

D4.4 Report on sustainability plan

WP4I Integration into national policies and sustainability
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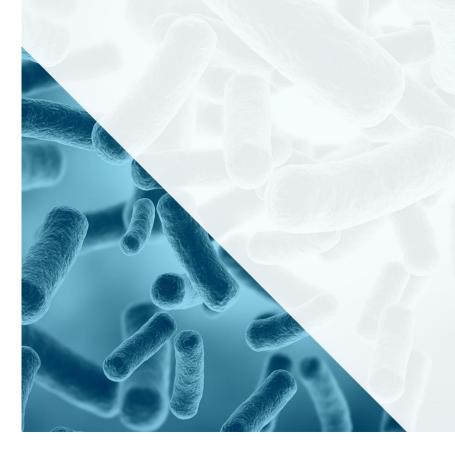




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LIST OF ACRONYMS

AC: Advisory Committee

AMR: Antimicrobial Resistance

AMS: Antimicrobial stewardship

CED: Council of European Dentists

CPME: Standing Committee of

European Doctors

DX.X: Deliverable produced by the WP

EAHP: European Association of Hospital

Pharmacists

ECDC: European Centre for Disease

Prevention and Control

EFSA: European Food Safety Authority

EMA: European Medicines Agency

EPHA: European Public Health Alliance

EPRUMA: European Platform for the Responsible Use of Medicines in

Animals

ESCMID: European Society of Clinical Microbiology and Infectious Diseases

ESNO: European Specialist Nurse

Organisation

EU: European Union

EUSJA: European Union of Science

Journalists' Associations

FAO: Food and Agriculture Organisation

FEMS: Federation of European

Microbiological Societies

FVE: Federation of Veterinarians of

Europe

GARDP: Global Antibiotic Research and

Development Partnership

HCAI: Healthcare-Associated Infections

HOPE: European Hospital and

Healthcare Federation

IMI: Innovative Medicines Initiative

IPC: Infection Prevention and Control

JA: Joint Action

JAMRAI: Joint Action on Antimicrobial Resistance and Healthcare-Associated

Infections

JPI AMR VRI: Joint Programming

Initiative on Antimicrobial Resistance

Virtual Research Institute

MoH-FR: French Ministry of Solidarity

and Health

MS: Members States

MSX.X: Milestone produced by the WP

MedTech EU: European association for the medical technology industry including diagnostics, medical

devices and digital health

NAP: National Action Plan

OECD: Organisation for Economic

Cooperation and Development

One Health EJP: One Health European

Joint Programme

PGEU: Pharmaceutical Group of the

European Union

SH: Stakeholders

UEMO: European Union of General

Practioners

WHO Europe: World Health

Organization Regional Office for

Europe

WP: Work Package

1. CONTEXT AND OBJECTIVES

Context

The overall aim of the European Joint Action (JA) on antimicrobial resistance and healthcare-associated infections (EU-JAMRAI) is to support EU Member States develop and implement effective One Health action plans against antimicrobial resistance (AMR) and healthcare-associated infections (HCAI).

The overarching task of EU-JAMRAI work package (WP) 4 is to foster the integration into national policies of the recommendations issued by the consortium and encourage healthcare workers, policy makers as well as other key actors to expand and maintain their implementation in their respective countries when and where needed. Several actions need to be maintained beyond the 3-year JA duration to ensure sustainability of the results and actions initiated during the JA.

Definition of "sustainability"

"Sustainability" refers to the strategy to consolidate, further develop or run once the EU-JAMRAI ends (in February 2021), the EU-JAMRAI elements/deliverables/results. This deliverable describes by which entity or organisation this might be done. There are two main ways to ensure sustainability: keep alive the network and cooperation between MS and/or continue an action at EU level, when and if necessary.

Method

D4.1 described in details the methodology used for the sustainability strategy of EU-JAMRAI. The first step was to identify the priority topics which should be maintained beyond the JA's term. These subjects were selected after a large consultation of the Executive Board, the Advisory Committee and the EU-JAMRAI's stakeholders. Some topics were explored in depth by the EU-JAMRAI and the objective here was to maintain the momentum. Other topics corresponded more to gaps and unmet needs identified throughout the course of the EU-JAMRAI. For these topics that were not covered in depth by the EU-JAMRAI, the WP4 tried to identify stakeholders that might be willing to lead such a work in the future. In total, 19 stakeholders were approached to discuss this.

To foster sustainability, seven policy briefs in total (Annex 1) were produced by the EU-JAMRAI (in four languages: English, French, German and Spanish) and a final one is under preparation. These policy briefs were disseminated as largely as possible: on social media, by e-mail (they were sent to the European Commission, the European Council, the European Parliament, the Advisory Committee and the EU-JAMRAI's stakeholders) as well as on the EU-JAMRAI website and interested stakeholders' websites (see D4.3). The EU-JAMRAI's key documents including the

first global Antibiotic Resistance Symbol were also largely disseminated. Stakeholders were furthermore asked to host and/or disseminate the EU-JAMRAI's outcomes in order to reach a larger audience (see D4.3).

Summary: Overview of the selected sustainability topics

Six topics have been considered as relevant for the sustainability of the EU-JAMRAI actions.

Topics explored in depth by the EU-JAMRAI:

- Develop a surveillance network of bacterial resistance in diseased animals;
- Boost innovation and ensure availability of existing antibiotics.

Gaps and unmet needs identified throughout the course of the EU-JAMRAI:

- Networking and mentorship/observership to ensure sustainability of the AMS and IPC actions;
- Core elements of AMS and IPC programmes to ensure sustainability of the AMS and IPC actions;
- Core competencies on AMS and IPC for health professionals to ensure sustainability of the AMS and IPC actions;
- Indicators and targets to monitor progress on the AMR European action plan and MS NAPs.

2. SPECIFIC MEASURES FOR PREVENTION AND CONTROL OF AMR AND HCAI TO BE SUSTAINED BEYOND THE JAMRAI

2.1 Topic 1: Develop surveillance of AMR in diseased animals

One Health scope: Animal health

Description and objective

WP7 worked on the development of an integrated and sustainable surveillance network of antimicrobial resistance in bacteria from diseased animals at a European level, called the European Antimicrobial Resistance Surveillance network in Veterinary medicine (EARS-Vet). To build on the momentum and the work done by the EU-JAMRAI, it is necessary to maintain and expand this work. For the future development of EARS-Vet, the objective would be: i) to further expand the network, by supporting additional MS to develop or improve their national surveillance system of AMR in diseased animals, ii) to launch a pilot phase where participating countries can start to share data and iii) to work towards harmonization and comparability of the data across Europe.

Main EU-JAMRAI outputs identifying this unmet need

Task 7.4.2 "AMR surveillance in diseased animals" contributed to fill the gaps by developing a preliminary network on AMR surveillance in diseased animals in Europe (EARS-Vet) and defining the scope (animal species - bacteria - antimicrobial combinations of interest), objectives and standards (antimicrobial susceptibility techniques and interpretation criteria) to be retained in EARS-Vet. This was done following a bottom-up approach, i.e. building on existing surveillance systems and taking into consideration the MS interests, specificities and diversity (e.g. in animal species or occurrence of diseases).

D7.5 Surveillance of antimicrobial resistance in bacteria from diseased animals: this deliverable presents the key results of Task 7.4.2, namely a review and evaluation of surveillance systems in place in MS, the identification of the main gaps and the formulation of appropriate strategies for future development of EARS-Vet, including the definition of the EARS-Vet scope, objectives and standards.

Task 7.4.2 results were further disseminated in four open-access peer-reviewed publications. <u>Publication 1</u> entitled 'Time to build the European Antimicrobial Resistance Surveillance network in Veterinary medicine (EARS-Vet)' described the

vision and objectives of the EARS-Vet network. Publication 2 (under review) entitled 'OASIS evaluation of the French surveillance network for antimicrobial resistance in diseased animals (RESAPATH): success factors at the basis of a well-performing volunteer system' presented the results of an in-depth evaluation of the French system for AMR surveillance in bacterial pathogens (called Resapath). Publication 3 (in preparation) entitled 'Review, description and analysis of national surveillance systems of AMR in bacterial pathogens of animals in Europe: a basis for the design of the European Antimicrobial Resistance Surveillance network in Veterinary medicine (EARS-Vet)', provided a detailed description and assessment of existing systems in Europe. Based on the results of publication 3, the publication 4 (in preparation) entitled 'Defining the scope of the European Antimicrobial Resistance Surveillance network in Veterinary medicine (EARS-Vet): a bottom-up and One Health approach' defined the scope of the EARS-Vet network.

2019 Council Conclusions

This topic is included into the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance - $n^{\circ}36$, 42. The Council of the EU highlights the need to strengthen and widen the scope of surveillance of AMR and HCAI rates, as well as the consumption of antimicrobials, both in the human and the animal health sectors.

EU-JAMRAI action to promote this topic

A policy brief "European Antimicrobial Resistance Surveillance network in Veterinary medicine (EARS-Vet)" (Annex I-5) was sent to the European Commission, to the European Council and to the European Parliament. It has also been disseminated among SH and the AC as well as posted on the EU-JAMRAI website (in four languages: English, French, German and Spanish). The EU-JAMRAI urged policy-makers to develop surveillance of AMR in diseased animals, and to leverage existing national systems at a European level.

Specific stakeholders were also targeted and asked to disseminate the documents in their networks: EFSA, FVE, EPRUMA, EMA, ECDC, EJP One Health, FAO and FAO Europe, JPIAMR, ESCMID/VetCAST, MS representatives, WHO-Europe.

In order to further progress with the development of EARS-Vet, an application for funding by the European Cooperation in Science and Technology COST Action was submitted in November 2020. The results of the call are expected in May 2021.

2.2 Topic 2: Boost innovation and ensure availability of existing antibiotics

One Health scope: Human health / Animal health

Description and objective

WP9 has done in-depth interviews with 13 countries pointing out a clear need for specific and detailed incentives. To build on the momentum and the work done by the EU-JAMRAI, it is necessary to maintain and expand this work. The objective would be to further work on boosting innovation and ensuring availability of existing antibiotics by facilitating regular collaboration and sharing of best practices between MS, ideally within a dedicated working group at EU level.

Main EU-JAMRAI outputs identifying this unmet need

WP9 output includes a publication of research priorities identified as gaps from existing European research agendas as compared to priorities of JAMRAI's members (D 9.1). A concrete strategy for implementing multi-country incentives in a European context to stimulate antimicrobial and diagnostic innovation and access was produced. This strategy is aligned with ongoing non-European efforts to implement incentives (D9.2).

MS4.1 "Survey of MS and SH's priorities" showed that boosting research and innovation in human health and animal health is a priority for MS.

2019 Council Conclusions

The 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance - $\frac{n^{\circ}44}{4}$. The conclusions call upon Member States to boost research and innovation in coordination and cooperation with the European Member States through the Joint Programming Initiative on Antimicrobial Resistance and the Global AMR R&D Hub.

EU-JAMRAI action to promote this topic

A policy brief "Incentivizing antibiotic access and innovation" (Annex I-7) was sent to the European Commission, the European Council and the European Parliament. It has also been disseminated among SH and the AC and posted on the EU-JAMRAI website (in four languages: English, French, German and Spanish). The EU-JAMRAI highlights the need for specific, detailed incentives that national policymakers can assess, tailor and implement. These incentives must be designed with the aim of ensuring national access to important antibiotics that meet public health needs.

Suggested methodology

Dedicated MS technical (sub-)group at EU level, for example within existing groups/committees, sharing experiences and collaborating on a voluntary basis, in liaison with DG RTD and relevant MS committees. Regular updates should be shared with a high-level EU committee.

2.3 Topic 3: Networking and mentorship / observership

2.3.1. Sharing best practices, experiences and tools / Networking

One Health scope: Human health / Animal health

Description and objective

To ensure the sustainability of the AMR and HCAI actions, the sharing of best practices between MS should be facilitated. A network of supervisory bodies might also facilitate the sharing of best practices and experiences between MS on this specific topic.

Main EU-JAMRAI outputs identifying this unmet need

MS4.1 "Survey of MS and SH's priorities" identifies networking, sharing experiences and feedback as a priority.

D5.3 "Strengthening supervision" provides information on a voluntary network of national supervisory bodies in Europe and the way to promote the cooperation of the different actors of this network.

2019 Council Conclusions

This topic is included into the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance $n^{\circ}35$, 56, 57. These conclusions are calling for a strong cooperation, through the One health Network, to tackle AMR by implementing bilateral and multilateral sharing of best practices in order to provide support to member states in the establishment of the NAPs and the national strategies on AMS and IPC.

EU-JAMRAI action to promote this topic

A policy brief on "The need for a reinforced AMR One Health Network" was sent to the European Commission, the European Council and the European Parliament. It has also been disseminated among SH and the AC and posted on the EU-JAMRAI website. The EU-JAMRAI urges to foster networking and the sharing of best practices through already existing bodies such as the AMR One Health Network.

2.3.2. Mentorship and observership programmes for AMS in all settings for human health and animal health professionals

One Health scope: Human health / Animal health

Definitions

Mentorship: an AMS team member needing advice can be supervised by an AMS expert for a certain period of time.

Observership: an AMS team member needing practical training can visit onsite another more expert facility during a certain period of time.

Cross-training (AMS/IPC) is possible according to national context.

Main EU-JAMRAI outputs identifying this unmet need

MS4.1 "Survey of MS and SH's priorities" identifies networking, sharing experiences and feedback as a priority.

D7.3 "Qualitative evaluation of the level of implementation and acceptance of antibiotic stewardship at different levels of healthcare and in animals, in different country settings" with a qualitative research of antimicrobial stewardship implementation in human health and the perception of antimicrobial stewardship in animal health.

2019 Council Conclusions

This topic is included into the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance (14 June 2019) n°36,37. These conclusions call for the development of common guidelines on IPC and AMS based on best practices for health professionals and their education as well as supporting a full implementation of available guidelines taking into account the specific national circumstances.

EU-JAMRAI action to promote this topic

EU-JAMRAI first did an inventory of existing mentorship/observership programmes on AMS, by contacting 11 stakeholders.

We found that some mentorship and observership programmes are already implemented in human health. However, these are not specifically focussed on IPC and AMS:

The ESCMID (European Society of Clinical Microbiology and Infectious Diseases)
has developed mentorship and observership programmes. Concerning the
latter, they have put in place Collaborative centres that members can visit for
five days to one month in order to observe expert teams. These centres are
highly experienced in a specific field. They are therefore able to offer

guidance and experience to observers. Observers use this opportunity to improve their knowledge and bring back new competencies to their facilities. Moreover, through the network of ESCMID Mentorship Centres across Europe, mentees can be supported and helped for one to two years by a mentor, who is an expert on specific topics. Therefore, the mentees can benefit from the mentor's competencies and experience.

The European Association of Hospital Pharmacists (EAHP) has also been coordinating a mentorship programme since 2018. As part of the <u>Statement Implementation Learning Collaborative Centers (SILCC)</u> initiative, hospital pharmacists have the possibility to visit 11 SILCC approved hospitals across Europe, where they can receive training in pharmacy procedures in accordance with the European Statements of Hospital Pharmacy.

WP4 then provided to interested stakeholders a one-page document (Annex II-1) presenting the existing programmes and identifying the objectives of such programmes. The objective here was to advocate for the implementation of mentorship/observership programmes by interested stakeholders.

After our discussions with stakeholders, CED, CPME and ESNO (human health) might consider implementing mentorship and observership programmes on AMS. Regarding animal health, FVE declared they might advocate and discuss the idea.

2.3.3. Mentorship and observership programmes for IPC professionals in all settings

One Health scope: Human health

Description and objective

Mentorship: an IPC team member needing advice can be supervised by an IPC expert for a certain period of time.

Observership: an IPC team member needing practical training can visit onsite another more expert facility during a certain period of time.

Cross-training (AMS/IPC) is possible according to national context.

Main EU-JAMRAI outputs identifying this unmet need

MS4.1 "Survey of MS and SH's priorities" identifies networking, sharing experiences and feedback as a priority.

2019 Council Conclusions

The 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance $n^{\circ}36$, 37. These conclusions call for the development of common guidelines on IPC and AMS based on best practices for health professionals and their education and support a full implementation of available guidelines taking into account the specific national circumstances.

EU-JAMRAI action to promote this topic

EU-JAMRAI first did an inventory of existing mentorship/observership programmes on IPC, by contacting 11 stakeholders.

WP4 then provided to interested stakeholders a one-page document (Annex II-1) presenting the existing programmes and identifying the objectives of such programmes. The objective here was to advocate for the implementation of mentorship/observership programmes by interested stakeholders.

After our discussions with stakeholders, CED, CPME and ESNO (human health) might consider implementing mentorship and observership programmes on IPC.

2.4 Topic 4: Core elements of AMS and IPC programmes

2.4.1. Core elements of AMS programmes in human health and animal health at national and facility levels for European countries

One Health scope: Human health / Animal health

Description and objective

Core elements of AMS programmes for European countries were identified as an unmet need. The EU-JAMRAI thus wanted to promote the idea of developing, using already published resources (WHO, EU-JAMRAI, literature...) and a structured consensus procedure, such core elements for European countries (including staffing standards). The objective would be to have core elements of AMS programmes ready to be implemented in every MS at national and facility levels (human health: hospitals, community, nursing homes; animal health: veterinarians' hospitals or practices, farms).

Example of such core elements developed for hospitals worldwide: https://www.ncbi.nlm.nih.gov/pubmed/29625170

Example of indicators developed for EU hospitals:

https://www.cdc.gov/drugresistance/pdf/TATFAR_REC1-FinalReport_2015.pdf

Main EU-JAMRAI outputs identifying this unmet need

MS4.1 "Survey of MS and SH's priorities" showed that MS and SH consider that having standards at European level is a priority for antimicrobial stewardship. Therefore, identifying core elements for European countries is necessary.

D7.2 "Report on workshop of implementation models of antibiotic stewardship tools". This report highlights the success factors, the barriers of the implementation and general recommendations on AMS.

D7.3 "Qualitative evaluation of the level of implementation and acceptance of antibiotic stewardship at different levels of healthcare and in animals, in different country settings" with a qualitative research of antimicrobial stewardship implementation in human health and the perception of antimicrobial stewardship in animal health.

2019 Council Conclusions

This topic is included into the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance (June 2019) - $\frac{n^{\circ}36}{37}$. These conclusions call for the development of common guidelines on IPC and AMS based on best practices for health professionals and their education and support a full implementation of available guidelines taking into account the national circumstances.

EU-JAMRAI action to promote this topic

A policy brief "The need to develop core elements at the European level on antimicrobial stewardship (AMS) and infection prevention and control (IPC)" (Annex I-2) was sent to the European Commission, the European Council and the European Parliament. It has also been disseminated among SH and the AC and posted on the EU-JAMRAI website (in four languages: English, French, German and Spanish). The EU-JAMRAI urges the European Commission to mandate the relevant EU Agencies, with the support of European professional societies, to develop core elements on AMS.

Here are some suggestions on the potential lead stakeholders and partners, based on our discussions with the stakeholders:

Human health:

- Lead stakeholder: ECDC (alternative: ESCMID)
- Potential partners: WHO-Europe, EPHA, CPME, UEMO, HOPE, CED, ESNO, EAHP, PGEU, FEMS

Animal health:

- Lead stakeholder: EFSA (alternative: a partnership between ESCMID/ESGVM and FVE)
- Potential partners: EPRUMA, FAO, OIE

Suggested methodology

Review followed by a consensus procedure, involving all MS. These core elements might be accompanied by a set of structure/process/outcome indicators (with targets), that could be used both at national and European level.

2.4.2. Core elements of IPC programmes at national and facility levels

One Health scope: Human health

Description and objective

Core elements of IPC programmes for European countries were identified as an unmet need. WP6 has done some exploratory work on this topic by defining a Universal Infection control framework. To build and expand on this, the EU-JAMRAI wanted to further promote the idea of developing, using already published resources (WHO, EU-JAMRAI, literature...) and a structured consensus procedure, such core elements for European countries (including staffing standards). The objective would be to have core elements of IPC programmes ready to be implemented in every MS at national and facility levels (human health: hospitals, community, nursing homes).

Example of such core elements developed for hospitals worldwide: https://www.cdc.gov/drugresistance/pdf/TATFAR_REC1-FinalReport_2015.pdf

Main EU-JAMRAI outputs identifying this unmet need

MS4.1 "Survey of MS and SH's priorities" showed that HCAI are a priority at all levels of the health system; therefore identifying core elements for European countries is necessary.

D6.1 "Revised guidelines for the implementation of infection control program in healthcare settings". The deliverable develops key components for the implementation of IPC programmes.

D6.2 "A Universal Infection Control Framework with specific roles priorities, resources and interventions for the implementation of an infection control plan in healthcare settings".

2019 Council Conclusions

This topic is included into the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance $\underline{n}^{\circ}36,37$. These conclusions call for the development of common guidelines on IPC and AMS based on best practices for health professionals and their education and support a full implementation of available guidelines taking into account the specific national circumstances.

EU-JAMRAI action to promote this topic

A policy brief "The need to develop core elements at the European level on antimicrobial stewardship (AMS) and infection prevention and control (IPC)" (Annex I-2) was sent to the European Commission, the European Council and the European

Parliament. It has also been disseminated among SH and the AC and posted on the EU-JAMRAI <u>website</u> (in four languages: English, French, German and Spanish). The EU-JAMRAI urges the European Commission to mandate the relevant EU Agencies with the support of European professional societies to develop core elements on IPC.

Here are some suggestions on the potential lead stakeholder and partners, based on our discussions with the stakeholders:

- Lead stakeholder: ECDC (alternative: ESCMID)
- Partners: WHO-Europe, EPHA, CPME, UEMO, HOPE, CED, ESNO, EAHP, PGEU, FEMS

Suggested methodology

Review followed by a consensus procedure, involving all MS. These core elements might be accompanied by a set of structure/process/outcome indicators (with targets), that could be used both at national and European level.

2.5 Topic 5: Core competencies on AMS and IPC for health professionals

2.5.1. Core competencies on AMS for AMS teams, the undergraduate and postgraduate training of non-prescribers and hospital administrators for human health and the undergraduate and postgraduate training of veterinarians and farmers for animal health

One Health scope: Human health / Animal health

Description and objective

Core competencies on AMS for European countries were identified as an unmet need. The EU-JAMRAI thus wanted to promote the idea of developing, using already published resources (WHO, JAMRAI, literature...), core competencies on AMS to include in the training of healthcare professionals in human health (AMS teams, non-prescribers and hospital administrators) and professionals in animal health (farmers and veterinarians), with a EU perspective.

Example of such core competencies: https://doi.org/10.1016/j.cmi.2018.09.022

Main EU-JAMRAI outputs identifying this unmet need

MS4.1 "Survey of MS and SH's priorities" identified the integration of AMR in the initial and continuous training program of healthcare professionals and veterinarians as a priority for MS.

D7.2 "Report on workshop of models for implementation of stewardship tools". This report highlights the success factors, the barriers of the implementations and general recommendations on AMS.

D7.3 Qualitative evaluation of the level of implementation and acceptance of antibiotic stewardship at different levels of healthcare and in animals, in different country settings": qualitative research of antimicrobial stewardship implementation in human health and the perception of antimicrobial stewardship in animal health.

2019 Council Conclusions

This topic is included into the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance - n^31 , 36, 37. These conclusions call for the development of common guidelines on AMS based on best practices for health professionals and their education and support a full implementation of available guidelines taking into account the national circumstances. The training of the health workforce should include the EU guidelines on AMS.

EU-JAMRAI action to promote this topic

The WP4 discussed the idea with several stakeholders, to explore if they would be interested in leading such a work in the future. We provided a one-page document presenting the core competencies' gaps, their objectives and a suggested methodology to interested stakeholders (Annex II-2).

Here are the stakeholders who expressed some interest and might be willing to consider leading such a work in the future:

Human health:

• ESCMID for AMS teams, EAHP for pharmacists, ESNO for nurses, HOPE for hospital administrators

Animal health:

FVE and EPRUMA

The WP4 incentivized the stakeholders to collaborate on the development of the core competencies.

Suggested methodology

Inspired by existing core competencies, using JAMRAI outputs and a literature review, followed by a structured consensus procedure involving all EU MS, these core competencies (relevant at EU level) could be identified by interested stakeholders in collaboration with partners.

2.5.2: Core competencies on IPC for the undergraduate and postgraduate training of healthcare professionals and hospital administrators

One Health scope: Human health

Description and objective

Core competencies on IPC for European countries were identified as an unmet need. The EU-JAMRAI thus wanted to promote the idea of developing, using already published resources (WHO, JAMRAI, literature...), core competencies on IPC to include in the training of healthcare professionals and hospital administrators with an EU perspective.

Example of such core competencies for IPC teams https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/infection-control-core-competencies.pdf

Main EU-JAMRAI outputs identifying this unmet need

- MS4.1 "Survey of MS and SH's priorities" identified the integration of IPC in the initial and continuous training program of healthcare professionals.
- D6.1 "Revised guidelines for the implementation of infection control programmes in healthcare settings". The deliverable develops key components for the implementation of IPC programmes.
- MS3.3 "Initial presentation of the training tools" provides six different training tools and the correct way to implement them within the target groups (such as clinical supervisors, hospital administrators, infection control committee, training staff).

2019 Council Conclusions

This topic is included into the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance - n^31 , 36, 37. These conclusions call for the development of common guidelines on IPC based on best practices for health professionals and their education and support a full implementation of available guidelines taking into account the specific national circumstances. The training of the health workforce should include the EU guidelines on IPC.

EU-JAMRAI action to promote this topic

WP4 discussed the idea with several stakeholders, to explore if they would be interested in leading such a work in the future. We provided a one-page document presenting the core competencies' gaps, their objectives and a suggested methodology to interested stakeholders (Annex II-2).

Here are the stakeholders who expressed some interest and might be willing to consider leading such a work in the future:

EAHP (for pharmacists), ESCMID (for healthcare professionals), ESNO (for nurses), HOPE (for hospital administrators).

The WP4 incentivized the stakeholders to collaborate on the development of the core competencies.

Suggested methodology

Inspired by existing core competencies, using JAMRAI outputs and a literature review, followed by a structured consensus procedure involving all EU MS, these core competencies (relevant at the EU level) could be identified by interested stakeholders in collaboration with partners.

2.6 Topic 6: Indicators and targets to monitor progress of the AMR European Action Plan and MS NAPs

One Health scope: Human health / Animal health

Description and objective

Indicators and targets to monitor progress of the AMR European Action Plan and MS NAPs were identified as an unmet need. WP7 has done some exploratory work on this topic by defining indicators used for monitoring antibiotic use and resistance in humans and animals. To build and expand on this, the EU-JAMRAI wanted to further promote the idea of developing, using a review of already published resources (WHO/OIE/FAO, European agencies, JAMRAI, literature...), followed by a structured consensus procedure involving all EU MS, a set of indicators and targets (e.g. quality indicators, proxy indicators, quantity metrics / AMS, IPC, antibiotic use and resistance) that could be used both at national and EU level to monitor progress of the AMR European action plan/national action plans.

Main EU-JAMRAI outputs identifying this unmet need

MS4.1 "Survey of MS and SH's priorities" showed that for MS and SH, indicators are the key to secure concrete outcomes.

D7.3 "Qualitative evaluation of the level of implementation and acceptance of antibiotic stewardship at different levels of healthcare and in animals, in different country settings": qualitative research of antimicrobial stewardship implementation in human health and the perception of antimicrobial stewardship in animal health.

D7.4 Surveillance of antimicrobial use and resistance in human health, results of a pilot study, with two sub-tasks:

- Task 7.4.1 "Surveillance in human medicine consumption and AMR" that aims to develop a simple surveillance system of antibiotic use and resistance including almost real-time feedback mechanisms.
- Task 7.4.2 "AMR surveillance in diseased animals" fills the gaps by focusing on AMR surveillance in diseased animals in the EU and identifying appropriate strategies depending on MS specificities towards their diversity in animal species and diseases.

2019 Council Conclusions

This topic is included into the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance) - $n^{\circ}33$, 42. The conclusions stress that One health surveillance programmes should be developed with a stronger and wider scope of surveillance of AMR and HCAI rates and consumption of antimicrobials. For this, establishing national measurable targets is needed, taking into account indicators developed by EFSA, EMA and ECDC, in order to monitor progress of reducing the spread of AMR.

EU-JAMRAI action to promote this topic

A policy brief "The need to develop indicators and targets for AMR action plans in the EU" (Annex I-3) was sent to the European Commission, the European Council and the European Parliament. It has also been disseminated among SH and the AC and posted on the EU-JAMRAI website (in four languages: English, French, German and Spanish). The EU-JAMRAI urges the European Commission to mandate the relevant EU Agencies with the support of European professional societies to develop indicators and targets to monitor progress of the AMR European Action Plan and MS NAPs.

Here are the suggested lead stakeholders for this work:

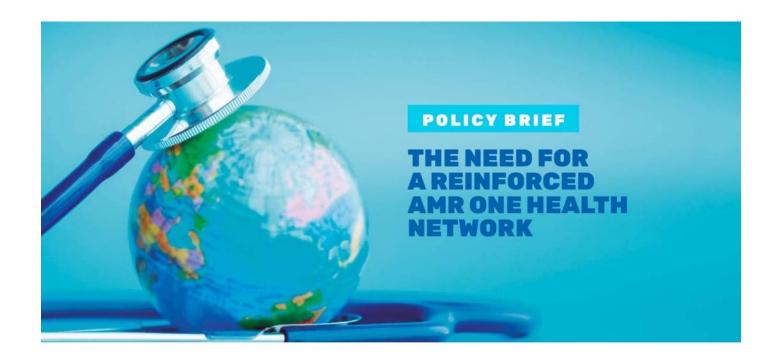
Human health: ECDC, EMAAnimal health: EFSA, EMA

Suggested methodology

Review and consensus procedure involving all MS conducted by key stakeholders to identify indicators and targets to monitor progress on the AMR European Action Plan and MS National Action Plans.

These indicators should be presented and discussed at the AMR One Health Network meetings and their adoption should be also discussed.





Antimicrobial resistance (AMR), known as the ability of microorganisms to resist antimicrobials, is a global and major issue that threatens human and animal health as well as the environment. These three sectors are all interrelated, as microorganisms can spread in all sectors. The issue of AMR thus requires a holistic and trans-sectoral approach, known as the One Health approach.



Following the 2016 and 2019 Council Conclusions on AMR, the EU-JAMRAI calls for an extension and strengthening of the mandate of the AMR One Health Network (OHN), to wholly address all components of the One Health trans-sectoral and integrated approach required to obtain a full impact of the EU action plan against AMR.



THE GLOBAL THREAT OF AMR

At the international level, AMR is recognized by the World Health Organization (WHO) as being one of the major global threats and is listed as a top priority for action on the global health agenda. The figures published by the WHO and the OECD are alarming:

33.000 patients die annually in the European Union as a result of infections caused by multi-resistant bacteria'. Antibiotic use and infection prevention and control practices vary a lot between countries. By 2050, Southern Europe will be the most strongly impacted by AMR: Italy, Greece and Portugal are forecasted to be the countries with the highest mortality rates if from AMR by the OECD

Concerning the animal sector, in the EU / EEA, about two thirds of total antimicrobial use is for food producing animals. Globally, if no effective action is put in place, antimicrobial use in food-producing animals will rise by 67% between 2010 and 2030.



THE EU AMR ONE HEALTH NETWORK

In 2016, the Council Conclusions on the next steps under a One Health approach to combat AMR* recognised the importance of cooperation between Member States and called on the European Commission to create an EU AMR One Health Network (OHN).

The main purpose of the OHN created in 2017 was to facilitate and enhance regular discussions between Member States on AMR policy options, exchange information and sharing of best practices and keep each other updated on the progress made on the implementation of NAP and the implementation of the EU Action Plan.

It is composed of government experts from the human health and animal health sectors, as well as EU agencies representatives (ECDC, EMA, and EFSA).

The 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance underlined the importance of the regular meetings of the 0HN. They called for a reinforced cooperation, through the 0HN, to address AMR by implementing bilateral and multilateral sharing of best practices in order to provide support to Member States in the establishment of the National action plans (NAPs) and the national strategies on Antimicrobial stewardship (AMS) and Infection prevention and control (IPC).





A PRESSING NEED TO EXTEND A

Using regular meetings such as the OHN and sectorial discussions at the EU level has also been identified by the EU-JAMRAI stakeholders and Member States as a priority and the most important element to sustain the fruitful cooperation in the fight against AMR. Indeed, during the three-year duration of the project, one of the main objectives of the EU-JAMRAI has been to strengthen a network of all the actors involved in the fight against AMR (general objective 2). Particularly, the Work Package 5 worked on sharing of best practices between MS, for example using country-to-country visits. The WP5 has also set up a network of supervisory bodies responsible for controlling activities related to AMR (e.g. control of the level of implementation of national policies, the level of compliance with legislation or adherence to guidelines or recommendations).



The EU-JAMRAI underlined how essential networking is to continue improving and sustaining this EU-wide collaboration between MS. Strengthening the role of the OHN would build further on the work done during the Joint Action

Acknowledging the importance of communication and coordination between European Member States to tackle the urgent issue of AMR, the EU-JAMRAI calls for the extension and the strengthening of the mandate of the EU AMR One Health Network by:

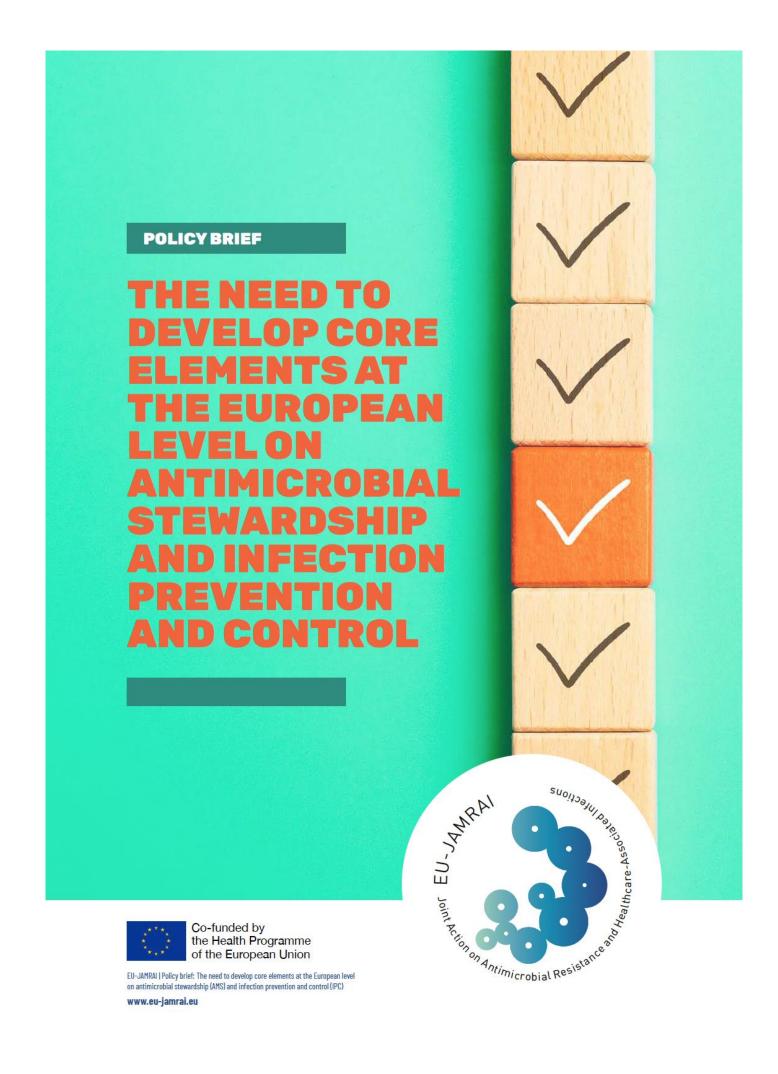
- Focussing also on the environmental sector: including inviting environmental sector representatives to join the AMR One Health Network. The work achieved within the EU-JAMRAI, and lately the impact of the COVID-19 pandemic, have highlighted the need to consider the AMR issue within a large One Health perspective.
- Preparing the agenda of the meetings with the EU Presidency in order to reflect Member States' priorities and issues to be discussed.
- Developing dedicated IT tools (or extend functionalities of existing ones) that will allow participants to share information during and between the meetings, to drive improvement of national activities. A password-protected web-based dynamic platform accessible to all MS representatives could be put in place, with interactive functionalities such as: repository of tools and documents, allowing sharing of success stories regarding AMR/HCAl-related interventions, contact list, forum of discussion. This platform would allow discussing common problems, sharing experiences information and best practices. This would allow more interactions between the MS representatives, ultimately leading to greater engagement and collaboration during the bi-annual meetings.
- Extending the duration of the bi-annual meetings of the OHN to two full days, so as to foster networking, give MS the possibility to contribute to the agenda, and allow more in-depth discussions around complex issues related to AMR at the European level.

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POLICY BRIEF

THE NEED TO DEVELOP CORE ELEMENTS AT THE EUROPEAN LEVEL ON ANTIMICROBIAL STEWARDSHIP AND INFECTION PREVENTION AND CONTROL

AN UNMET NEED



Antimicrobial resistance (AMR), known as the ability of microorganisms to resist the action of antimicrobials, is a global and major issue that threatens human and animal health as well as the environment, which are all interrelated, as microorganisms can spread in all sectors. The issue of AMR requires a holistic and multi-sectoral approach, known as the One Health approach.

Excessive and inappropriate use of antimicrobial drugs as well as poor infection prevention and control (IPC) practices are the two main drivers of AMR. If AMR continues to increase, we would revert to a world where infectious diseases are no longer treatable, leading to prolonged illnesses, disabilities, mortality, and at the same time increasing the cost of healthcare.

International organisations act for the prevention of antimicrobial resistance: OIE, WHO and FAO, in relation with UNEP, are

engaged in a Tripartite plus alliance to coordinate the strategies to combat AMR. WHO published the Global Action Plan to combat AMR in 2015 while the European Union adopted an updated European One Health action plan against AMR in 2017. According to the European Commission guidelines², the control of AMR can only be achieved by combining strong IPC measures (including those targeting healthcare associated infections), and programmes promoting prudent use of antimicrobials known as antimicrobial stewardship (AMS) programmes. From an economic perspective, the OECD demonstrated that the implementation of AMS and IPC programmes is cost-saving³.

However, despite these plans and guidelines, EU member states do not reach the same level of achievements concerning health policies on AMS and IPC. This represents a barrier to the effective implementation of AMS and IPC programmes at the European level.

To overcome this obstacle, the EU-JAMRAI strongly invites the Member States and the European Commission to mandate the relevant EU Agencies with the support of European medical societies to develop core elements on AMS and IPC. They should be implementable at national and facility levels, both in human and animal health, that are relevant to the EU, in order to create the minimum framework to be used by all EU Member States.





THE GLOBAL THREAT OF AMR

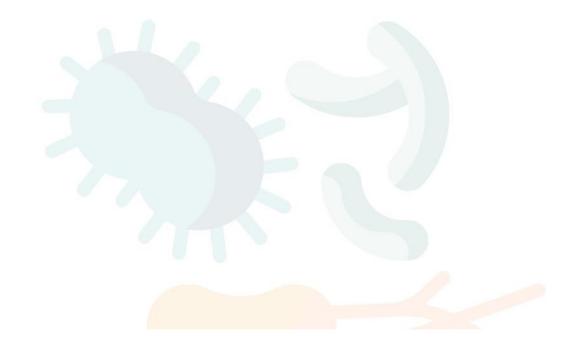
At the international level, AMR is recognized by the WHO as being one of the major global threats and is listed as a top priority for action on the global health agenda. Indeed, the figures published by the ECDC and the OECD³ are alarming:

- 33.000 patients die annually in the EU/EEA as a direct consequence of infections caused by multidrug-resistant bacteria⁴.
- Antibiotic use and infection prevention and control practices vary a lot between countries. By 2050, Southern Europe will be the most strongly impacted by AMR: Italy, Greece and Portugal are forecasted to be the countries with the highest mortality rates⁴ from AMR.

Concerning the animal sector, in the EU / EEA, about two thirds of total antimicrobial use is for food producing animals. Globally, if no effective action is put in place, antimicrobial use in food-producing animals will rise by 67% between 2010 and 2030°. Across the EU, between 2011 and 2016, it has been estimated that sales of veterinary antimicrobials were reduced by 20 %°, but use still remains too high.

AMR also has a significant impact on the cost of healthcare in EU/EEA countries. In 2019, the OECD and the ECDC estimated that, due to extra healthcare costs induced by AMR, 1.1 billion euros are expected to be spent yearly across EU/EEA countries between 2015 and 20507.

If no effective public health action is put in place in the coming years, AMR rates and its impact will grow further.





WHAT CAN BE

As the European One Health Action Plan against AMR1 is urging to make the EU a best practice region and to shape the global agenda, establishing harmonized core elements guiding AMS and IPC programmes in the EU is necessary.

Without a common framework, effective AMS and IPC programmes that have the ability to reduce the burden of AMR at the European, national and facility level cannot be implemented properly.

The 2019 Conclusions of the EU Council urged for the development of common guidelines on IPC and AMS based on best practices and for supporting their implementation.

The European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) found that the Member States and stakeholders interviewed consider that having standards at the European level was a priority for effective implementation of AMS and IPC programmes.

Some core elements have already been developed at international level, but several gaps need to be addressed in order to have such core elements fully implemented in the EU (see Table below).

Furthermore, in animal and environmental health, we are not aware of existing core elements at international level.

Infection Prevention and Control (IPC)

Human health

Existing core elements at national and facility (hospital) level

Antimicrobial Stewardship (AMS)

Human health

- The 2016 WHO guidelines¹⁰ The 2019 WHO Minimum Requirements11
- The 2019 WHO Antimicrobial stewardship toolkit12

- **Gaps to** address
- Adapted to the EU?
 - Develop core competencies at national and facility level for animal health?

Existing core elements at facility (hospital) level only

- A 2015 literature review and expert consensus with a European perspective¹³
- The 2015 TATFAR common structure and process indicators14

- Gaps to address
- Need to be updated?
- Focus only on hospitals, need to be developed for nursing homes and primary care





WHAT CAN BE DONE?

The EU-JAMRAI therefore urges the European Commission, together with EU Member States but also key stakeholders such as professional organisations, to address these gaps. These core elements on AMS and IPC programmes, both at national and facility/setting level (e.g. hospital/nursing homes/primary care), for human and animal health, could be developed on the basis of the examples described above. A solid methodology is advisable, for example:

Review of the existing published and grey literature and existing quidance / recommendations;

- Followed by a structured consensus procedure involving all EU Member States representatives.
- These core elements must be complemented by a standard structure/process/outcome evaluation framework, with relevant indicators, that could be used both at national and European level if accompanied with quantified achievable targets. This can follow the same process as the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR) work¹⁵.



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AN UNMET NEED



Antimicrobial resistance (AMR), known as the ability of microorganisms to resist the action of antimicrobials, is a global and major issue that threatens human and animal health as well as the environment, which are all interrelated, as microorganisms can spread in all sectors. The issue of AMR requires a holistic and multi-sectoral approach, known as the One Health approach.

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International organisations act for the prevention of antimicrobial resistance: OIE, WHO and FAO, in relation with UNEP, are engaged in a Tripartite plus alliance to coordinate the strategies to combat AMR. WHO published the Global Action Plan to combat AMR in 2015 while the European Union adopted an updated European One Health action plan against AMR in 2017. According to the European Commission guidelines², the control of AMR can only be achieved by combining strong IPC (including those targeting healthcare-associated infections), and programmes promoting prudent use of antimicrobials known as antimicrobial stewardship (AMS) programmes. From an economic perspective, the OECD demonstrated that the implementation of AMS and IPC programmes is cost-saving³.

However, despite these plans and guidelines, EU Member States do not reach the same level of achievements concerning their AMR national action plans. There is a need to support Member States and to monitor the European One Health action plan with indicators and targets.

The EU-JAMRAI is urging the European Commission to establish indicators and targets to monitor the progress of the EU Action Plans, with a One Health perspective. The establishment of these indicators and targets should be mandated to European health Agencies (i.e. ECDC, EMA and EFSA) with the support of European medical societies.





THE GLOBAL THREAT OF AMR

At the international level, AMR is recognized by the WHO as being one of the major global threats and is listed as a top priority for action on the global health agenda. The numbers published by the ECDC and the OECD³ are alarming:

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- Antibiotic use and infection prevention and control practices vary a lot between countries. By 2050, Southern Europe will be the most strongly impacted by AMR: Italy, Greece and Portugal are forecasted to be the countries with the highest mortality rates from AMR by the OECD.

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AMR also has a significant impact on the cost of healthcare in EU/EEA countries. In 2019, the OECD and ECDC estimated that, due to extra healthcare costs induced by AMR, 1.1 billion euros are expected to be spent yearly across EU/EEA countries between 2015 and 2050.

If no effective public health action is put in place in the coming years, AMR rates and its impacts will grow further.





WHAT CAN BE DONE?

As the European One Health Action plan against AMR¹ is urging to make the EU a best practice region and to shape the global agenda, having a set of indicators and targets to monitor progress across Europe is necessary.

The 2019 Council Conclusions on AMR encourage Member States and the Commission to "strengthen and widen the scope of surveillance of AMR and healthcare-associated infections rates and consumption of antimicrobials, both in the human and the animal health sectors", in establishing, for Member States, "national measurable targets (...) and monitor progress towards reducing the spread of AMR, taking into account to the appropriate extent the indicators developed by EFSA, EMA and ECDC". The European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) highlighted that Member States and stakeholders consider indicators for human and animal health as the key to secure concrete outcomes. Moreover, the European guidelines for the prudent use of antimicrobial in human health and the guidelines for the prudent use of antimicrobials in veterinary medicine also recommend developing indicators on AMS.

The European Commission requested that ECDC, EMA and EFSA produce a scientific opinion on outcome indicators for AMR One Health Action that could use existing surveillance data. These agencies published in 2017 a Joint Scientific Opinion with a list of general outcome indicators on AMR in humans and food-producing animals¹². However, the last report of the European Court of Auditors highlighted that these indicators were not used enough by Member States or by the European Commission, to monitor progress⁵.

EU-JAMRAI
highlighted that
Member States and
stakeholders consider
indicators for human
and animal health as the
key to secure concrete
outcomes.

Moreover, no target / objective to reach was defined for each of these indicators, which makes it difficult to assess the room for improvement.

A cross-sectional survey conducted in 2016 by the ESCMID Study Group for Antimicrobial stewardship (ESGAP) found that only 29% of the European participating countries had national indicators on antibiotic use in human health with both clear targets and incentives¹³. A survey conducted in 2019 by the Transatlantic Taskforce on Antimicrobial Resistance (TAFTAR) highlighted that only nine countries out of 30 responding countries had implemented targets for the reduction of antibiotic use in humans and 17 countries were working to establish such targets¹⁴. Some examples of indicators and targets are provided below.

Indicators	Targets
Number of antibiotic prescriptions for 1000 inhabitants per year in primary care	<250
Proportion of children treated with third-generation cephalosporins over the year, out of children receiving antibiotics in primary care	<3%





WHAT CAN BE DONE?

Concerning the animal sector, EMA recommended in 2016 that "over the course of the next three to four years, all Member States should reduce the use of colistin in animals at least to a target level of 5 mg colistin/population correction unit. [...] Member States are also encouraged to set stricter national targets, ideally below 1 mg colistin/PCU as a desirable level".¹⁵

Establishing a set of key structure/process/outcome indicators (e.g. quality indicators, proxy indicators, quantity metrics, on antibiotic use and resistance, AMS and IPC) and targets should be a priority, with a One Health perspective. The EU-JAMRAI therefore urges the European Commission to initiate such a

work, in relation with the relevant EU agencies and EU Member States. These indicators and targets, on the basis of the examples described above, might be developed using the following methodology:

- Review of the existing published and grey literature and existing guidance / recommendations;
- EU agencies (EMA, ECDC, EFSA) to provide advice on possible target values;
- Followed by a structured consensus procedure involving all EU Member States representatives.



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BACK-GROUND



Antimicrobial resistance (AMR) poses a serious challenge; in the European Union (EU) alone it is estimated that AMR costs approximately EUR 1.5 billion annually in healthcare costs and productivity losses. Three of the most important areas with the highest added value for action are promoting the prudent use of antimicrobials, enhancing cross-sectorial work, and surveillance of AMR and antimicrobial consumption.



Antimicrobial stewardship is defined as "a coherent set of actions which promote using antimicrobials responsibly" and is one of the core strategies to combat AMR. European guidelines for the prudent use of antimicrobials in both human and animal health²³, were developed with the purpose of providing practical guidance on the development and implementation of strategies to promote appropriate use of antimicrobials. European countries vary in their focus and level of implementation of antimicrobial stewardship actions.

Better surveillance is part of the key objectives of the European

One Health Action Plan against AMR with the aim of making the EU a best practice region. Surveillance of AMR and antimicrobial consumption (AMC) is paramount in monitoring progress of AMR National Action Plans (NAPs), and specifically of antimicrobial stewardship programmes. A One Health AMR surveillance system is essential to understand the magnitude of the problem, identify trends, determine how AMC and AMR are linked, evaluate policies and set priorities. Although in the EU gaps in surveillance remain and one of these gaps is a Europe-wide surveillance system for AMR in sick animals.

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^{*} Commission Notice — Guidelines for the prudent use of antimicrobials in veterinary medicine 0.J C 299, 11.9.2015, p. 7-2



WHAT EU-JAMRAI ADDS TO THE SITUATION

Antimicrobial stewardship in human medicine

- The EU-JAMRAI identified a lack of efficient and easily accessible tools to facilitate the implementation of antimicrobial stewardship at both country and healthcare level
- Existing guidelines, tools and implementation methods stratified by level-of-care (hospital, long-term care facility (LTCF) and community setting) were identified and reviewed and a repository was made. This repository has been well received and already used, among others, by the ARCH Network⁴.
- Results from a one-day workshop with participants from 22 different European countries, showed that hospitals currently have more actions in place than community settings. Whilst there has been a lot of recent action for family doctors, experience with long-term care facilities (LTCF) is lagging behind. Although there were different success factors and problems specific to individual countries, there was also a lot of common ground (e.g. good leadership and clear lines of accountability and well-functioning IT) which meant countries could benefit directly from findings in other member states.

A qualitative study was conducted in seven different European countries to assess attitudes towards core elements of antimicrobial stewardship at national, hospital, LTCF and primary care levels, focusing on success stories and barriers to stewardship implementation. The results are already being used to inform the content and action points of upcoming NAPs.

The results of a qualitative study of antimicrobial stewardship implementation are already being used to inform upcoming NAPs.

Antimicrobial stewardship in veterinary medicine

- To assess the level of implementation and acceptance of antimicrobial stewardship programmes (ASP), an electronic questionnaire was disseminated through partners and stakeholders of the EU-JAMRAI.
- Core components needed for implementation were identified which can be used by member states when planning their own stewardship programmes. In animals this is broader than in humans, due to the variety of production systems and animal species.
- The results of the questionnaire are already being used to propose a stewardship program suitable for adaptation and use in both companion and production animal, structured around different strategic and specific actions
- When developing an ASP, it is important to define objectives, identify all actors that need to be involved, and periodically assess the progress and success, in order to constantly improve and address the need to review the strategy.

 $^{^{*} \}text{Aim to bridge the gap between hum} \\ \text{An and animal su} \\ \text{Reveillance data, antibiotic policy, and stewards} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Reveillance data, antibiotic policy, and stewards} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Reveillance data, antibiotic policy, and stewards} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Reveillance data, antibiotic policy, and stewards} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Hip to bridge the gap between hum} \\ \text{An animal su} \\ \text{Hip to bridge the gap between hum} \\ \text{Hip to bridge th$



EU-JAMRAI DDS TO TH

Surveillance of AMR and antimicrobial consumption in human health

- In order to shorten the current time gap between AMR and AMC data collection and assessment, a near-real time surveillance system has been piloted within the EU-JAMRAI, during a 2.5 year period, collecting 41 indicators each trimester: 19 AMC indicators for hospital care (HC); 10 AMC indicators for primary care (PC); 7 AMR indicators for HC; and 5 AMR indicators for PC.
- 17 partners from 11 countries enrolled the study, reinforcing their surveillance systems by providing data on a quarterly basis, from hospitals and/or primary care at a local, regional or national scope. This approach would complement the current surveillance on AMR and AMC data in the EU/EEA Member States, which are informed to the ECDC and assessed on a yearly basis.
- In addition to the innovative quarterly based surveillance, this pilot system introduced new indicators to increase the knowledge of AMR and AMC status from healthcare centres level up to the regional or national level, allowing each healthcare centre to monitor their own AMR and AMC data evolution over time, in order to carry out local, regional or national interventions on a more timely manner:

- A new AMC indicator for hospitals to monitor consumption in DDD per 1000 bed-days, complementing the current EU/ EEA AMC surveillance data for HC that are expressed as DDD per 1000 inhabitants
- A new AMR indicator to monitor the incidence density of resistant isolates from all clinical samples per 1000 beddays in hospitals and per 1000 inhabitants in primary care, complementing the current EU/EEA AMR surveillance data that are expressed as resistance percentage from invasive (blood and cerebrospinal fluid) isolates



Surveillance of AMR in animals⁵

- AMR surveillance efforts in the animal sector in Europe produce useful data on the possible spread of AMR to humans through the food chain, but they are of little help to inform antimicrobial treatment guidelines and support antimicrobial stewardship in the veterinary sector.
- As part of the EU-JAMRAI, a broad consultation of experts from 14 countries and from European stakeholder organizations (incl. ECDC, EFSA, EMA, EURL-AR and FVE) led to the conclusion that time had come to build a European Antimicrobial Resistance Surveillance network in Veterinary medicine (EARS-Vet), in order to fill the current surveillance gap in diseased animals in Europe and complement the existing EFSA and EARS-Net monitoring.
- National AMR experts were consulted during 12 country visits about their expectations from

- EARS-Vet and under which conditions they would be ready to participate. Of note, 11 countries already have a national surveillance system in place. These were described and analysed to define, via a pragmatic bottom-up approach, the EARS-Vet objectives, scope (i.e. AMR hazards of interest) and standards (i.e. microbiological techniques and interpretation criteria).
- Among others, EARS-Vet would help i) to support the development of evidence-based guidelines for antimicrobial stewardship in veterinary medicine, ii) to better characterize links between AMC and AMR in animals and iii) to support risk assessment of AMR transmission from animals to humans via non foodborne related routes. Overall, EARS-Vet would contribute to a much stronger One health strategy for AMR surveillance in Europe.



CALL FOR ACTION =

Antimicrobial stewardship in humans

- We encourage Member States to use the repository and the reports as tools for improvement and more successful implementation of antimicrobial stewardship at different levels of human healthcare, which will be an added value to the implementation of the national and EU action plans.
- The EU should prioritize further efforts on antimicrobial stewardship by developing European core elements for antibiotic stewardship programmes at national level, as well as all levels of healthcare. The qualitative evaluation conducted in EU-JAMRAI can contribute with valuable information about the most appropriate core elements of antimicrobial stewardship programmes and the most significant enablers and barriers for successful implementation.



The EU should prioritize further efforts on antimicrobial stewardship by developing European core elements for antibiotic stewardship programmes at national level.

Antimicrobial stewardship in veterinary medicine

We encourage Member States for further consensus procedure involving the key stakeholders in animal health to be able to publish a white book on the implementation of antimicrobial stewardship in animal health, including definition of a common structure, description of the core elements, the roles of each core professional and indicators to assess the progress.

Surveillance of AMR and antimicrobial consumption in human health

We encourage policymakers to consider improving AMR and AMC surveillance in the EU by supporting real-time or near-real-time surveillance systems in addition to the existing surveillance systems.

Surveillance of AMR in animals⁵

- We encourage policymakers to build on Member States strong interest in monitoring AMR in diseased animals at a European level, with a number of countries already having national surveillance in place.
- The EU regulation 2016/429 (Animal Health Law) opens for the possibility to regulate AMR surveillance in diseased animals in Europe; EFSA was requested to provide, by March 2022, "a scientific opinion for the listing and categorisation of transmissible animal diseases caused by bacteria resistant to antimicrobials".
- EU-JAMRAI built a preliminary network of 13 countries and set the technical basis for EARS-Vet (scope, objectives, standards). The next step will consist in launching a pilot phase where participating countries start sharing data and produce a first EARS-Vet report, thereby delivering a proof-of-concept for a European AMR surveillance in diseased animals.
- We strongly encourage European decision-makers to consider EARS-Vet as a possible resource for future implementation if, AMR surveillance in diseased animals becomes mandatory in Europe.

⁸ Mader Rodolphe, Damborg Peter, Amat Jean-Philippe, Bengtsson Björn. Bourely Clémence, Broens Els M. Busani Luca, Crespo-Robledo Paloma, Filippitzi MariaEleni, Fitzgerald William, Kaspar Heike, Madero Cristina Murioz, Norström Madelaine, Nykäsenoja Suvi, Pedersen Karl, Pokludova Lucie, Urdahl Anne Margrete, Vatopoulos Alkiviadis, Zafeiridis Christos, Madec Jean-Yves, on behalf of EU-JAMRAITZ Building the European Antimicrobial Resistance Surveillance network in veterinary medicine (EARS-Vet). Euro Surveill. 2021;26(4):pii=2001359. https://doi.org/10.2807/1580-7917-ES.2021.26.4.2001359







CONTEXT AND RATIONALE BEHIND EARS-VET

Antimicrobial resistance (AMR) should be tackled through a One Health approach, as stated in the EU One Health Action Plan.

In the human sector, the ECDC monitors AMR in invasive bacteria from hospitalised patients (European Antimicrobial Resistance Surveillance Network, EARS-Net) and in Salmonella spp. and Campylobacter spp. (European Food- and Waterborne Diseases and Zoonoses Network, FWD-Net). In the animal sector, the EFSA coordinates an active monitoring of AMR in commensal and zoonotic bacteria from healthy food-producing animals at slaughter and food thereof, according to Directive 2003/99/CE of the European Parliament and the Council and the Commission Implementing the Decision 2013/652/EU. Since 2011, EU agencies deliver their findings in joint inter-agency antimicrobial consumption and resistance analysis (JIACRA) reports. The JIACRA II report concluded that monitoring of AMR should also include animal pathogens.



CONTEXT AND RATIONALE BEHIND EARS-VET

While the EFSA monitoring provides valuable insights into the potential for AMR spread to humans through the food chain, it also has limitations: i) it does not inform on AMR occurrence in specific animal pathogens; this information is needed to rationalize antimicrobial use and improve antimicrobial stewardship in the veterinary sector, ii) it focuses exclusively on foodborne AMR transmission, while AMR transmission from animals to humans can occur via multiple other routes and iii) it targets healthy animals that have either never been treated with an antimicrobial, or been treated a long time before sampling for AMR testing, thereby limiting the sensitivity of the surveillance system, i.e. its ability to detect AMR, and the possibility to study direct associations between AMR and antimicrobial consumption. Hence, an important gap that remains is a European coordinated programme on surveillance of AMR in bacterial pathogens of animals, i.e. in diseased animals.

There is currently no EU regulation on AMR surveillance in bacterial pathogens of animals. However, the EU Regulation

2016/429 (Animal Health Law) opens for the possibility to regulate AMR surveillance in veterinary medicine. As a first step in this direction, EFSA received a mandate from the European Commission to provide, by March 2022, "a scientific opinion for the listing and categorisation of transmissible animal diseases caused by bacteria resistant to antimicrobials" (excluding those already covered by Directive 2003/99/CE). However, the way surveillance should be implemented is not part of this mandate.

Of note, a number of EU countries (at least 11) already have a national surveillance system of AMR in bacterial pathogens of animals. However, these systems are fragmented, do not all monitor the same animal species, bacterial species and antimicrobials, and do not all use the same methodologies and interpretative criteria. In addition, other countries are currently developing their surveillance system, without European guidance. There is an urgent need for a harmonized and coordinated approach for AMR surveillance in bacterial pathogens of animals across Europe.

Hence, time has come to build the European Antimicrobial Resistance Surveillance network in Veterinary medicine (EARS-Vet), which should be set up and designed so that it can complement and integrate with existing ECDC and EFSA monitoring systems. EARS-Vet would represent a major step towards a stronger and truly One-Health strategy for surveillance of AMR, interlinked with the monitoring of antimicrobial consumption in Europe.



This conclusion, as well as the following technical information, results from a collective agreement within a multidisciplinary group of 30 experts from 14 European countries in consultation with relevant EU bodies (ECDC, EFSA, EMA), built as part of the

EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) 2018-2021 co-funded by the EU Health Programme.

Joint Action Antimicrobial Resistance and Healthcare-Associated Infections

EARS-VET OBJECTIVES

EARS-Vet would be in charge of reporting on the current AMR situation, following AMR trends and detecting emerging AMR in bacterial pathogens of animals in Europe in order to:

- Inform on AMR occurrence in specific animal pathoqens;
- Contribute to the development of evidence-based guidelines for antimicrobial prescription in animals, thereby supporting antimicrobial stewardship in the veterinary sector;
- iii. Investigate direct links between antimicrobial consumption and AMR in both animals and humans, by providing AMR data collected close to animal pointof-care; as such, EARS-Vet could complement the current pool of data covered by the JIACRA reports;
- iv. Support risk assessment of human exposure to AMR from animal reservoirs via non-food related routes (e.g. direct contact with companion or food animals);
- Provide timely information for policy makers and allow exploring the benefits of interventions at European level;
- Provide relevant information that could be of use to medicines agencies in the evaluation or revision of marketing authorisations;
- vii. Contribute to estimate the burden of AMR in the animal sector.

EARS-VET DESIGNAND STANDARDS

EARS-Vet would operate as a network of national surveillance systems of AMR in diseased animals, similarly to EARS-Net in the human sector. All these national surveillance systems perform passive data collection, although a few countries complement their passive scheme with an active sampling. Using a bottom-up approach that takes into account what national surveillance systems currently monitor, as well as what EFSA and ECDC already cover, EU-JAMRAI partner countries agreed on a tentative EARS-Vet scope including 220 combinations of animal species - sample types - bacterial species - antimicrobials of interest and EARS-Vet standards for antimicrobials susceptibility testing.

EARS-Vet would operate as a network of national surveillance systems of AMR in diseased animals, similarly to EARS-Net in the human sector.

EU-JAMRAI | Policy brief: European Antimicrobial Resistance Surveillance network in Veterinary medicine (EARS-Vet)



FUTURE STEPS TO BUILD EARS-VET

Building on EU-JAMRAI achievements, the next steps will consist in launching an EARS-Vet pilot phase where participating countries will start to share and jointly analyse their data, and finally produce a first EARS-Vet surveillance report. The level of representativeness and comparability of AMR data across national surveillance systems will also be assessed. Future EARS-Vet developments also include the integration of molecular (WGS) data for AMR bacterial clones and genes surveillance, as well as the inclusion of other AMR hazards of interest, such as those to be identified as priorities in the EFSA scientific opinion on the listing and categorisation of transmissible animal diseases caused by bacteria resistant to antimicrobials.

To achieve these next steps, and more generally to ensure the sustainability of EARS-Vet, strong political commitment from EU and national decision makers is needed. On the short term, we urge them i) to provide financial support to EARS-Vet, e.g. by funding an EARS-Vet pilot phase and ii) to provide political support to EARS-Vet, by encouraging Member States to promote surveillance of AMR in bacterial pathogens of animals in their country and to invite relevant national contact points to join the EARS-Vet initiative.

To achieve these next steps, and more generally to ensure the sustainability of EARS-Vet, strong political commitment from EU and national decision makers is needed.

On the long-term, EARS-Vet could potentially be taken over by EU bodies (e.g. EFSA), should they receive the mandate to coordinate AMR surveillance in bacterial pathogens of animals (e.g. under the umbrella of the Animal Health Law). This would ensure the integration of EARS-Vet within the European landscape of AMR surveillance and related initiatives, and contribute to achieving a stronger One-Health surveillance of AMR in Europe.

Reference: This policy brief is based on the following publication: Mader Rodolpheet al. Building the European Antimicrobial Resistance Surveillance network in veterinary medicine (EARS-Vet). Euro Surveill. 2021;25(4):pi = 2001359. https://doi.org/10.280/11560-79171.5.2021.26.4.200359





POLICY BRIEF

THE URGENT NEED TO FOSTER RESEARCH ON INFECTION PREVENTION AND CONTROL TO IMPROVE HEALTH SECURITY

THE PROBLEM

Joint Action
Antimicrobial Resistance and
Healthcare-Associated Infections

Effective Infection Prevention and Control (IPC) measures are necessary to control the spread of infections, like COVID-19, as well as minimise everyday healthcare-associated infections. Fewer infections in hospitals result in lower consumption of antibiotics, thereby reducing antibiotic resistance. Yet, despite the critical importance of IPC measures, its research needs are often neglected



As COVID-19 has demonstrated to the world, the only steps that can be taken to control the spread of a novel virus with pandemic potential are effective Infection Prevention and Control (IPC) measures, like handwashing, social distancing, and even isolation. In non-pandemic times IPC measures are also critical to stop the spread of infections. Every year more than 2.5 million healthcare-associated infections occur in the European Union and European Economic Area, causing millions of extra days of hospital stays.1 Fewer infections in hospitals result in lower consumption of antibiotics, thereby reducing antibiotic resistance.

Effective IPC measures go well beyond handwashing. Ideally

IPC should be designed into any new healthcare facility. For instance, purchases of sinks, showers, or bathtubs in healthcare institutions should include an analysis of the evidence of how easily they can be disinfected. Placement and design of hand sanitisers should be based upon evidence of where healthcare personnel are most likely to use them. Avoidance of ventilator-associated infections should be based on evidence for sterilising both the equipment and insertion site. IPC evidence is crucial, but scarce. When IPC research projects compete for funding against other thematic areas, like breakthrough technologies to combat climate change, big data against social inequities, or potential new cancer treatments, they are often perceived as dull, receiving low innovation marks.

Cassini A. Plachouras D. Eckmanns T, et al. Burden of six healthcare-associated infections on European population health: estimating incidence-based disability-adjusted life years through a population prevalence-based modelling study. PLoS medicine 2018; 13(10).



THE PROBLEM

This neglect is apparent in the evidence available. Many IPC guidelines are based upon weak scientific evidence.²³ The research priorities of IPC are often neglected in important international research agendas. Many countries do not identify IPC research as important in hindering the spread of antibiotic resistance.⁴ In this regards, many countries implement a bundle of IPC interventions without knowing which ones are the most cost-effective for their particular context.



THE RECOMMENDATION

With European IPC experts the EU-JAMRAI has developed a list of IPC research priorities. Financing these research priorities is critical to strengthening infection prevention and control.

The lack of IPC research may be due to a global lack of awareness of the most urgent IPC needs and knowledge gaps. To address this issue, the European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI)

has developed a list of IPC research priorities, based upon existing scientific literature and validated by European IPC experts. The most urgent priorities are in bold text. We urge policymakers, research funders, academics, and industry to adopt and prioritise these research needs. Investment will have wide-ranging benefits, including lowering the number of hospitalised patients, hindering antibiotic resistance, and strengthening global health preparedness for the next pandemic.



Patient environment (facilities and staffing)

- Insufficient data are available on the impact of infrastructural changes at the facility level on the reduction of infections and resistance. This includes the accessibility to specific equipment, density of hand washing points, availability of single occupancy rooms, and more.
- 2. Research is needed to explore the impact of patient-to-bed ratio on the spread of infections
- and resistance, including instances of overcrowding. This should include analyses of staff workload, available staffing (including presence of IPC professionals), bed occupancy, and visitor frequency.
- Research is needed to study the interaction between the human and hospital microbiome.

Bernios-Torres St. Umscheid CA. Bratzler DW, et al. Centers for disease control and prevention guideline for the prevention of surgical site infection, 2017, JAMA surgery 2017; 152(8): 784-91.

^{*} O'Grady NP, Alexander M. Burns LA, et al. Guidelines for the prevention of intravascular catheter-related infections. Clinical infectious diseases 2011; 52(9): e162-e93.

^{*} European Union Joint Action on Antimic robial Resistance and Healthcare-Associated Infections (EU-JAMRAV). Gathering of national research priorities from at least five European countries and gap identification, 2019.

^{*} Lacotte Y, Ärdal C, Ploy M-C. Infection prevention and control research priorities to combat antimicrobial resistance and healthcare-associated infections. (under consideration) 2020.

EU-JAMRAI | Policy brief: The urgent need to foster research on infection prevention and control to improve health security.

THE RECOMMENDATION



Behavioural science

- 4. Studies are needed to assess the demographic, organizational, economic, sociological, and behavioural factors facilitating success but also the barriers and challenges to implement effective IPC programmes.
- Patients and their families are key elements in the chain of transmission in healthcare facilities. Studies addressing the impact of patient and family-oriented education and communication campaigns (involving patients associations) on the rate of hospital-acquired infections are needed.



Interventions

There is a need for high-quality studies addressing the effectiveness of hospital-based IPC programmes, including their impact, cost-effectiveness, and ideal composition.



Guidelines

- 7. Many best practice IPC recommendations are based upon weak evidence. For example, the World Health Organization identified, in its Global Guidelines for the Prevention of Surgical Site Infection, 20 recommendations with a "low" quality of evidence. The evidence base supporting IPC guidelines needs to be strengthened.
- Situational analyses in different settings (high, medium or low-incomes countries) but also different healthcare settings (intensive care units, short or
- long stay, medico-social facilities) are needed to better understand potential adaptations of IPC guidelines.
- A better understanding of the different patient screening strategies is needed for risk management. This includes who should be screened, when (including start and stop of screening), and how movement between healthcare institutions should trigger screening. Research should include both clinical impact and cost-effectiveness.



Training

- Additional tools are needed to evaluate IPC training programmes and implement them.
- New innovative ways of training should be evaluated such as e-learning, simulation, self-directed training modules or mentorship for IPC education. There is a lack of study on the impact of these in-
- novative training tools on the practice change and infection rate in healthcare facilities.
- Minimal standard requirements for the recruitment and training of IPC professionals should be investigated.

EU-JAMRAI | Policy brief: The urgent need to foster research on infection prevention and control to improve health security.

THE RECOMMENDATION :

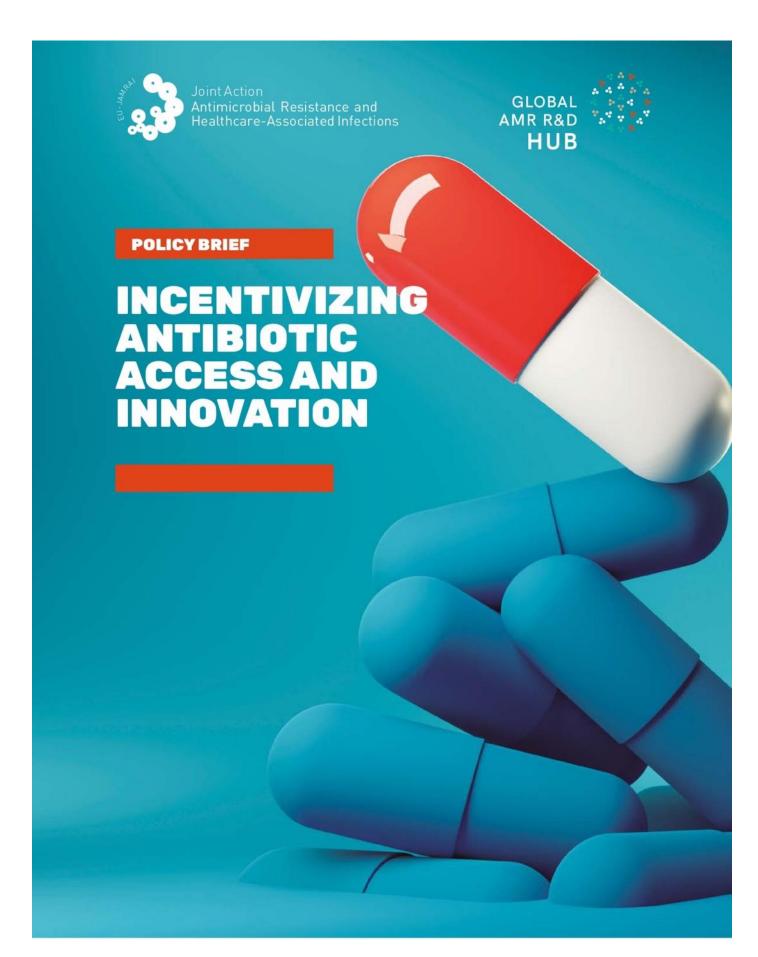


Surveillance and monitoring

- Research is needed to assess and validate the reliability of surveillance based on available patient clinical information (syndromic-based surveillance) rather than microbiological data or prescription databases, i.e., data gathered for other primary purposes.
- There is a lack of published standards to monitor IPC practices beyond hand hygiene. Evidence-based standardised audit protocols need to be
- created addressing, for example, catheter-related bloodstream/urinary tract infections and ventilator-associated pneumonia.
- 15. There are a number of innovative, new methods to monitor compliance to IPC practices, including electronic and infrared approaches. These need to be tested in multiple settings to assess their value for IPC programmes.



Research is needed to assess the impact of IPC measures in different operational contexts including small farms, industrial farms, feedlots, slaughterhouses, fish farms, and more. IPC measures may include the density of the animal populations, vaccinations and antibiotic use in animals, as well as the infection control measures of the workers.





EU-JAMRAI & Global AMR R&D Hub | Policy brief: Incentivizing antibiotic access and innovation

www.eu-jamrai.eu







PREDICTABLE ACCESS TO LIFE-SAVING ANTIBIOTICS IS UNDER THREAT

Antibiotic resistance imperils global health, with multi-drug resistant bacterial infections accounting for over 33,000 deaths in Europe alone in 2015. The number of annual global deaths is unknown but predicted to be large. Yet contrary to the public health need, antibiotic innovators and manufacturers are struggling.

New antibiotics are unable to generate revenues large enough to sustain the interest of multinational players and even small developers are failing to cover their costs, resulting in bankruptcies of small antibiotic innovators. Melinta, an American antibiotic innovator went bankrupt in December 2019, after receiving regulatory approval in the United States and Europe for an antibiotic judged as "innovative" against a "critical" priority pathogen by the World Health Organization. Physicians use new antibiotics as a last resort in order to preserve their efficacy. Whereas this is sound stewardship, it dis-incentivizes innovation since unit sales determine revenues.

Simultaneously, shortages of older antibiotics are increasing. Due to antibiotic resistance patterns and prescribing habits, the markets of some essential antibiotics are small, including those for children. Tendering processes based solely on price and automatic price reductions for generic medicines reduce profitability, leading to a consolidation of supply. The dependency on sole manufacturers may come as a surprise, when there is suddenly no medicine available. For example, in 2017 a fire at a raw material factory in China resulted in a global shortage of piperacillin/tazobactam. During the COVID-19 pandemic, supply chains have been unable to meet demand as well as challenged by supply disruptions due to lockdowns and border closures.

Several prominent reports have assessed the challenges to antibiotic access and innovation and have made recommendations, including calls for "pull" incentives, aiming to increase revenues for marketed, innovative antibiotics. We set out to understand countries' perceptions of these recommendations, through frank and anonymous dialogue. As a part of the EU Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) we performed in-depth interviews with policymakers and AMR experts in ten European countries. These insights were made more globally representative with support of the Global AMR R&D Hub who supported the inclusion of a further three countries from other continents. The aim of the interviews was to understand the barriers and facilitators for implementing incentives that promote antibiotic access and innovation.

European countries interviewed were: Belgium, Denmark, France, Germany, Luxembourg, the Netherlands, Norway, Romania, Spain, and Sweden. We interviewed policymakers from Ministries of Agriculture and Research in nine of these countries.

² Supplementary pool included interviews with the Ministries of Health and other AMR experts in Canada and South Africa, and an interview with an AMR expert in Japan.





PREDICTABLE ACCESS TO LIFE-SAVING ANTIBIOTICS IS UNDER THREAT

EUROPEAN "PULL" MECHANISMS



The Pharmaceutical Strategy for Europe (2020) states that the EU will pilot a pull incentive in 2021. Three countries are already underway:

England will pay an annual fixed payment determined through a health technology assessment (including both patient and societal value) for the supply of a new antibiotic. The payment is not dependent upon sales volumes. The pilot has selected two antibiotics. Target implementation date is Spring 2022.

Germany has revised the way it assesses new "reserve" antibiotics, allowing for higher unit prices in line with the value of the new antibiotic.

Sweden has signed agreements with suppliers of five new antibiotics for an annual revenue guarantee. Swedish hospitals continue to purchase as normal with the funding from the pilot study paying the difference between the guarantee and actual sales. The agreements started July 15, 2020 and will continue for two years.

ELEVEN COUNTRIES EXPRESSED GENERAL SUPPORT FOR ANTIBIOTIC INCENTIVES

Interviewees expressed support for antibiotic incentives in 11 of 13 countries. Yet, it was clear from the interviews that policy-makers' support is high-level and general. Almost all countries are uncertain which incentive is appropriate for their country, how to implement an incentive, and how much it will cost. They prefer to wait for evidence from Germany, Sweden, and the United Kingdom (see box). Nine of the 10 European countries interviewed would prefer a common, European or multinational incentive, as long as it is independent from national health technology assessment, medicine pricing, and reimbursement.

Policymakers were clear that incentives should only apply to antibiotics that meet public health needs and that the public health value must be demonstrated through showing benefit in clinical situations against multi-drug resistant infections (see quote).

Whereas policymakers expressed concerns about the lack of antibiotic innovation, this was not the principal driver for support for new incentives. Rather, countries (9 of 11) indicate a preference for a model that ensures access to both old and new antibiotics, with the highest priority for older antibiotics.

"Antibiotics are being approved for indications where there is no intention that they will be used. This sends the wrong signal...would prefer that antibiotics are tested against drug-resistance instead. If the trials need to be done in [high-resistance countries] and they are performed according to existing standards, this is preferable."







COUNTRIES DO NOT HAVE PREDICTABLE ACCESS TO LIFE-SAVING ANTIBIOTICS

Predictable access to life-saving antibiotics is a common global challenge. Twelve of 13 countries indicated that shortages of existing antibiotics is a serious problem. Eight out of 13 indicated that this resulted in greater use of broad-spectrum antibiotics and thereby potentially increasing antibiotic resistance. As important antibiotics continue to be unavailable, doctors change prescribing habits, potentially away from evidence-informed prescribing guidelines. Interestingly, we also interviewed veterinary counterparts in European countries, who stated that there was no indication of shortages of veterinary antibiotics, despite often being comprised of the same active pharmaceutical ingredients.

National medicines agencies and procurers lack the tools to work proactively to avoid antibiotic shortages. They know which factories produce the raw materials and finished medicines for only their own marketed medicines, but do not have access to data about the global market for a specific medicine. Factory information is generally considered a business secret and cannot be made publicly available. When countries are notified of a supply disruption, it is too late to find a solution if all companies are dependent upon the same raw material supplier. This is a common problem since the world supply of active pharmaceutical ingredients is highly concentrated in a few countries. A lockdown in one geographic region can have significant implications for the world's medicine supply. Trans-

parency is needed to understand supply chain resilience. New Zealand has already taken steps, openly publishing the name and location of raw material and finished product factories for all its marketed medicines.

Unpredictable access is not only a challenge for older antibiotics but also for new ones. New antibiotics are not widely available. For example, the new antibiotic combination meropenem/vaborbactam, judged as "innovative" by the World Health Organization against "critical" priority pathogens, was approved by the European Medicines Agency in 2018 but is currently marketed in only five EU countries.

A lockdown in one geographic region can have significant implications for the world's medicine supply.

SPECIFIC, DETAILED INCENTIVES MUST BE COMMUNICATED TO FACILITATE IMPLEMENTATION

The results of these interviews point to a clear need for specific, detailed incentives that national policymakers can assess, tailor, and implement. These incentives must be designed with the aim of ensuring national access to important antibiotics that meet public health need. EU-JAMRAI aims to publish a recommendation in early 2021.





ABOUT EU-JAMRAI =

EU-JAMRAI is a European Union Joint Action on Antimicrobial Resistance (AMR) and Healthcare-Associated Infections (HCAI) that brings together 44 partners and more than 40 stakeholders. Our mission is to foster synergies among EU Member States by developing and implementing effective One Health policies to fight the rising threat of AMR and to reduce HCAL EU-JAMRAI started in September 2017 and will finish in February 2021.

Our mission is to foster synergies among EU Member States by developing and implementing effective One Health policies.





ANNEX II: DOCUMENTS SENT TO THE STAKEHOLDERS

1) Example of a one page document on mentorship/observership

ESNO - Mentorship and observership programmes: objectives and application

What are observership and mentorship programmes?

An observership programme allows a team/professional needing practical training to visit onsite another more expert facility during a certain period of time. The observers can learn from their observations and bring back new competencies.

A mentorship programme creates a strong and trustful collaboration between an expert that supervises a team/member needing advice during a certain period of time. Mentorship can be organised remotely.

Objectives

Antimicrobial stewardship (AMS) and Infection prevention and control (IPC) are the two essential pillars to tackle antimicrobial resistance (AMR). Evidence-based good practices and competencies are essential and both theoretical and hand-on trainings are needed.

Observership and mentorship programmes offer a great opportunity to:

- Share and improve knowledge and experience
- Promote evidence-based best practices and practical tips
- Engage with an expert team.

Evidence and examples

The literature shows that mentorship programmes are beneficial on several aspects: they improve patient outcomes, encourage research, develop health professionals training and competencies¹. At the European level, the 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance strongly recommend developing such programmes².

For example, the ESCMID (European Society of Clinical Microbiology and Infectious Diseases) has developed mentorship and observership programmes. Concerning the latter, they have put in place Collaborative centres that members can visit for five days to one month in order to observe expert teams. These centres are highly experienced in a specific field. They are therefore able to offer guidance and experience to observers. Observers use this opportunity to improve their knowledge and bring back new competencies to their facilities. Moreover, through the network of ESCMID Mentorship Centres across Europe, mentees can be supported and helped for one to two years by a mentor, who is an expert on specific topics. Therefore, the mentee can benefit from the mentor's competencies and experience. The European Association of Hospital Pharmacists (EAHP) has also been coordinating a mentorship programme since 2018. As part of the Statement Implementation Learning Collaborative Centers (SILCC) initiative, hospital pharmacists have the possibility to visit 11 SILCC approved hospitals across Europe, where they can receive training in pharmacy procedures in accordance with the European Statements of Hospital Pharmacy.

How could ESNO implement such programmes?

Based on its network, ESNO could develop such programmes across Europe. Nurses/facilities with a specific expertise on AMS and/or IPC can welcome/mentor nurses from other facilities/countries. To implement these programmes, we suggest that:

¹ Sheri, Krish and al, 2019. A scoping review of mentor training programs in medicine between 1990 and 2017, Med Educ Online; 24(1): 1555435.

² Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance, 14 June 19, n°35, 56, 57. EUjamrai_D4.3_ Update_Report on Integration plan_WP4_MoH_20210225

- ESNO defines selection criteria and a standard operating procedure. As an example, the Infectious Diseases Society of America (IDSA) defined such <u>criteria</u> for AMS.
- ESNO identifies facilities/nurses/teams that demonstrate a strong experience in a field related to AMS and/or IPC and who are willing to participate in an observership/mentorship programme.
- ESNO launches and promotes these initiatives among its members.

2) Example of a one page document on core competencies on IPC and AMS

EAHP - Core competencies on IPC and AMS for pharmacists: objectives and application

What is a core competency?

The EU-JAMRAI uses the <u>ECDC's definition</u> of a core competency referring to "the proven ability to use knowledge, skills and personal, social and/or methodological abilities, in work or study situations and in professional and personal development" that should be a minimum pre-requisite. These core competencies should guide the design of undergraduate and postgraduate training of these professionals.

Objectives

Antimicrobial resistance (AMR) is a major public health issue that impacts all health professionals' practices on a daily basis. As overuse and misuse of antibiotics is a key driver of AMR, antimicrobial stewardship programmes, which have been defined by WHO³, as a "coherent set of actions which promote the responsible use of antimicrobials", should be implemented in human health. The same is true for Infection Prevention and Control programmes.

The training of pharmacists on infection prevention and control (IPC) and antimicrobial stewardship (AMS) thus constitutes a major element to act on in order to prevent Healthcare-Associated Infections (HAI) and AMR. However, training and curricula are very heterogeneous across Europe. Therefore, designing a list of common core competencies, which could be used as a reference for the undergraduate and postgraduate training of pharmacists across Europe would be very useful. Such a list would provide a standardisation of the competencies at the European level that could be beneficial on several aspects, such as a better recognition of pharmacists' training among European countries, an improvement of best practices' exchange, among others.

Core competencies' unmet needs and examples of existing core competencies

The 2019 Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance encourage the development of common guidelines on IPC and AMS that should be included in the training of the healthcare workforce⁴. In 2013, the ECDC developed <u>a list</u> of core competencies for hospital-based IPC professionals in the European Union according to their career level (introductory or expert levels). Classified into four areas (programme management, quality improvement, surveillance and investigation of HAIs, infection control activities) that are divided into 16 domains gathering detailed core competencies, this list provides a common reference aiming to create a European training strategy for IPC teams (see annex 1).

However, to the best of our knowledge, such core competencies are not available in Europe for all the other healthcare professionals. Indeed, the EU-JAMRAI highlighted gaps in the training of healthcare professionals on IPC. Thus, it was recommended that "an initial and continuous training on IPC should be in place for all healthcare professionals involved in patient care" at the national and the facility levels. The training strategy should target all professionals involved in health service delivery, including hospital administrators, clinical department supervisors and healthcare workers directly involved in patient care. In addition, training opportunities on IPC should also be available to other professionals who support health service delivery (e.g. cleaners, auxiliary service staff).

In 2018, WHO published <u>a competency framework</u> for health workers' education and training on antimicrobial resistance based on the mapping of training and education resources around the world and then refined by a

³ WHO (2019). Antimicrobial stewardship programmes in health-care facilities in low and middle income countries - a WHO practical toolkit, https://www.who.int/publications/i/item/9789241515481.

⁴ Council Conclusions on the next steps towards making the EU a best practice region in combatting antimicrobial resistance, 14 June 19, n°31, 36, 37, https://data.consilium.europa.eu/doc/document/ST-9765-2019-INIT/en/pdf
EUjamrai_D4.3_ Update_Report on Integration plan_WP4_MoH_20210225 I 58

WHO expert consultation group. Classified into four domains and targeting four categories of health workers, this framework provides a reference tool that can be used all over the world.

Regarding AMS, the European Society of Clinical Microbiology and Infectious Diseases (ESCMID) generic competencies working group developed a consensus-based set of generic competencies focusing on antimicrobial prescribing and stewardship for European prescribers through a structured consensus procedure (RAND-modified Delphi procedure with two questionnaire rounds, a meeting in between, and a final review) (see annex 2). No such international work has been done for non-prescribers, to the best of our knowledge.

How could EAHP develop such core competencies for pharmacists?

Based on its experience, partnerships and network, EAHP would be ideally placed (in collaboration with relevant partners) to lead a work to design a list of core competencies on AMS and IPC targeting the training of pharmacists.

These core competencies, on the basis of the examples described above, might be developed thanks to the following methodology:

- In collaboration with its partners, EAHP uses the EU-JAMRAI's outputs and prepares a review of the existing published and grey literature and existing guidance / recommendations to assess the training needs for pharmacists in Europe.
- Then, it will be followed by a structured consensus procedure involving all the EU Member States in order to list these core competencies on IPC and AMS as a frame of reference for the training of pharmacists across the European Union.

Annexes - Examples of core competencies on AMS and IPC

<u>Annex 1:</u> European Centre for Disease Prevention and Control. Core competencies for infection control and hospital hygiene professionals in the European Union. Stockholm: ECDC; 2013

 $\underline{https://www.ecdc.europa.eu/sites/default/files/media/en/publications/Publications/infection-control-core-competencies.pdf}$

Table A2. Areas, domains and competencies in infection control and hospital hygiene for junior and senior specialists (introductory and expert levels)

Area 1. Programme management

Domain	Competencies for a junior specialist – introductory level	Competencies for a senior specialist – expert level
Elaborating and advocating an infection control programme	 Advocate the importance of healthcare- associated infections (HAIs) as a crucial element of patient safety and highlight their potential human, economic and reputational burden to the decision-makers of the healthcare organisation 	 Advocate the importance of healthcare- associated infections (HAIs) as a crucial element of patient safety and highlight their potential human, economic and reputational burden to the decision-makers of the healthcare organisation
	 Contribute to the development of the infection control programme Contribute in involving identified stakeholders in the infection control programme Identify needs for the protection of healthcare workers in their respective healthcare organisations Take a lead role as appropriate for the healthcare organisation to formulate, propose and liaise with other key players to produce appropriate indicators in relation to the control of healthcare-associated infections, taking into account the official policy on internal transfer of information and public health disclosure of information Foster and promote team work in infection control Lead the team to ensure that it has shared vision and works cohesively 	Prepare and present an outline of an infection control programme focusing on key elements: mission statement, description of objectives and indicators, presentation of action plan, including outcomes, success measures, rules for the functioning of the infection control committee, operating manual, links to other patient safety and healthcare organisation programmes Identify and communicate the requirements of an infection control programme to relevant internal and external stakeholders (including patient advocates) and develop strategies for involving them in the infection control programme
		 Take a lead role as appropriate for the healthcare organisation to formulate, propose and liaise with other key players to produce appropriate indicators in relation to the control of healthcare-associated infections, taking into account the official policy on internal transfer of information and public health disclosure of information Foster and promote team work in infection control Lead the team to ensure that it has shared vision and works cohesively
Management of an infection control programme, work plan and projects	Contribute to the management of an infection control programme or other programmes on adverse events (from conception to impact evaluation, including budgeting) according to EU, national or local regulations and healthcare organisation policies Participate in the formulation of an organisational structure for controlling HAIs Collate data regarding the infrastructure in	 Manage an infection control programme or other programmes on adverse events (from conception to impact evaluation, including budgeting) according to EU, national or local regulations and healthcare organisation policies Play a key role in formulating an organisational structure for controlling HAIs and antimicrobial resistance (AMR) in the healthcare organisation – while interacting

Annex 2 : Dyar OJ et al. ESCMID generic competencies in antimicrobial prescribing and stewardship: towards a Clinical Microbiology Infection. 2019. European consensus. and (1),pp.13-19. https://pubmed.ncbi.nlm.nih.gov/30414817

ESCMID generic competencies in antimicrobial prescribing and stewardship.

Section 1: core concepts in microbiology, pathogenesis and diagnosing infections

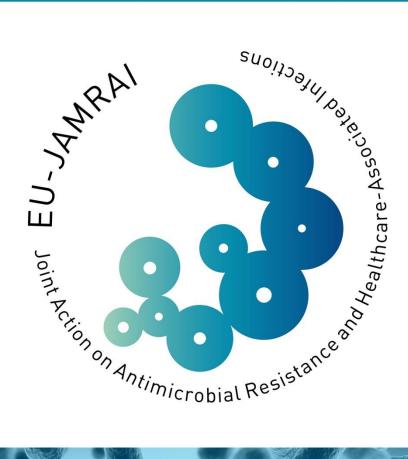
- 1 Every independent prescriber must understand:
 - 1.1 The nature and classification of microorganisms that commonly cause infections in humans
 - 1.2 The common microbiological aetiology of human infections, and the ways in which microorganisms are commonly acquired in community and hospital settings
 - 1.3 The differences between colonization (e.g. isolation of bacteria from a venous leg ulcer with no signs of inflammation) and
- 1.4 That an inflammatory response can be due to both infectious and non-infectious causes (e.g. acute pancreatitis)
- 2 Every independent prescriber must know how to:
 - 2.1 Take a thorough history and perform a physical examination to diagnose common infections and to assess their severity
 - 2.2 Use and interpret investigations that can help in informing diagnosis of an infection and in monitoring the response to treatment (e.g. microbiological investigations, biomarkers, point-of-care tests)

Section 2: antimicrobial prescribing

- 1 Every independent prescriber must understand:
- 1.1 How and where to access relevant guidance on antimicrobial prescribing and stewardship
- 1.2 When not to prescribe antimicrobials (e.g. antibiotics for viral infections, or when there is bacterial colonization)
- 1.3 That best practices for some infections may not include antimicrobial treatment (e.g. incision and drainage of abscesses, removal of foreign material)
- 2 Every independent prescriber must understand how to select the appropriate antimicrobial, using relevant guidance when possible, as well as the key elements of initiating prescribing an antimicrobial:
 - · Obtaining relevant microbiological cultures or relevant tests before commencing treatment
 - The timing of antimicrobial administration in different situations (e.g. as soon as possible for life-threatening infections, less urgently for chronic bone infections)
 - The choice and dose of agent, and the route of administration
 - The duration of treatment, review dates and stop dates
- 3 Every independent prescriber must understand the key elements of continuing and rationalizing antimicrobial therapy:
- . Monitoring antimicrobial levels when indicated, and adjusting doses (e.g. for patients with renal impairment)
- . Changing antibiotics according to microbiology results and clinical condition, ideally to a narrower spectrum (de-escalation), or if needed to a broader spectrum (escalation)
- Reviewing antibiotic therapy at 48-72 hours and regularly thereafter in hospitalized patients, and in appropriate situations in the community
- · Switching antibiotics from intravenous to oral administration as soon as possible when indicated (according to guidelines)
- · Stopping antimicrobials if there is no evidence of infection based on clinical findings and investigations (e.g. negative microbial cultures, imaging reports)
- 4 Every independent prescriber must understand the need to document the important details of the antimicrobial treatment plan (e.g. agent, dosing, administration route, clinical indication, duration and review dates) in the prescription chart, medical records and transfer notes to other healthcare institutions
- 5 Every independent prescriber must understand:
 - 5.1 That empirical treatment should be guided by local antimicrobial susceptibility patterns
 - 5.2 The clinically relevant spectrum of activity for commonly prescribed antimicrobials
- 5.3 The basic principles of pharmacokinetics and pharmacodynamics
- 6 When prescribing an antimicrobial, every independent prescriber must know:
- 6.1 The antimicrobial class that the agent belongs to, and the contraindications to its use
- 6.2 The name and class of antimicrobial being prescribed, if prescribing by trade name
- 7 Every independent prescriber must understand single prophylactic dosing for surgical and other procedures for which prophylaxis has been shown to be effective, and that additional prophylactic antimicrobial doses can occasionally be needed (e.g. when the duration of the operation/procedure is prolonged)
- 8 Every independent prescriber must know:
 - 8.1 Common antimicrobial and drug/food interactions
 - 8.2 Common side-effects of antimicrobials, including allergy, how to monitor for them, and what to do when they are suspected (e.g. documenting allergic reactions in patient records, reporting side-effects)
- 9 Every independent prescriber must understand any legal requirements for prescribing antimicrobials in their country, and comply with these when prescribing

Section 3: antimicrobial stewardship

- 1 Every independent prescriber must understand that:
- 1.1 Antimicrobials need to be used responsibly to prevent the emergence and spread of antimicrobial resistance
- 1.2 Optimizing antimicrobial use can limit the common side-effects and collateral damage related to treatment (e.g. their disruptive effects on the normal host flora, which may lead to Clostridium difficile infection, super-infection with Candida
- 1.3 It is important to avoid unnecessary uses of antimicrobials, especially those with a broad spectrum
- 1.4 Transmission of microorganisms in community and hospital settings can significantly amplify antimicrobial resistance
- 2 Every independent prescriber must understand local stewardship policies based on national (or international where these do not exist) evidence-based guidelines
- 3 Every independent prescriber must understand and engage with any locally or nationally agreed quality measures for assessing antimicrobial prescriptions (e.g. compliance with guidance, adverse events, reviews of antibiotic therapy at 48-72 hours in hospitalized patients)
- 4 Every independent prescriber must know how to communicate with patients and their carers, nurses, pharmacists and other healthcare professionals about:
 - 4.1 When antimicrobials are not needed
 - 4.2 Complying with the duration and frequency of administration of their prescribed antimicrobials
- 5 Every independent prescriber must recognize that it is a duty of care to co-operate with others more expert than oneself, such as the antimicrobial stewardship team, when such expertise is needed





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