

Antimicrobial Susceptibility and Resistance and Coordinated Development of Antimicrobial Drugs and AST Devices

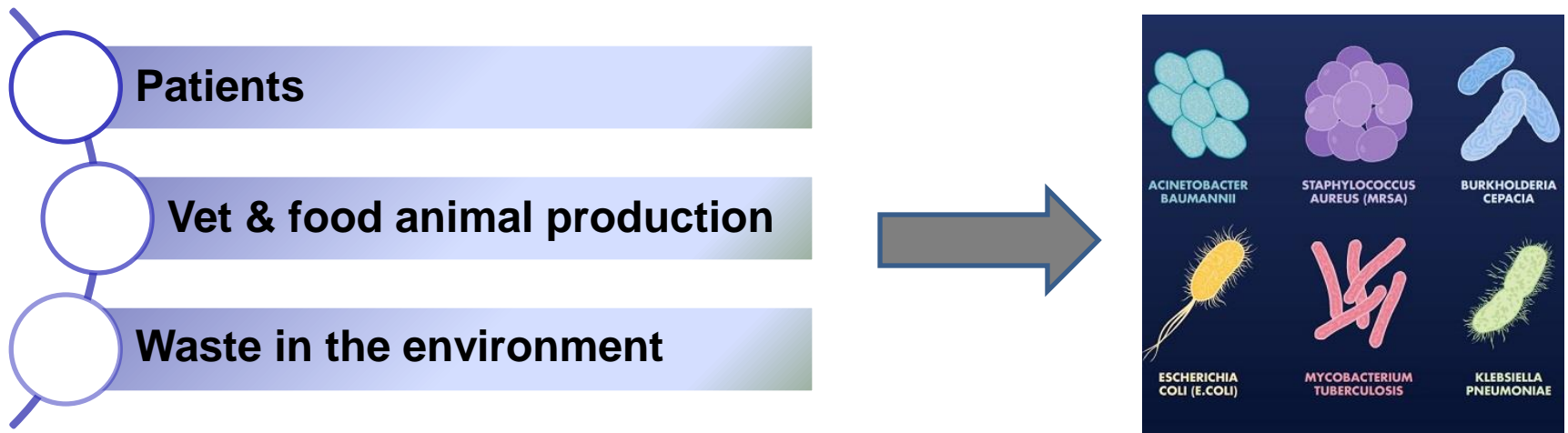
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What is AMR and One Health

- Selection pressure on bacteria to mutate in order to survive the antibiotic effect occurs every time we use antibiotics in

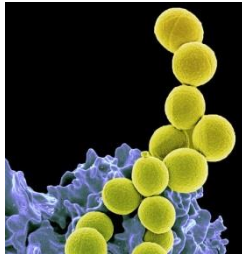


- Growing human and animal populations along with increasing international trade and travel have accelerated the spread of resistant strains of bacteria, creating a global concern.

Consequences of AMR- Patient and Society

Mortality

- Every 45 seconds, a person dies from an infection caused by resistant bacteria (*Kumar et al.*).
- That's 48,000 people every year in the EU + US, and it's getting worse (*EU commission 2011 & CDC 2013*)



Morbidity

- Use antibiotics that are more toxic & more expensive (*Lushniak et al. 2014*)
- Resistant infections require longer hospital stays, more doctors visits, longer recuperations and experience a higher incidence of long-term disability (*CDC 2013*).

Economic

- U.S. \$21-34 billion- the estimated yearly cost to the US health system as well as 8 million extra days in the hospital (*Spellberg et al 2011*)
- By 2050, antibiotic resistance may lead to U.S. \$100 trillion in induced world GDP loss as estimated by the O'Neill report (2015)

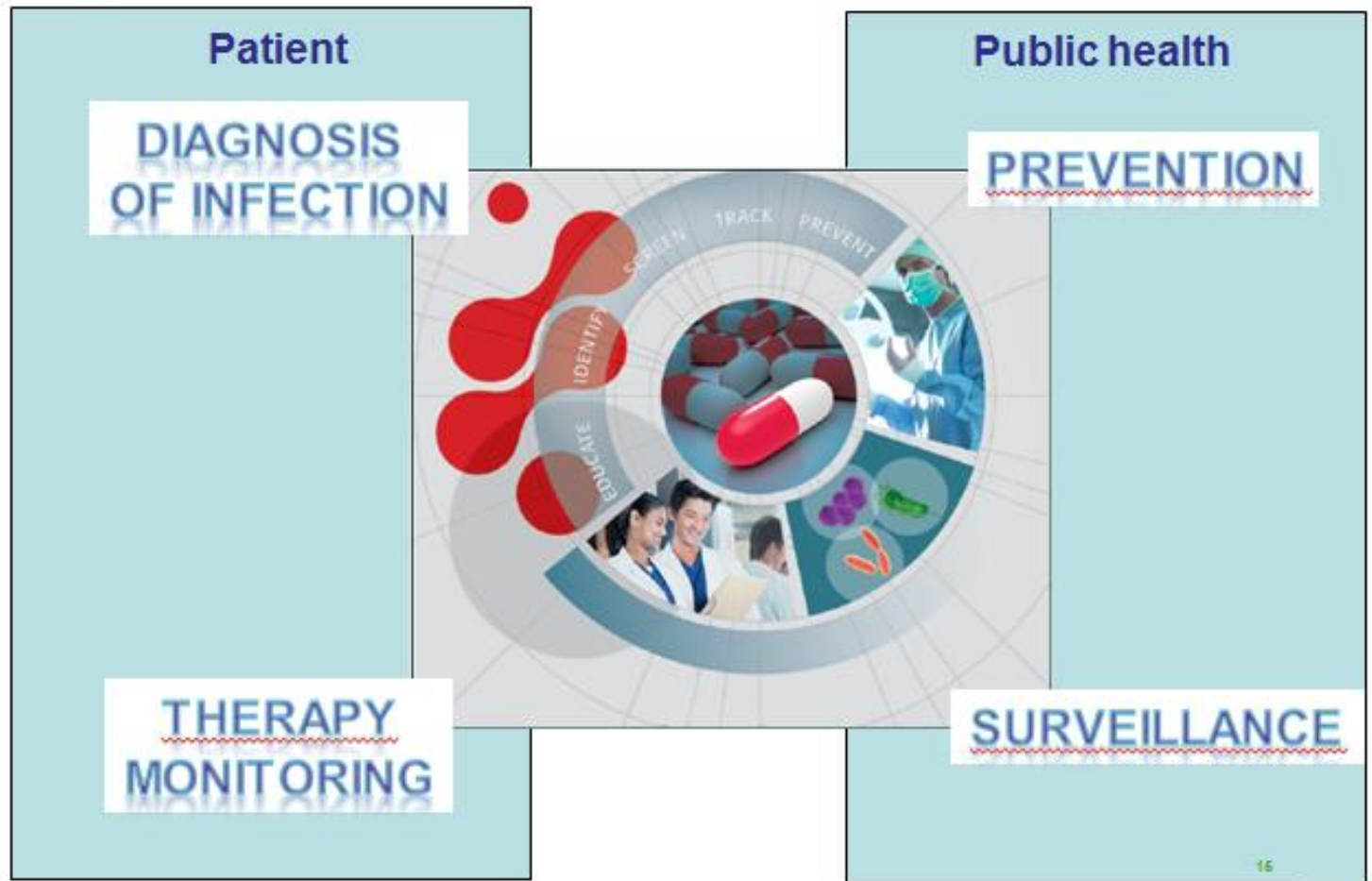
Consequences of AMR- Modern Medicine

- Antibiotics are one of the major breakthroughs of modern medicine and they have made many of our current “medical miracles” possible:
 - organ transplants,
 - cancer treatments,
 - therapies which beneficially modify our immune system (e.g. rheumatoid arthritis, psoriasis or Crohn’s disease) and
 - complicated surgical procedures.



Without antibiotics, the infection complications of these medical interventions would be too frequent, harmful and possibly lethal.

Critical Role -AST Devices in AMR Fight



Coordination Drugs and AST devices

- Coordination of Drug labeling and AST device labeling is critical.
 - Often considerable delays in getting new drugs onto AST devices.
 - Breakpoints change and updating drug and device labeling is a challenge.



Recent FDA Initiatives

- CDC-FDA Antimicrobial Resistance Isolate Bank
- 21st Century Cures
 - AST interpretive Criteria website
 - Recognition of SDOs
- Coordinated Development Draft Guidance
- FDA September 13, 2017 Public Workshop

Future Opportunities for Collaboration with Stakeholders on other AST Challenges

