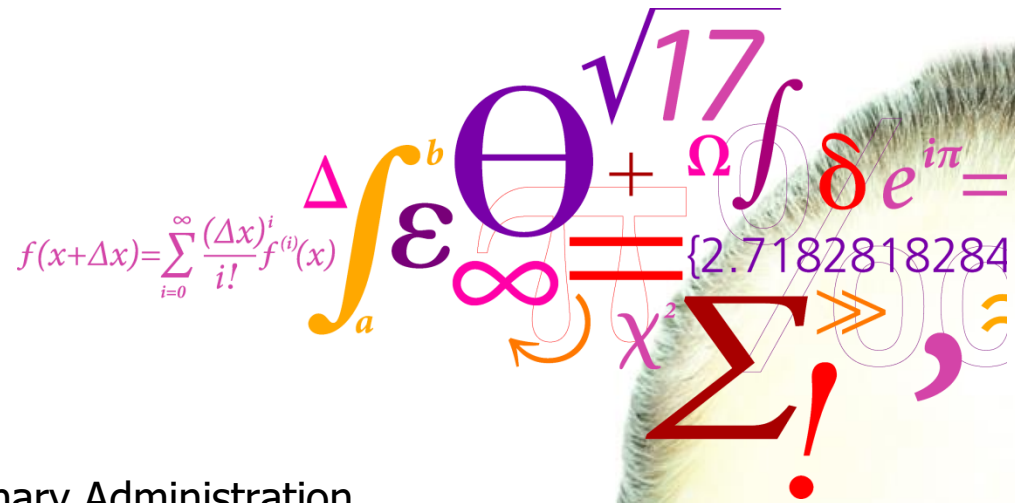


Risk assessment of AMR

Discussion & Further Thoughts



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Selecting the EMA guideline approach

Objectives

- Guideline assess emerging/additional resistance
 - We assessed known resistance
- Guidelines assess risk of future
 - We assessed present risk

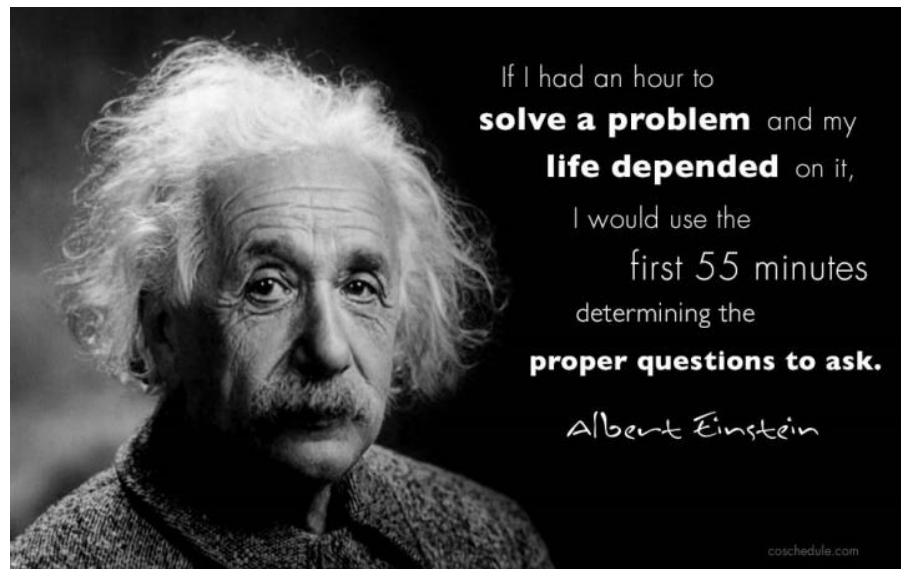
Advantages

- Official reference
- Traditional approach
- Good starting point
- Stepwise description
- Data requirements
- Clear figure
- The 'pathway' idea



Challenges- Risk question

- **Precise, relevant and applied risk question**
 - Simplifies work process
 - Aligns expectations between assessor and users
- **Limitations, boundaries and level of detail**
 - Before start
 - Standardised throughout process



Challenges-Categorisations

- **Categorisations**

- Differentiated risk may not be expressed with too few scores
 - Direct contact with goats
 - High in Greece, very low in Sweden =>EU score?

- **Consequence score**

- Low prevalence? Low cost? Low severity?

- **Qualitative scales**

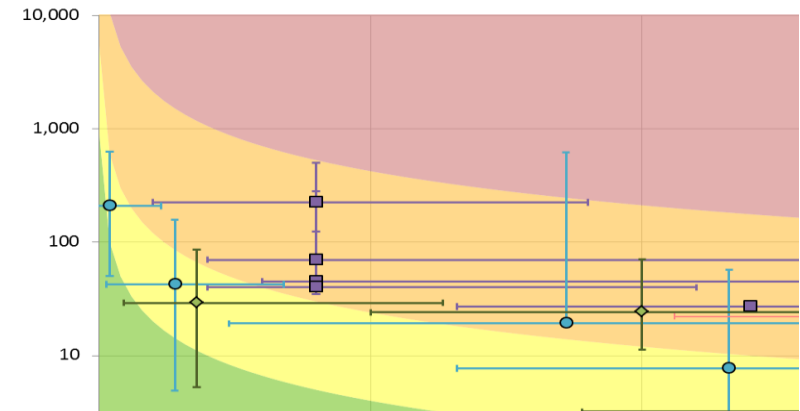
- Relative to:
 - Other continents?
 - EUs mean?
 - Historical?

Challenges– Missing data

- **Multi-sector team national associations/agencies:**
 - Human, food, livestock sector, pharmaceutical and private veterinarians
 - Difficult to find all information
- **Particular risk of data gaps**
 - Relevance of potential hazard
 - Importance of antimicrobial groups in humans
 - Data on consequences at EU level
- **Handling missing data or unknowns**
 - Precautionary principle or “not assessed”?

Challenges – Communicating Uncertainty

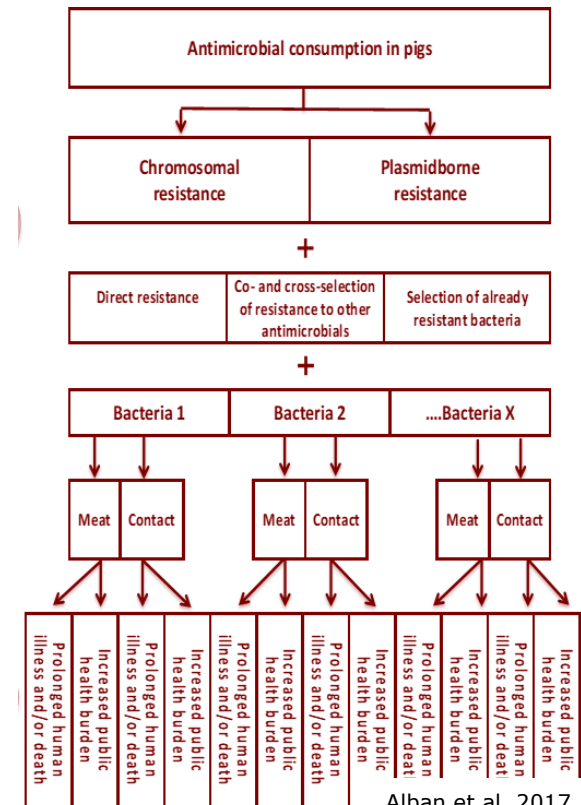
- **Communicating uncertainty is difficult!**
 - Even for experienced risk assessors
 - Very difficult and intangible topic
 - But very important for decision-making
- **May lead to**
 - Lack of transparency and consistency
 - Lower value for EMA and the society
- **Guidance to standardise**



Challenges -Focus

- **Multidisciplinary team of specialists**
 - Difficult to
 - Keep track of decisions (Hazard ID)
 - Communicating progress
 - Reply to challenges

- **Lack of visible risk pathway**
 - Different visions
 - ⇒ Reduced productivity and motivation
 - ⇒ Some loss of confidence from peers



Alban et al, 2017

Continued challenges in risk assessment of AMR

- **Transfer of mobile elements**

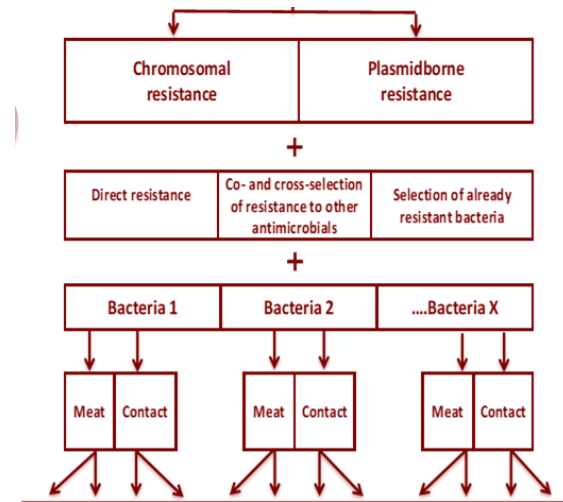
- Many unknowns
 - Relative importance of pathways
 - Which bacteria
- Surveillance data only for bacteria

- **Drug use today**

- => Adverse effect in many years time
- => Not necessarily linear increase
- => Is resistance reversible?

- **Novel RA approaches**

- Cumulative risk assessment frameworks
 - Chemical or ecological
- In combination with infections frameworks?



Continued challenges in risk assessment of AMR

Present risk

- Status quo
- Today's data is directly applicable
- Minimum uncertainty

Future risk

Scenario

- Levels of drug consumption
- Levels of resistance mechanisms or resistant bacteria
- Importance in public health of drug (+ cross-resistance drugs)
- Novel resistance determinants (co-resistance)

Evaluation assessment

- Do risk factors change?
- Does the scenario hold?

Congratulations on the guideline Version 2



Thank you for your interest in our work

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