Biointelect

AMR Commercialisation Workshop

19th November 2019

QT Hotel Canberra, ACT

Australian Government

MTP Connect
MedTech and Pharma Growth Centre

Biointelect

Welcome and Opening Remarks:

Prof Brendan Murphy, Australian Government Chief Medical Officer
Dr Daniel Grant, CEO, MTP Connect

Acknowledgement of Country

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Aims of the Workshop

- Bring together key Australian stakeholders *to discuss opportunities and challenges associated with research, development and commercialisation of novel antimicrobial therapies and related technologies in Australia,* as a follow-up to the AMR Industry workshop which took place in Sydney in August 2019
- Stakeholders are from all parts of the MTP sector – commonwealth, state and territory governments, industry, NGOs and key academic institutions involved in AMR research

FOUR KEY TOPICS:

Antimicrobial R&D, translation and commercialisation

International partnerships and collaborations

Regulation of antimicrobials and regulatory incentives

Pricing & reimbursement policy framework

Outcomes of the Workshop

Raise awareness of the AMR challenges, develop a **white paper** and **foster relationships and ongoing collaboration** towards longer term stakeholder engagement with a credible, stronger, whole of sector approach

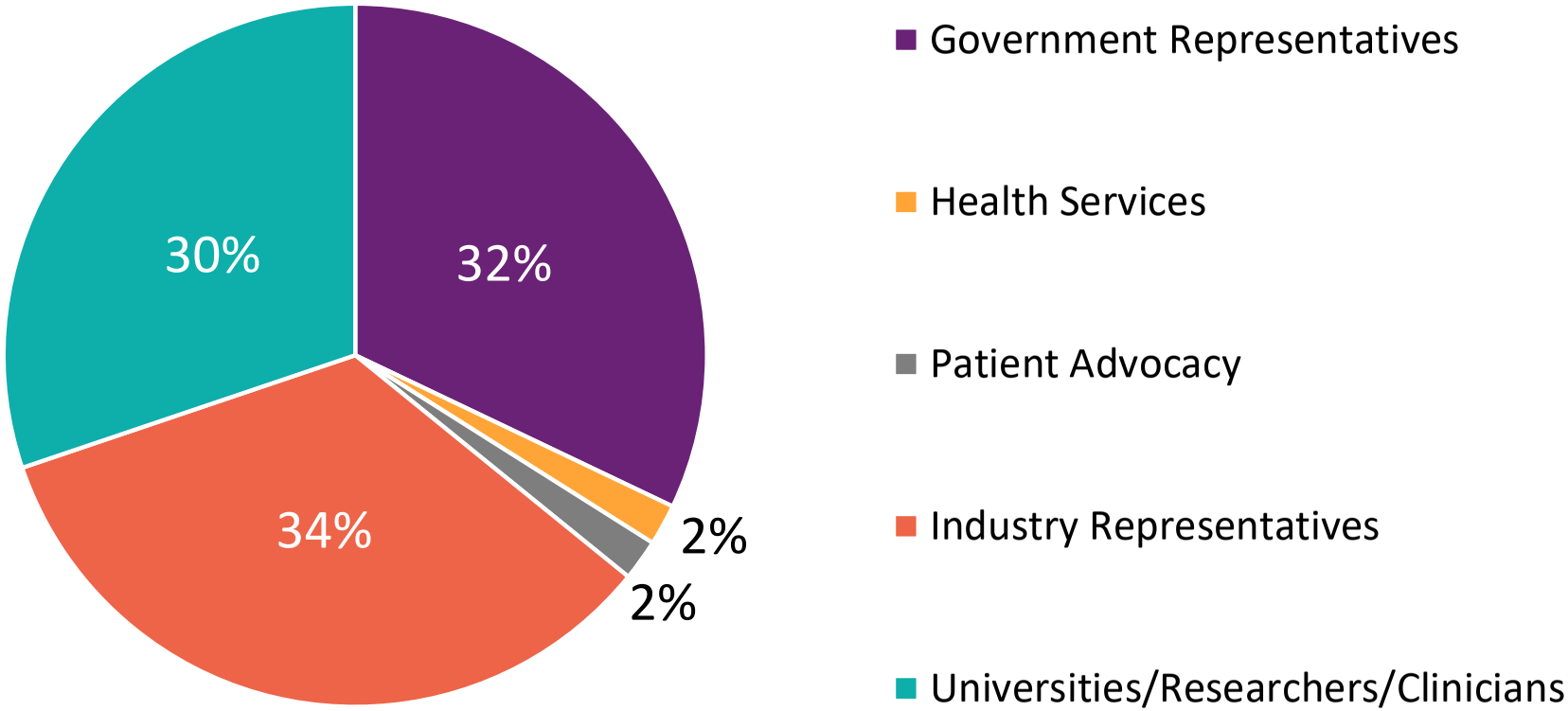
We welcome your participation and thank you in advance for your significant contribution to this important dialogue

National AMR strategy

- The Commonwealth Government's first National AMR strategy 2015-2019 was released in 2015
- The new National AMR strategy will be finalised by the end of 2019. This workshop provides the opportunity to inform the implementation plan
- The first industry AMR Workshop was held in August 2019 with participants developing an AMR Industry Position paper highlighting issues under the four themes we will discuss today

Workshop Participants

- Participants represent the Commonwealth, state and territory governments, researchers/clinicians, industry, health services and patient advocacy



Agenda

Workshop format: 6 hours in length (4 facilitated sessions with 1.5 hours break) from 10:00 until 16:00	
9:30 - 10:00	Arrivals and registration
10:00 - 10:15	Welcome and introductions
10:15 - 11:20	Session 1: R&D translation and commercialization
11:20 - 12:00	Session 2: International partnerships and collaborations
12:00 - 13:00	Lunch break
13:00 - 13:50	Session 3: Regulation of antimicrobials
13:50 - 14:20	Break
14:20 - 15:30	Session 4: Pricing, reimbursement and supply chain
15:30 - 16:00	Synthesis, summary and close

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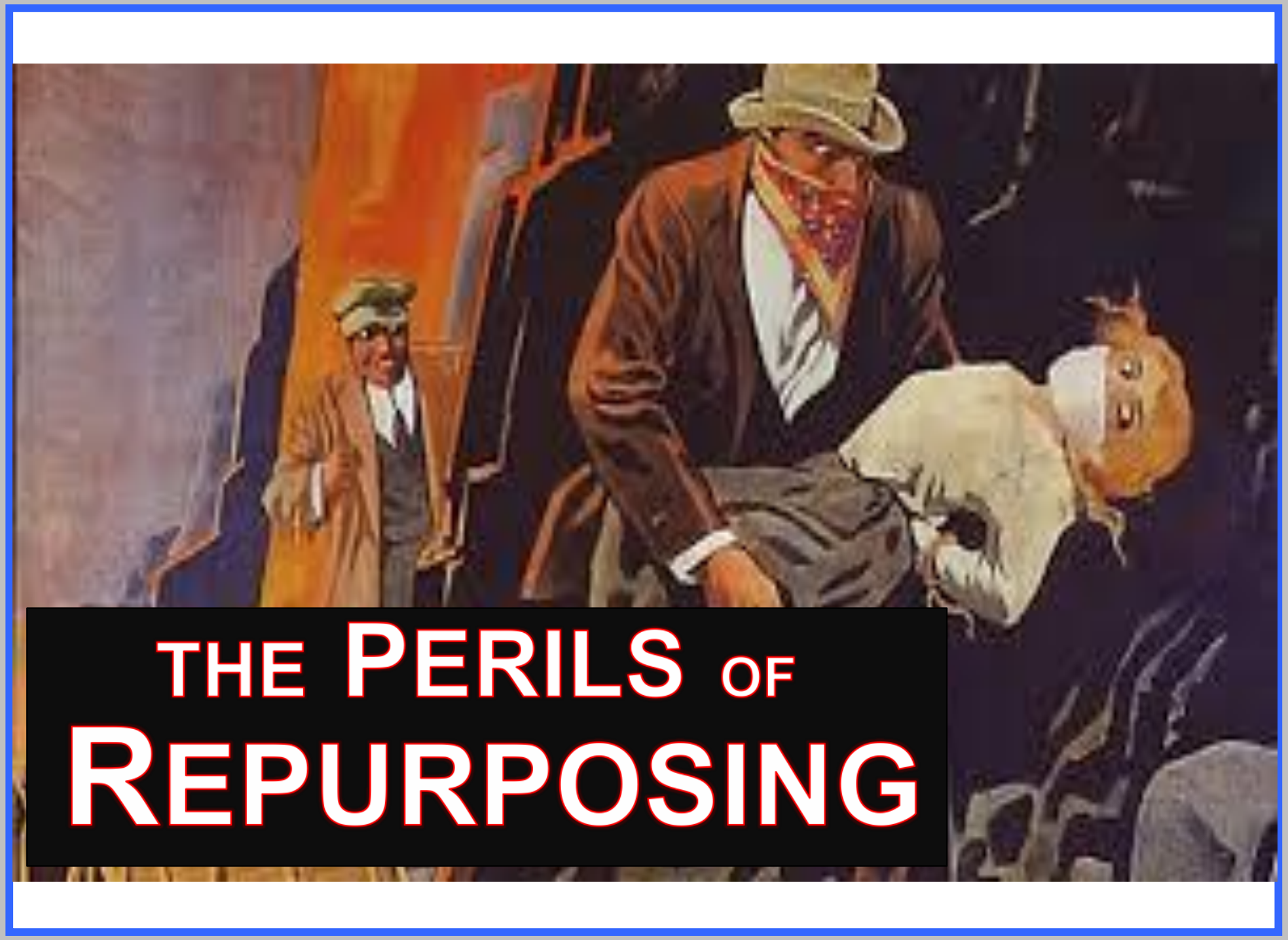
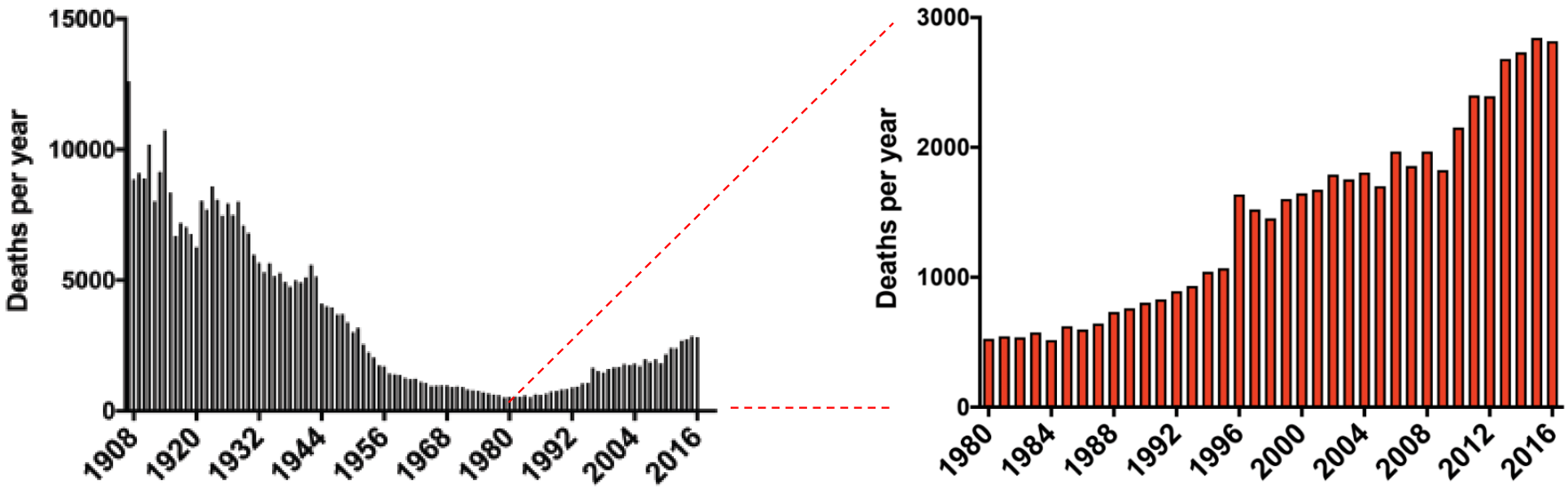
Session 1:
R&D Translation and Commercialisation


THE PERILS OF
REPURPOSING

INFECTIOUS DISEASES DEATHS IN AUSTRALIA



1980 -> 2016

- Median age (+8 years)
- Population increase (2x)
- Antibiotic resistance

TOTAL DEATHS (2016)

- 25% cardiac disease
- 25% cancer
- 10% infectious disease*
- 7% injury + suicide

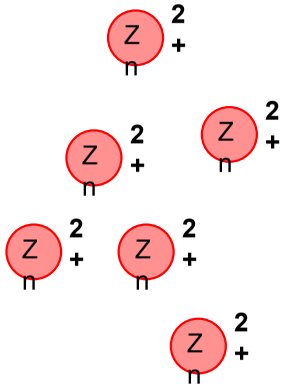
*underlying cause

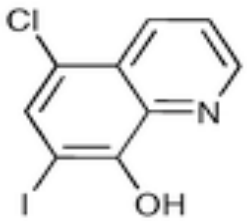
POPULATION ADJUSTED

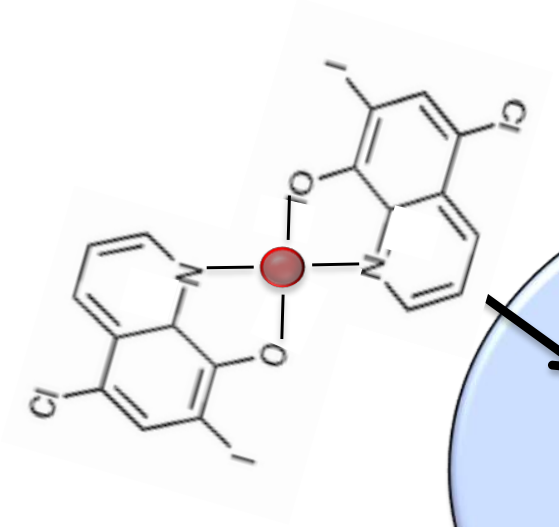
- cardiac 50% down
- cancer 30% up
- infectious 291% up

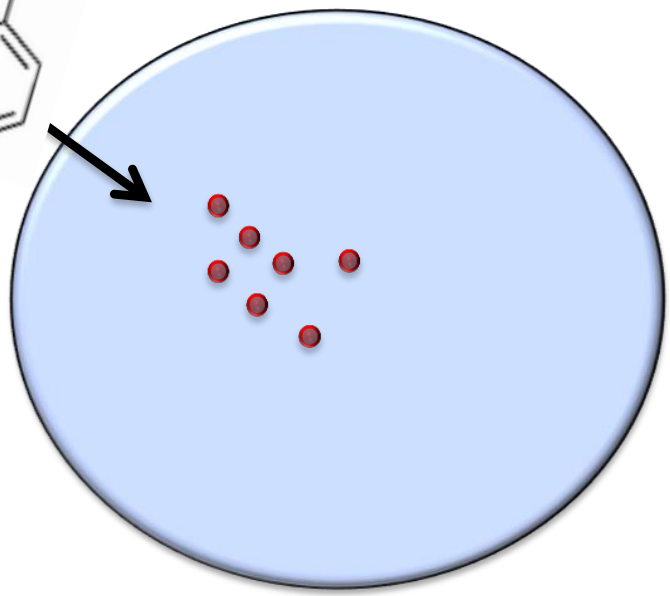
REPURPOSING IONOPHORES

- Ionophores “mask” the charge of metal ions
- Facilitates the transport of metal ions across cell membranes



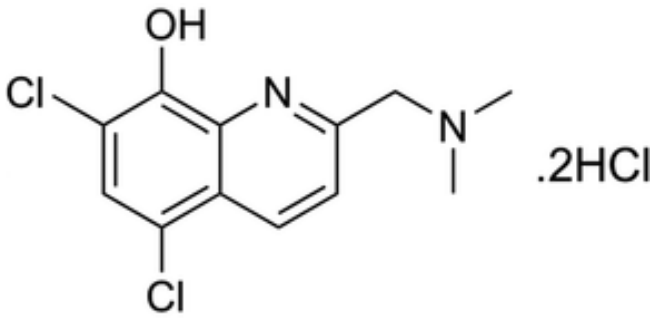






REPURPOSING THE IONOPHORE PBT2

Alterity THERAPEUTICS



PBT2

- **ASX and NASDAQ listed neuronal degeneration Biotech (Melbourne)**
- **PBT2 composition of matter patent (US7619091to Dec 2025)**

REPURPOSING THE IONOPHORE PBT2

- 2 x Phase 1 human trials
  - up to *800 mg/day* for 7 days (oral)
  - safe and well tolerated
- 2 x Phase 2 human trials
  - Alzheimer's and Huntinton's disease
  - up to 250 mg/day for *12-52 weeks* (oral)
  - safe and well tolerated

Safety, tolerability, and efficacy of PBT2 in Huntington's disease: a phase 2, randomised, double-blind, placebo-controlled trial

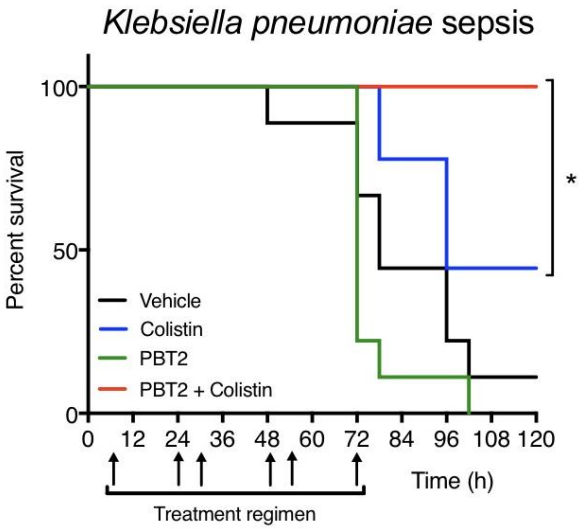
*Huntington Study Group Reach2HD Investigators**

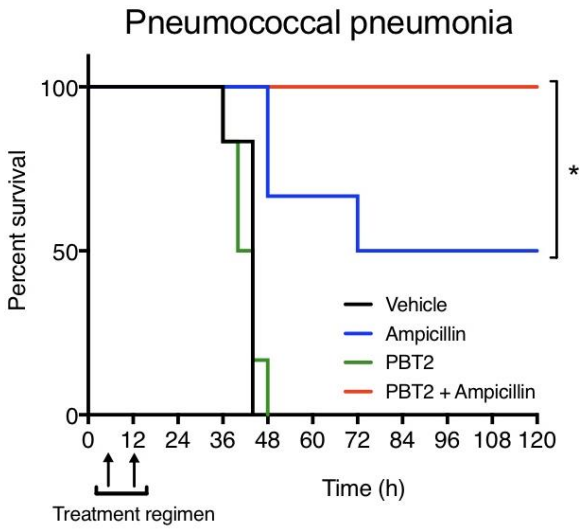
Summary

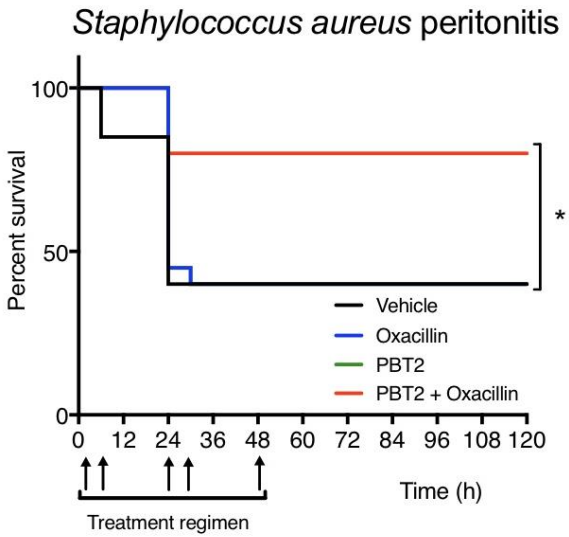
Safety, efficacy, and biomarker findings of PBT2 in targeting Aβ as a modifying therapy for Alzheimer's disease: a phase IIa, double-blind, randomised, placebo-controlled trial

*Lars Lannfelt, Kaj Blennow, Henrik Zetterberg, Stellan Batsman, David Ames, John Harrison, Colin L Masters, Steve Targum, Ashley I Bush, Ross Murdoch, Janet Wilson, Craig W Ritchie, on behalf of the PBT2-201-EURO study group**

REPURPOSING THE IONOPHORE PBT2 TO BREAK ANTIBIOTIC RESISTANCE







- **Multiple classes of bacterial antibiotic resistance broken**
- ***In vivo* efficacy demonstrated against multiple pathogens**
- **Method of use PCT/AU2018/051116 filed Oct 2018**

HURDLES ENCOUNTERED IN REPURPOSING

- Harmonising "*method of use*" and "*composition of matter*" IP
- Composition of matter IP lapses in 2025
- Access to human trail PK/PD/toxicity data
- Bridging funding for development of this discovery into human trials (NHMRC Development, MRFF, CARB-X etc)
- Navigating the broken(?) commercial pipeline for antibiotic development

IONOBIOTICS – A NEW THERAPEUTIC STRATEGY AGAINST ANTIBIOTIC RESISTANT PATHOGENS

UQ

Mark Walker
Alastair McEwan
Maree Smith
Lisa Bohlmann
David De Oliveira
Cheryl Ong
Amanda Cork
Mark Schembri
Duy Phan
Tania Rivera Hernandez
Amelia Soderholm

U Adelaide

Chris McDevitt
Erin Brazel

Griffith

Mark Von Itzstein
Mike Jennings
Ibrahim El-Deeb

U Otago

Greg Cook
Scott Ferguson
Nichaela Harbison-Price

U Melbourne

Mark Davies

AID
Australian Infectious Diseases research centre
Queensland Institute for Medical Research
The University of Queensland

Queensland Institute of Medical Research

opal Biosciences

AMR Workshop November 2019

Julie Phillips | Managing Director

Opal Biosciences Limited is an innovative player in infectious disease treatment

An Australian biotechnology company committed to tackling a serious global health threat


SMILES EVERYONE !
WE'RE ALL GOING TO DIE

Huge Opportunity

- High unmet need
- Australia has capability

Huge Barriers

- Visibility of industry
- Fragmented capabilities
- Lost expertise
- Poor value proposition

Opal's journey

- Nice pathogens to target
- Couldn't find animal models
- Found different nice pathogens
- Found model (in US) but couldn't access it
- Approached NIH/USAMRIID and found new pathogens

- Vehicle in formulation was toxic to rodents
- Tried to raise $$ to reformulate
- Almost zero funding
- Topical development – no investment proposition
- Paid for expensive overseas reformulation – but no further SS

- Topical developer recruiter IV formulator
- Funding tight
- Investment proposition worse

opal Biosciences

opal Biosciences

Antimicrobial Drug Development: The BioCurate Perspective

Paul Field
Business Development Advisor
BioCurate

BioCurate

BioCurate is a joint venture between Monash University and the University of Melbourne

Weak Global Pipeline

- Big pharma has abandoned new antibiotics with a few exceptions for CAP, UTI e.g. Merck (Recarbrio) - only 11 antibiotics in clinical development address pathogens on the WHO list of critical threats
- Most new antibiotics belong to existing classes, against which bacterial resistance has been observed or could easily develop
- Only one of the *novel* antibiotics in development has the potential to treat Gram-negative bacteria, which cause some of the hardest-to-treat infections including carbapenem-resistant *Acinetobacter baumanni*, *Pseudomonas aeruginosa* and *Enterobacteriaceae*
- Only 3 antibiotics in the clinic have the potential to treat *Neisseria gonorrhoea* which is one of the top three most urgent threats (WHO)

Australia

Australia has unrealised potential to contribute to the global pipeline of new antibiotics

- Biotech companies
  - eg. Reece, Opal, Boulos & Cooper
- Academic and research expertise
  - eg. Monash Institute of Pharmaceutical Sciences, UQ
- Clinical capabilities
  - eg. UQCCR (MERINO Trial)

BioCurate

- Est. 2016 by UoM and Monash
- 150 years of combined biotech/pharma industry experience
- Responsible for 70 drugs currently in the clinic including over 35 Investigational New Drug applications (INDs)
- Directly involved in 15 deals worth a cumulative total of over $2.1B
- Investing in the development of drugs discovered by UoM and MU
- Focused on therapeutic areas where there are models of commercialisation (cancer, CNS, inflammation etc.)

BioCurate

BioCurate is a joint venture between
Monash University and the University of Melbourne

BioCurate's Core Business – Drug Development

- UoM and Monash have brought a number of antibiotic drug candidates to BioCurate for potential investment;
  - Broad and narrow spectrum antibiotics, NCEs and repurposed drugs
  - Analogues of existing antibiotics eg. levamisole
  - Novel combinations and reformulations eg. Polymixin B
- But the business case is weak for investment in new antibiotics;
  - Achaogen, Milenta etc.
  - FDA has approved 16 antibiotics since 2000 but only 5 have generated sales in excess of US$100m per annum
  - Big pharma has abandoned the space e.g. Sanofi, Pfizer, Novartis etc.

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Investors

In the absence of big pharma licensing partners, BioCurate looking to sources of finance and follow-on investment

- Repair Impact Fund
- Wellcome Trust
- European Investment Bank AMR Fund (@Euro 500m)
- BARDA
- US$500m CARB-X
  - Direct acting small molecules
  - Bacterial vaccines
  - Alternative therapies (e.g. bacteriophages)
  - Diagnostics

…….CARB-X funds pre-clinical and Phase 1 R&D and is the ideal partner

Australia Needs a CARB-X Accelerator

- CARB-X distributes grants through its network of global accelerators – but Australia does not have a CARB-X accelerator
- BioCurate considered responding to the CARB-X call for accelerators in Feb 2019 - but not financially attractive
- CARB-X has no plans for another round of accelerators in 2020 but would likely make an out-of-cycle investment if there was a cash commitment from Australia
- The CARB-X accelerator in India (C-CAMP) is supported by the Indian Govt
- An Australian accelerator could improve access to international funding for Australian researchers and biotech companies;
  - Direct acting NCEs
  - Reformulated antibiotics
  - Diagnostic tests for resistance-guided therapy
  - Bacterial vaccines, synthetic biology

Antimicrobial Drug Development: An MSD Perspective

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Session 2
International partnerships and collaborations

Overview of the international landscape for infectious disease programs in context of market failure

Disease / Disease group	Level of market failure[3]	Dedicated global and regional R&D entities / initiatives
Bacterial infections[1]	High	WHO/DND*i* GARDP, CARB-X, IMI, Global AMR R&D Hub
Fungal infections	High	--
HIV	Low, but very high for paediatric applications	IAVI, IPM
Influenza	Low	--
Malaria	High	MMV, MVI,
Neglected tropical diseases	Very high	TDR, DNDi, Sabin Institute, FIND, GHIT
Emerging diseases with pandemic potential[2]	Very high	WHO R&D Blueprint, CEPI, FIND
Tuberculosis	High	Global Alliance for TB Drug Development, TB Vaccine Initiative
Viral hepatitis	None	--

[1] Bacterial infections that are not classified as neglected tropical diseases. TB is listed separately
[2] R&D Blueprint: Revised list of priority diseases. Arenaviral hemorrhagic fevers (including Lassa Fever); Crimean Congo Haemorrhagic Fever; Filoviral diseases (including Ebola and Marburg); Middle East Respiratory Syndrome Coronavirus; other highly pathogenic coronaviral diseases (such as Severe Acute Respiratory Syndrome; Nipah and related henipaviral diseases; Rift Valley Fever; Severe Fever with Thrombocytopenia Syndrome; Zika; Disease X
[3] Very high: no commercial market/no financing mechanisms; High: limited commercial markets; Low: significant commercial markets/financial incentives (adapted from the Special Programme for Research and Training in Tropical Diseases) by WHO

Industry initiatives

Initiative	Description/Output to date
amr INDUSTRY ALLIANCE UNITED AGAINST ANTIMICROBIAL RESISTANCE	Private Sector coalition set up to provide sustainable solutions to curb antimicrobial resistance, with over 100 biotech, diagnostics, generics and research-based pharmaceutical companies and associations joining forces. At least USD 2 billion in R&D dedicated to AMR-related products in 2016: covering R&D-related costs for early-stage R&D exploring new product classes, 10 antibiotics in late-stage clinical development, 13 clinical bacterial vaccine candidates, and 18 AMR-relevant diagnostic products, as well as other preventive therapies; 1/3 of the Alliance companies that produce antibiotics currently have a strategy, policy or plan in place to address the issue of the release of antibiotics in their own manufacturing effluent that may contribute to AMR https://www.amrindustryalliance.org/
BEAM Alliance	BEAM (Biotech companies in Europe combating AntiMicrobial Resistance) Alliance is a strong Network of approx. 65 small and medium-sized European companies involved in developing innovative products and kits to tackle antimicrobial resistance (AMR). In numbers, members of the BEAM Alliance together contribute over 120 potential new antibiotic compounds or curative and preventive technologies to this pipeline (majority target critical pathogens as mentioned by the WHO priority list) https://www.amrindustryalliance.org/

Innovative Medicines Initiative Vision: The biggest public private partnership in life sciences

The Strategic Research Agenda has been written to reflect a summary of the **major challenges currently facing the European healthcare system, the pharmaceutical industry and the regulatory framework**. It is intended to provide a **framework that will underpin the development of specific projects or research programmes** which will be prioritised for funding as described below.

IMI will drive **a new and integrated approach to R&D.** While offering enormous opportunity, **no one sector or institution can achieve the potential that these scientific advances offer if working in individual silos**. Only by **engaging all key stakeholders can the vision of IMI2 of delivering the right treatment to the right patient at the right time for priority diseases be realised**.

IMI and AMR: 16 Projects since 2008 totalling ≈ 530m €
EFPIA contributions ≈ 190m €

ND4BB COMBACTE CARE

DRIVE AB RE-INVESTMENT IN R&D AND RESPONSIBLE ANTIBIOTIC USE

AB-Direct Antibiotic Distribution & Recovery
Part of IMI AMR Accelerator

ND4BB COMBACTE CDI

iABC inhaled Antibiotics in Bronchiectasis and Cystic Fibrosis

AMR Accelerator

ND4BB COMBACTE MAGNET

GNA NOW IMI AMR ACCELERATOR

RESPIRI NTM

ND4BB ENABLE

RESPIRI TB

VALUE-Dx

ND4BB TRANSLOCATION

TRIC-TB

https://www.imi.europa.eu/projects-results/project-factsheets

NHMRC funding on AMR

Calendar Year	Expenditure
2009	$9,040,949
2010	$10,089,195
2011	$9,258,359
2012	$12,941,875
2013	$14,198,819
2014	$16,531,731
2015	$21,337,315
2016	$22,538, 449
2017	$23,013,107
2018	$24,948,428
Total	$163,898,226

Investment in AMR research and development in Australia remains strong, with $164 million invested through the National Health and Medical Research Council (NHMRC) over the last 10 years (2009 – 2018) across 299 grants.

The total investment across the 299 grants equals $201.3m. The largest proportion was allocated to basic science investigations ($106.3m across 178 grants), followed by clinical medicine at $51.4m across 85 grants.

A total of $31.4m was allocated across 27 grants to public health investigations and $12.2m were allocated across 9 grants for health services research. (Note: These were categories self-selected by the applicants).

Source: Courtesy of NHMRC

Variety of government investments in infectious diseases

NCAS

INTEGRATED SYSTEMS FOR Epidemic Response

NHMRC

Australian Government
Australian Research Council

Australian Government
Medical Research Future Fund

AMR Research Hub

MTPConnect
MedTech and Pharma Growth Centre

CREMARA – The Centre for Research Excellence in Minimising Antibiotic Resistance from Acute Respiratory Infections

PRISM²

Vaccine Exchange

CEPI
New vaccines for a safer world

CRE REDUCE
CENTRE FOR RESEARCH EXCELLENCE
Redefining Antimicrobial Use To Reduce Resistance

CREID
PROTECTING THE PUBLIC FROM EMERGING INFECTIOUS DISEASES

APPRISE
AUSTRALIAN PARTNERSHIP FOR PREPAREDNESS RESEARCH ON INFECTIOUS DISEASE EMERGENCIES

DMTC

TBCRE

ACREME
AUSTRALIAN CENTRE OF RESEARCH EXCELLENCE IN MALARIA ELIMINATION

HOT NORTH
Improving Health Outcomes in the Tropical North

Australian Government

INDO-PACIFIC CENTRE FOR HEALTH SECURITY

Do we have the right model for product development ? Or do we need National Research Agenda with industry

"I don't know what these dots are ... but ya mind if I connect 'em?"

- What are our priority pathogens ?
- Where are the product gaps ?
- What is the rest of the world doing ?
- How can we contribute and benefit?
- Capitalise on Australian capability with Australian and regional needs in mind
- Recognise role of industry in product development

FIND

Because diagnosis matters

- Programs in a range of infectious diseases including TB, malaria
- Expanding program in AMR and epidemic preparedness
- Australia is a donor to FIND (through DFAT)
- Enabling AMR surveillance in a number of Asian and African countries
- Collaborating with SpeeDx in the development of new antibiotic susceptibility and resistance tests for NG
- Supporting WHO Collaborating Centres in Australia
- Participant in the new ARC Research Hub to Combat AMR
- Committed to resistance-guided therapies as an alternative to syndromic management of bacterial infections
- Collaborating with the Burnet, active projects in PNG and elsewhere
- FIND is a CARB-X Dx Accelerator (the FIND team is based in the USA)

GARDP

Global Antibiotic Research & Development Partnership

A joint DNDi / WHO initiative

- Programs in STIs, including XDR NG, and neonatal sepsis
- Objective is to bring 5 new treatments to the market by 2023
- GARDP is a NFP – able to support 2nd and 3rd line treatments, provide stewardship
- Donors include UK, Netherlands, Germany, South Africa– but not Australia
- Majority of clinical trial sites are in donor countries or LMICs
- Seeking to run clinical studies in Australia but need Australian support
- Collaborating with CO-ADD at the University of Queensland
- Participant in the ARC Research Hub to Combat AMR led by the Kirby Inst.
- Will collaborate with Australian biotech companies in the Hub

Session 2: International partnerships and collaborations

10 mins	**Presentation: International landscape, *including FIND&GARDP***	**Jennifer Herz, *Managing Director, Biointelect***
20 mins	**Discussion: How can Australia enhance collaboration?**	**ALL PARTICIPANTS**
10 mins	**Report Back**	**TABLE CHAIRS**

- What are the top three issues identified for this topic?
- Why have you chosen these issues?
- Please propose ways forward to address, stakeholders, roles…

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Session 3:
Regulation of antimicrobials

Australian Government
Department of Health
Therapeutic Goods Administration

AMR Commercialisation Workshop

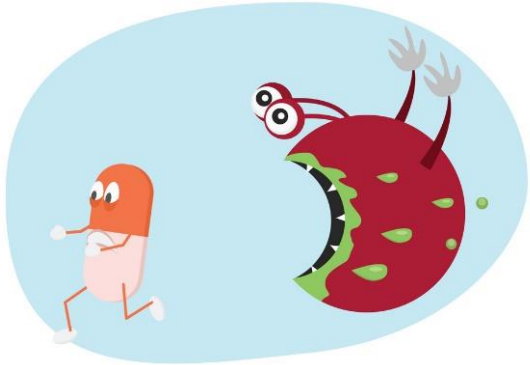
Regulation of Antimicrobials

Mr Adrian Bootes
Assistant Secretary

Medicines Regulation Division
Prescription Medicines Authorisation Branch, TGA

https://www.tga.gov.au/tga-presentation-amr-commercialisation-workshop-19-november-2019

19 November 2019



TGA Health Safety Regulation

Session 3: Regulation of antimicrobials

10 mins	**Presentation: Current approval process, clinical trials and SAS**	**Adrian Bootes, *Assistant Secretary, Medicines Regulation Division, TGA***
30 mins	**Discussion**	**ALL PARTICIPANTS**
10 mins	**Report Back**	**TABLE CHAIRS**

- What are the top three issues identified for this topic?
- Why have you chosen these issues?
- Please propose ways forward to address, stakeholders, roles…

Session 4:
Pricing, reimbursement and supply chain

"Pull" incentives to reward new product approval….

EDITORIAL

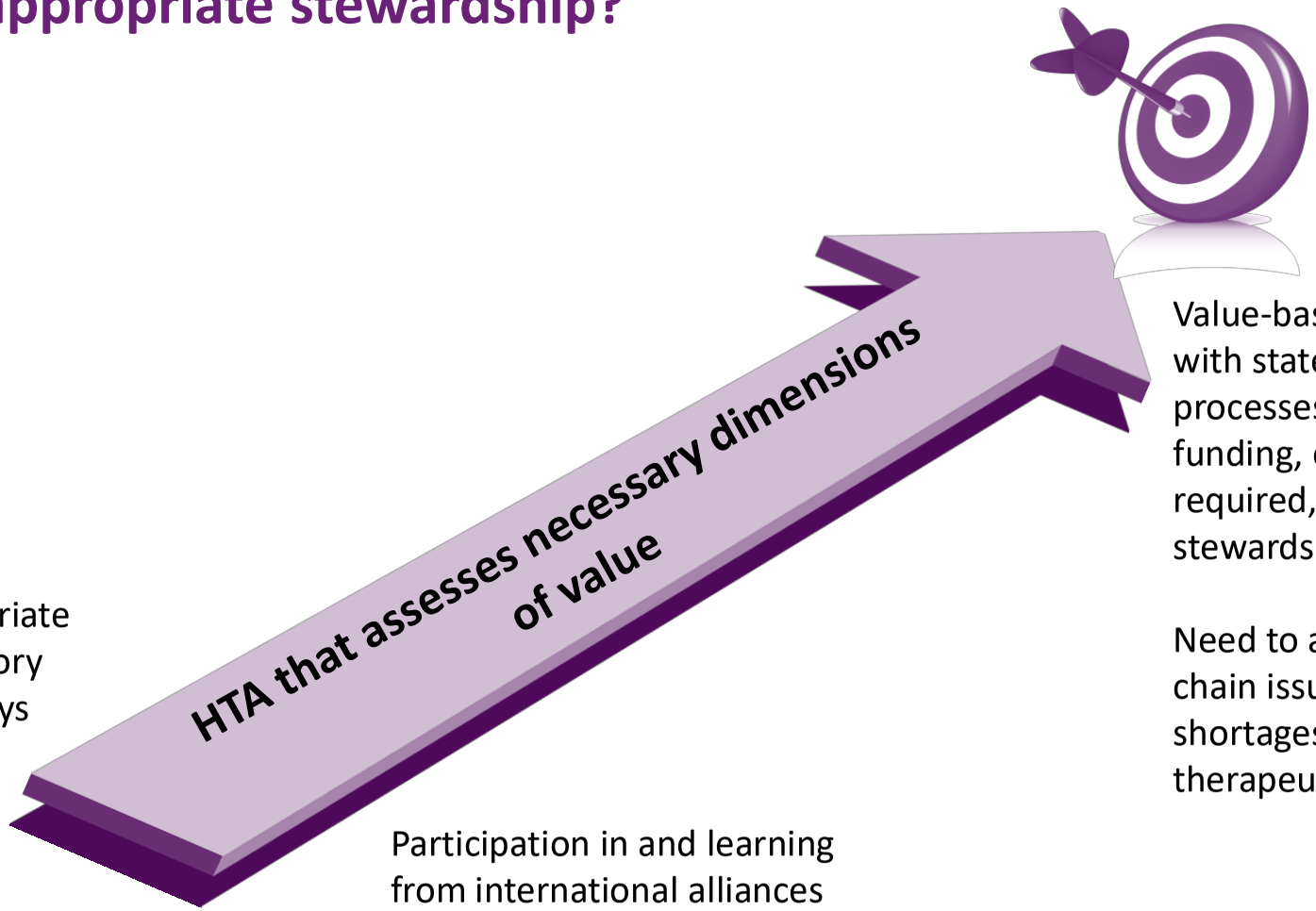
nature biotechnology

Wanted: a reward for antibiotic development

Addressing the commercial failure of the antibiotic market should be a priority for governments seeking to encourage development of new drugs against resistant bugs.

NATURE BIOTECHNOLOGY VOLUME 36 NUMBER 7 JULY 2018 555

The challenge: How to provide market incentives that utilise HTA to assess value and are linked to workable national funding mechanisms and appropriate stewardship?



Value-based pricing that links with state and federal processes and channels for funding, ensuring supply when required, under appropriate stewardship

Need to also recognise supply chain issues and potential for shortages of older, low cost therapeutics

Appropriate regulatory pathways

Participation in and learning from international alliances

National and international therapeutics development

Internationally, more countries are recognising need for 'affirmative action' in terms of HTA and reimbursement

- Summarises the current state of HTA and contracting for antibiotics and recent proposals that have been advanced for revising both. **This research focussed on five countries which have been taking initiatives in the area of AMR:** France, Germany, Italy, Sweden, and the UK (England and Scotland).

- Antibiotics give rise to spill over benefits and/ or costs, beyond the impact on the immediate consumer which are not accounted for in market transactions. In the context of health care, these are benefits and costs to the health system beyond those attributable to the treated patient.

- Estimates suggest that a considerable part of the value of new antibiotics will come over time from these types of benefits, such as preventing the transmission of infections to other patients and slowing down the development of resistance to other drugs.

- These are 'public health effects' as they accrue to the payer in the future and to future patients. Good policy design should 'internalise' these public health effects into the payer's assessment of value, but conventional HTA methods only include benefits and costs associated with treating the immediate patient, thus reinforcing the low returns for new antibiotics and hitting at incentives for innovation.

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NHS ENGLAND: INNOVATIVE MODEL FOR THE EVALUATION AND PURCHASE OF ANTIMICROBIALS

NHS England + NHS Improvement + NICE

"… a model that pays companies for antimicrobials based primarily on their expected value to the NHS, as opposed to the actual volume used"

PHASE 1 (end of 2019)

- Development of an evaluation framework
- Development of a negotiation framework
- Identification of 2 products to assess

PHASE 2 (end of 2020)

- Value assessment of 2 products
- Commercial discussion
- Implementation of payments
- Monitoring the use of selected products

3 YEAR PILOT LIKELY (end 2023)

"… an adapted HTA framework, informed by health economic modelling and expert opinion"

https://www.nice.org.uk/Media/Default/About/what-we-do/NICE-guidance/antimicrobial guidance/AMR-launch-statement.docx

How to retain central role of HTA while dealing with complex set of technical issues?

The University Of Sheffield.

UNIVERSITY of York

EEPRU Policy Research Unit in Economic Evaluation of Health & Care Interventions

FRAMEWORK FOR VALUE ASSESSMENT OF NEW ANTIMICROBIALS

Implications of alternative funding arrangements for NICE Appraisal

Authors: Claire Rothery[1], Beth Woods[1], Laetitia Schmitt[1], Karl Claxton[1,2], Stephen Palmer[1], Mark Sculpher[1]

[1] Centre for Health Economics, University of York

[2] Department of Economics and Related Studies, University of York

Central to the proposed alternative NHS funding arrangements of new AMs is the need to characterise the expected value of a new product over an appropriate time horizon.

- **This means taking into account the same values as other health technologies**; i.e. health benefits accruing at a population level, expected costs borne by the payer, and the opportunity costs associated with expenditure, **but also additional elements of value for AMs,** including:
- **diversity value** (benefits of having a range of treatments available to reduce selection pressure and preserve the efficacy of existing AMs);
- **transmission value** (benefits of avoiding the spread of infection in the population);
- **enablement value** (benefits of enabling surgical and medical procedures to take place);
- **spectrum value** (benefits of replacing broad spectrum with narrow spectrum AMs that target specific pathogens);
- **insurance value** (benefits of having treatments available in case of sudden, or major, increase in prevalence of infections)

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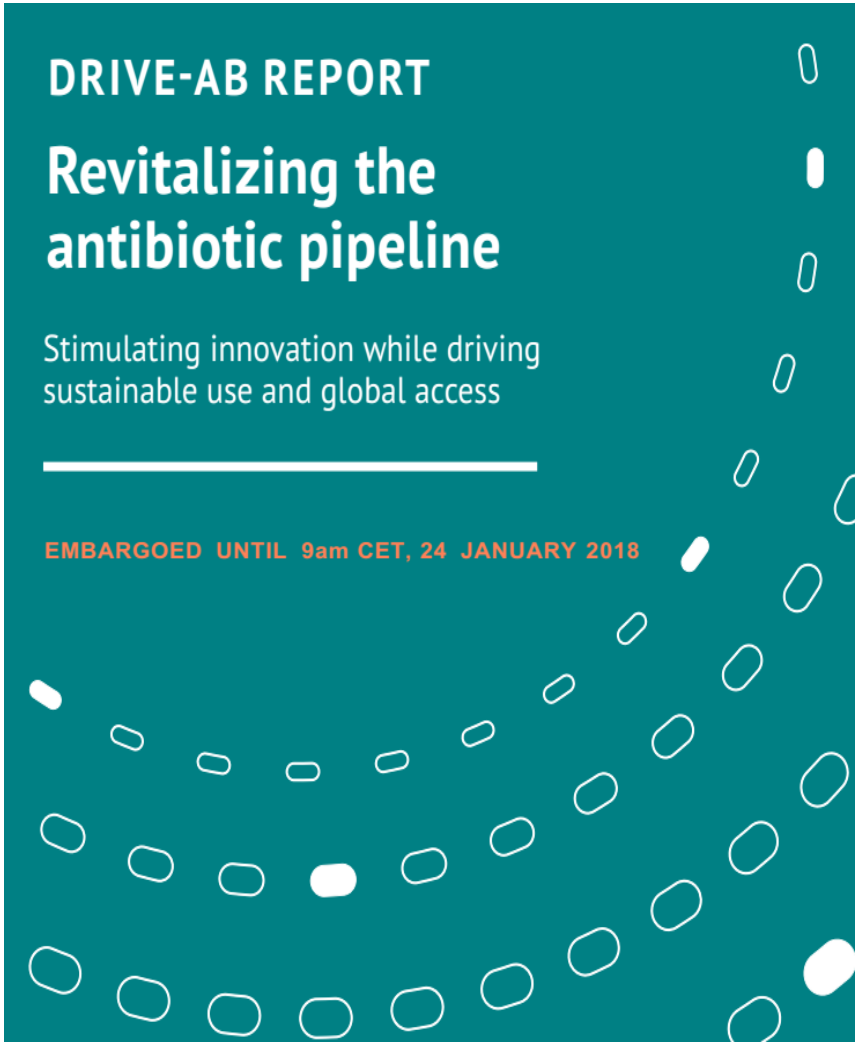
Or are there more pragmatic HTA solutions?



$$ICER_{ABX} = \frac{C - S - S_t - S_d}{V + V_t + V_d}$$

***V_t* is the benefits of reduced transmission** of the disease to the rest of the population, in terms of QALYs from avoided infections.

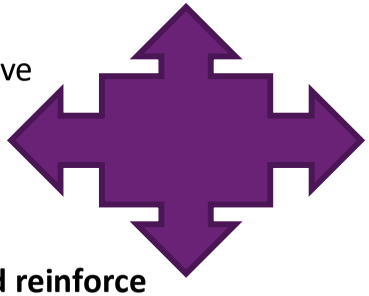
***V_d* is the "diversity value"** – the benefit at the population level of protecting the existing portfolio of antibiotics, in terms of QALYs flowing from the avoidance of other resistant infections

***C* is the total purchase and administration cost** of using the antibiotic for the population of interest: heuristically, if *N* people are treated, then *C=Nc*.

***S* is the total cost savings (for example in avoided treatment and reduced bed-days) for the treated population, and *S_t* and *S_d* are the cost savings from avoided transmission and protection of existing antibiotics.**

Beyond HTA: Procurement mechanisms, hospital procurement and stewardship

Procurement of antibiotics used in hospital settings is often tender-based and may be regulated through tariff-based payments, (e.g. using DRGs), consisting of a single lump sum payment for the whole illness episode (i.e. diagnostic, provider care and medications). This system creates a disincentive to the appropriate use of new antibiotics, if their value is reflected in a high price.



Reimbursement reform can complement and reinforce key antimicrobial stewardship components, including the use of diagnostics, de-escalation, regimen monitoring, and surveillance. These can support appropriate use to preserve existing treatments / alternative treatment options. Reimbursement reform should also result in predictability in costs for the health system and reflect the value of a novel antibiotic over its life-cycle.

Payer reform is needed to better capture the societal value of antibiotics in HTA. The objective is to create an evidence-based value assessment that then can serve as a foundation for commercial discussions.

IFPMA Policy Position on AMR

There is increasing support to the idea that payments delinking value from volumes prescribed may represent a longer-term solution, since the overall value of a new antibiotic to the whole population is likely to be enhanced by restricting its use within a stewardship programme.

OHE Report

One new business model option is based on the concept of insurance, where in exchange for making the new antibiotic available in a market, payers agree to provide companies upfront and/or annual negotiated payments at a fixed price or preset fee. Antibiotics are either purchased in addition to the annual fee or a certain volume may be covered by that fee. May also include a revenue limit/cap in the event of large demand requirements due to a catastrophic resistant infection outbreak. From the health care system perspective, this ensures the availability of the new antibiotic and manages the unpredictability of resistance levels while at the same time improving budget predictability. The company is insured against the commercial risk of very low use at launch as it will at least receive the upfront/annual fee regardless of the volume of antibiotic used.

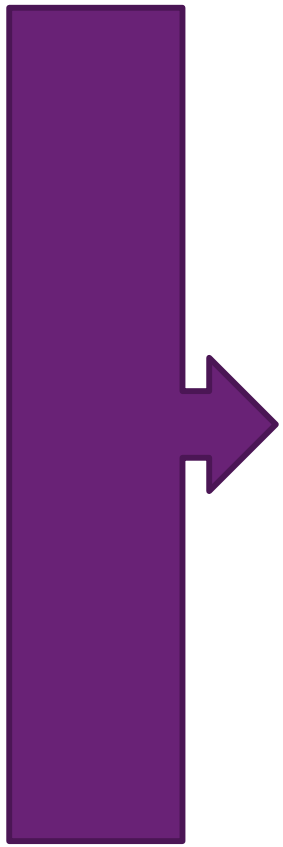
Company submission to the Australian consultation on AMR

Beyond HTA: Procurement mechanisms, hospital procurement and stewardship

Current pricing, reimbursement and procurement models can contribute to shortages, via tendering for small quantities with limited sales revenue

Need to also recognise supply chain issues and potential for shortages of older, low cost therapeutics.

Movement of patients from one institution to another, coupled with antibiotic shortages in one or more of those institutions makes effective stewardship extremely difficult



Solutions needed to combine value-based pricing that links with state and federal processes and channels for funding, ensuring supply when required, under appropriate stewardship.

Questions for discussion (recognising we will not solve technical complexities at this meeting!)

- Are current HTA processes and guidelines in Australia capable of more fully considering the value novel antibiotics bring to society?
- If not, how might they be modified to better consider additional dimensions of value, recognising that to do so for the 'long list' of value dimensions is likely to result in a prolonged and highly complex HTA?
- What are the 'must have' elements of value that an HTA process might include at a minimum?
- How might necessary expert opinion be brought into the HTA process?
- Would dynamic transmission models help, or would that be added complexity and delay?
- Are there opportunities to improve market rewards via existing systems in hospitals or via funding channels other than the PBS, while optimising stewardship?
- What are the sector specific roles and responsibilities in this area? How do we move the discussion forward and seek a balance between efficiency and complexity?

Session 4: Pricing, reimbursement and supply chain

10 mins	**Presentation: Introduction to key issues**	**David Grainger, *Head Global Health Outcomes and Policy, Biointelect***
30 mins	**Discussion**	**ALL PARTICIPANTS**
10 mins	**Report Back**	**TABLE CHAIRS**

- What are the top three issues identified for this topic?
- Why have you chosen these issues?
- Please propose ways forward to address, stakeholders, roles…