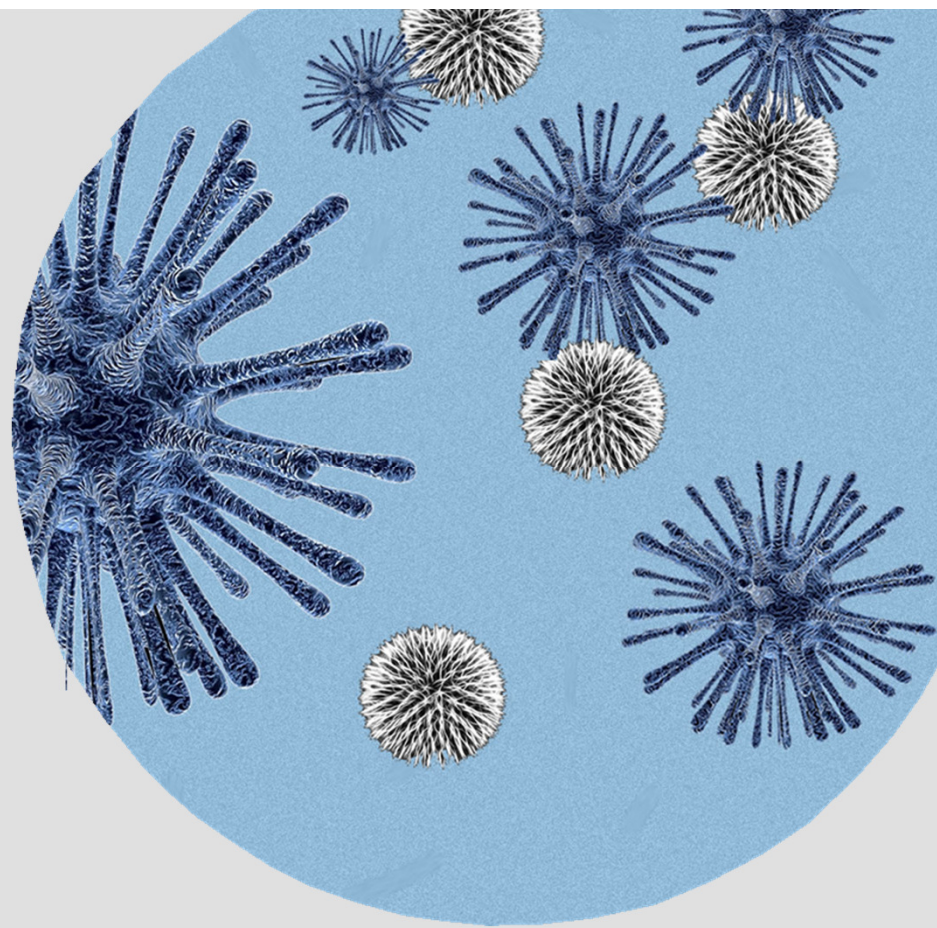
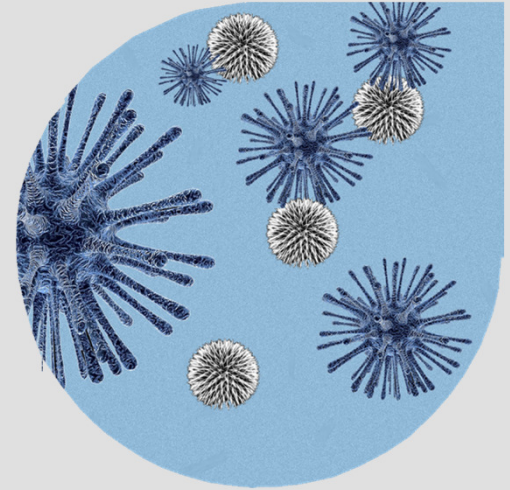


*Challenge:
Common Needs,
functional
requirements and
Business Case*

Barcelona, 15/12/2018





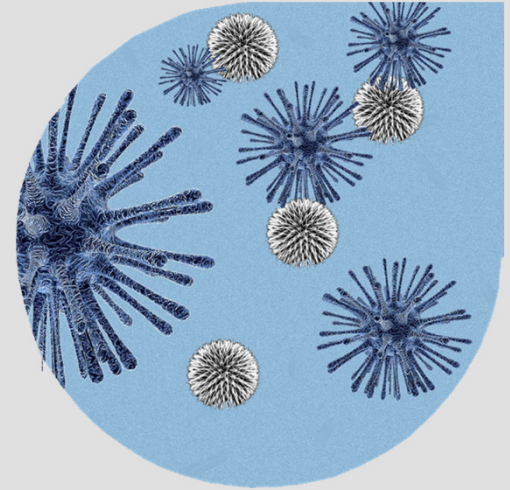
Problems

- **Antimicrobial Resistance (AMR) is responsible for 25,000 deaths and a loss of €1.5 billion in extra costs every year in the EU alone.**
- **Worldwide, an estimated 700,000 people die each year** from antibiotic resistant infections, and the World Bank has warned that, by 2050, drug-resistant infections could cause global economic damage on a par with the 2008 financial crisis.

(Source: European Commission, 2017)

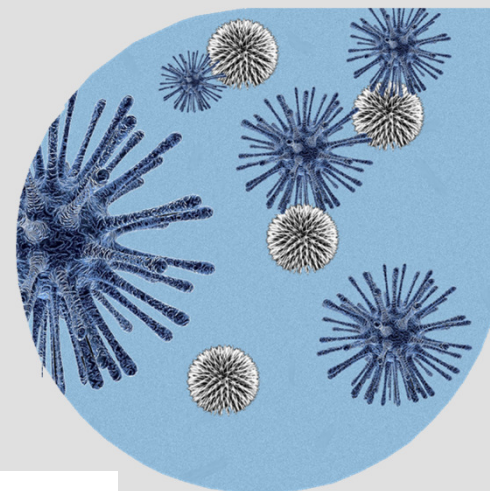
17/01/2018





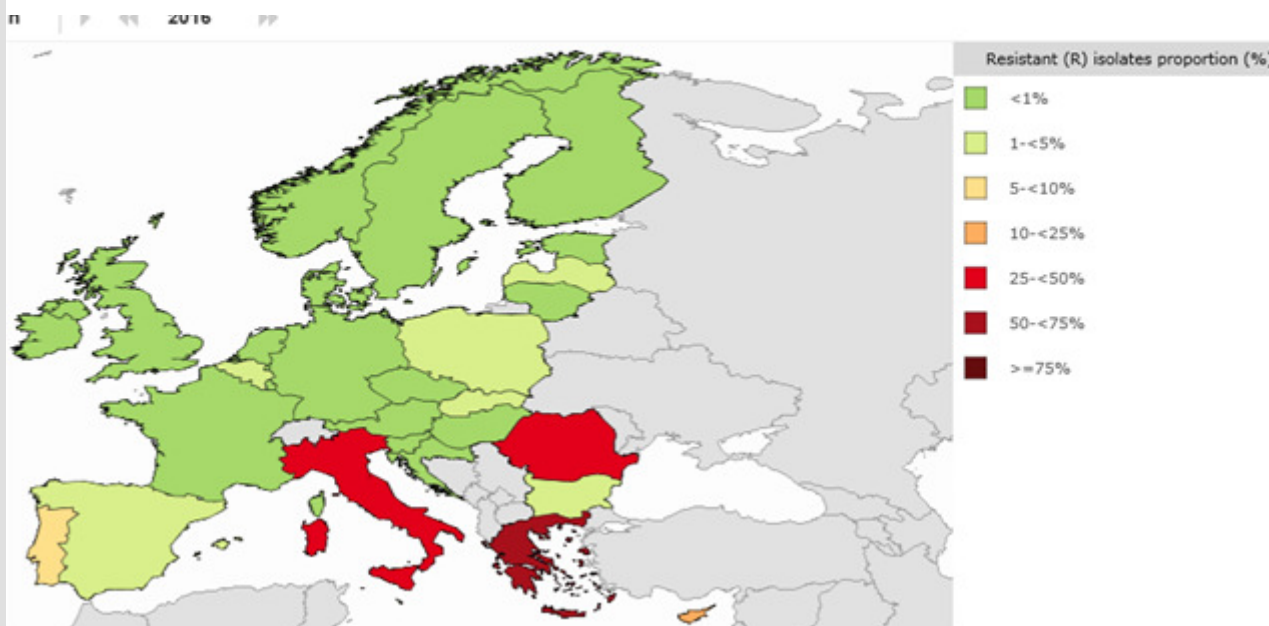
Problems

- **Infections caused by MDROs is a common problem** in the majority of the healthcare services of worldwide communities (including the ones of ANTISUPERBUGS PCP contracting authorities).

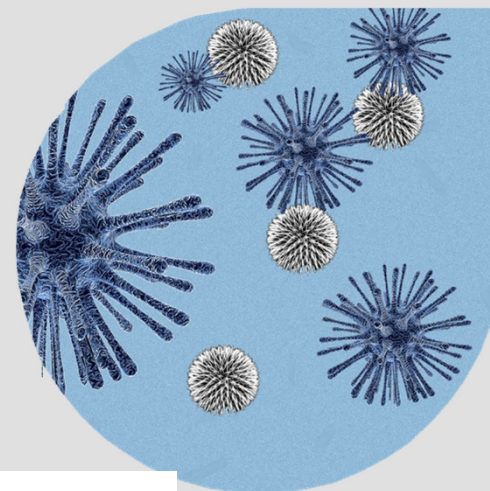


Problems

Proportion of *Klebsiella* spp. with carbapenem resistance 2016

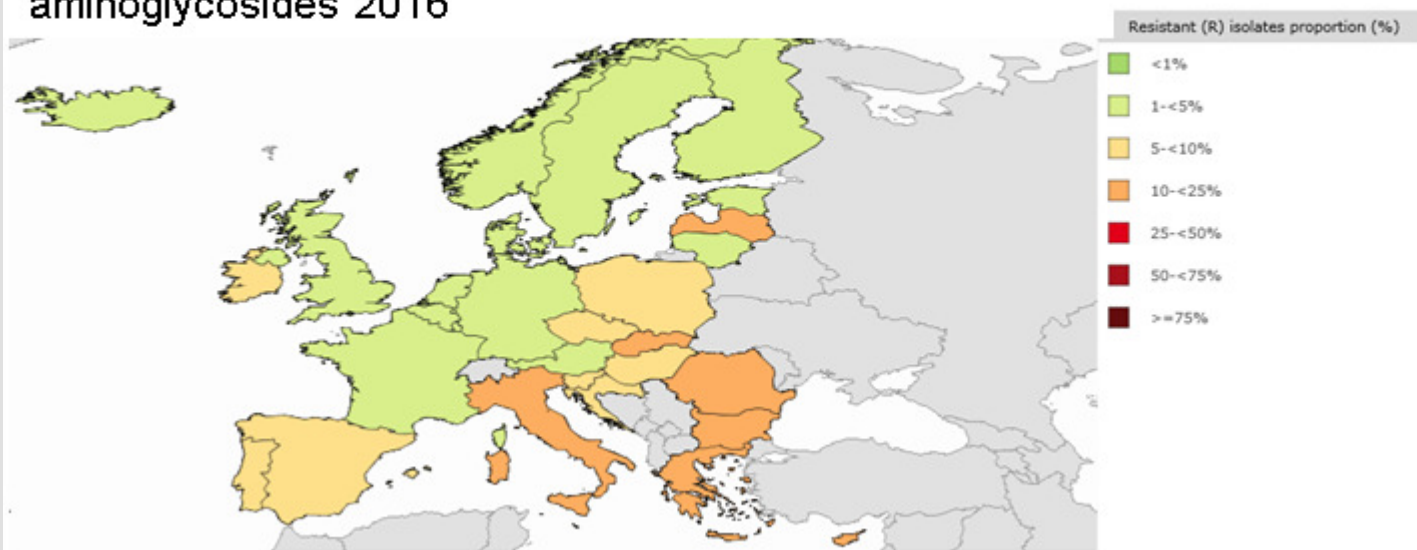


Source: EARS-net

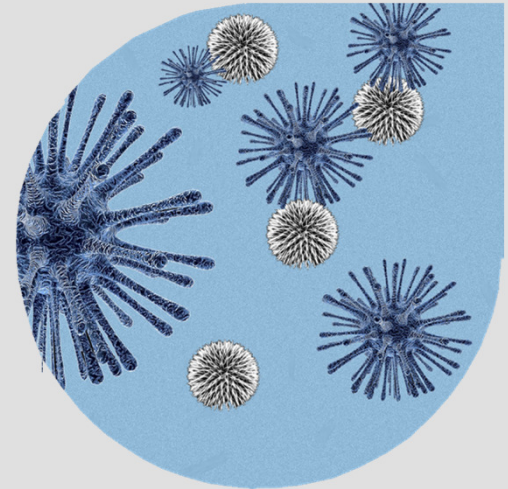


Needs

Proportion of *E. coli* with combined resistance to 3rd generation cephalosporins, fluoroquinolones and aminoglycosides 2016

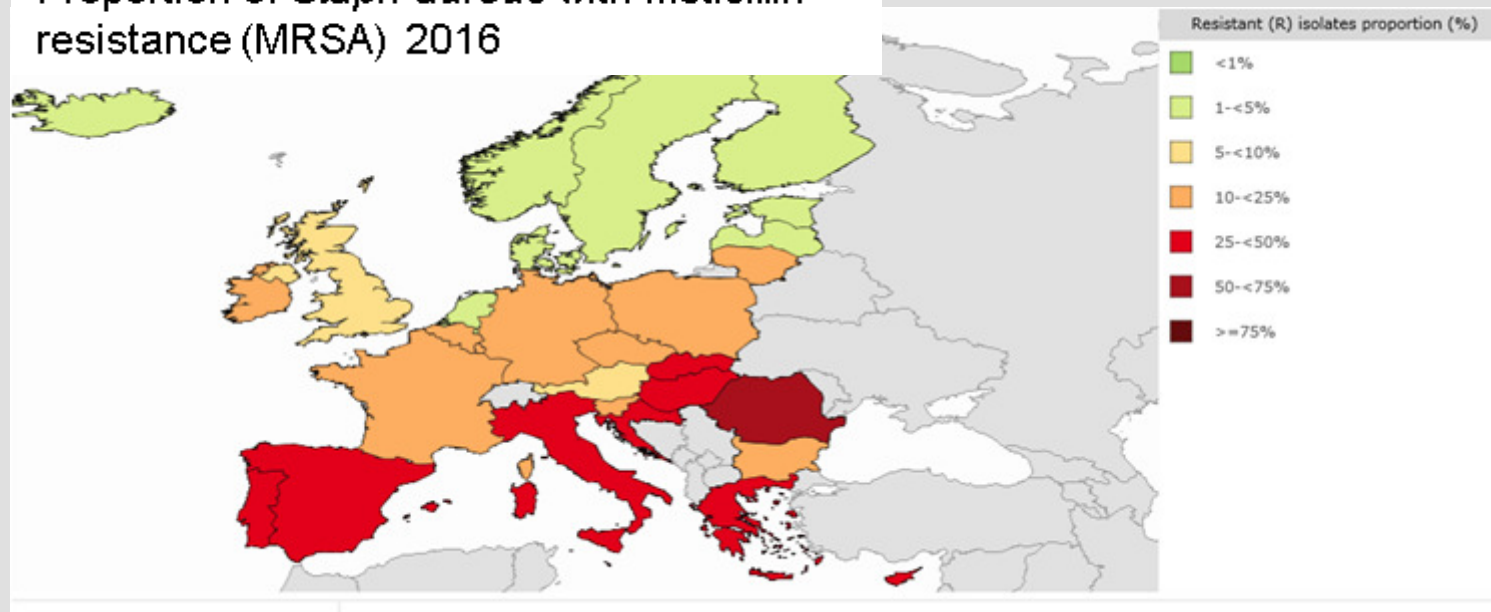


Source: EARS-net

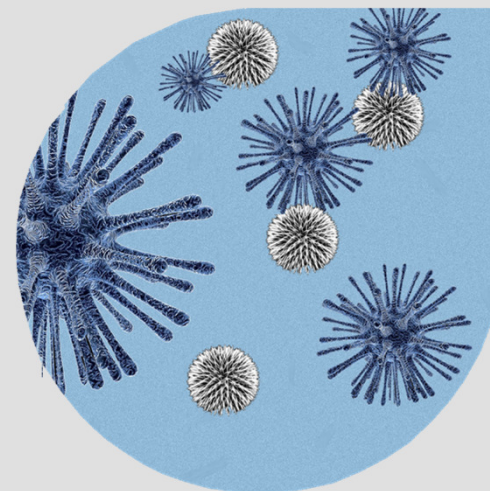


Needs

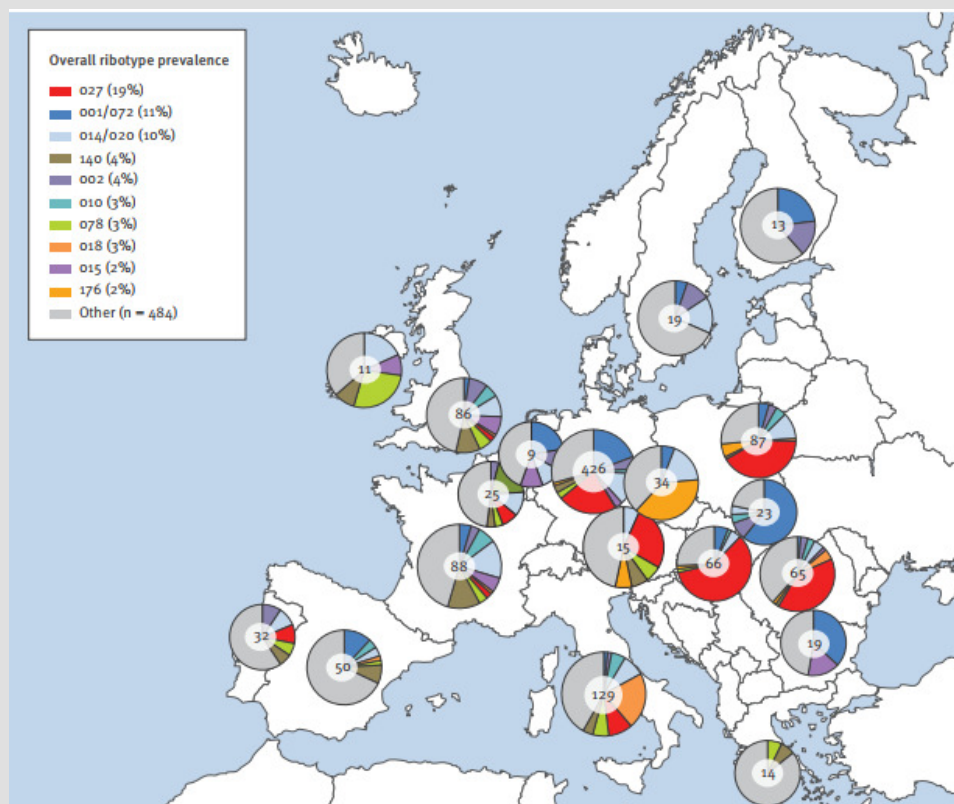
Proportion of *Staph aureus* with meticillin resistance (MRSA) 2016



Source: EARS-net



Problems



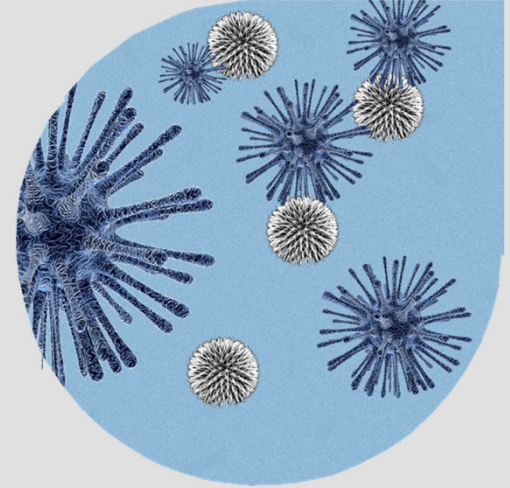
Geographical distribution of *Clostridium difficile* PCR ribotypes, by participating European country^a, EUCLID, 2012–13 and 2013^b (n = 1,196)

17/01/2018

(Source: Eurosurveillance, 2016)

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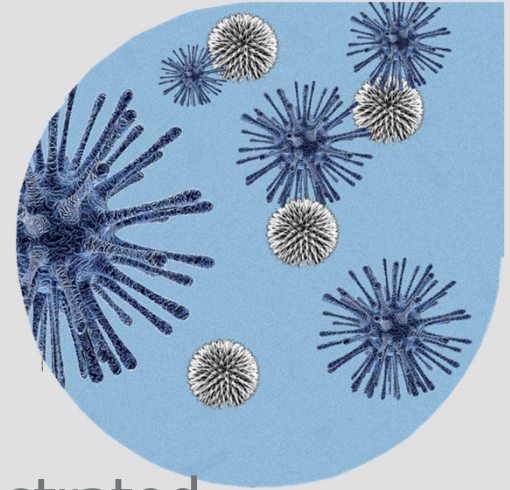


Problems

- Antimicrobial resistance is also due **excessive and inappropriate use of antimicrobial medicine**
- High variability of antibiotic consumption:



(Source: European Commission, 2017)

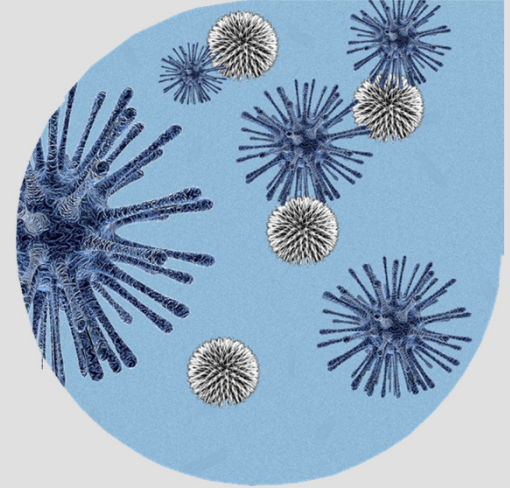


Problems

- **Continuous surveillance** has been demonstrated **effective** to prevent the propagation of MRDOs infections and to reduce the length of stay.

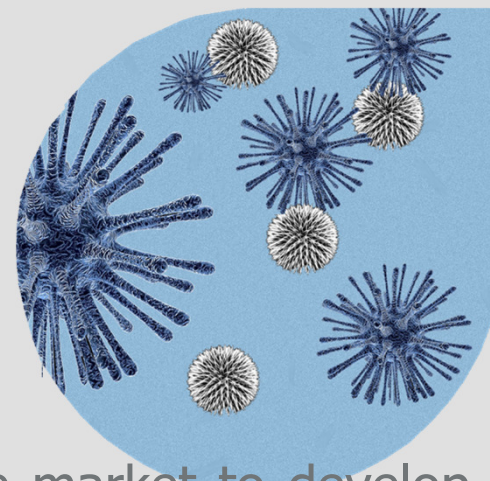
(Source: Souverein D, Houtman P, Euser SM, Herpers BL, Kluytmans J, Den Boer JW (2016) Costs and Benefits Associated with the MRSA Search and Destroy Policy in a Hospital in the Region Kennemerland, The Netherlands. PLoS ONE 11(2): e0148175. doi:10.1371/journal.pone.0148175)

- Continuous surveillance is currently **very expensive and not feasible for all organisms and the ability of different facilities and different countries to implement it varies widely**



Problems

- Although great effort has been concentrated on admission epidemiology, surveillance & Infection Control, patients continue to acquire **MRDOs in hospital and their clinical outcomes are adversely affected compared to their initial prognosis.**
- Currently no technological solution offers **continuous detection of colonisation on human bodies and environmental surfaces.**



Challenge

The ANTISUPERBUGS PCP buyers group challenges the market to develop **novel technologies aimed to upgrade and strengthen current Surveillance & Infection Control Systems of patients and environment enabling real time prevention, real time reporting and prompt intervention**

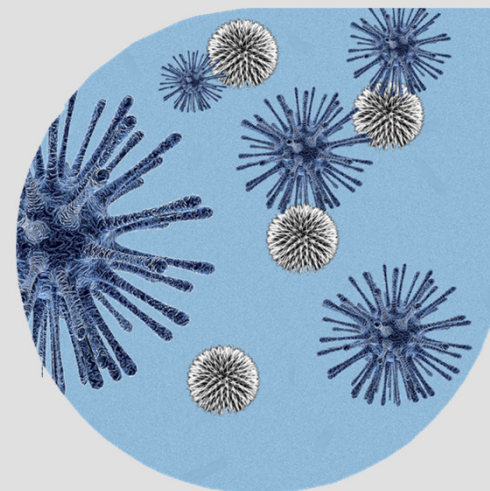
Thanks to these novel technologies ANTISUPERBUGS PCP buyers group will:

- **improve the quality of care processes in hospitals**
- **reduce both the costs and the operational impact resulting from infections caused by Multi-Drug Resistant Organisms (MDROs, otherwise known as Superbugs)**
- **improve the appropriateness of antimicrobial medicine usage**
- **reduce the community and social care impact of MDROs acquired in hospital**

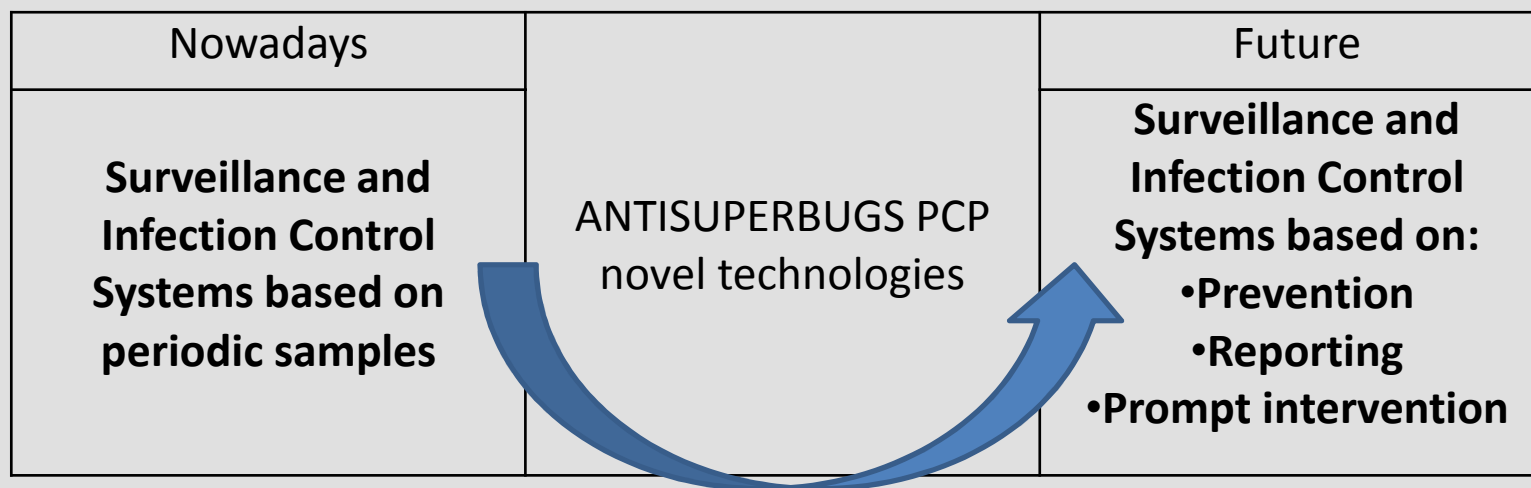
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Challenge



Areas of Impact

Acute care facilities:

Medical services

Surgical services

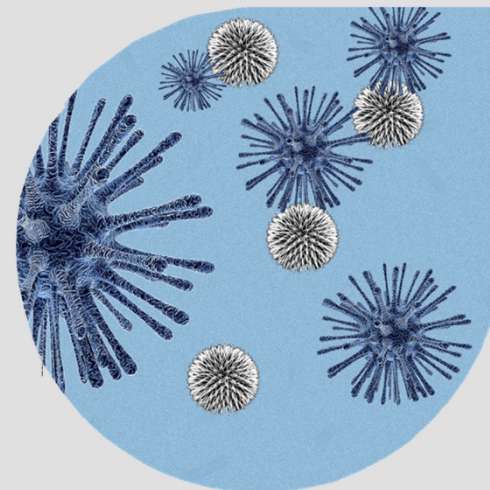
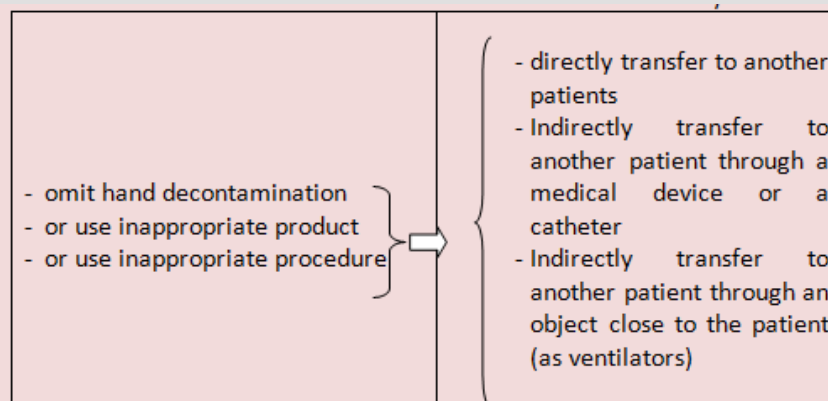
ICUs

Emergency rooms

Other augmented care areas such as:

- dialysis units,
- transplant services
- special care baby units
- burns services
- oncology services
- MRDOs inpatients

- 1- Hospitalization of infected/colonized patients
- 2- Microbial transmission between patients either directly or via HCW hands or the environment



- Clinical suspicion of HAI and sample gathering
- (depending on hospital policies and only for high risk patients) Weekly screening to detect MRSA by PCR or culture (including skin flora present in the perineal area or faecal samples)
- results take 1 day and half



MRDOs infection 'journey' steps



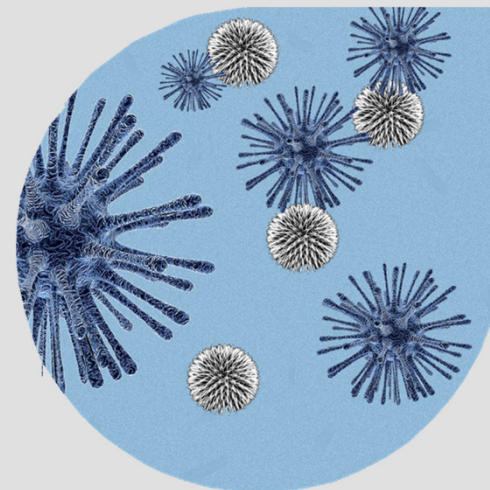
Steps impacted most by ANTISUPERBUGS

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Challenge



- Confirmation of colonized or infected patient
- Review of clinical history or database of colonized patients
- Notification to Epidemiology
- Management of the risk to infect other patients, healthcare professionals and support staff
- Transmission-Based Precautions and
- Either assignment of bed in isolation room
 - Or transfer to another hospital
 - Or death

(if needed) More samples collection (e.g. blood analysis)

Cleaning of bed and hospital environment



MRDOs infection 'journey' steps



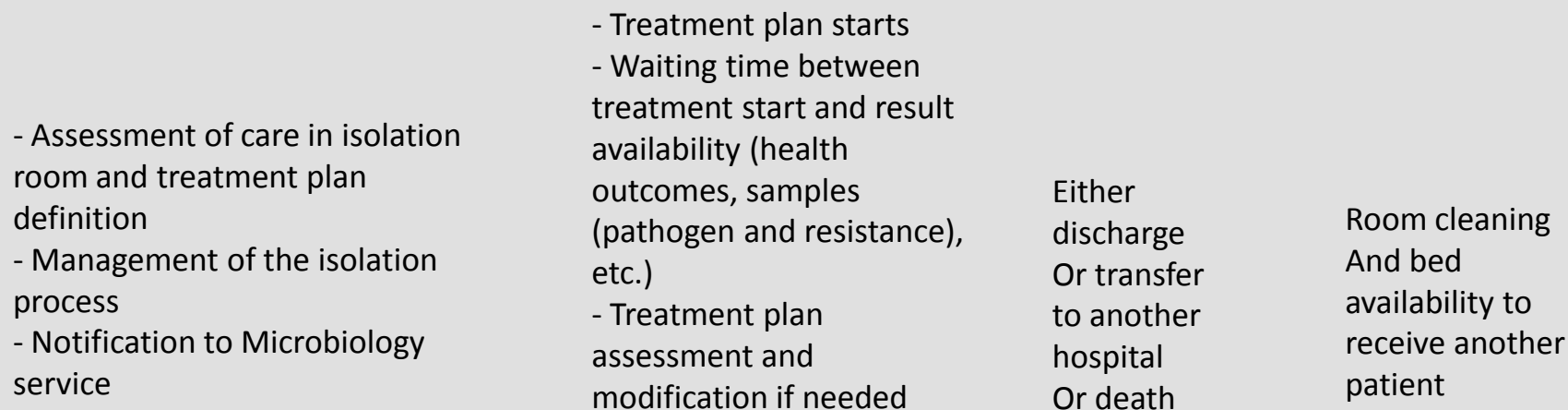
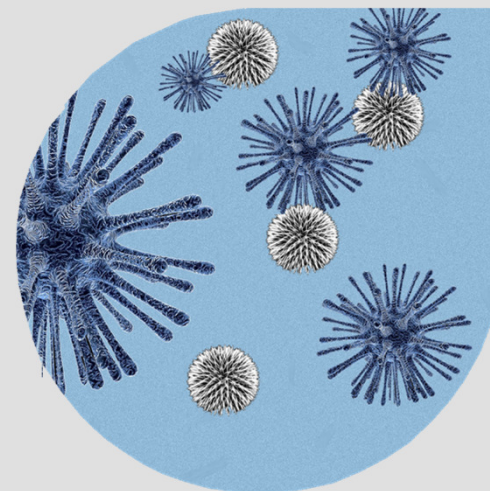
Steps impacted most by ANTISUPERBUGS

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Challenge



MRDOs infection 'journey' steps

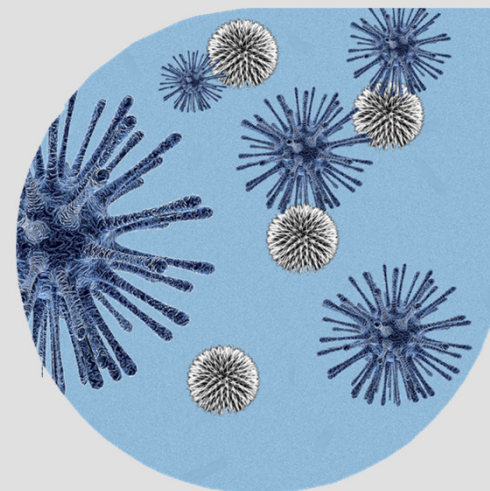


Steps impacted most by ANTISUPERBUGS

17/01/2018

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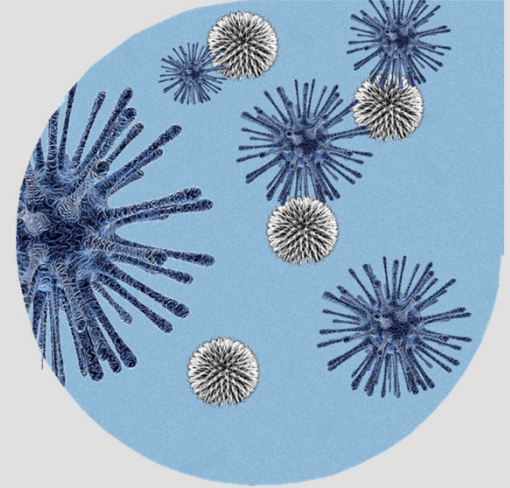


Initial list of common functional requirements

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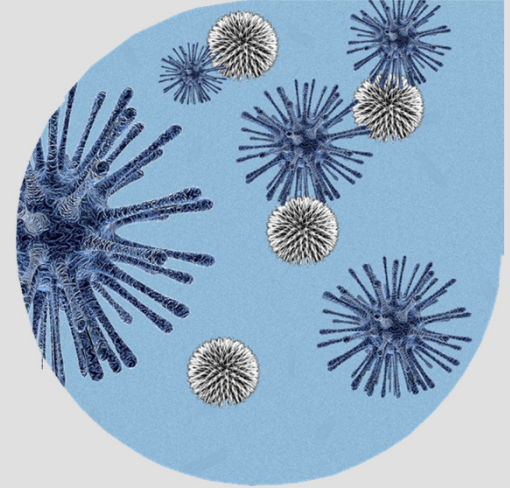


Initial list of common functional requirements

Clinical

Early detection of superbugs on patients and on surfaces (including colonized individuals)

- in situ test that rapidly detects
 - carbapenem-resistant producing gram-negative bacilli +/- extended-spectrum beta-lactamases (ESBLs) production and either E. coli or Clostridium difficile or both (to be confirmed later by the microbiology service)
- Flexibility to integrate detection capabilities for additional MRDOs or future proofing
- Flexibility to integrate detection capabilities for additional clinically relevant HAIs microorganism and vectors
- continuous or high frequency detection
- 99,9% of sensitivity (also in adverse environments) and specificity of micro-organism identification.
- Sensitivity at least of PCR test (low false negatives)

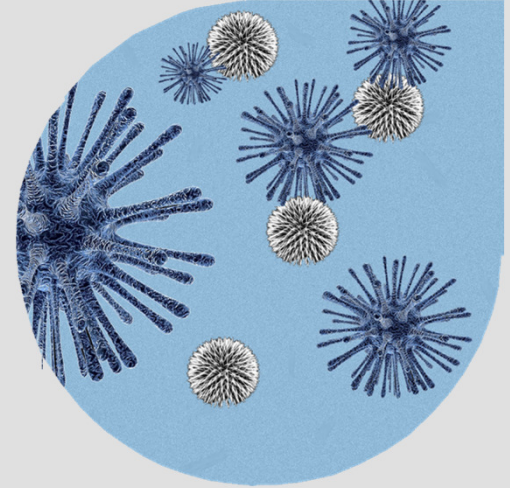


Initial list of common functional requirements

Clinical

Early detection of superbugs on patients and on surfaces (including colonized individuals)

- Acceptable to patients
- Minimally invasive
- Continuous surveillance system for contamination by MRDOs (including colonized individuals) and potentially other healthcare associated pathogens on high contact surfaces
- Ability to sense all the places at more risk of either to be colonized or to be HAIs vectors (e.g.: flush handles, commodes, sinks, bed rails, remote controls, bed linen, curtains, door handles, keyboards, tablets)
- To be deployed/installed into existing healthcare environments
- Can be used in crowded areas

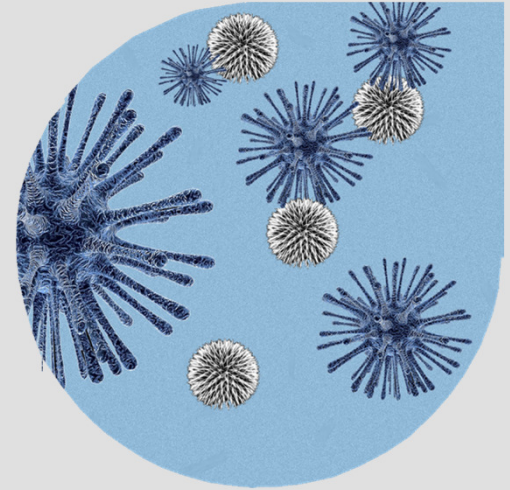


Initial list of common functional requirements

Clinical

early detection of superbugs on patients and on surfaces (including colonized individuals)

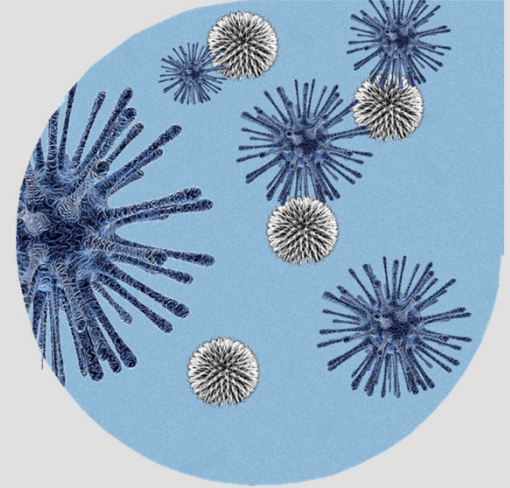
- Availability of remote alert system
- Availability of alert system to be triggered where the contamination is detected inform in real time the hospital information system of the risks of infection
- integration with electronic patient health record and the hospital information system (linking the infection with the place of detection) using interoperability standards (HL7, etc)
- (nice to have) destroy specific superbugs



Initial list of common functional requirements

Economic

- o In case of patients screening: cost effective compared to common practice (e.g.: weekly screening by PCR or culture, estimated to be 40-50 Euros/per each PCR test per person, requiring 1 day and half)
- o In case of surface screening: cost effective compared to existing screening practices (e.g.: such as ATPase testing)

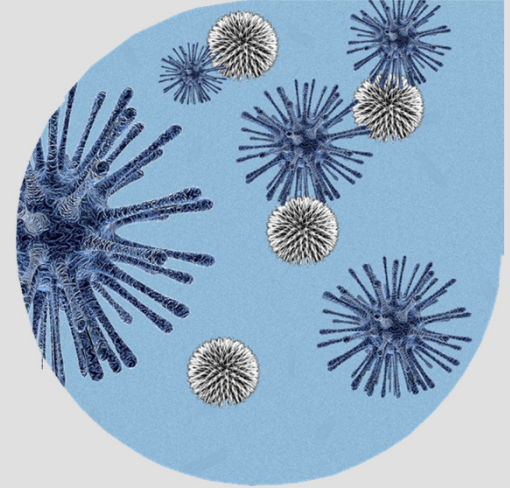


Initial list of common functional requirements

Life cycle

o Installation and Replacement

- ☐ Allows to be integrated in the regular health care or support staff routines
- ☐ Easy to be integrated into different hospital facilities and architectures
- ☐ Appropriate supply integrated into existing systems



Initial list of common functional requirements

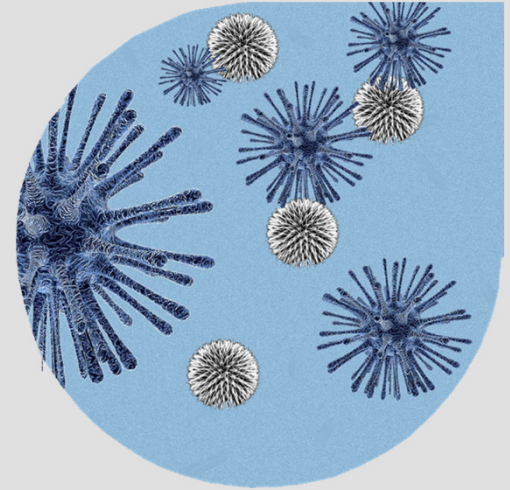
Life cycle

o Use and Management

- ☐ Comfortable for users (inpatients or health & support staff)
- ☐ Easy and risk-free to use, minimally demanding human interaction for early detection
- ☐ Continuously working system (24 hours) with high frequency sensing the system should provide highly interoperable data
- ☐ The system must have a self-diagnostic function
- ☐ Highly usable user interfaces

17/01/2018



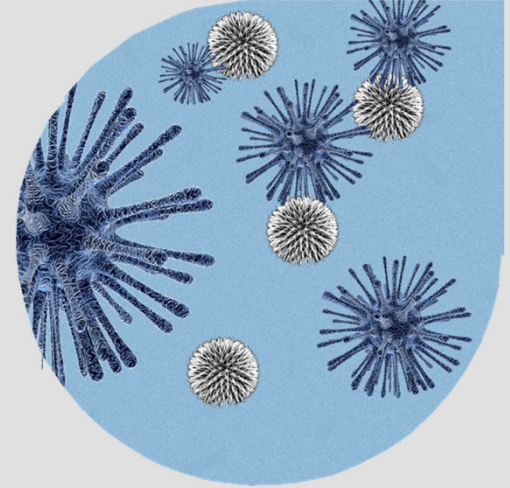


Initial list of common functional requirements

Life cycle

o Maintenance, scalability and renewal

- ☐ Easy to maintain – the buyer can self-manage
- ☐ Easy to upgrade and renew
- ☐ Easy to deploy throughout the system
- ☐ Minimal or no recalibration required
- ☐ Minimum or no consumables
- ☐ Cheap consumables (if any)
- ☐ the covering material (if any) of the sensing components should be cleanable

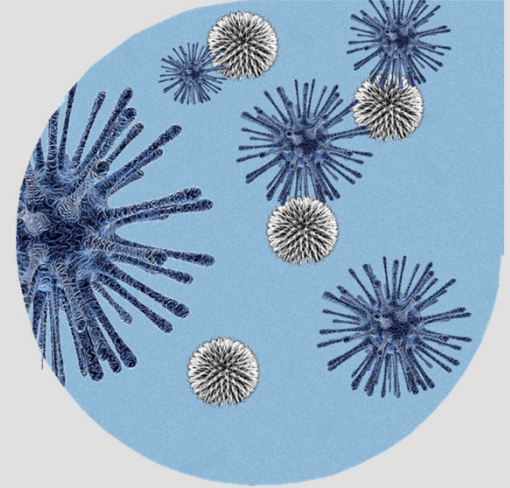


Initial list of common functional requirements

Life cycle

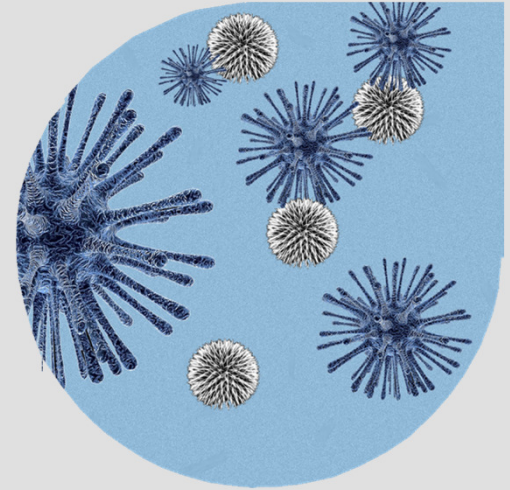
o Disposal

- ☐ No toxic material to be handled by the personnel
- ☐ Using existing disposal routes
- ☐ Environmentally friendly, limited amount of single-use material



Business case

- ICO/VINCAT:
In **Catalonia**, in 2013, the estimated cost of the five most important nosocomial infections generated € 30 million extra costs.
- STH and MFT:
In the **UK**, the cost of HCAI to the NHS is estimated at over £1 billion per year



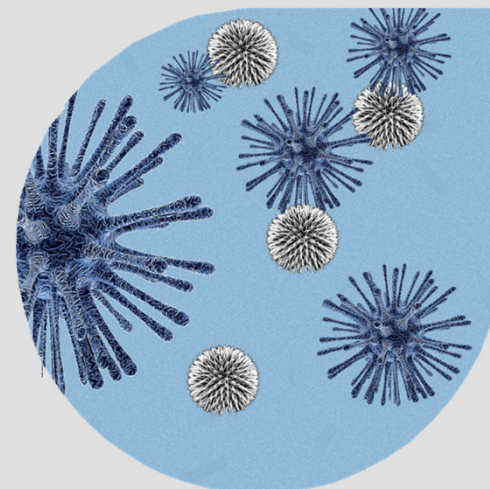
Business case

- MFT has had an ongoing problem since 2009 with CPE – mainly a type called KPC (Klebsiella pneumoniae carbapenemase). In 2014 it confirmed 14 people with a bloodstream infection had died in the past four years.
- Despite the precautions taken in Manchester, in 2015 the bug was found in the Heart Centre in the Manchester Royal Infirmary building. Two wards had to be closed on four occasions for deep cleaning, but the usual infection control measures didn't work and the bug continued to be found.
- It is estimated the outbreak in Manchester cost £8.4 million.

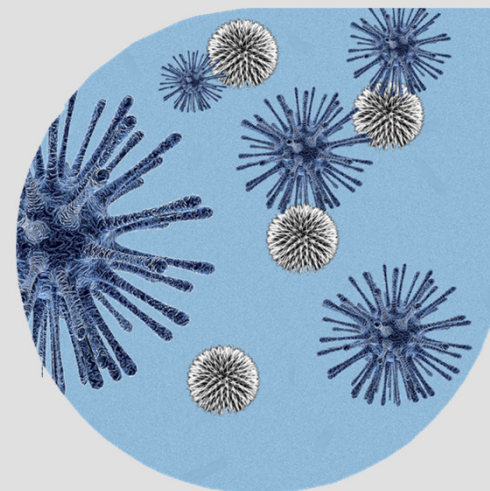
Business case

Tabella 1: Frequenza di resistenze in isolamenti da emocolture in Italia, dati EARS-net 2015 e trend 2006-2015

	Italia 2015 (%) (categoria) [§]	Media europea 2015 (%) (categoria) [§]	Trend 2012-15 [*]
<i>Klebsiella pneumoniae</i>			
resistente a cefalosporine 3 ^a generazione	55,9 (6)	30,3 (5)	>
resistente agli aminoglicosidi	34,0 (5)	22,5 (4)	
resistente ai carbapenemi	33,5 (5)	8,1 (3)	
MDR (R a cefalosporine di 3 ^a generazione + aminoglicosidi + fluorochinoloni)	29,7 (5)	18,6 (4)	
<i>Escherichia coli</i>			
resistente a cefalosporine 3 ^a generazione	30,1 (5)	13,1 (4)	>
resistente a fluorochinoloni	44,4 (5)	22,8 (4)	>
resistente agli aminoglicosidi	20,2 (4)	10,4 (4)	
MDR (R a cefalosporine di 3 ^a generazione + aminoglicosidi + fluorochinoloni)	14,6 (4)	5,3 (3)	
<i>Pseudomonas aeruginosa</i>			
resistente a piperacillina-tazobactam	29,5 (5)	18,1 (4)	
resistente a ceftazidime	21,7 (4)	13,3 (4)	
resistente agli aminoglicosidi	17,2 (4)	13,3 (4)	<
resistente a carbapenemi	23,0 (4)	17,8 (4)	
<i>Acinetobacter spp.</i>			
resistente a carbapenemi	78,3 (7)	Non riportata	
<i>Staphylococcus aureus</i>			
resistente alla meticillina	34,1 (5)	16,8 (4)	
<i>Streptococcus pneumoniae</i>			
NS alla penicillina	12,3 (4)	Non riportata	
NS ai macrolidi	24,5 (4)	Non riportata	<#
<i>Enterococcus faecium</i>			
resistente ai glicopeptidi (VRE)	11,2 (4)	8,3 (3)	>



- **PAT – Provincia Autonoma di Trento**
Piano Nazionale di Contrasto dell'Antimicrobico-Resistenza (PNCAR) - 2017-2020 just released
- Comply and perform better than the both national and regional MDROs infection prevention and control targets
- Comply and perform better than the national antibiotic usage target (5% reduction by 2020 in healthcare settings)



Thank you

- Contact name
- email
- <http://www.antisuperbugs.eu>

