

MINISTRY OF HEALTH OF THE REPUBLIC OF MOLDOVA NATIONAL AGENCY FOR PUBLIC HEALTH



Republic of Moldova - experience on the mapping exercise results and outcomes



Background (1)

The National Epidemiological Surveillance of AMR System was established in the R. of Moldova - 2018

- ✓ Order no. 711, of June 7, 2018 "On the National Epidemiological Surveillance of Antimicrobial Resistance System"
- ✓ The Regulation on the National Epidemiological Surveillance of Antimicrobial Resistance System which includes the structure and attributions of each part of the system

Regulamentul privind Sistemul național de supraveghere epidemiologică a rezistentei antimicrobiene



MINISTERUL SĂNĂTĂȚII, MUNCII ȘI PROTECȚIEI SOCIALE AL REPUBLICII

ORDIN

"DI " (IKUE 2018
Cu privire la sistemul național
de supraveghere epidemiologică
a rezistenței antimicrobiene

pr. 7//

În scopul intensificării acțiunilor de prevenire şi reținere a dezvoltării rezistenței microorganismelor la preparatele antimicrobiene, fortificării sistemului național de supraveghere epidemiologică şi control al bolilor transmisibile şi evenimentelor de sărătute publică (Hodfirea de Guvern nr. 951 din 25.11.2013), implementării prevederilor Regulamentului Sanitur Internațional (HG nr. 531 din 03.07.2014 cu privire la acțiunile de implementare a Regulamentului Sanitur Internațional în prevenirea transmiterii transfrontaliere a pericolelor pentru săriatatea publică), sporirea călității serviciilor de laborator microbiologice prin integrarea în rețelele internaționale de sapraveghere, precum și implementarea acțiunilor stipulate în pct. 93, subpct 9 (HG nr. 1032 din 20.12.2013 cu privire la apreborea Strategiei naționale de sănătate publică pentru anii 2014-2020), și în temeiul Regulamentului privind organizarea şi funcționarea Ministerului Sănătății, Muncii și Protecției Sociale, aprobat prin Hodfirlera Guvernului nr 694 din 30.07.2017,

ORDON:

- A institui sistemul național de supraveghere epidemiologică a rezistenței antimicrobiene.
- 2. A nominalizar
- Agençia Naţională pentru Sănătate Publică instituţie responsabilă de organizzarea funcţionării, coordonarea şi controlul calității sistemului naţional de supraveghere a rezistenţei antimicrobiene;
- Secția Supraveghere epidemiologică a infecțiilor asociate asisteaței medicale și rezisteața antimicrobiană a Agenției Naționale pentru Sănătate Publică -Punct Focal Național pentru supravegherea epidemiologică a rezistenței antimicrobiene;
- Laboratorul Microbiologie din cadrul Agenției Naționale pentru Sănătate Publică - laborator de referință în sistemul național de supraveghere epidemiologica a rezistenței antimicrobiene.
- A aproba Regulamentul privird Sistemul național de supraveghere epidentiologică a rezistenței antimicrobiene, în conformitate cu Anexa.

mă (RAM) este o problemă globală de sănătate publică ce evoluează nele tări din Regiunea Europeană ponderea agenților patogeni cu icrobiene depășește 50%, fiind atestată o tendință de creștere rapidă a i și răspăndire a fenomenului de rezistență Rețeaua internațională de ntimicrobiene în Regiunea Europei de Est și Asiei Centrale (engl. European Surveillance of Antimicrobial Resistance - CAESAR) e supraveghere a Biroului Regional pentru Europa al Organizației icicietății Europeane de Microbiologie Clinică și Boli Infecțioase (engl. so of Clinical Microbiology and Infectious Diseases) și al Institutului i Mediu din Olanda.

ierea standardizată, combaterea și prevenirea apariției și răspândirii irile din regiunea europeană a OMS. CAESAR reprezintă o extindere eghere a Rezistenței Antimicrobiene (engl. European Antimicrobia rik - EARS-Net) al Comisiei Europene, coordonate de către Centrul trol al Bolilor (engl. - European Centre for Disease Prevention and 8 țări membre ale Uniunii Europene, plus Norvegia, Islanda și supraveghere epidemiologică permite colectarea datelor, analiza enței la antimicrobiene, raportarea și compararea datelor din regiunea ei EARS-Net, și permite elaborarea rapoartelor standardizate, în baza

Sistemul national de supraveghere epidemiologică a rezistenței re Supravegherea RAM) va permite alinierea la standardele etelele internaționale de supraveghere CAESAR.

a preparatelor antimicrobiene – presupune activități privind dului general de prescriere, eliberare, distribuire și administrare a sentarea pe bază de protocoale a prescrierii, vizând prevenirea apariție

iene – include antibioticele, medicamentele antivirale, antifungice și substanțe active de origine sintetică sau naturală care distrug sau care ismelor. Utilizate în mod obișnuit în medicină (de exemplu, infecții i îngrijirea nou-născuților prematuri), acestea sunt vitale în prevenirea și animale.

parate antimicrobiene (RAM) - reprezintă capacitatea i bacteriile, să devină din ce în ce mai rezistente la un preparat anterior receptive. RAM este o consecintă a selectiei naturale și a

Background (2)

The NES of AMR System in the Republic of Moldova is structured on 2 levels

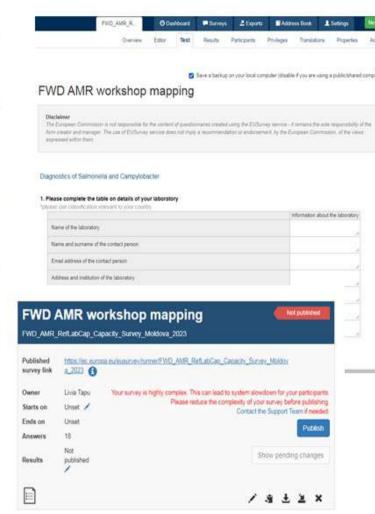
- Level I national, National Reference Microbiology Laboratory in AMR
- Level II includes (24) the territorial microbiological laboratories of National Agency for Public Health (10) and Public Medical Institutions - Hospitals (10) and private laboratories (4).



Communication with laboratory network within mapping exercise

"Mapping of the local/regional laboratories capacities for the detection and characterization of Salmonella and Campylobacter"

- 18 labs that reported more consistent data to the National AMR Surveillance System have participated in the survey
- the survey was conducted online, using EU Survey platform,
- the participating labs completed the questionnaire translated into Romanian with the help of FWD AMR-RefLabCap Project team
- National Reference Laboratory communicate with network laboratories routinely via phone, emails and at trainings
- Annually, workshops on AMR issues are organized by NLR with the support of WHO Country Office (microbiologists, epidemiologists, clinicians, clinical pharmacologists, veterinarian specialists etc.)



Membership of networks and national surveillance of Salmonella spp. and Campylobacter spp.

Voluntary surveillance -

- ✓ Data reporting on *Salmonella* spp. within international AMR surveillance networks
- ➤ Central Asian and European Surveillance of Antimicrobial Resistance (CAESAR) since 2018.

(Salmonella spp. isolated from blood, CSF)

➤ Global Antimicrobial Resistance Surveillance System (GLASS) since 2021.

(Salmonella spp. isolated from stool)

Mandatory surveillance

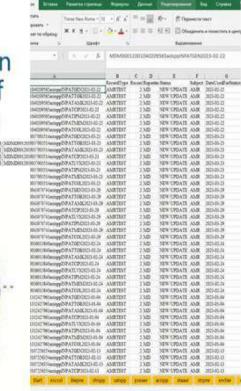
✓ Data reporting on Salmonella spp. and Campylobacter spp. to National Agency for Public Health Laboratories



Central Asian and Eastern European Surveillance of Antimicrobial Resistance

Global AMR

Surveillance System



Weaknesses in the laboratory network identified during the mapping exercise (1)

- 44% of participating labs do not carry out phenotypic and/or genotypic AMR testing of Campylobacter spp. bacterial isolates;
- Only Public Health laboratories have the capacity to perform detection, identification and antimicrobial susceptibility testing of *Campylobacter* spp. isolates;
- Only 11% laboratories are accredited to the SM SR EN ISO 15189:2014 clinical standard (MOLDAC), plus the NRL. The other laboratories are accredited by National Health Assessment and Accreditation Council;
- Insufficient financial resources for accreditation and re-accreditation to the SM SR EN ISO 15189:2014 clinical standard for all labs in the network;

Weaknesses in the laboratory network identified during the mapping exercise (2)

- The laboratories did not participate in the EQA exercise for Campylobacter spp.;
- None of labs performs molecular tests for Salmonella and Campylobacter, because of insufficient financial resources for reagents acquisition.
- There is no connection between the Public Health laboratory information system and other laboratories from medical institutions.
- Data on AMR is reported by paper, no software is used for this purpose, only a few laboratories and the National Reference Laboratory collect the data and use e-IRF (CAESAR) and WHONET.

Gaps in the laboratory network identified during the mapping exercise (1)

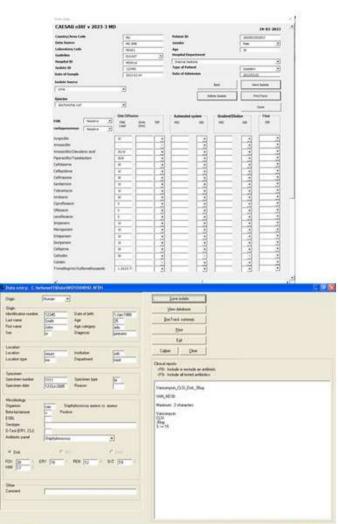
- Laboratories perform phenotypic or genotypic AMR testing of bacterial isolates in accordance with national methodical indications,
- The "EU protocol for harmonized monitoring of antimicrobial resistance in human Salmonella and Campylobacter isolates" is not officially implemented at the national level.
- Only Public Health Labs report Campylobacter spp. isolates to National Agency for Public Health, according existing legislation.
- Clinical microbiological labs have not implemented the methodology for diagnostic of infections caused by Campylobacter spp.
- The laboratories rate the staffing situation in relation to the workload resulting from the testing of *Salmonella* and *Campylobacter* as not fully adequate and the most affected areas are:
 - >quality assurance;
 - diagnostic testing;
 - ➤paperwork and accreditation procedures;
 - >training and continuing education of staff.

Gaps in the laboratory network identified during the mapping exercise (2)

 The AMR surveillance of pathogens is done according to the legislative framework

(Order of Ministry of Health No. 711 / 2018).

- All isolates of Salmonella spp. from blood, CSF and stool are reported,
- Campylobacter spp. is not included in the list of reported pathogens.
- A digital system for reporting data on AMR isolates is not implemented.
- The NRL collects the data from the network labs on paper referral sheets, then reports it to CAESAR and GLASS using e-IRF and WHONET software.



Strengths in the laboratory network identified during the mapping exercise (1)

- Network labs have recommendations, national guidelines and SOPs regarding the submitting of clinical samples.
 Guidance documents are developed and distributed by the National Reference Laboratory, printed and laid out with WHO support.
- All labs have implemented the EUCAST methodology (EUCAST disk diffusion method for antimicrobial susceptibility testing, Guidance documents and Expert rules and expected phenotypes, clinical breakpoints).
- The disc-diffusion method, MIC determination methods, including automated methods, according to EUCAST recommendations, are used to perform antimicrobial susceptibility tests.
- All labs use control materials from reliable sources, the NRL provides control
 materials/strains for detection/identification and antimicrobial susceptibility
 testing for Salmonella spp. and Campylobacter spp. in order to ensure the
 quality of investigations.
- All laboratories hold accreditation certificates (either CNEAS or MOLDAC SM SR EN ISO 15189:2014).



Strengths in the laboratory network identified during the mapping exercise (2)

 Laboratories from national network have the capacity to detect, identify and test antimicrobial susceptibility by classical and/or automated methods for Salmonella spp.







- Laboratories from territorial PHC have the capacity to detect, identify and test antimicrobial susceptibility for strains of Campylobacter spp.
- The NRL provides support on standardization of detection, identification, antimicrobial susceptibility testing methods for Salmonella spp., Campylobacter spp.:
- ✓ "Microbiological diagnosis of intestinal infections" for the detection of Salmonella spp.
- ✓ "Laboratory diagnosis of Campylobacter in human and food products" for the detection of Campylobacter spp.

DIAGNOSTICUL DE LABORATOR
AL CAMPYLOBACTER ÎN PROBE UMANE
ȘI PRODUSE ALIMENTARE

Indicatii metodice

Chisinău, 2019

Strengths in the laboratory network identified during the mapping exercise (3)

- Labs send identified isolates of Salmonella spp. to the NRL for further testing (Order of Ministry of Health No. 711 of 2018)
- Campylobacter spp. is currently not reported for AMR surveillance.
- Territorial Public Health Laboratories are obliged send for confirmation to the NRL all isolates of Campylobacter spp.

(According to Order of Ministry of Health No. 2 / 2015 towards the approval of the Instruction regarding the monitoring of causative agents of diarrhea and other acute diarrheal diseases)

- Labs provide guidance on sampling practices of patients suspected to be infected with Salmonella spp.
 and Campylobacter spp.
- Labs send positive AMR isolates and the referral sheet form to the NRL.
- All laboratories are members of CAESAR and GLASS, they send data to these networks, but after confirmation of susceptibility and resistance mechanisms by NRL.

Next steps in improving national laboratory network for Salmonella spp. and Campylobacter spp. (1)

- ➤ Implementation of the "EU protocol for harmonized monitoring of antimicrobial resistance in human *Salmonella* and *Campylobacter* isolates" at national level;
- ➤ Implementation of the diagnostic methodology for infections caused by *Salmonella* spp. and *Campylobacter* spp. in all laboratories;
- ➤ Accreditation of all laboratories to the SM SR EN ISO 15189:2014 clinical standard, use of reference materials for all laboratory activities. Internal audit on the quality assurance of the results;
- ➤ Training of laboratory staff on diagnostic methods and phenotypic or genotypic characterization of *Salmonella* spp. and *Campylobacter* spp.;

Next steps in improving national laboratory network for Salmonella spp. and Campylobacter spp. (2)

- ➤ Identification of financial resources for the acquisition of tests and the coverage of diagnostic investigations especially for *Campylobacter* spp.;
- Extending the list of pathogens in the National AMR Epidemiological Surveillance System with the addition of *Campylobacter* spp.;
- ➤ Identification of financial resources for the maintenance of laboratory information systems and the implementation of the national integrated digital system;
- ➤ Digitization of AMR data reporting by labs from national network and staff training on electronic reporting of AMR data, including data for *Salmonella* and *Campylobacter*.

Thank you for your attention!

