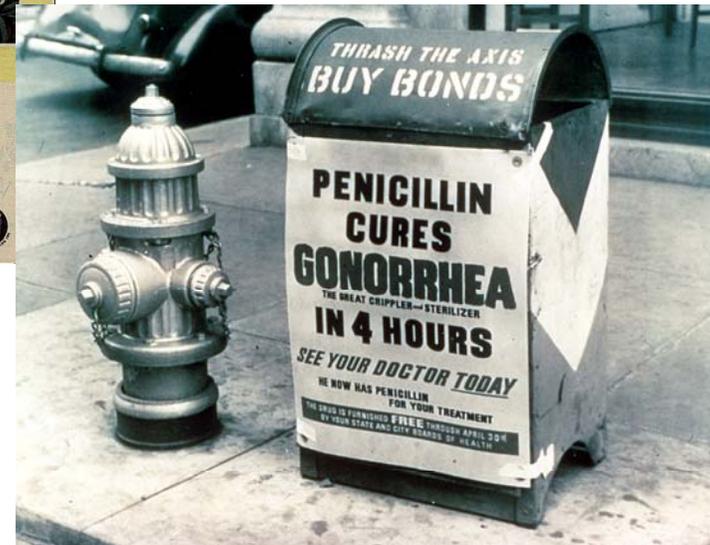
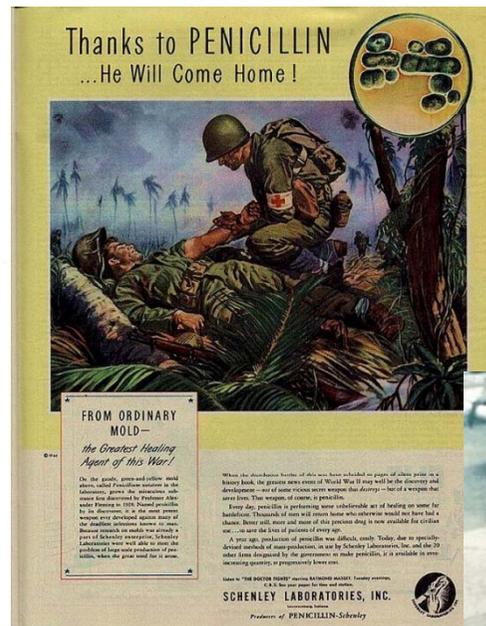
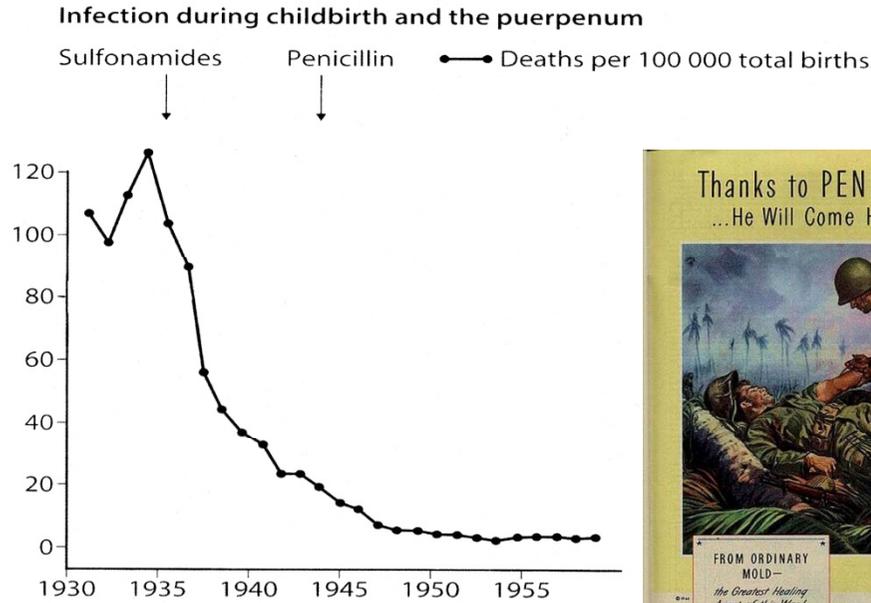


The next 40 years

Laura JV Piddock

British Society for Antimicrobial Chemotherapy

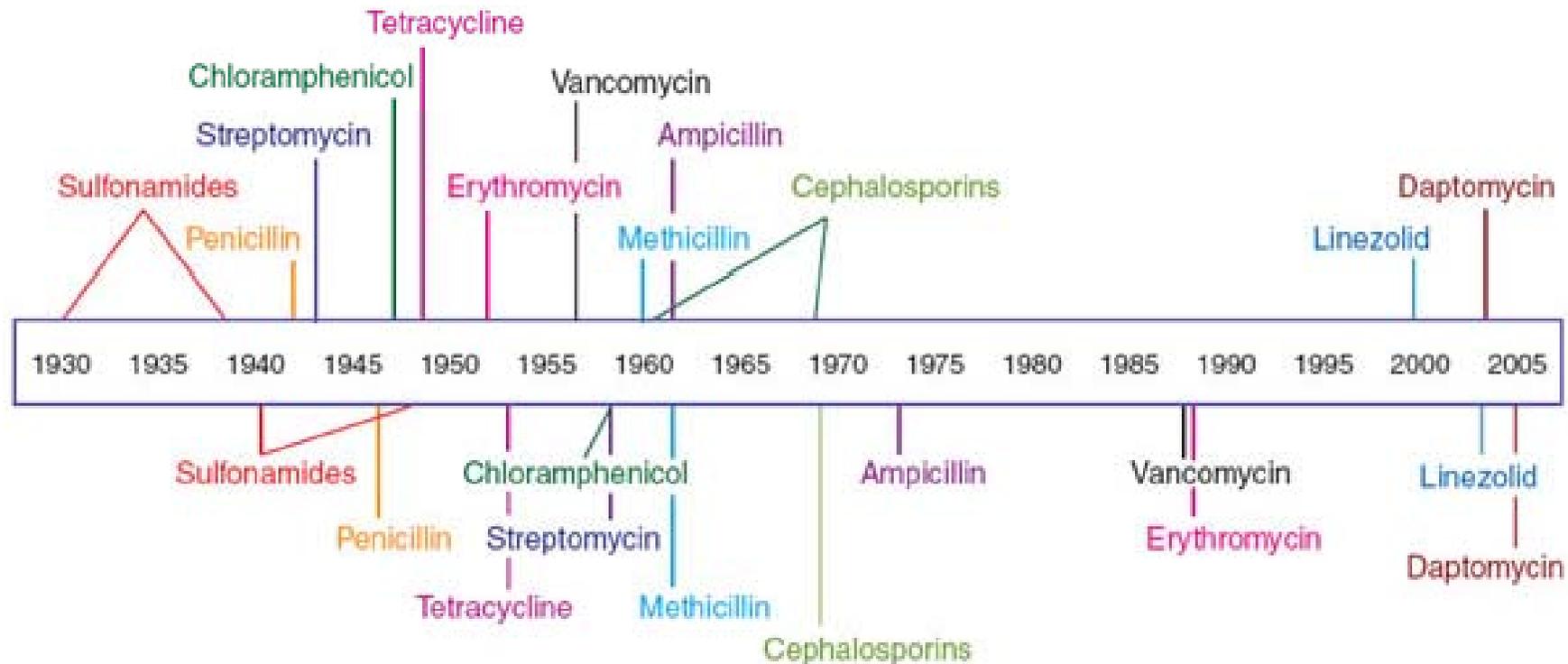
The impact of antibiotics



(Adapted) slide courtesy of Richard Wise

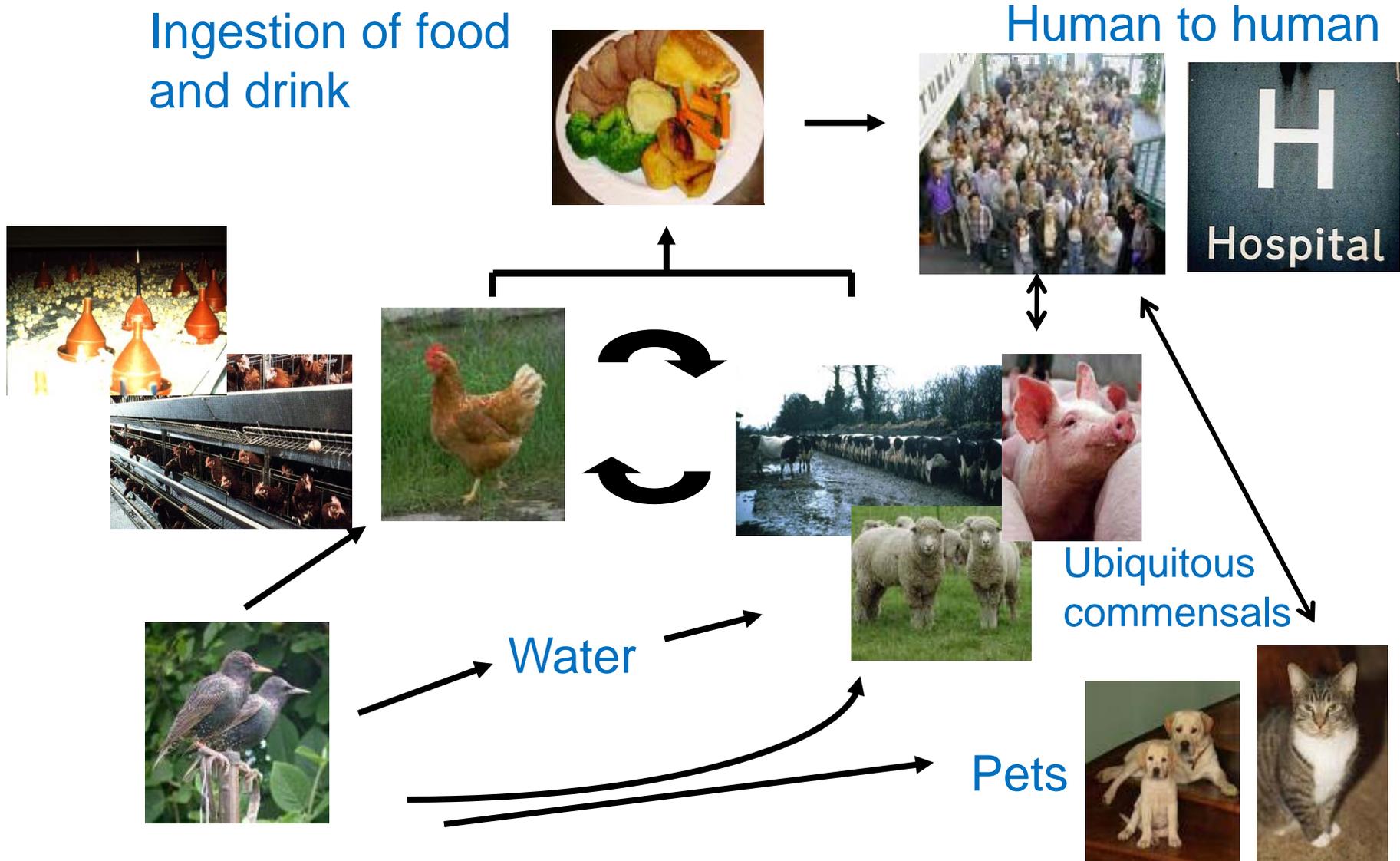
Timeline of antibiotic deployment and the evolution of antibiotic resistance.

Antibiotic deployment

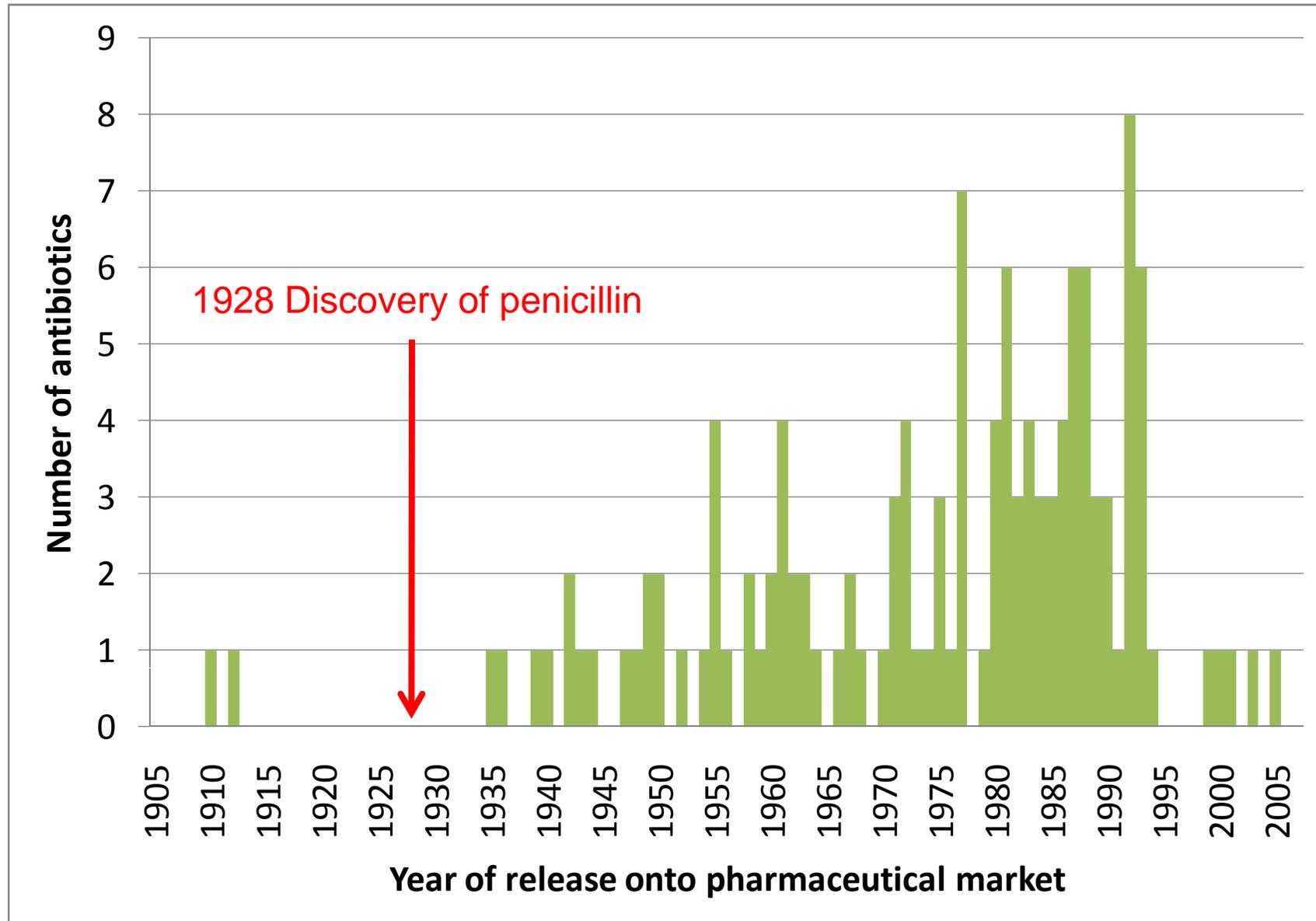


Antibiotic resistance observed

Bacterial movement between ecosystems



Timeline of antibiotic discovery and development



Antibiotic use benefit the individual and Society

Monday, January 7, 2009 **METRO**
Baby dies as ward is hit by killer bug

ONE baby has died and six others were in an isolation ward last night after a bug hit a hospital's neo-natal unit. The baby, who was born prematurely at Birmingham's Heartlands Hospital nearly two weeks ago, was one of two to become infected with Serratia bacteria. Staff at the Bordesley Green hospital hope the second will be able to go home 'in the few weeks'. Five other babies, who tested positive for Serratia on their skin, are in a six-cot isolation unit 'as a precaution', the hospital said. Serratia can prove deadly if it attacks the infant's lungs.

unt infection
 culosis



**BETRAYAL
 OF THE
 CANCER
 PATIENTS**

Rationing watchdog accused of talking
 down wonder drug's power to save lives



Adapted from White, A: E...on, 2006

Where we are now in 2011

- Waxing and waning of pathogens and resistances
- More opportunistic infections
 - often by Gram negative bacteria with innate MDR
- New resistances
- Few new agents

The Urgent Need Initiative

Regenerating antibacterial drug discovery and development

- Chair: Richard Wise
 - 8 members
 - 8 overseas advisors (ASM, IDSA, ReAct)
- Research, regulation and economics
- Report: <http://www.bsac.org.uk/News/TUN>

A Working Party of the
British Society for Antimicrobial Chemotherapy

Research

- An anti-infective, unlike other drugs
 - Has multiple targets (bacterial species).
 - Needs activity for many different infections.
 - Be effective in various and several body sites.
- Genuine rarity of drug classes for Gram negative bacteria
 - Agents need to permeate and evade innate efflux.
- Over-optimism in the 1990s for what genomics could deliver
- Reduction in research capacity
 - Mergers among big pharma, which reduced the number and diversity of discovery teams.
 - Reduction of funding to academia.

Regulatory hurdles



"No, those aren't my diplomas.
They're my regulations."

Licensing and Regulation

Exists to support the public health agenda and ensure the safety of patients, **but**

- Process is risk averse and can be particularly onerous for the approval of an anti-infective
- Main difficulties
 - Increasing bureaucracy,
 - Lack of clarity within the regulatory framework
 - Global differentiation in the clinical trials process
 - Lack of international harmonization
 - Continual changes to processes
 - Ineffective pathways for dialogue between organisations



***Rapid
Diagnostics***

**'Taking the
guesswork
out of
prescribing'**

Slide courtesy of Roger Finch

Failure to bring agents to market

Lack of return on investment.

- Poor return as usually a short term course.
- Restriction of prescriptions for fear of selection of resistant strains.
- Estimates of the financial return (Net Present Value) lower than for other drugs and vaccines.
- Complexity and high cost of Phase III clinical trials – deters small companies
- Many infections are by antibiotic susceptible bacteria – can use cheap generic antibiotics

Economics: evaluating societal and human cost

- Prices of antibiotics need to relate to their value (not versus old products/generics)
- Evidence needed for the
 - economic cost
 - human costs of untreatable infections
 - human and economic costs of resistance
 - potential cost/s of inaction
- Involvement of NICE

Not just a UK concern...

- WHO statistics
 - Infections are 2-5 of the top 10 causes of death
 - Infections impact upon the other 5-8 causes
- WHO 2009: “*Antibiotic resistance - one of the three greatest threats to human health*”
- WHO World Health Day. 7 April 2011
Antimicrobial resistance: no action today, no cure tomorrow

So what are BSAC going to do?

- **Short term (<12 months): raise the profile**
 - Alliance of charities (and patient groups).
 - Engage with research councils, industry and other key funders.
- **Medium term (24-36 months)**
 - All Party Parliamentary Group Select Committee on Antibacterial Drug Discovery and Development
 - Identify key opportunities for influencing policy/strategy
 - Model and measure societal costs
- **Long term (<60 months): changes in legislation**
 - use of patient samples and information, thus making disease surveillance more cost and time effective
 - Licensing and regulation

The next 40 years?

- New molecules from academia
- Using genomics to provide new natural products
- Quantify the impact of loss of antibiotics (resistance)
- Encouraging industry to produce new antibiotic products – the biggest challenge?