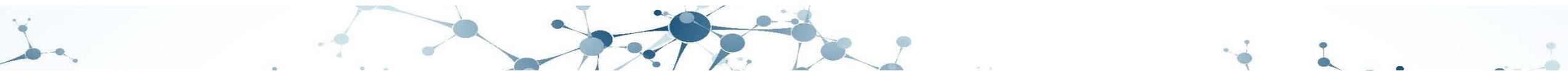
ABPI and AWTTC confidentiality agreement
Appraisal FAQs
Appraisal principles and process flowchart
Appraisal process flow diagram & timeline
Budget Impact template (Excel 2007)
Budget Impact template (Excel 2003)
Clinical expert questionnaire and declarations of interest form
Clinician and Patient Involvement Group (CAPIG) Information
Clinician and Patient Involvement Group (CAPIG) Terms of reference
Decision process for full & limited submissions
Exclusion criteria
Form A
Form A guidance notes
Form B
Form B guidance notes
Form C
Form C guidance notes
Independent review process
Industry engagement
Information for companies attending AWMSG appraisal meetings
Letter to companies following a NICE negative
Life-extending, end of life medicines
Orphan, ultra orphan and rare disease medicines
Process for implementing NICE HST advice
Recommendation wording
Requirement for LHBS to implement AWMSG recommendations within three months
Summary guidelines for appraising medicines
Summary information for patients to be completed by the company
Therapeutic Development Assessment (TDA) Partnership Group
Template for raising an issue during an appraisal



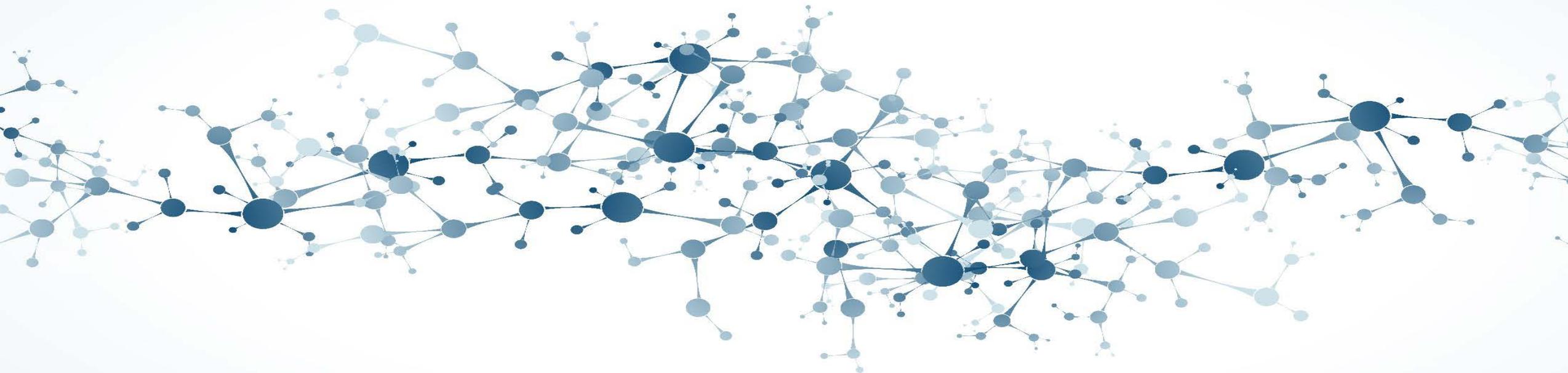


Closing notes

- Budget impact analysis **complements** cost-effectiveness analysis
- Budget impact analysis subject to **uncertainty**
- Money savings are **realised differently** to resource savings
- **Opportunity cost** of funding new interventions
- A positive AWMSG recommendation with a positive budget impact will require an alternative technology to be **displaced**
- Will this impact overall health benefits?



Thank you, and questions...



AWTTC
All Wales Therapeutics
& Toxicology Centre

All Wales Therapeutics and Toxicology Centre
Academic Building
University Hospital Llandough
Penlan Road
Penarth
Vale of Glamorgan
CF64 2XX



PAMS
Patient Access to
Medicines Service



WNPU
Welsh National
Poisons Unit



WeMeReC
Welsh Medicines
Resource Centre



Yellowcard
Centre
Wales



WAPSU
Welsh Analytical
Prescribing Support Unit

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