

Civil Society Engagement in The Fight Against AMR: From the New National Plan in Italy To the AMR Patient Alliance at The European Level

Mariano Votta^{1*} and Maira Cardillo²

¹Director, Active Citizenship Network, c/o Cittadinanzattiva APS, Via Imera, 2 - 00183 Rome, Italy.

²Junior Project Manager, Active Citizenship Network, c/o Cittadinanzattiva APS, Via Imera, 2 - 0183 Rome, Italy.

*Corresponding author

Mariano Votta, Director, Active Citizenship Network, c/o Cittadinanzattiva APS, Via Imera, 2 - 00183 Rome, Italy.

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Abstract

The World Health Organization (WHO) has recognized antimicrobial resistance (AMR) as one of the top 10 public health threats worldwide, as it compromises the ability to treat even minor infections and puts surgical procedures and other advanced, life-saving medical interventions at serious risk [1]. The year 2025 will mark 10 years since the adoption of the WHO Global Action Plan against AMR [2], and despite the progress made to date, there is still a need to initiate concrete and effective actions to eradicate this phenomenon, which is still too little widespread in the collective consciousness: it is no coincidence that some experts label it with the name "silent tsunami" [3], while others speak of a "neglected pandemic" [4], and already this is a message that should not be overlooked, and a more than valid reason to engage in the fight against AMR. In this regard, how to raise awareness, and what contribution can be expected from civic organizations and patients' advocacy groups (PAGs) in support of initiatives – both institutional and non-institutional – to counter AMR? This article illustrates an experience of civic activism that has managed to cross national borders from Italy.

Keywords: Antimicrobial Resistance (AMR), Health Threat, Vaccination, European Union, Immunization, Patients' Rights, Civic Participation, Patients' Advocacy Groups (PAGs)

AMR in Italy & at the EU level: introductory overview

Antimicrobial resistance (AMR) is a serious threat to global public health, economic well-being, and security. If no action is taken, it is estimated that antimicrobial resistance will result in a loss of \$100 trillion in economic output each year by 2050 and most importantly in the loss of 10 million lives worldwide [5, 6].

Before the pandemic, the phenomenon caused about 33,000 deaths in Europe each year from infections caused by antibiotic-resistant bacteria: of these, more than 10,000, or one-third of the total, occur in Italy [7]. This is the sad record held by Italy, which tops the continental rankings for the number of deaths linked to antimicrobial resistance, according to a report published by the Istituto Superiore di Sanità on the occasion of the 2019 World Antimicrobial Awareness Week (WAAW) [8]. Among the causes is certainly an inappropriate use of antibiotics, not only in the human but also in the veterinary field, and

still today the epicenter of this drama is the hospital, where a series of incorrect behaviors, such as infrequent hand washing by healthcare workers, also affect it. According to a study by the European Centre for Disease Prevention and Control (ECDC), in 2019 the risk - in Italy - of contracting infections during a hospitalization was about 6%. On an absolute level we are talking about 530 thousand cases each year, data that put Italy in last place among all countries in Europe [9].

To all this should be added that antibiotic consumption in Italy is higher than the European average (both at the territorial and hospital level, especially in the age groups between 2 and 5 years old and over 85 years old) and that, above all, in our country antibiotics are inappropriately prescribed in a quarter of cases, according to the 2020 National Report on Antibiotic Use in Italy, edited by the Italian Medicines Agency (AIFA) [10].

In a nutshell, experts warn that by 2050, globally, antimicrobial resistance could cause more deaths than cancer [11], but more importantly, without effective action, AMR will take us back to a pre-antibiotic era when death from infection was much more common: and this is another message not to be overlooked.

It would be enough to become aware of this scenario to recognize its urgency and thus the need for action, also in light of the principles established by the European Charter of Patients' Rights [12],

Including:

- the right to compliance with quality standards *"Everyone has the right to access high-quality healthcare services, based on the establishment and adherence to precise standards. The right to quality healthcare services requires that healthcare facilities and professionals practice satisfactory levels of technical performance"*.
- the right to information: *"Everyone has the right to access all kinds of information concerning both his or her health status and health services and how to use them, as well as all the information that scientific research and technological innovation make available"*.
- Above all, the right to safety: *"Everyone has the right to be free from harm resulting from the malfunction of healthcare services, malpractice, and medical errors, and has the right to access healthcare services and treatment that ensure high standards of safety"*. In order to guarantee this right, the Charter claims *"hospitals and health services must continuously monitor risk factors and ensure that electronic health devices are maintained in good condition and that operators are trained appropriately. All healthcare professionals must be fully responsible for the safety of every step and element of medical treatment. Doctors must be able to prevent the risk of errors through background monitoring and constant education. Healthcare staff members who report the existence of risks to their superiors and/or colleagues must be protected from possible adverse consequences"*.

Fighting paradoxes on AMR in the age of Covid-19 from a citizen perspective

One of the ten most urgent threats for Global Health but totally underestimated among the populations; more dangerous than car accidents & cancer but not enough prioritized in the EU and National public health policies. Interlinked with Covid-19 pandemic but almost ignored by the media. The world is losing its most powerful tool in healthcare, antibiotics, and in the meantime, research is still waiting for EU incentive mechanisms as well as an overall strategy to integrate the development of - and access to - affordable and of quality antimicrobials.

Despite the fight against Antimicrobial Resistance (AMR) requires policies focused on the prevention and extension of vaccinations, the health expenditure for prevention programmes is the "Cinderella" of the public health budget.

Patient engagement efforts on increasing awareness on AMR are not accompanied by more widespread initiatives targeted to citizens: how do we behave at the supermarket with regards to foods produced "without any use of antibiotics"? What lies be-

hind this label and why it should not be overlooked? How can we value our informed choices as consumers? These are some of the paradoxes on AMR addressed in occasion of the European training course open to the leaders of PAGs across Europe and organized on 4th July 2022 in a digital format by Active Citizenship Network (ACN) [13], the European branch of the Italian NGO Cittadinanzattiva [14], established in 1978 to promote citizens' activism for the protection of rights, the care of common goods, the support for people in conditions of weakness.

The mentioned training course was realized in the framework of the European project "AMR Patient Alliance – developing educational repository for patient and caregiver awareness of drug resistant infections" [15] and was promoted by the International Alliance of Patients' Organizations (IAPO) [16] and its IAPO P4PS Observatory [17] in partnership with the Spanish patients' association ALCER [18] and Cittadinanzattiva/Active Citizenship Network. This is one of the most recent activities on the subject put in place by Cittadinanzattiva, which for its long-standing commitment on the topic in Italy, it is formally a member of the Gruppo Tecnico di Coordinamento (GTC) del PNCAR (PNCAR Technical Coordination Group) [19], established by the Decree of the Director General for Health Prevention [20] from the Italian Ministry of Health of November 3, 2017. The Technical Group has the task of coordinating, monitoring, and updating the National AMR Plan and Strategy, to harmonize the strategies already in place, and facilitate the achievement of short- and medium- to long-term goals.



Figure 1: Save the Date realized for the Italian training course organized on 4 July 2022 in the framework of the European project "AMR Patient Alliance – developing educational repository for patient and caregiver awareness of drug resistant infections".

Towards the new Italian Action Plan on Antimicrobial Resistance

Always in Italy, Cittadinanzattiva recently helped formulate recommendations in light of the new National Plan for the Fight against Antimicrobial Resistance (PNCAR), which is as urgent as ever also considering that the previous one had a duration of 2017-2020 [21], later extended for 2021. The PNCAR represents a tool to translate the national strategy into practice, providing a coordinated and sustainable direction to counter AMR at the national, regional, and local levels through a multi-sector "one health" approach [22].

In particular, Farindustria (the association set up by the pharmaceutical companies operating in Italy) [23] promoted the

establishment of a multidisciplinary Task Force, to which, representatives from the academic-scientific world, civic and patient associations – including Cittadinanzattiva – and the pharmaceutical industry, all participated with the aim of providing recommendations on combating AMR. The recommendations [24] that emerged from this Task Force covered the following aspects:

1) Role of vaccine prevention as a tool to combat antimicrobial Resistance

a) National Vaccine Registry

Quickly complete the National Vaccine Registry and make it accessible throughout Italy. Indeed, this is a fundamental tool for planning vaccination campaigns for all preventable diseases, managing the administration of vaccinations, and the timely supply of an adequate number of vaccines to meet the health demands of the population. It will also support the collection of data and evidence on the positive role of vaccinations in combating AMR, as well as the implementation of the Electronic Health Record with the entry of the vaccinations performed.

b) Vaccinations & Diagnostic and Therapeutic Care Pathways

Include all vaccinations, including those foreseen in the National Vaccine Prevention Plan (PNPV) calendar, within Diagnostic and Therapeutic Care Pathways (Percorsi Diagnostici Terapeutici Assistenziali – PDTAs – in Italian) [25] in a uniform manner nationwide to protect people with one or more diseases from the risks of contracting vaccine-preventable infectious diseases.

c) Vaccination culture

Encourage the training of health professionals on the issue, with particular reference to the mechanisms through which vaccines are able to combat the spread of antimicrobial resistance; promote communication to citizens to create a culture of vaccination, including from a perspective of combating antimicrobial resistance; and encourage the achievement of the vaccination coverage targets set out in the National Vaccine Prevention Plan (PNPV).

d) National Plan for the Fight against Antimicrobial-Resistance & National Vaccine Prevention Plan

Highlight the key role of vaccination in combating antimicrobial resistance in both the new National Plan for the Fight against Antimicrobial Resistance (PNCAR) and the new National Vaccine Prevention Plan (PNPV), both of which are being updated by the Ministry of Health in the first half of 2022.

e) Shared position by scientific societies

Develop an official position shared by the scientific societies on the role played by the vaccinations foreseen in the National Vaccine Prevention Plan (PNPV) calendar in the fight against AMR, with the aim to support, through multidisciplinary, the value of vaccinations.

2) Value, access, and innovation of the new antibiotics against bacterial resistance [26]

a) Evaluation methodology of the new antibiotics against resistant bacterial strains

Adapt current methodologies for determining the value of antibiotics to the characteristics of these drugs, keeping in mind that this will require a broader perspective and analysis of scenarios and evidence beyond those needed for current registration applications.

b) Criteria for the granting of "innovative" drug status to the new antibiotics against resistant bacterial strains

Use specific indicators capable of effectively measuring the degree of innovativeness of new antibiotics, adapting, if necessary, the current evaluation elements supporting the claim of innovativeness (therapeutic need, added therapeutic value and robustness of scientific evidence).

c) Ad hoc reimbursement models for the new antibiotics active for bacterial resistance

Given that antimicrobial stewardship will give restrictive guidance on the use of new antibiotics in the treatment of infections caused by resistant strains to reduce the likelihood that new forms of resistance will develop, it is necessary to identify reimbursement modalities [27] that will provide developers with enough economic return to increase and maintain R&D investment in this area over time.

3) Appropriate use of antibiotics

a) Healthcare facilities

Use the resources provided for the "Health" Mission of the National Recovery and Resilience Plan (NRRP) [28], to address the structural, technological, and organizational deficiencies that to date have been barriers to the full implementation of the actions contained in the National Plan in the Fight against Antimicrobial Resistance (PNCAR).

b) Training of healthcare professionals

Ensure that the funds provided by the NRRP regarding the initiation of an extraordinary training plan on care-related infections to all the healthcare and non-healthcare staff in hospitals and primary care, are directed toward specific programs on antimicrobial stewardship and infection control.

c) Multidisciplinary teams

Guarantee the presence of a multidisciplinary team (medical experts, microbiologists, hospital pharmacists, etc.) within health facilities with the responsibility for defining stewardship programs and their implementation.

d) Administration of new antibiotics

Ensure timely access to new antibiotics in urgent and emergency situations by extending the prescription of these "life-saving" drugs to other specialists with specific expertise on antibiotic use (intensivists, hematologists, etc.) by providing for it as part of antimicrobial stewardship projects.

In addition, in the context of precise therapeutic recommendations, it might be useful to provide a "regulated free access window", which would enable patients to timely receive the necessary treatment during the first decisive hours.

4) Integration between antibiotic stewardship and diagnostic stewardship

Develop antibiotic stewardship programs that are strongly integrated with diagnostic stewardship ones in the definition of the Diagnostic and Therapeutic Care Pathways in a uniform manner nationwide.

5) Informing citizens

Promote communication campaigns targeted not only to patients, but to the whole population, on the appropriate and informed use of antibiotics, aiming to raise the level of citizen awareness.

Towards an AMR citizens' alliance

Hand in hand with its work at the national level, on the topic of antimicrobial resistance (AMR) Cittadinanzattiva has also engaged extensively at the European level, through its EU branch Active Citizenship Network. In particular, since 2018:

- Were promoted training initiatives targeted to leaders of civic and patient associations; communication campaigns [29] in the context of the "World Antimicrobial Awareness Week" which is celebrated every year in November (from the 18th to the 24th) by the World Health Organization (WHO); institutional meetings at the European Parliament to raise awareness on patients' rights for the Interest Group of MEPs, called MEPs Interest Group "European Patients Rights and Cross-border Healthcare" [30] promoted by Active Citizenship Network since 2015.

- For instance, in the aftermath of the 2019 European elections, 17 organizations active in the field of human and animal health (including Active Citizenship Network) sent an open letter [31] to the new members of the European Parliament urging them to consider antimicrobial resistance among the priorities of their mandate and to support the establishment of a parliamentary group dedicated to the issue, in collaboration with civil society and other stakeholders.

- Not surprisingly, Active Citizenship Network is among the associations in the "AMR Stakeholder Network" [32] supporting the "MEPs fight AMR" [33], the Interest Group of MEPs dedicated to antimicrobial resistance (AMR) and promoted by the European Public Health Alliance (EPHA) in late 2019.

- Since many years Cittadinanzattiva/Active Citizenship Network participates to the "Global Anti-Infectives (AI) & Antimicrobial Resistance (AMR) Patient Advocacy Advisor Summit" [34], open also to international – and not only European – stakeholders.

- Above all, Cittadinanzattiva/Active Citizenship Network is one of the few civil society organizations to have succeeded in being officially recognized as a collaborating stakeholder to the Stakeholder Forum of the European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI) [35], the most important initiative on the topic launched in 2017 by the European Commission to foster collaboration among European countries to implement "One Health" policies to tackle antimicrobial resistance (AMR) and healthcare-associated infections (HCAI).

The EU-JAMRAI, which ended in 2021, involved 44 European partners and more than 40 stakeholders [36]. In this context, among other factors, Active Citizenship Network also contrib-

uted - as a member of the jury of the EU-JAMRAI Antibiotic Resistance Symbol Contest [37] - to the definition of an international symbol with which to recognize the threat of antimicrobial resistance (AMR) and the initiatives to combat it.



Figure 2: International symbol of Antimicrobial Resistance (AMR) defined in the context of the EU-JAMRAI Antibiotic Resistance Symbol Contest, held on 18 November 2019 and of which Active Citizenship Network was part as a member of the jury.

- In 2020, Active Citizenship Network dedicated the 14th European Patients' Rights Day celebrations [38] to the topic of antimicrobial resistance (AMR), a decision made before the outbreak of the pandemic: the Covid-19 pandemic later reinforced this decision, considering the interconnections between the two emergencies. In fact, as one can recall, at the beginning of the pandemic, before the discovery of the Covid-19 vaccine, antibiotics were widely used in Sars-Cov-2 patients: hence the concern that the combination of sometimes an uncontrolled demand for antibiotics and, on the other hand, the empirical use of antibiotics seen in the first wave of the pandemic may have led to a further increase in antimicrobial resistance.



Figure 3: Save the Date realized in occasion of Active Citizenship Network's 14th European Patients' Rights Day entitled "ONE health approach, MULTIPLE answers: citizens' engagement & stakeholders' actions to tackle antimicrobial resistance and sustain EU progress" held on 18-19 November 2020

- In particular, during the European Patients' Rights Day focused on AMR, the International Alliance of Patients' Organizations (IAPO) officially announced the "AMR Patient Alliance" and its commitment, together with Active Citizenship Network and other PAGs and relevant international experts as members of its Advisory Group, to draft

a “Global Patient Consensus Statement and Call to Action on Antimicrobial Resistance” [39]. Through the Consensus Statement and Call to Action patient communities pledge to support actions to address AMR through four pillars: raising AMR awareness and strengthening health literacy; advocating for evidence-based solutions; ensuring a patient-centered approach in antimicrobial development and access; strengthening public health measures. The aim of this advocacy initiative is to call on patients first, and then also on civil society more in general, to commit to bigger engagement in both advocacy, education, awareness-raising and everyday activities related to this fight.

Conclusion

Reducing the misuse of antibiotics by prioritizing their proper use seems to be one of the preconditions for preserving their effectiveness and limiting the emergence of resistance. On the other hand, it should be reiterated that antibiotics represent a value to safeguard and a public health priority. Therefore, it is also necessary to support research, promote good practices for example in the areas of hygiene and sanitation in healthcare that are capable of reducing antimicrobial resistance and simultaneously ensure savings for the healthcare system, accelerate the approval of new antibiotics for the treatment of resilient infections. As for ourselves, we are well aware that there is a huge discrepancy between the seriousness of the situation and the low level of citizens’ awareness, not only in Italy. We cannot just wait for November’s World Antimicrobial Awareness Week (WAAW) [40], when the world turns its attention to this silent killer threatening to revert a century of medical progress in the treatment of infectious diseases. It is necessary to play a role since the beginning because “AMR is the battle we can fight together, and it’s one we have to start now” as underlined during the 14th European Patients’ Rights Day focused on AMR.

The problem is not a simple one, and solutions are certainly complex and interrelated. We know that progress would be slow, and the current pandemic has only set further challenges in achieving this goal. Our generations have enjoyed the 20th century discovery of antibiotics, and we need to make sure their efficacy will serve future generations as well. Appropriate antibiotic use is everybody’s business, and it is essential if we want to preserve the antibiotics and other antimicrobials’ effectiveness for as many patients as possible, and for as long as possible.

Declarations

Each of the authors confirms that this manuscript has not been previously published by another international peer-review journal and is not under consideration by any other journal. Additionally, all of the authors have approved the contents of this paper and have agreed to the submission policies of the journal.

Authors’ contribution

Each named author has substantially contributed to conducting the underlying research and drafting this manuscript. Additionally, to the best of our knowledge, the named authors have no conflict of interest, financial or otherwise.

Conflict of interest

The authors listed on the first page declare that they do not have any conflict of interest.

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References

1. World Health Organization (WHO): Antimicrobial Resistance.
2. WHO Global Action Plan against AMR.
3. The silent tsunami: stemming the tide of AMR in the Covid-era.
4. Infezioni Obiettivo Zero: “The neglected pandemic of antimicrobial resistance”.
5. Epicentro Istituto Superiore di Sanità: Epidemiological Aspects.
6. International Coalition of Medicines Regulatory Authority: Statement of the World Medicines Regulatory Authority on Combating Antimicrobial Resistance.
7. Quotidiano Sanità: Antimicrobial resistance, draft Plan expected in 2021. 40 mln euro funding each year. The announcement at Camerae Sanitatis.
8. Il Fatto Quotidiano: “Antibiotic resistance, ISS: “Italy first among EU countries in number of deaths”.
9. Quotidiano Sanità: Antimicrobial resistance, draft Plan expected in 2021. 40 mln euro funding each year. The announcement at Camerae Sanitatis.
10. Italian Medicines Agency (AIFA): 2020 National Report on Antibiotic Use in Italy.
11. Epicentro Istituto Superiore di Sanità: Epidemiological Aspects.
12. Active Citizenship Network: European Charter of Patients’ Rights.
13. Active Citizenship Network.
14. Cittadinanzattiva.
15. Active Citizenship Network: “AMR Patient Alliance – developing educational repository for patient and caregiver awareness of drug resistant infections” European project.
16. International Alliance of Patients’ Organizations (IAPO).
17. IAPO P4PS Observatory.
18. Federación Nacional de Asociaciones ALCER (Asociación para la Lucha Contra las Enfermedades del Riñón).
19. Ministero della Salute: PNCAR Technical Coordination Group.
20. Ministero della Salute: Decree of the Director General for Health Prevention (IT language).
21. National Plan for the Fight against Antimicrobial Resistance (PNCAR).
22. National Plan for the Fight against Antimicrobial Resistance (PNCAR), 2017-2020, leaflet.
23. Farindustria.
24. Farindustria Task Force: Report “Recommendations for an effective strategy against Antimicrobial Resistance”, June 2022.
25. Diagnostic and Therapeutic Care Pathways represent a tool used worldwide that aims to standardize the clinical approach to certain categories of patients (IT language).
26. Cassini, A., Högberg, L. D., Plachouras, D., Quattrocchi,

-
- A., Hoxha, A., Simonsen, G. S., ... & Hopkins, S. (2019). Attributable deaths and disability-adjusted life-years caused by infections with antibiotic-resistant bacteria in the EU and the European Economic Area in 2015: a population-level modelling analysis. *The Lancet infectious diseases*, 19(1), 56-66.
27. Dovepress: Dutescu, I. A., & Hillier, S. A. (2021). "Encouraging the Development of New Antibiotics: Are Financial Incentives the Right Way Forward? A Systematic Review and Case Study. *Infection and drug resistance*". <https://doi.org/10.2147/IDR.S287792>
 28. National Recovery and Resilience Plan (NRRP):
 29. Health Europa Quarterly: "Fighting the AMR Paradoxes in the Age of Covid-19", December 2020.
 30. MEPs Interest Group "European Patients' Rights and Cross-border Healthcare".
 31. Open letter to the Members of the European Parliament on the importance to sustain EU progress in fighting against antimicrobial resistance (AMR), September 2019.
 32. European Public Health Alliance (EPHA): AMR Stakeholder Network.
 33. European Public Health Alliance (EPHA): MEPs fight AMR.
 34. Active Citizenship Network: Our policy on patient safety: focus on Healthcare-Associated Infections (HAIs) and Antimicrobial Resistance (AMR).
 35. Stakeholder Forum of the European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI).
 36. EU-JAMRAI: "A New European Action to Tackle Antimicrobial Resistance and Healthcare-Associated Infections", 2020.
 37. European Joint Action on Antimicrobial Resistance and Healthcare-Associated Infections (EU-JAMRAI).
 38. Active Citizenship Network: 14th European Patients' Rights Day.
 39. AMR Patient Alliance: Global Patient Consensus Statement and Call to Action on Antimicrobial Resistance.
 40. World Health Organization (WHO): World Antimicrobial Awareness Week (WAAW).

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