



EUROHEALTH

RESEARCH • DEBATE • POLICY • NEWS



➤ Tackling Antimicrobial Resistance

- Strengthening implementation of AMR national action plans
- Fostering the development of novel antibiotics
- Tackling AMR in the community
- Quantifying the benefits of vaccines in combating AMR
- Integrating primary care and public health
- Access to health services in Serbia
- Norway's Healthcare Communities
- Patient safety and medical liability in Italy

EUROHEALTH

Quarterly of the
European Observatory on Health Systems and Policies
Eurostation (Office 07C020)
Place Victor Horta/Victor Hortaplein, 40/10
1060 Brussels, Belgium
T: +32 2 524 9240
F: +32 2 525 0936
Email: contact@obs.who.int
<http://www.healthobservatory.eu>

SENIOR EDITORIAL TEAM

Sherry Merkur: +44 20 7955 6194 s.m.merkur@lse.ac.uk
Gemma Williams: +44 20 7107 5304 g.a.williams@lse.ac.uk
David McDavid: +44 20 7955 6381 d.mcdavid@lse.ac.uk

EDITORIAL ADVISOR

Willy Palm: palmw@obs.who.int

FOUNDING EDITOR

Elias Mossialos: e.a.mossialos@lse.ac.uk

LSE Health, London School of Economics
and Political Science
Houghton Street, London WC2A 2AE, United Kingdom
T: +44 20 7955 6840
F: +44 20 7955 6803
[http://www2.lse.ac.uk/LSEHealthAndSocialCare/
aboutUs/LSEHealth/home.aspx](http://www2.lse.ac.uk/LSEHealthAndSocialCare/aboutUs/LSEHealth/home.aspx)

EDITORIAL ADVISORY BOARD

Paul Belcher, Reinhard Busse, Josep Figueras,
Julian Le Grand, Willy Palm, Suszy Lessof, Martin McKee,
Elias Mossialos, Richard B. Saltman, Sarah Thomson

DESIGN EDITOR

Steve Still: steve.still@gmail.com

PRODUCTION MANAGER

Jonathan North: northj@obs.who.int

SUBSCRIPTIONS MANAGER

Caroline White: caroline.white@lshtm.ac.uk

Article Submission Guidelines

Available at: <http://tinyurl.com/eurohealth>

Eurohealth is a quarterly publication that provides a forum for researchers, experts and policymakers to express their views on health policy issues and so contribute to a constructive debate in Europe and beyond.

The views expressed in *Eurohealth* are those of the authors alone and not necessarily those of the European Observatory on Health Systems and Policies or any of its partners or sponsors. Articles are independently commissioned by the editors or submitted by authors for consideration.

The Observatory is a partnership, hosted by WHO/Europe, which includes other international organizations (the European Commission, the World Bank); national and regional governments (Austria, Belgium, Finland, Ireland, Norway, Slovenia, Spain, Sweden, Switzerland, the United Kingdom and the Veneto Region of Italy); other health system organizations (the French National Union of Health Insurance Funds (UNCAM), the Health Foundation); and academia (the London School of Economics and Political Science (LSE) and the London School of Hygiene & Tropical Medicine (LSHTM)). The Observatory has a secretariat in Brussels and it has hubs in London at LSE and LSHTM and at the Berlin University of Technology.

© WHO on behalf of European Observatory on Health Systems and Policies 2020. No part of this publication may be copied, reproduced, stored in a retrieval system or transmitted in any form without prior permission.

Design and Production: Steve Still

ISSN 1356-1030



List of Contributors

Lucy Abel • Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Michael Anderson • Department of Health Policy, London School of Economics and Political Science, UK

Vesna Bjegovic-Mikanovic • Centre School of Public Health, University of Belgrade, Serbia

Chris Butler • Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Fidelia Cascini • Department of Life Sciences and Public Health, Catholic University of the Sacred Heart, Italy

Mariangela Contenti • Fondazione Italia in Salute, Italy

Ben Cooper • Nuffield Department of Medicine, University of Oxford, UK

Federico Gelli • Fondazione Italia in Salute, Italy

Oliver van Hecke • Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Cristina Hernández-Quevedo • European Observatory on Health Systems and Policies, London School of Economics and Political Science, UK

Janko Jankovic • Centre School of Public Health, University of Belgrade, Serbia

Mark Jit • Department of Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine; Statistics, Modelling and Economics Unit, National Infections Service, Public Health England, UK

Aleksandra Jovic-Vranes • Centre School of Public Health, University of Belgrade, Serbia

Marina Karanikolos • European Observatory on Health Systems and Policies, London School of Hygiene & Tropical Medicine, UK

Elias Mossialos • LSE Health, Department of Health Policy, London School of Economics and Political Science, UK

Bernd Rechel • European Observatory on Health Systems and Policies, London School of Hygiene & Tropical Medicine, UK

Matthew Renwick • Department of Health Policy, London School of Economics and Political Science, UK

Walter Ricciardi • Department of Life Sciences and Public Health, Catholic University of the Sacred Heart, Italy

Anna Sagan • European Observatory on Health Systems and Policies, London School of Economics and Political Science, UK

Milena Santric-Milicevic • Centre School of Public Health, University of Belgrade, Serbia

Giada Scarpetti • Department of Health Care Management, Berlin Institute of Technology, Germany

Ingrid Sperre Saunes • Department of Health Services Research, Norwegian Institute of Public Health, Norway

Zorica Terzic-Supic • Centre School of Public Health, University of Belgrade, Serbia

Sarah Tonkin-Crine • Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Milena Vasic • Institute of Public Health of Serbia "Dr Milan Jovanovic Batut", Serbia

Dejana Vukovic • Centre School of Public Health, University of Belgrade, Serbia

Kay Wang • Nuffield Department of Primary Care Health Sciences, University of Oxford, UK

Eurohealth is available online at: <http://www.euro.who.int/en/about-us/partners/observatory/publications/eurohealth> and in hard-copy format. If you want to be alerted when a new publication goes online, please sign up to the *Observatory e-bulletin*: <http://www.euro.who.int/en/home/projects/observatory/publications/e-bulletins>

To subscribe to receive hard copies of *Eurohealth*, please send your request and contact details to: bookorder@obs.euro.who.int

Back issues of *Eurohealth* are available at: <http://www.lse.ac.uk/lsehealthandsocialcare/publications/eurohealth/eurohealth.aspx>

SYSTEMS FOR THE FUTURE

2 EDITORS' COMMENT

Eurohealth Observer

3 STRENGTHENING IMPLEMENTATION OF **ANTIMICROBIAL RESISTANCE NATIONAL ACTION PLANS** – Michael Anderson and Elias Mossialos

8 **FOSTERING** CLINICAL DEVELOPMENT AND COMMERCIALISATION OF **NOVEL ANTIBIOTICS** – Matthew Renwick and Elias Mossialos

12 **TACKLING ANTIMICROBIAL RESISTANCE** IN THE **COMMUNITY** – Oliver van Hecke, Sarah Tonkin-Crine, Lucy Abel, Kay Wang and Chris Butler

16 **QUANTIFYING THE BENEFITS OF VACCINES** IN COMBATING ANTIMICROBIAL RESISTANCE – Mark Jit, Michael Anderson and Ben Cooper

Eurohealth International

20 **INTEGRATING PRIMARY CARE AND PUBLIC HEALTH** – Bernd Rechel

Eurohealth Systems AND Policies

25 TOWARDS **EQUAL ACCESS TO HEALTH SERVICES** IN **SERBIA** – Vesna Bjegovic-Mikanovic, Milena Vasic, Dejana Vukovic, Janko Jankovic, Aleksandra Jovic-Vranes, Milena Santric-Milicevic, Zorica Terzic-Supic and Cristina Hernández-Quevedo

29 **NORWAY'S HEALTHCARE COMMUNITIES** ARE SET UP TO BUILD BRIDGES BETWEEN HOSPITALS AND PRIMARY CARE – Ingrid Sperre Saunes, Anna Sagan and Marina Karanikolos

34 **PATIENT SAFETY AND MEDICAL LIABILITY** IN **ITALY** – Fidelia Cascini, Mariangela Contenti, Giada Scarpetti, Federico Gelli and Walter Ricciardi

Eurohealth Monitor

38 NEW PUBLICATIONS

39 HSPM COUNTRY NEWS



© alphaspire, shutterstock

The release of the spring issue of *Eurohealth* coincides with health systems globally facing unprecedented challenges in light of the rapid spread of COVID-19. In this quickly evolving outbreak, it can be difficult to keep up with how countries are responding to the crisis. We would therefore like to draw our readers' attention to a new online COVID-19 Health System Response Monitor (<https://www.covid19healthsystem.org>). This innovative platform will clearly present country evidence by systematically mapping and analysing health system responses.

The extraordinary events brought about by the COVID-19 pandemic brings home the fundamental importance of investing in and building resilient health systems that can effectively absorb and respond to adverse shocks. It also serves as an important reminder that health is a global issue and tackling many of the greatest health threats of our time requires concerted multilateral and cross-sectoral collaboration and action. This is not only true when responding to infectious disease outbreaks, but also when confronting other critical issues that are not yet as prominent in public consciousness. One such issue, and the focus of this edition of *Eurohealth*, is Antimicrobial Resistance (AMR), recently identified by World Health Organization* as an 'urgent global health challenge' to be addressed in the next decade of action.

In this issue's **Observer** section we are pleased to introduce four articles that consider critical elements involved in tackling the complex problem of AMR. These articles draw on evidence from a recently published European Observatory on Health Systems and Policies/Cambridge University Press book '*Challenges to Tackling Antimicrobial Resistance: Economic and Policy Responses*'. In the first article, Anderson and Mossialos assess the implementation status of National Action Plans (NAPs) for AMR. Despite being a key mechanism to build engagement among stakeholders and coordinate a range of actions across human, animal, and environmental health, the authors find implementation across Europe has been inconsistent. Renwick and Mossialos next review the current state of the global market for antibiotics and antibiotic innovation, and identify progress and challenges in fostering antibiotic research and development. The crucial issue of tackling AMR in the community is then

considered by Hecke, et al. with the authors finding that a number of interventions targeting clinicians, patients and the public can be effective in optimising antibiotic prescribing and use in the community. Finally, Jit et al. explore the important role that vaccines can play in combating AMR, even though their value in doing so is often underestimated.

The article in the **International** section discusses integration between public health and primary care. The author discusses the factors that help this collaboration related to the outside environment, conditions within the organisation as well as interactions between team members.

In Eurohealth **Systems and Policies**, the articles provide an analysis of key issues emerging from the most recent Health System Reviews (HiTs) on Serbia and Norway. For Serbia despite having universal health coverage, the authors discuss the remaining inequities in the utilisation of health services. Norway's health care system is being reorganised via a local governance reform, with Healthcare Communities providing a new type of partnership between hospitals and their municipalities. In the final article on the implementation of Italy's 2017 law on patient safety and medical liability, Cascini and colleagues look at the path thus far and find that progress has been uneven and varies by region.

We hope you enjoy the issue and we wish you well over the coming weeks and months.

Sherry Merkur, *Editor*
Gemma Williams, *Editor*

Cite this as: *Eurohealth* 2020; 26(1).

* <https://www.who.int/news-room/detail/17-01-2020-lack-of-new-antibiotics-threatens-global-efforts-to-contain-drug-resistant-infections>

STRENGTHENING IMPLEMENTATION OF ANTIMICROBIAL RESISTANCE NATIONAL ACTION PLANS

By: Michael Anderson and Elias Mossialos

Summary: Antimicrobial resistance is one of the major challenges of our time. Countries use national action plans as a mechanism to build engagement among stakeholders and coordinate a range of actions across human, animal, and environmental health. However, implementation of recommended policies such as stewardship of antimicrobials, infection prevention and control, and stimulating research and development of novel antimicrobials and alternatives remains inconsistent. Improving the quality of governance within antimicrobial resistance national action plans is an essential step to improving implementation. Countries must engage with a cyclical process of continuous design, implementation, monitoring and evaluation to achieve these aims.

Keywords: *Antimicrobial Resistance, Antibiotic Resistance, Governance, Implementation*

Introduction

Antimicrobial resistance (AMR) is driven by inter-related dynamics in the human, animal, and environmental health sectors and is one of the most significant and complex public health issues of our time. Antimicrobials encompass a broad set of agents used to treat microbial infections such as antibiotics, antifungals, and antivirals. Effective antimicrobials are responsible for several breakthroughs in modern medicine, including many surgical procedures and cancer treatments.¹

Drug-resistant pathogens are already a major challenge for all health care systems. Approximately 670,000 infections occurred in European Union/European Economic Area (EU/EEA) countries

in 2015, leading to approximately 33,000 deaths. The health burden of infections due to bacteria resistant to antibiotics on the EU/EEA population is comparable to that of influenza, tuberculosis and HIV/AIDS combined.² If not addressed, AMR is projected to cost the global economy up to €90 trillion by 2050, due to losses in international trade, livestock production and increased health care expenditure.³

International and national efforts to combat AMR have grown steadily over the last two decades. Two landmark international developments include the launch of the World Health Organization (WHO) Global Action Plan on AMR in 2015, which asked all countries to develop national action plans (NAPs)

Michael Anderson is Research Officer and Elias Mossialos is Head of Department and Director of LSE Health, Department of Health Policy, London School of Economics and Political Science, London, UK. Email: M.Anderson@lse.ac.uk

by 2017,⁴ and the United Nations (UN) General Assembly political declaration on AMR in 2016 where countries committed to work at national, regional, and global levels to develop and implement multisectoral NAPs across human, animal, and environmental health in accordance with the ‘One Health’ approach.⁵

At the European level, the European Commission issued the “Communication on an Action Plan against the rising threats from AMR” in 2011.⁶ This was updated through the adoption of the 2017 EU One Health Action Plan against AMR, which includes the ambitions: (i) to make the EU a best practice region; (ii) boost research, development and innovation, and (iii) shape the global agenda.⁷

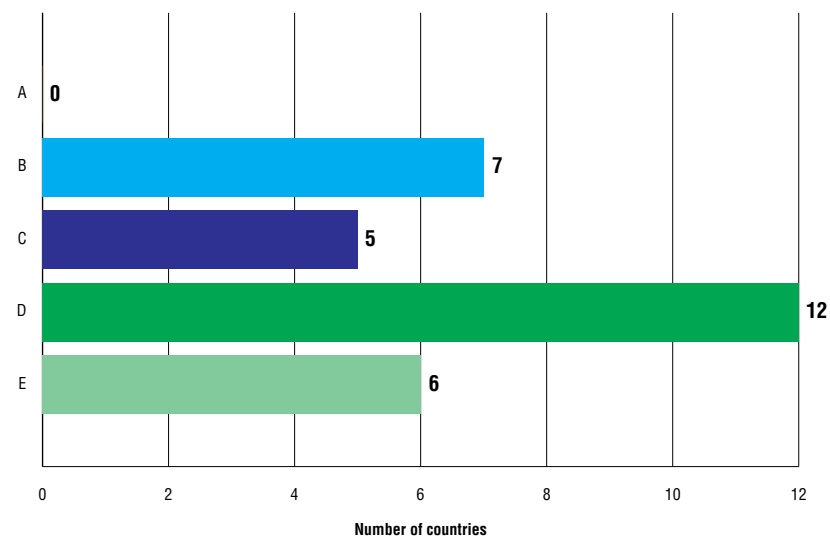
There is widespread consensus that the response to AMR requires multiple actions, including improving awareness and understanding of AMR, strengthening the knowledge and evidence base through surveillance and research, reducing the incidence of infection through effective sanitation, hygiene and infection prevention measures, optimising the use of antimicrobials in human and animal health and stimulating research and development (R&D) in novel antimicrobials and alternatives.⁸

Progress to date in implementing AMR national action plans

The UN Interagency Coordination Group on Antimicrobial Resistance (IACG) concluded that currently the greatest challenge in AMR is not designing a NAP but implementing it.⁹ The contrasting cultures, behaviours and incentives of each sector and relevant stakeholders is what makes the successful implementation of AMR NAPs so challenging. In the IACG’s final report to the Secretary-General of the UN, among other measures, the need to strengthen the implementation of One Health AMR NAPs was once again highlighted.⁹

The Food and Agriculture Organization of the UN, the World Organisation for Animal Health, and WHO together form a tripartite body that monitors country progress in developing policies to tackle AMR.¹⁰ The tripartite has established

Figure 1: Progress of EU/EEA countries in developing and implementing national action plans on AMR



Notes:

A – No national AMR action plan

B – National AMR action plan under development or plan involves only one sector or ministry

C – National AMR action plan developed that addresses human health, animal health and other sectors

D – Multi-sectoral AMR action plan approved that reflects Global Action Plan objectives, with an operational plan and monitoring arrangements

E – Multi-sectoral AMR action plan has funding sources identified, is being implemented and has monitoring in place

Source: ¹⁰

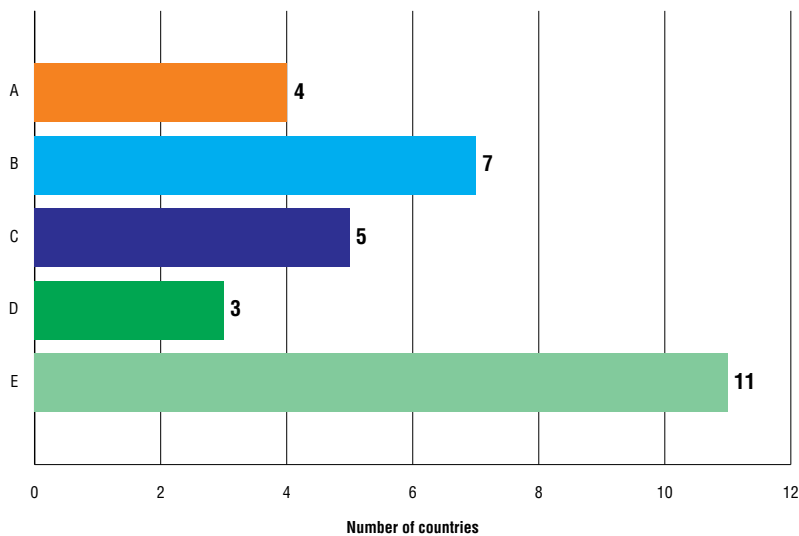
a Global Database for Antimicrobial Resistance Country Self-Assessment that provides information on a broad range of national policies and actions such as the existence of a One Health NAP, surveillance systems for antibiotic use and resistance pathogens, infection, prevention and control measures, and training of veterinary and health personnel. The database exposes how the strength of implementation of AMR NAPs varies significantly across EU/EEA countries. For example, while all EU/EEA countries have an AMR NAP implemented or under development, in 23% (7/30) of cases this only involves one sector or ministry. Many AMR NAPs do not have an operational plan or any monitoring plans, and only 20% (6/30) of EU/EEA countries have a multi-sectoral AMR action plan which has funding sources identified and is currently being implemented with monitoring in place (see Figure 1).

The necessitated ‘One Health’ approach recommended for AMR NAPs requires the participation of stakeholders across the human, animal, and environmental health

sectors. This is necessary during design and implementation to avoid initiatives and programmes operating in silos. A recommended approach taken by many countries is to use a national intersectoral coordinating mechanism (ICM), which offers a forum for relevant ministries and organisations to coordinate their actions. However, participation and coordination is also relevant within sectors, for example in human health across health care systems (primary, secondary and long-term care), as well as between public and private providers.¹¹ Most EU/EEA countries (87%, 26/30) have at least an intersectoral working group; however, only 37% (11/30) of countries have progressed to use an integrated ‘One Health’ approach during implementation of their NAP (see Figure 2).

Infection prevention and control (IPC) is a major component of any AMR NAP. Within human health, IPC involves a combination of actions such as hygiene measures (i.e. hand disinfection), the isolation of infected patients, screening of incoming patients, and environmental

Figure 2: Progress of EU/EEA countries in developing and implementing AMR 'One Health' national intersectoral coordinating mechanisms

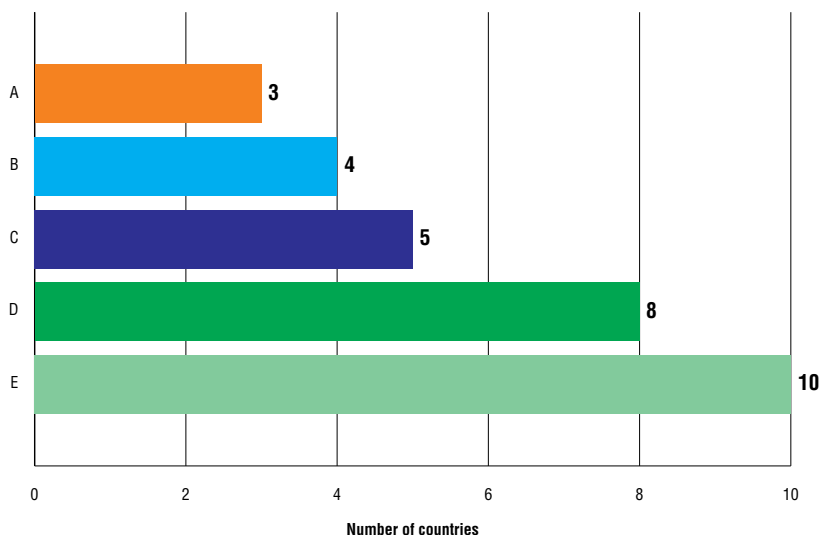


Notes:

- A – No formal multi-sectoral governance or coordination mechanism exists
- B – Multi-sectoral working group(s) or coordination committee on AMR established with government leadership
- C – Multi-sectoral working group(s) is (are) functional, with clear terms of reference, regular meetings, and funding for working group(s). Activities and reporting/accountability arrangements are defined
- D – Joint working on issues including agreement on common objectives, including restriction of use of critically important antimicrobials
- E – Integrated approaches used to implement the national AMR action plan

Source: ¹⁰

Figure 3: Progress of EU/EEA countries in developing and implementing infection prevention and control measures in human health settings



Notes:

- A – No national IPC policy or plan is available
- B – A national IPC policy or operational plan is available, with standard operating procedures (SOPs), guidelines and protocols available to all hospitals
- C – National IPC SOPs, guidelines and protocols are implemented in selected health care facilities
- D – Several infection control measures in IPC plans are implemented nationwide and monitored
- E – All relevant infection control measures are implemented in all targeted health facilities. Compliance and effectiveness regularly evaluated and published

Source: ¹⁰

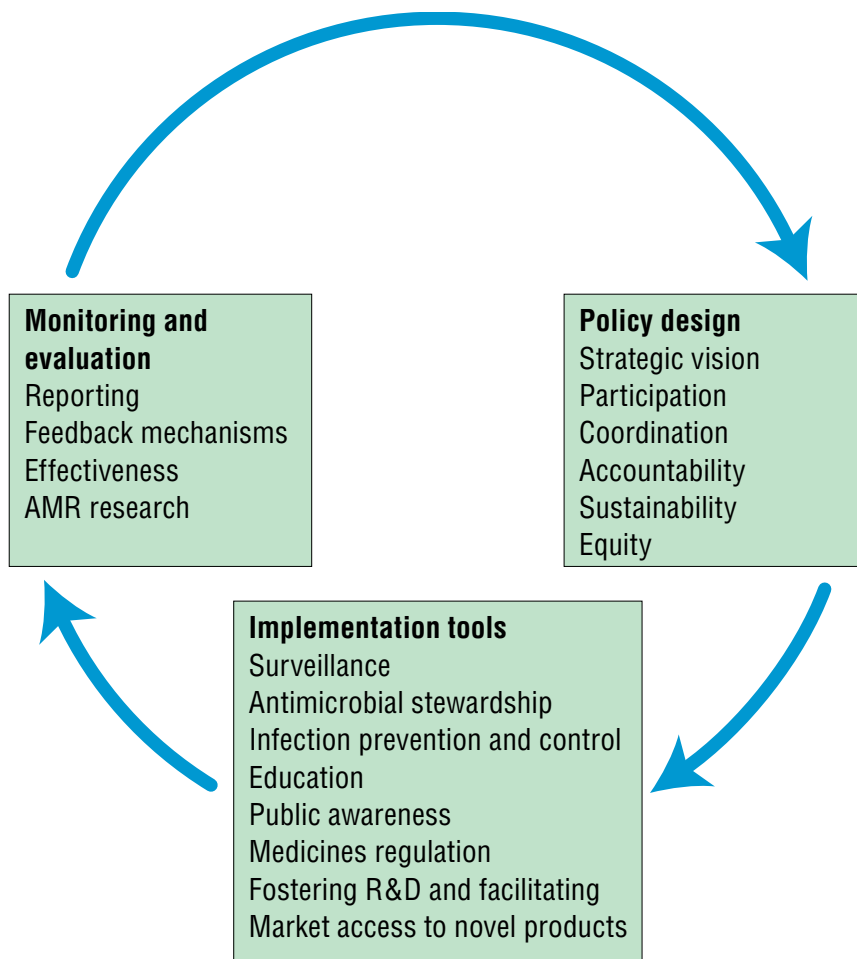
cleaning. IPC activities are typically supported by a multidisciplinary team including specialist infection control nurses and infectious disease physicians, and should take place across the whole health care system including hospitals, community and long-term care facilities. While 90% (27/30) of EU/EEA countries have a national IPC policy available, the degree of implementation, monitoring and evaluation of national IPC policy varies significantly (see Figure 2). Notably, compliance and effectiveness of IPC policies are only regularly evaluated and published in 33% (10/30) of countries.

“ requires the participation of stakeholders across the human, animal and environmental health sectors

A new approach to governance for AMR

By reviewing a few select examples from the WHO/FAO/OIE AMR tripartite database, it is clear that implementation of AMR NAPs is inconsistent. To overcome this, a key strategy is to improve governance. When defining governance, it is important to state it is not synonymous with government, but instead governance is concerned with actions by a broad range of societal organisations, how they relate to the public, and how decisions are taken. One commonly used governance framework, albeit from a health system perspective, dissects governance into five dimensions: Transparency, Accountability, Participation, Integrity and Capacity (TAPIC).¹² The London School of Economics and Political Science (LSE), in conjunction with colleagues from European Centre for Disease Prevention and Control (ECDC) have developed a

Figure 4: Antimicrobial resistance governance framework



Source: ¹³

governance framework, specific to AMR policy which draws upon similar principles (see Figure 4).

The framework consists of 18 domains with 52 indicators that are contained within three governance areas: policy design; implementation tools; and monitoring and evaluation. To consider the dynamic nature of AMR, the framework is conceptualised as a cyclical process, which is responsive to the context and allows for continuous improvement and adaptation of NAPs on AMR.

Policy design contains many fundamental governance principles seen in previous health system governance frameworks such as strategic vision and strong leadership, wide participation by relevant stakeholders in the development of NAPs, and coordination across multiple sectors and levels of service delivery (at national

and sub-national levels). Other domains contained within policy design include transparency regarding the development, participation and progress of AMR NAPs, sustainability in funding and planning of actions, equity implications of AMR policies, and determining who is ultimately accountable for achieving the objectives of the NAP.

Implementation tools consist of essential interventions outlined within international guidance from WHO, the Food and Agriculture Organization, the World Organisation for Animal Health, and the European Commission. These include domains on surveillance, antimicrobial stewardship programmes, infection prevention and control measures, education of relevant professionals, public awareness activities, and medicines regulation. The indicators within these domains reflect how they should be

implemented across the human, animal, and environmental health sectors. The final domain within this governance area covers whether there are appropriate policies and incentives in place to encourage R&D of novel antimicrobials and alternatives. More detail and evidence on effective implementation tools to tackle AMR is available in a book recently published by the European Observatory on Health Systems and Policies and the Organisation for Economic Co-operation and Development,¹⁴ and summarised in an associated policy brief.¹⁵

“the strength of implementation of AMR national actions is heavily reliant upon effective governance”

Monitoring and evaluation encompasses reporting and feedback mechanisms that allow for regular review and evaluation of AMR NAPs such as the publication of annual progress reports, and the feedback of surveillance data to health care and veterinary professionals. Other domains within monitoring and evaluation include ensuring mechanisms to evaluate the effectiveness and cost-effectiveness of AMR policies and interventions are in place, as well as ensuring there is a national multidisciplinary ‘One Health’ research agenda that aims to understand the drivers of and potential strategies to tackle AMR.

The framework has many benefits. First, it offers practical guidance to policymakers involved in the design, implementation, monitoring and evaluation of AMR NAPs, as well as providing a tool to allow independent assessment of the quality of governance of pre-existing AMR NAPs to increase accountability and stimulate

debate. Second, it emphasises the need for a ‘One Health’ approach throughout by highlighting the importance of coordination and participation across the human and animal health sectors. Thirdly, the cyclical nature of the framework ensures it is equally applicable to AMR NAPs at different stages of development, and facilitates continuous improvement. Finally, it succinctly and effectively summarises evidence from a broad range of sources including a review of health system governance frameworks, published guidance by international organisations such as WHO, FAO, OIE and the European Commission, and the input of 25 experts from other international organisations, government ministries, policy institutes, and academic institutions.

Conclusions

As well as a concerted global effort, there is a need for consistent and effective action at the national level to tackle AMR. To date, implementation of national policies to tackle AMR by countries has been inconsistent. To address this, improving the quality of governance within AMR NAPs that take a ‘One Health’ approach is essential. Countries should aim to engage with a cyclical process of continuous design, implementation, monitoring and evaluation that remains responsive to changing resistance patterns, behaviours and incentives of stakeholders, and technological developments.

References

- 1 Holmes AH, Moore LSPP, Sundsfjord A, et al. Understanding the mechanisms and drivers of antimicrobial resistance. *The Lancet* 2016;387: 176–87.
- 2 Cassini A, Högberg LD, Plachouras D, et al. 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* 2019;19(2):56–66.
- 3 O’Neill J. Tackling drug-resistant infections globally: final report and recommendations. *The Review on Antimicrobial Resistance*, 2016. Available at: https://amr-review.org/sites/default/files/160518_Final%20paper_with%20cover.pdf
- 4 World Health Organization. *Global Action Plan On Antimicrobial Resistance*, 2015. Available at: <https://www.who.int/antimicrobial-resistance/global-action-plan/en/>
- 5 UN. General Assembly. *High-Level Plenary Meeting on Antimicrobial Resistance*, 2016. Available at: <https://digitallibrary.un.org/record/842813?ln=en>
- 6 European Council. Communication from the Commission to the European Parliament and the Council: Action plan against the rising threats from Antimicrobial Resistance. *Official Journal of the European Union* 2011.
- 7 European Commission. *A European One Health Action Plan against Antimicrobial Resistance*, 2017. Available at: https://ec.europa.eu/health/amr/sites/amr/files/amr_action_plan_2017_en.pdf
- 8 Interagency Coordination Group on Antimicrobial Resistance. *Antimicrobial resistance: national action plans IACG Discussion Paper*, 2018. Available at: https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_AMR_National_Action_Plans_110618.pdf
- 9 IACG. *No Time to Wait: Securing the Future from Drug-Resistant Infections*. Report to the Secretary-General of the United Nations, 2019. Available at: https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1
- 10 WHO/OIE/FAO. *Global Database for Antimicrobial Resistance Country Self Assessment*, 2018. Available at: <https://amrcountryprogress.org/>
- 11 Dar OA, Hasan R, Schlundt J, et al. Exploring the evidence base for national and regional policy interventions to combat resistance. *The Lancet* 2016;387:285–95.
- 12 Greer SL. Governance: A framework. In Greer SL, Wismar M and Figueras J. *Strengthening Health System Governance: Better policies, stronger performance*. European Observatory on Health Systems and Policies Series. Maidenhead: Open University Press, 2014.
- 13 Anderson M, Schulze K, Cassini A, Plachouras D, Mossialos E. A governance framework for development and assessment of national action plans on antimicrobial resistance. *The Lancet Infectious Diseases* 2019;19:e371–84.
- 14 Anderson M, Cecchini M, Mossialos E. *Challenges in Tackling Antimicrobial Resistance: Economic and Policy Challenges*. European Observatory on Health Systems and Policies Series. Cambridge University Press, 2019
- 15 Anderson M, Clift C, Schulze K, et al. *Averting the AMR crisis: What are the avenues for policy action for countries in Europe?* European Observatory Policy Brief 32. Copenhagen: European Observatory on Health Systems and Policies. Available at: <https://www.ncbi.nlm.nih.gov/pubmed/31287637>

Challenges to Tackling Antimicrobial Resistance: Economic and Policy Responses

Edited by: Michael Anderson, Michele Cecchini and Elias Mossialos

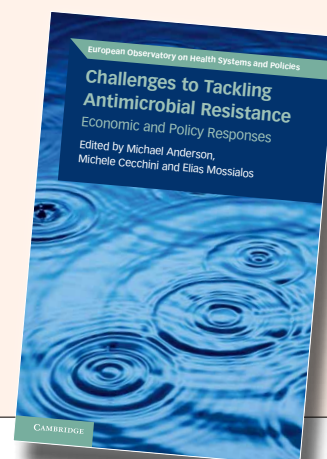
Cambridge University Press; ISBN: 978-1-108-79945-4

Produced with the financial assistance of the European Union

Available at: <https://tinyurl.com/TacklingAMR>

By bringing together in one place the latest evidence and analysing the different facets of the complex problem of tackling AMR, this book offers an accessible summary for policymakers, academics and students on the big questions around AMR policy. It provides:

- A comprehensive, multidisciplinary overview of policy areas relating to AMR
- An accessible summary of the latest scientific evidence available on effective policies to tackle AMR



- A summary of the economic challenges and responses relevant to AMR, such as quantifying the economic impact of AMR, encouraging the research and development of novel antimicrobials and diagnostics, and promoting the role of vaccines in combating AMR.

FOSTERING CLINICAL DEVELOPMENT AND COMMERCIALISATION OF NOVEL ANTIBIOTICS

By: Matthew Renwick and Elias Mossialos

Summary: Novel antibiotics are desperately needed to combat progressively resistant strains of bacteria, but there are too few innovative antibiotics in the clinical pipeline because of ongoing scientific, regulatory and economic challenges inherent to the antibiotics market. Global and national antibiotic incentive programmes are making progress in revitalising the pipeline but there are gaps in the incentivisation agenda. The pipeline could be improved by increasing funding of clinical trials to help drugs reach market approval, creating a market entry reward programme to facilitate commercialisation, and supporting coordinated international and national action on repairing the antibiotic pipeline and market.

Keywords: Antibiotics, Antimicrobial Resistance, Drug Discovery, Drug Development

Introduction

In the past, developing new antibiotics appeared to be the easiest solution to overcome resistant pathogens. As bacteria evolved to become resistant to certain antibiotics, treatment for these infections could be supplemented or replaced by newer generations of the same antibiotic or by a new, more effective class of antibiotic. The world saw a boom in new antibiotics and classes between 1940 and 1990 as pharmaceutical companies leveraged scientific breakthroughs and were rewarded with high-value patents.

However, due to a combination of financial, regulatory, and scientific barriers to continued development of

new antibiotics, the focus of research and development (R&D) shifted away to other therapeutic areas. In 1990, there were 18 major pharmaceutical companies active in antibiotic R&D, but by 2020 this number has fallen to eight and they continue to divest from the market.¹ The number of new antibiotics marketed each decade has also significantly decreased and no novel classes of antibiotics with distinct chemical structures have been developed.² In conjunction, global antibiotic consumption increased by 65% between 2000 and 2015, mostly driven by low- and middle-income countries.³ The void in R&D alongside uncontrolled use has meant that the

Matthew Renwick is Research Associate in Health Policy and Economics and **Elias Mossialos** is Head of Department and Director of LSE Health, Department of Health Policy, London School of Economics and Political Science, London, UK. Email: m.renwick@alumni.ubc.ca

antibiotic pipeline is frighteningly thin relative to the unrelenting advance of antibiotic resistance.

This article provides a brief summary of our recently published chapter in the book “Challenges to Tackling Antimicrobial Resistance.”* We review the current state of the global market for antibiotics and antibiotic innovation, as well as identifying progress and challenges in fostering antibiotic R&D. We highlight some key policy gaps that must be addressed and put forth possible solutions.

“Many drug candidates will be discarded on the way at a financial loss”

Current antibiotic pipeline

In 2017, the World Health Organization (WHO) published a priority pathogens list, which outlines the antibiotic-resistant bacteria that pose the greatest threat to global public health.¹ This list aims to guide antibiotic R&D based on medical need as opposed to the economic factors that have traditionally directed antibiotic investment. At the top of this list, categorised as “critical”, are the gram-negative, carbapenem-resistant strains of *A. baumannii*, *P. aeruginosa*, and the *Enterobacteriaceae* family, which are important causes of community and hospital-acquired infections. Carbapenems are a class of highly effective antibiotics that are often used as a last resort drug for treatment of severe bacterial infections. In 2013, the United States (US) Centers for Disease Control and Prevention (CDC) had published a US-focused urgent threats list for antibiotic resistance, which highlighted many of the same pathogens.

The most current pipeline assessment is conducted by The Pew Charitable Trusts. As of September 2019, there are 21 drugs in the pipeline that are expected to have activity against a WHO critical threat or CDC urgent pathogen: 7 in Phase I clinical trials, 5 in Phase II, and 9 in Phase III.² The Pew Trusts has also recently published a five-year longitudinal analysis of the antibiotic pipeline between 2014 and 2018 and concluded that the pipeline is stagnant and insufficient to meet the growing threat of antibiotic resistance.³ Over this period, 67 antibiotics were in clinical development, 10 of which stalled in development and 15 were discontinued. Ten drugs were approved during this period, but none of them targeted a WHO critical pathogen.

There is no single definition of what makes an antibiotic novel or innovative. Bacteria develop resistance to antibiotics through exposure and create protective mechanisms against frequently encountered antibiotics. The more unique a new antibiotic is compared to existing antibiotic structures means that bacteria are unlikely to have encountered the chemical components of the new antibiotic. Consequently, there is less risk for baseline resistance levels in target bacteria, known as cross-resistance, for these more unique antibiotics. Problematically, almost all of the pipeline drugs are redevelopments of classic antibiotic compounds or are combination therapies of existing antibiotic molecules.⁴ Of the 10 antibiotics approved between 2014 and 2018, only two drugs meet at least one of the WHO criteria for innovation: (1) known absence of cross-resistance to existing antibiotics; (2) new chemical class; (3) new target; or (4) new mechanism of action in terms of the biochemical process through which a drug produces its pharmacological effect.⁵

Barriers to antibiotic R&D

The success rate of moving an antibiotic from basic research to market approval is estimated to be between 1.5–3.5% and can take 15 years.⁶ The economic, regulatory, and scientific barriers to antibiotic R&D can best be categorised based on the steps of the antibiotic value chain: initial research, preclinical trials, clinical trials, market approval, and, finally, commercialisation.

The basic science and discovery research behind understanding and identifying new molecules for candidate drugs has been scientifically challenging. Bacteria, particularly gram-negative varieties, have proven highly resilient to recent experimental research on destruction mechanisms.⁷ Discovery research has predominantly been tackled by academics funded by the public sector, while clinical trials have been the domain of private pharmaceutical companies, thus leaving a gap in funding and appropriate actors in the preclinical phase.

Antibiotic clinical trials and post-approval follow-on trials have been estimated to cost on average \$130 million and \$146 million (about €117 million and €131 million), respectively.⁸ Many drug candidates will be discarded on the way at a financial loss. These costs and uncertainties are often prohibitively high for small and medium sized enterprises (SMEs). Despite the challenge of economies of scale, SMEs own a significant share of antibiotics in clinical development. An added practical challenge is that recruiting patients with acute bacterial infections for clinical trials is logistically difficult due to the short treatment windows and lack of rapid point-of-care diagnostic tools to identify participants.

Market approval of new antibiotics is necessary for ensuring the drug’s quality, safety and efficacy. However, there are procedural differences between national drug regulatory agencies in approving antibiotics that make global licensing time-consuming and expensive. These differences relate to patient selection criteria, definitions of clinical endpoints, specification of statistical parameters, and rules regarding expedited approvals.

Finally, the economic reward for commercialising a new antibiotic is minimal or negative relative to other therapeutic areas, such as neurologic, diabetes, and cardiovascular drugs.⁹ At present, novel antibiotics are not destined to generate significant revenue even with their immense public health value. Potential sales volumes are restricted by short treatment durations and hospital stewardship programmes that limit access. In addition, the large overlap in clinical

* See Anderson M, Cecchini M, Mossialos E. *Challenges in Tackling Antimicrobial Resistance: Economic and Policy Challenges*. European Observatory on Health Systems and Policies Series. Cambridge University Press, 2019.

application of newly patented antibiotics with existing generic alternatives places downward pressure on prices.

Incentive mechanisms for antibiotic R&D

Push and pull incentives are broadly used to classify the two main types of mechanisms for supporting antibiotic R&D.¹⁰ Push incentives, such as research grants, reduce the cost of researching and developing new antibiotics. In contrast, pull mechanisms increase the potential revenue of a successfully marketed antibiotic. This may be through outcome-based rewards that directly increase revenue such as monetary prizes, reimbursement premiums, advanced market commitments to purchase the drug, and patent buyouts by governments. If large enough, outcome-based pull rewards could replace the traditional revenue stream generated by the sales volumes of a licensed antibiotic. This concept is referred to as ‘delinkage’ since the antibiotic’s revenue would be delinked or decoupled from its sales, thus removing the incentive to promote the drug’s use.¹¹ Alternatively, pull mechanisms may be legal or regulatory, providing incentives such as accelerated procedures for marketing approval or extensions to the patent period.

A recent systematic review identified at least 47 different push and pull mechanisms, each with unique advantages and disadvantages.¹² These mechanisms must work together to target the economic criteria necessary for rebalancing the market: (1) improve profitability; (2) make market participation feasible for SMEs; (3) encourage investment by large pharmaceutical companies; and (4) facilitate cooperation across all stakeholders. In addition, an effective incentive package will support antibiotic sustainability and facilitate patient access to new antibiotics.

Programmes supporting antibiotic R&D

Promisingly, government agencies, non-governmental organisations, and drug developers have come together to form major international and national programmes to strengthen the antibiotic

pipeline. There are now over 58 different initiatives that incentivise the development of antibiotics, operating either at multilateral, European Union (EU), or national levels.¹³ At the multilateral level, key initiatives include the Joint Programming Initiative on Antimicrobial Resistance (JPIAMR), the Global Antibiotic Research and Development Partnership (GARDP), the Combating Antibiotic Resistant Bacteria Biopharmaceutical Accelerator (CARB-X), the European and Developing Countries Clinical Trial Partnership (EDCTP), and the Global Antimicrobial Resistance Innovation Fund (GAMRIF). Other important initiatives are the EU’s Innovative Medicines Initiative (IMI) and its subsidiary New Drugs for Bad Bugs Program (ND4BB), as well as the US Biomedical Advanced Research and Development Authority (BARDA).

Charitable organisations such as the Wellcome Trust and the Bill and Melinda Gates Foundation have been strong champions for combatting antimicrobial resistance and co-finance many of these initiatives. Finally, from a regulatory perspective, the Transatlantic Taskforce on Antimicrobial Resistance (TATFAR), a working group of technical experts from Canada, the EU, US, and Norway, has been collaborating and sharing strategies to support the antibiotic pipeline and improve the market approval process.

Policy implications and next steps

The extensive array of antibiotic R&D programmes and incentives is commendable, and strides are being made towards reviving the antibiotics pipeline. However, major antibiotic developers, such as Novartis and Sanofi, continue to divest from the market indicating that the antibiotics market is still highly dysfunctional and unappealing to developers.¹⁴ The end goal should be a continuum of incentivisation that reflects the economic need, cost distribution, and barriers of the entire antibiotic value chain. Our chapter delves into multiple ways this continuum can be repaired. However, for the purposes of this article we will discuss three of the most critical policy objectives that need to be addressed: (1) augment push-funding of antibiotic clinical trials;

(2) implement a strong pull incentive in the form of a global market entry reward for successful commercialisation of novel antibiotics; and (3) facilitate coordinated international and national action on repairing the antibiotic pipeline and market.

“the antibiotics market is still highly dysfunctional and unappealing to developers”

Most push-funding for antibiotic R&D is directed towards basic antimicrobial science and less so towards clinical development.¹⁵ While early-stage push-funding of antimicrobial science is integral to the R&D process, there is a need for more late-stage push-funding of preclinical and clinical trials to help translate scientific innovation into marketable products.¹⁶ As more drug candidates transition to clinical development, it may be beneficial to pool disparate early-stage push-funding and re-allocate it to late-stage push-funding to ensure viable antibiotics make it to the market approval stage. In addition, programmes like BARDA and the IMI, which specifically fund clinical trials, could be further expanded. SMEs would particularly benefit from this improvement in clinical funding.

Market entry rewards (MERs) have been repeatedly endorsed by health policy experts as an effective pull incentive for commercialisation and distribution of licensed antibiotics.¹⁰⁻¹⁴ A MER is a financial prize for the successful development of an innovative antibiotic that meets pre-defined criteria and adheres to conditions related to sustainability and patient access.¹⁷ A MER would offer the same revenue stream otherwise generated by a novel, patented drug on the market while removing the incentives for developers to drive up sales volumes

for profit. MER rewards can be tailored based on the degree of delinkage, total reward size, payout timeline, access and stewardship requirements, and other features.^{10 13}

It is expected that a MER would need to be approximately \$1 to 2 billion (about €900 million to €1.8 billion) per first-entrant novel antibiotic to entice developers to invest in R&D and gamble on inventive antibiotic projects.^{13 14} With the ten-year goal of bringing 10 to 15 novel antibiotics to market, a MER programme is estimated to cost between \$10 and \$30 billion (about €9 billion and €27 billion). Despite the abundance of expert literature calling for an international MER programme, no nation has been willing to take the lead in establishing such a global fund or make a firm financial commitment. This inaction stems from the large sums involved, insufficient political support, the complexity of coordinated action, and a lack of capacity and expertise to implement such a scheme.

Intra- and international cooperation and communication will be essential to increasing push funding efficiently and developing a global MER programme. Presently, national governments, global institutions, non-governmental organisations, and industry are independently investing their resources in antibiotic R&D projects and funding programmes.¹¹ This is partially responsible for the current mismatched and incomplete global incentives. In addition, many of the antibiotic R&D initiatives operate in isolation from other initiatives despite their commonalities. There is a clear risk of duplicating efforts with initiatives that have similar mandates and receive interweaving funding from different payers.

Born out of the 2017 G20 Summit, The Global Antimicrobial R&D Hub is an international partnership that aims to coordinate antibiotic R&D under a unified One Health continuum. The Hub is comprised of 19 countries, the European Commission, Wellcome Trust, and Bill and Melinda Gates Foundation. While still in its early stages of development, the Hub is well positioned to actively facilitate a

more balanced complement of incentive mechanisms. They could press for greater clinical development funding as well as implement and advocate for a global MER programme. This collaborative Hub is a large step towards unifying efforts; however, the Hub will need continued and growing political and financial support from many countries for it to become an effective international instrument against antibiotic resistance.

Countries should also be developing their own national action plans (NAPs) on antimicrobial resistance that reinforce global guidance from the Hub and other international organisations such as WHO, The Food and Agriculture Organization of the UN, and the World Organization for Animal Health. Anderson, et al. have proposed a framework that can help policy makers design, implement, monitor, and evaluate their national action plan.¹⁵ Part of a comprehensive national action plan involves creating a viable market for novel products within the country and fostering national R&D of antibiotics.

References

- 1 Access to Medicine Foundation. *Antimicrobial Resistance Benchmark 2020*. Available at: https://accessmedicinefoundation.org/media/uploads/downloads/5e43ebfba86d8_Antimicrobial_Resistance_Benchmark_2020.pdf
- 2 Silver LL. Challenges of antibacterial discovery. *Clin. Microbiol. Rev* 2011;24:71–109.
- 3 Klein EY, Van Boeckel TP, Martinez EM, et al. Global increase and geographic convergence in antibiotic consumption between 2000 and 2015. *PNAS* 2018;115:E3463–70.
- 4 World Health Organization. *Global priority list of antibiotic-resistant bacteria to guide research, discovery, and development of new antibiotics*, 2017. Available at: https://www.who.int/medicines/publications/WHO-PPL-Short_Summary_25Feb-ET_NM_WHO.pdf
- 5 Pew Charitable Trusts. *Antibiotics currently in global clinical development*, 2019. Available at: https://www.pewtrusts.org/-/media/assets/2019/08/arp_antibiotics_currently_in_global_clinical_development_data_table_v2.pdf?la=en&hash=F729686986DD0403BCF05F5E61F91AB545066B77
- 6 Lepore CJ, Kim W, Thomas J, Visi D, Talkington K. *Longitudinal Analysis of the Antibiotics Clinical Pipeline*, 2019. Available at: <https://www.pewtrusts.org/-/media/assets/2019/09/pipeline-trends-analysis-poster---aug-2019.pdf>
- 7 World Health Organization. *Antibacterial agents in clinical development*, 2017. Available at: https://www.who.int/medicines/areas/rational_use/antibacterial_agents_clinical_development/en/
- 8 The Review on Antimicrobial Resistance. *Securing new drugs for future generations: the pipeline of antibiotics*, 2015. Available at: https://amr-review.org/sites/default/files/SECURING_NEW_DRUGS_FOR_FUTURE_GENERATIONS_FINAL_WEB_0.pdf
- 9 Renwick MJ, Brogan DM, Mossialos E. A systematic review and critical assessment of incentive strategies for discovery and development of novel antibiotics. *Journal of Antibiotics* 2016;69:73–88.
- 10 Rex JH, Outtersson K. Antibiotic reimbursement in a model delinked from sales: A benchmark-based worldwide approach. *The Lancet Infectious Diseases* 2016;16:500–5.
- 11 Simpkin VL, Renwick MJ, Kelly R, Mossialos E. Incentivising innovation in antibiotic drug discovery and development: Progress, challenges and next steps. 2017;70:1087–96.
- 12 Kelly R, Zoubiane G, Walsh D, Ward R, Goossens H. Public funding for research on antibacterial resistance in the JPIAMR countries, the European Commission, and related European Union agencies: A systematic observational analysis. *Lancet Infect. Dis.* 2016;16:431–40.
- 13 Årdal C, Findlay D, Savic M, et al. *DRIVE-AB: Revitalizing the antibiotic pipeline – Stimulating innovation while driving sustainable use and global access*, 2018. Available at: <http://drive-ab.eu/wp-content/uploads/2018/01/DRIVE-AB-Final-Report-Jan2018.pdf>
- 14 The Review on Antimicrobial Resistance. *Tackling drug-resistant infection globally: Final report and recommendations*, 2016. Available at: https://amr-review.org/sites/default/files/160518_Final_paper_with_cover.pdf
- 15 Anderson M, Schulze K, Cassini A, Plachouras D, Mossialos E. A governance framework for development and assessment of national action plans on antimicrobial resistance. *The Lancet Infectious Diseases* 2019;19:e371–84.

TACKLING ANTIMICROBIAL RESISTANCE IN THE COMMUNITY

By: Oliver van Hecke, Sarah Tonkin-Crine, Lucy Abel, Kay Wang and Chris Butler

Summary: Antimicrobial resistance is an important societal issue. Making sure patients in the community get the right antibiotic at the right time is important to preserve our existing antibiotics. In this article, we discuss some of the interventions that have shown promise in optimising antibiotic-prescribing and use in the community, both in, and outside the consultation room. We outline the factors needed to evaluate the cost-effectiveness of such interventions in the context of antimicrobial resistance, and highlight the caveats and challenges for policymakers.

Keywords: Primary Care, Antimicrobial Stewardship, Intervention, Community

Introduction

Antimicrobial resistance (AMR) is an important societal issue and central to the global health policy agenda. Unless we make better use of our existing antibiotics now, 10 million extra people are likely to die each year by 2050 because of antibiotic-resistant bacteria (“superbugs”). However, the impact of AMR is broader than theoretical predictions of mortality rates. AMR is already affecting countries’ ability to reach their Sustainable Development Goals.

Poor infection prevention and control and antibiotic use are the two most important risk factors for a patient developing a resistant bacterial infection.¹ Likewise, at a population level, important public health factors such as rates of vaccine uptake, different health care systems and social norms, human migration and tourism, sanitation, and population densities will all influence the prevalence of AMR. Recent evidence from primary care shows that patients in the community with antibiotic-resistant infections are more difficult to

treat, making people sicker for longer and increasing the burden on the health service.² This suggests that we need to refocus our agenda by showing that AMR also adversely impacts on patients’ recovery from even common infections in the community.

In the United Kingdom (UK), over 70% of all antibiotics are prescribed in the community or ambulatory health care settings (general practice, outpatient, emergency departments) compared to hospital inpatient settings (11%).³ Primary care doctors (family doctors/general practitioners) and more recently, nurse practitioners and pharmacists working in community settings, are responsible for antibiotic prescribing.

Why is antimicrobial stewardship important?

In an era of antibiotic resistance, it is critical that patients receive the right antibiotic at the right time with the least harm to present and future patients. This is antimicrobial stewardship (AMS) in a

Oliver van Hecke is General Practitioner (GP) and NIHR Academic Clinical Lecturer, **Sarah Tonkin-Crine** is Senior Researcher and Health Psychologist, **Lucy Abel** is Health Economist, **Kay Wang** is NIHR Postdoctoral Fellow and GP, **Chris Butler** is GP and Professor of Primary Care, Nuffield Department of Primary Care Health Sciences, University of Oxford, Oxford, UK. Email: oliver.vanhecke@phc.ox.ac.uk

nutshell. In some parts of the world where there is an excess of antibiotic use, AMS strategies will involve optimising their use and improve the quality of prescribing. In resource-poor settings, AMS strategies will involve providing better access to antibiotics.

Patients presenting in primary care with respiratory, urinary, skin or dental infections account for the majority of antibiotic prescriptions. The vast majority of antibiotics (60%) are prescribed for acute respiratory tract infections (RTIs), such as your typical coughs, sore throats, earache.¹ Whilst antibiotics are effective for some RTIs (e.g. community-acquired pneumonia), the bulk of acute RTIs are self-limiting where there is no additional benefit from antibiotics. Thus, there is a need to reduce the number of prescriptions for these types of infections and to empower patients to self-manage their symptoms. For other infections, such as urinary or skin infections, antibiotics do offer more benefit for patients. For these presentations, the aim of AMS strategies may not be to reduce antibiotic prescriptions but instead to improve the quality of antibiotic prescribing by using first-line narrow-spectrum antibiotics, where appropriate.

“many interventions were trialled in European general practice and are therefore context-specific”

Promoting evidence-based antibiotic prescribing through AMS programmes is critical. However, such AMS efforts have largely been undertaken in hospitals rather than in the community. Therefore, it is important to strengthen AMS strategies in the community by implementing and evaluating community interventions to tackle AMR.

Table 1: Community interventions to optimise antibiotic-prescribing and use

	Intervention	Target
<i>During the consultation</i>	Education (guidelines, outreach visits, educational materials); Computerised decision support tools; Educational meetings; Audit and feedback; Financial incentives; Point-of-care tests (POCTs)	Clinician-focused
	Enhanced communication training; Shared-decision making; Delayed prescribing strategies; Patient educational materials	Clinician and patient-focused
<i>Outside the consultation</i>	National antibiotic awareness campaigns	Public

Source: Authors' own

Types of community interventions to tackle AMR

There have been many interventions targeted at clinicians, patients and the public (see Table 1). However, in this article we focus on specific interventions which appear to show promise in tackling AMR in community settings and for which there is more robust evidence than other interventions. Almost all interventions have focused on acute RTIs. Importantly, many interventions were trialled in European general practice and are therefore context-specific. This does not necessarily mean that other interventions would not be effective elsewhere, but context-specific evidence is needed.

Firstly, by empowering clinicians with enhanced communication strategies and shared-decision making, we consider the role of the patient in the consultation and can include intervention components targeted at the patient.² Clinicians tend to overestimate patient expectations for antibiotics which can contribute to unnecessary prescribing. Eliciting patient expectations for treatment and concerns about their illness, through specific communication techniques, can help a clinician to provide reassurance and information about self-care rather than an unnecessary antibiotic prescription.

Secondly, incorporating point-of-care tests (POCTs) or rapid diagnostic tests within the consultation have to potential to optimise antibiotic prescribing in primary care.^{3,4} However, we should be cautious.

The clinical and cost-effectiveness of POCTs are context-specific, and some POCTs, although accurate, do not provide additional diagnostic power over and above current clinical diagnosis, and do not contribute to better targeting of antibiotic treatment or benefit patients when used in clinical practice. For example, most of the evidence for POCTs is based on trial evidence from high-income European general practice, limited to acute RTIs in adults rather than in children.

Thirdly, delayed prescribing strategies to reduce antibiotic use. Delayed prescriptions are considered appropriate for infections which are mostly associated with self-limiting symptoms. When given a delayed prescription a patient is given information about the likely duration of symptoms and encouraged to only take antibiotics if symptoms continue for longer than expected or if symptoms worsen.⁵

Lastly, public antibiotic awareness campaigns. Campaigns have mostly been multi-faceted (e.g. patient informational material, mass media), often seasonal, focusing on RTIs, targeting specific age-groups and ‘at risk’ groups.⁶ The key messages in these campaigns have targeted the knowledge, attitudes and behaviours of patients seeking, or self-medicating with antibiotics, and informing the public that most RTIs are caused by viruses and thus cannot be treated by antibiotics. The evidence for their effectiveness is less clear, especially long-term. For example, in the UK, the “Antibiotic

Guardian Campaign” was launched in September 2014, aiming to increase awareness and engagement with AMR by health professionals and the public. The campaign included a website where people could make online pledges to act to reduce AMR (www.antibioticguardian.com). The impact of the campaign was assessed via an online survey sent to 9,016 self-selected “Antibiotic Guardians” to assess changes in self-reported knowledge and behaviour.¹⁰ Results indicated that this campaign led to increases in self-reported knowledge of AMR and self-reported behaviour change in line with pledges. However, respondents were mostly health care professionals or connected to the health care system; less than a third of respondents pledged as members of the public.

“the influence of culture and context on antibiotic use is currently underexplored”

A recent WHO evaluation of public-facing antibiotic awareness campaigns highlighted that the majority of campaigns are not based on behaviour-change theory and campaign evaluations had not determined whether these interventions had the desired effect of changing the public’s attitudes towards antibiotics and the impact on antibiotic resistance.¹⁰ Very few public campaigns have systematically evaluated their effect on efforts to reduce unnecessary antibiotic prescribing and antibiotic resistance. More recent work acknowledges that AMR needs to be reframed by creating tailored educational materials and awareness campaigns aiming to optimise antibiotic use on outcomes that people can relate to, and, importantly, ensure they reach their intended audience.¹¹

Assessing cost-effectiveness of community interventions

The uptake of AMS interventions relies on a compelling health-economic justification. There are a number of linked components to consider in assessing the cost-effectiveness of AMS interventions.

Firstly, effective AMS interventions need to reduce antibiotic prescribing without reducing health benefits. This is important because if reducing prescribing results in inferior health outcomes, then this will need to be weighed against the value of reducing the health consequences of future AMR, and against that of alternative interventions that may have improved health outcomes. Next, is the cost of the intervention. Many new interventions, such as POCTs, will cost considerably more than the antibiotics they replace. For example, in England, amoxicillin costs £0.91 (€1.05), while a CRP test costs £5.53 (€6.30), and if additional appointments are required, the cost of these extra resources will quickly add up.¹² However, most cost-effectiveness analyses continue to ignore AMR as an outcome or consequence entirely. This final component of AMS cost-effectiveness, the value of AMR itself in economic terms, is an opportunity cost to prevent AMR in terms of benefits foregone now, such as current health and cost savings.¹³ There is considerable uncertainty around both how much society is willing to give up to avoid future AMR.¹⁴ Importantly, all these components are required to make a transparent judgement on whether AMS interventions are truly cost-effective.

There have been a small number of interventions attempting to consider these outcomes in cost-effectiveness analysis. One study evaluated the proportion of societal costs, which have been estimated in several large analyses such as the O’Neill report,¹⁴ attributable to a single prescription of antibiotics. They then applied this single cost to each prescription to give some idea of the opportunity cost of antibiotic prescriptions in RTI.¹⁵ However, as yet, studies are unable to provide valid results on the cost-effectiveness of AMS strategies, and considerable methodological work in this area is still required.

Challenges for policymakers

Policymakers should be cautious about assuming that an intervention which is effective in one context is likely to be effective in another, whether that is due to a difference in health care organisation, culture or country. That said, it is encouraging to see that the same interventions (mentioned above) across multiple European countries, have been shown to be effective in different health care organisations and in health systems with different financial structures.¹⁶ However, we would caution that the influence of culture and context on antibiotic use is currently underexplored and other studies have highlighted that such factors may be a barrier in transferring effective interventions from one context/country to another, especially for low and middle-income countries where interventions could have significant resource implications and disrupt existing patient workflows.¹⁷

AMS interventions have tended to focus on reducing the overall antibiotic prescribing rate. However, this might be too simplistic. Quality indicators that focus on the diagnostic process are also needed for common infections managed in primary care, similar to those successfully employed in chronic diseases like diabetes and cardiovascular diseases, which have led to improved outcomes. Adopting quality indicators will likely improve the appropriateness of antibiotic prescribing and complement current financial incentives in primary care to reduce overall antibiotic prescribing.¹⁸ This is highlighted by a recent review where the majority of identified quality indicators focused on the choice of antibiotic (72%) rather than the diagnostic process leading to a diagnosis (6%), and the decision to prescribe an antibiotic (22%).¹⁹

Another limitation of the available evidence concerns the long-term effects of interventions. Many trials of interventions have focused on short-term outcomes, either a few weeks or months post-intervention with recent evidence showing the transience of initially effective interventions. For example, the use of enhanced communication strategies were more likely to have a long-term effect than the use of CRP-POCT when

reducing antibiotic prescribing for RTI.²⁰ This suggests that interventions based on enhancing the skills of health professionals may be implemented more easily than the use of novel technologies because there is potentially less disruption to clinical practice and skills can be rehearsed and learnt more easily.

“most cost-effectiveness analyses continue to ignore AMR as an outcome or consequence entirely

Lastly, policymakers should carefully consider the introduction of concurrent national public health campaigns that can be construed to be conflicting, e.g. sepsis campaigns advocating early detection and antibiotic administration versus antibiotic awareness campaigns encouraging self-care and promoting the use of fewer antibiotics.¹⁸ Likewise, there should also be an awareness that hospital-derived antibiotic stewardship measures, e.g. hand hygiene and infection control, might compete with the public's mistaken beliefs of being less “hygienic” to promote a young child's developing microbiome.

Conclusions

Policymakers wanting to address AMR should refocus their agenda by showing that AMR adversely impacts on patients' recovery from even common infections in the community. The literature to date has focused on RTIs in general practice. However, there are other common infections, e.g. urinary tract infections, where AMS strategies are urgently needed to optimise antibiotic prescribing. Reframing AMR into campaigns

that the general public can engage with are urgently needed. Evidence-based community AMS interventions require further evaluation in real-world settings, and include low and middle-income countries where little is known about the influences on antibiotic-related behaviours.

References

- Costelloe C, Metcalfe C, Lovering A, et al. Effect of antibiotic prescribing in primary care on antimicrobial resistance in individual patients: systematic review and meta-analysis. *BMJ* 2010;340:c2096.
- van Hecke O, Wang K, Lee J, et al. The implications of antibiotic resistance for patients' recovery from common infections in the community: a systematic review and meta-analysis. *Clin Infect Dis.* 2017;65(3):371–82.
- Public Health England. *English surveillance programme for antimicrobial utilisation and resistance (ESPAUR) 2018–2019*. London, 2019.
- Goossens H, Ferech M, Vander Stichele R, Elseviers M; ESAC Project Group. Outpatient antibiotic use in Europe and association with resistance: a cross-national database study. *The Lancet* 2005;365(9459):579–87.
- Tonkin-Crine SKG, Tan PS, van Hecke O, et al. Clinician-targeted interventions to influence antibiotic prescribing behaviour for acute respiratory infections in primary care: an overview of systematic reviews. *Cochrane Database Syst Rev.* 2017;9:CD012252.
- Aabenhus R, Jensen JUS, Jørgensen KJ, et al. Biomarkers as point-of-care tests to guide prescription of antibiotics in patients with acute respiratory infections in primary care. *Cochrane Database Syst Rev.* 2014;11.
- Stuart B, Hounkpatin H, Becque T. Delayed antibiotic prescribing for respiratory tract infections: protocol of an individual patient data meta-analysis. *BMJ Open.* 2019 Jan 21;9(1):e026925.
- Huttner B, Goossens H, Verheij T, Harbarth S. Characteristics and outcomes of public campaigns aimed at improving the use of antibiotics in outpatients in high-income countries. *The Lancet Infectious diseases* 2010;10(1):17–31.
- Chaintarli K, Ingle SM, Bhattacharya A, Ashiru-Oredope D, Oliver I, Gobin M. Impact of a United Kingdom-wide campaign to tackle antimicrobial resistance on self-reported knowledge and behaviour change. *BMC Public Health* 2016;16:393.
- Saam M, Huttner B, Harbarth S. *Evaluation of antibiotic awareness campaigns*. Geneva: WHO Collaborating Centre on Patient Safety, 2017.
- Van Hecke O, Butler CC, Wang K, Tonkin-Crine S. Parents' perceptions of antibiotic use and antibiotic resistance (PAUSE): a qualitative interview study. *J Antimicrob Chemother.* 2019;74(6):1741–7.

- Joint Formulary Committee. *British National Formulary (online)*. London: BMJ Group and Pharmaceutical Press, 2016. Available from: <http://www.medicinescomplete.com>
- Coast J, Smith RD, Millar MR. Superbugs: Should antimicrobial resistance be included as a cost in economic evaluation? *Health Econ* 1996;5(3):217–26.
- O'Neill J. Tackling Drug-Resistant Infections Globally: final report and recommendations, 2016. Available from: <https://amr-review.org/Publications.html>
- Opong R, Smith RD, Little P, et al. Cost effectiveness of amoxicillin for lower respiratory tract infections in primary care: an economic evaluation accounting for the cost of antimicrobial resistance. *Br J Gen Pract* 2016;66(650).
- Little P, Stuart B, Francis N, et al. The effect of web-based training in communication skills and an interactive patient booklet and the use of a CRP point of care test in acute respiratory tract infection (RTI): a multi-national cluster randomised factorial controlled trial. *The Lancet* 2013;382(9899):1175–82.
- Van Hecke O, Mendelson M, Butler CC, Tonkin-Crine S. Adopting point-of-care testing for common infections in South Africa: a qualitative study of primary care clinicians. *BMJ Open* 2019;25;9(11):e029260.
- Van Hecke O. *Antibiotic Prescribing and Resistance in Primary Care: Implications for Intervention*. Thesis (D.Phil.), University of Oxford, 2018.
- Saust LT, Monrad RN, Hansen MP, Arpi M, Bjerrum L. Quality assessment of diagnosis and antibiotic treatment of infectious diseases in primary care: a systematic review of quality indicators. *Scandinavian journal of primary health care* 2016;34(3):258–66.
- Cals JWL, de Bock L, Beckers P-JHW, et al. Enhanced Communication Skills and C-reactive Protein Point-of-Care Testing for Respiratory Tract Infection: 3.5-year Follow-up of a Cluster Randomized Trial. *Ann Fam Med* 2013;11(2):157–64.

QUANTIFYING THE BENEFITS OF VACCINES IN COMBATING ANTIMICROBIAL RESISTANCE

By: Mark Jit, Michael Anderson and Ben Cooper

Summary: Vaccination is one of the most effective measures to reduce antimicrobial resistance. As vaccines are highly specific to their targeted pathogens, they are less likely to induce resistance compared to antibiotics. Their impact on resistance or antibiotic prescriptions has already been demonstrated for vaccines against pathogens such as *Streptococcus pneumoniae* and influenza, but greater investment and development is needed for vaccines which target pathogens such as *Vibrio cholerae*, *Salmonella typhi*, *Escherichia coli*, common health care-associated infections and respiratory and diarrhoeal viruses. To value vaccines correctly, economic evaluations need to take account of multiple health system, ecological and epidemiological pathways through which vaccination affects antimicrobial resistance and use.

Keywords: Vaccines, Economic Evaluation, Antimicrobial Resistance

Introduction

The development and use of vaccines is a key strategy to combat antimicrobial resistance (AMR). A recently published chapter ‘The role of vaccines in combating antimicrobial resistance’ within the book; *Challenges in Tackling Antimicrobial Resistance: Economics and Policy Responses* offers a comprehensive review of this summary.¹ In this article we provide an overview of the key issues discussed in the chapter.

Vaccines have a number of characteristics which make them particularly effective at combating AMR. First, vaccines usually have little effect on the evolution of microorganisms besides the targeted

strains. This is because vaccines work by enabling the immune system to recognise antigens that are highly specific to their targeted pathogens. In contrast, antibiotics can impose selective pressure on both targeted and non-targeted microorganisms to develop resistance. Second, due to the specific nature of vaccines, vaccines can be developed that target specific strains of a pathogen that are most pathogenic or prone to developing resistance. This has been the case with pneumococcal conjugate vaccines, where the serotypes selected for vaccine development were generally the ones most likely to cause invasive disease.² Thirdly, vaccines and antimicrobials can work in a synergistic fashion – vaccines can reduce the rate

Mark Jit is Professor, Vaccine Epidemiology, Department of Infectious Disease Epidemiology, London School of Hygiene & Tropical Medicine, and Principal Mathematical Modeller, Statistics, Modelling and Economics Unit, National Infections Service, Public Health England, London, UK; **Michael Anderson** is Research Officer, Department of Health Policy, London School of Economics and Political Science, London, UK; **Ben Cooper** is Associate Professor, Nuffield Department of Medicine, University of Oxford, Oxford, UK. Email: mark.jit@lshtm.ac.uk

at which populations are infected and hence extend the time until a pathogen evolves resistance to an antimicrobial. Finally, vaccines can be administered only a few times and provide long-lasting population-wide effects by preventing the onset of disease. In contrast, antimicrobials need to be continuously administered with each infection. While they can be used prophylactically to prevent disease onset, more commonly they are used to treat rather than prevent infections. They also have less potential to prevent onward transmission of resistant microorganisms, as there is usually a delay between the onset of infectiousness and receiving treatment.

“The potential benefit of vaccines to reduce AMR is frequently underestimated”

Pathways by which vaccines can reduce AMR

The potential benefit of vaccines to reduce AMR is frequently underestimated because people only consider a subset of the pathways by which vaccines can affect antimicrobial use and resistance. In total, we consider six pathways by which vaccines can reduce the burden of AMR. ¹ ²

Pathway 1: *Preventing infections by focal pathogens*

Vaccines may reduce the incidence of infection by a resistant pathogen. This can occur both through direct protection to those vaccinated, and through indirect protection resulting from reduced exposure to the infection in the unvaccinated (herd immunity).

Pathway 2: *Bystander effects*

Any vaccines that lead to changes in antibiotic use could potentially have an impact on AMR in organisms

not targeted by the vaccine, such as commensal bacterial pathogens, as a result of reduced antibiotic selection pressure. For example, since influenza infections are frequently treated with antibiotics (either inappropriately for the primary viral infection, or for a secondary bacterial infection), an effective and widely used vaccine that reduces the number of influenza infections should result in population-wide reductions in antibiotic use.

Pathway 3: *Infection severity effects*

Vaccines that reduce the risk of symptomatic infection without reducing the risk of carriage/asymptomatic infection can lead to reductions in the proportion of infections which are treated with antimicrobials and therefore a reduction in the selection pressure for resistant phenotypes.

Pathway 4: *Subtype selection effects*

Some vaccines may target subtypes of a pathogen population which are more likely to be resistant. As a result, overall resistance may decrease. However, it is also possible that vaccines may target subtypes which are less likely to be resistant. In these circumstances, overall resistance may increase.

Pathway 5: *Interspecific effects*

Bacteria and viruses interact in complex ways. For example, influenza or respiratory syncytial virus (RSV) infections may increase the risk of secondary bacterial infections and patients with certain viral infections may transmit more bacterial pathogens. Vaccination against one organism could therefore reduce transmission of another, leading to declines in both resistant and sensitive phenotypes.

Pathway 6: *Selective targeting effects*

Interventions, such as hygiene improvements or vaccination, could lead to differential effects if targeted to certain population groups. For example, if a resistant strain of a given pathogen transmits preferentially in hospitals (where antibiotic use is high), targeting the hospital population with a vaccine could have a greater overall effect on

the resistant strain, leading to declines in resistance in both hospitals and the community.

Priorities for vaccine investment and development to tackle AMR

Vaccines are already used effectively to tackle AMR in many countries. In the United States, the introduction of the seven-valent pneumococcal conjugate vaccine (PCV7) was associated with an 84% reduction in multidrug-resistant invasive pneumococcal disease. ³ In the Canadian province of Ontario, the introduction of a universal influenza immunisation programme was associated with reductions in prescriptions of antimicrobials for respiratory tract infections. ⁴ However, to fully capitalise on the benefits of vaccines to tackle AMR there are a number of vaccine investment and development needs which need to be prioritised.

Vibrio cholerae

Resistant and multi-resistant cholera is a significant issue for many health care systems. An oral cholera vaccine which is effective at preventing medically-attended cholera already exists. ⁵ Use of this vaccine clearly has the potential to reduce AMR through its direct effect on cholera; however, there is a need for greater investment to increase access to this vaccine, particularly in low and middle income countries (LMICs).

Salmonella typhi

A ciprofloxacin-resistant lineage of *Salmonella typhi* infection has emerged in many countries. Two vaccines have been available since the 1990s and are recommended by the World Health Organization (WHO): the live Ty21a vaccine and the Vi-polysaccharide vaccine. ⁶ While they are both effective, their protection is partial and relatively short-lived, typically up to two years. However, there are several promising next-generation conjugate vaccines in development, including two vaccine candidates having received licensure in India. ⁷ Gavi, the Vaccine Alliance, has opened a funding window for this vaccine, which will help increase access to these vaccines in LMICs.

Escherichia coli

Infections caused by *E. coli* are a major cause of morbidity and associated antibiotic use. In particular, enterotoxigenic *E. coli* (ETEC) is a leading cause of diarrhoea in children in developing countries. Ciprofloxacin-resistant ETEC strains represent a major challenge for ETEC treatment strategies in some parts of the world. While there are no licensed vaccines for ETEC, vaccine development for ETEC is a WHO priority. There are a number of ETEC vaccine candidates in development and currently undergoing phase II trials. The introduction of an ETEC vaccine could play an important role in reducing resistance primarily through its impact on reduced antibiotic consumption but also through reduced bystander selection.

“AMR does not respect borders, and many countries will simultaneously benefit from effective vaccines”

Health care associated infections

Multi-resistant health care associated infections are a common issue across all health care systems. They are particularly prevalent in hospital settings, where antibiotics exert high selection pressure. Vaccines against some of these infections are in development. For example, there are ongoing phase II/III clinical trials for *Staphylococcus aureus* and *Pseudomonas aeruginosa*, which are opportunistic infections that are common causes of skin, respiratory and urinary tract infections.¹⁰ The “ESKAPE” pathogens (*Enterococcus*, *Klebsiella*, *Acinetobacter*, *Enterobacter*) are responsible for some of the most

severe AMR problems. Yet, with the exception of *P. aeruginosa*, there is little activity in developing vaccines or other immunotherapies for these pathogens that has extended beyond animal models and it is thought unlikely that these vaccines will be available within the next 10 years. Major technical hurdles to developing vaccines for these “ESKAPE” pathogens exist such as limited understanding of pathogen biology including natural immunity, limited knowledge of vaccine targets, the existence of multiple strains and a complex epidemiology where resistance determinants frequently move between different bacterial strains and species.

Viral infections

Respiratory syncytial virus (RSV) is a common virus that can cause cold-like symptoms in adults and is also the causative agent for bronchiolitis in children. There is no licensed RSV vaccine, but a number are undergoing clinical trials, including vaccines that are likely to be optimal for the paediatric population as well as some that are likely to be appropriate for pregnant women and older people. Viruses are also responsible for many diarrhoeal illness, and vaccines against these viruses may also lead to reductions in antibiotic use and reduced resistance by altering bystander selection. For example, the well-established rotavirus vaccines protect against the most common cause of severe diarrhoea in young children and can prevent up to a third of severe diarrhoea cases in developing countries.¹¹ Finally, a vaccine against norovirus is a priority for development. Norovirus accounts for nearly 20% of all cases of acute gastroenteritis.¹² Two candidate vaccines have reached clinical trials and there are a number of candidates at preclinical development stages.¹³

Quantifying the economic benefit of vaccines that prevent antimicrobial resistance

The value for money of a vaccination programme can be estimated using an economic evaluation such as a cost-effectiveness analysis, which considers the balance between the incremental costs and incremental health impacts of an intervention. As discussed throughout this

article, AMR reduction is a key benefit of vaccines but a recent review of published models of the impact of vaccines on the dynamics of AMR did not find any studies that considered the economic value of this benefit.⁴

The simplest way to estimate the benefit of vaccines that prevent AMR is to multiply the reduction in risk of acquiring a resistant strain in vaccinated individuals with the health detriment and financial cost of being infected with such a strain. However, there are several reasons why this approach may be too limited. First, as discussed, there are several other pathways by which vaccines can combat AMR, including herd immunity, bystander effects, infection severity effects, subtype effects, interspecific effects, and selective targeting effects. Therefore, the benefit of vaccination must be measured taking account of these pathways. Second, several reviews have highlighted how the wider benefits of vaccination on households and economies are often overlooked.¹⁴ The economic cost of AMR is substantial when considering reductions in labour productivity, the need to fund research into developing new antimicrobials, and the implications of potentially being unable to perform routine medical procedures such as surgery because of untreatable surgical site infections.¹⁵ Finally, it is important to consider the global nature of the benefits of vaccines that prevent AMR. AMR does not respect borders, and many countries will simultaneously benefit from effective vaccines. Economic models rarely consider this externality, which may discourage manufacturers from developing vaccines. This market failure could be addressed through mechanisms like advanced market commitments and market entry rewards, which have effectively been utilised by Gavi and others for pneumococcal vaccines.

Access to vaccines

Positively, there has been growing attention to the role of vaccines in reducing the health burden of infectious diseases and combating AMR. The result is a promising vaccine development pipeline. However, there are concerns regarding the prices of vaccines and the subsequent implications for equity

of access, particularly in LMICs. The cost of fully vaccinating a child with all WHO recommended vaccines has risen from \$0.67 in 2001 to \$45.59 in 2014.¹⁶ There was also a 12-year gap between the first high-income country introduction of hepatitis B vaccines and the first introduction in a low-income country.¹⁷ Gavi was set up in 2000 as a public–private partnership in order to address this access gap. However, most middle-income countries, including some of the highest users of antibiotics, are not eligible. Vaccine purchasers in middle-income countries need strong economic rationales to introduce new vaccines in the face of many competing health priorities. Hence, establishing the value proposition for vaccine development and use has become increasingly important.

Conclusions

Vaccines are crucial to combating AMR. However, when quantifying the economic benefit of vaccines, their impact on AMR is often ignored. Adequately valuing this benefit is important in prioritising the vaccine development pipeline, as well as choosing between alternative interventions (such as a new vaccine and a new antibiotic). To fully capture the value of vaccines in reducing AMR, three sets of pathways need to be quantified. First, the *health system pathway*, which governs the impact of vaccines on antimicrobial prescriptions. This will require clinical trial and surveillance data on antimicrobial prescription rates. Second, the *epidemiological pathway*, which governs the impact of vaccines on AMR (both directly and through reduced prescribing). This will require dynamic transmission

models that capture both direct and indirect effects of vaccines. Finally, the *economic pathway*, which governs the value of reduced AMR. This will make use of macroeconomic models which explore the long-term consequences of alternative resistance rates on labour productivity, the need to continuously develop new antibiotics and antibiotic classes, as well as the wider health-system effects.

References

- Jit M, Cooper B. Chapter 8: The role of vaccines in combating antimicrobial resistance. in Anderson M, Cecchini M, Mossialos E. *Challenges in Tackling Antimicrobial Resistance: Economic and Policy Challenges*. European Observatory on Health Systems and Policies Series. Cambridge University Press, 2019.
- Hausdorff WP, Bryant J, Paradiso PR, et al. Which pneumococcal serogroups cause the most invasive disease: implications for conjugate vaccine formulation and use, part I. *Clin Infect Dis* 2000;30(1):100–21.
- Lipsitch M, Siber G. How can vaccines contribute to solving the antimicrobial resistance problem? *mBio* 2016;7(3):e00428.
- Atkins KE, Lafferty EI, Deeny SR, et al. Use of mathematical modelling to assess the impact of vaccines on antibiotic resistance. *Lancet Infect Dis* 2018;18(6):e204–13.
- Kyaw MH, Lynfield R, Schaffner W, et al. Effect of introduction of the pneumococcal conjugate vaccine on drug-resistant *Streptococcus pneumoniae*. *New Engl J Med* 2006;354(14):1455–63.
- Kwong JC, Maaten S, Upshur RE, et al. The effect of universal influenza immunization on antibiotic prescriptions: an ecological study. *Clin Infect Dis* 2009;49(5):750–56.
- Azman AS, Parker LA, Rumunu J, et al. Effectiveness of one dose of oral cholera vaccine in response to an outbreak: A case-cohort study. *Lancet Glob Health* 2016;4(11):e856–63.
- Anwar E, Goldberg E, Fraser A, et al. Vaccines for preventing typhoid fever. *Cochrane Database Syst Rev* 2014;1:CD001261.
- Meiring JE, Gibani M, TyVAC Consortium Meeting Group. The Typhoid Vaccine Acceleration Consortium (TyVAC): Vaccine effectiveness study designs: accelerating the introduction of typhoid conjugate vaccines and reducing the global burden of enteric fever. Report from a meeting held on 26–27 October 2016, Oxford, UK. *Vaccine* 2017;35(38):5081–8.
- Czaplewski L, Bax R, Clotie M, et al. Alternatives to antibiotics – a pipeline portfolio review. *Lancet Infect Dis* 2016;16(2):239–51.
- Soares-Weiser K, Maclellan H, Bergman H, et al. Vaccines for preventing rotavirus diarrhoea: Vaccines in use. *Cochrane Database Syst Rev* 2012;2:CD008521.
- Ahmed SM, Hall AJ, Robinson AE, et al. Global prevalence of norovirus in cases of gastroenteritis: A systematic review and meta-analysis. *Lancet Infect Dis* 2014 14(8):725–30.
- Cortes-Penfield NW, Ramani S, Estes MK, et al. Prospects and challenges in the development of a Norovirus vaccine. *Clin Ther* 2017;39(8):1537–49.
- Jit M, Hutubessy R, Png ME, et al. The broader economic impact of vaccination: reviewing and appraising the strength of evidence. *BMC Medicine* 2015;13:209.
- Jit M, Ng DHL, Luangsanatip N, Sandmann F, et al. Quantifying the economic cost of antibiotic resistance and the impact of related interventions: rapid methodological review, conceptual framework and recommendations for future studies. *BMC Med* 2020;18(1):38.
- Médecins Sans Frontières The right shot: bringing down barriers to affordable and adapted vaccines, 2nd edn. Geneva: MSF, 2015. Available at: <https://msfaccess.org/right-shot-bringing-down-barriers-affordable-and-adapted-vaccines-2nd-ed-2015>
- GAVI Alliance Investing in immunisation through the GAVI Alliance – The evidence base. Geneva: GAVI Alliance, 2012. Available at: <https://www.gavi.org/library/publications/the-evidence-base/investing-in-immunisation-through-the-gavi-alliance—the-evidence-base/>

Averting the AMR crisis

By: M Anderson, C Clift, Kai Schulze, et al.

Observatory Policy Brief 32

Freely available for download: http://www.euro.who.int/___data/assets/pdf_file/0005/397652/PolicyBrief_PB32_FINAL_WEB.pdf?ua=1

This policy brief summarises some of the key policy avenues for tackling antimicrobial resistance (AMR). Following the widely accepted ‘One Health’ approach to combating AMR,



the brief aims to support the implementation of national action plans on AMR, drawing on numerous examples of effective policies implemented by European Union Member States and involving the human, animal and environmental health sectors.

INTEGRATING PRIMARY CARE AND PUBLIC HEALTH

By: Bernd Rechel

Summary: There are many calls for improved integration between primary care and public health, but also sizeable obstacles to achieving this, such as differences in the ways the two sectors are organised and financed, as well as differences in education, culture and approach. This article, based on a new Observatory policy brief, describes the types of interventions that come into consideration, the principles that should be followed, and the factors that can facilitate successful collaboration. While there is no universal template that can be followed by all countries, improved integration promises to yield substantial benefits to patients and wider populations.

Keywords: *Primary Care, Public Health, Integration, Interventions, Facilitating Factors*

Introduction

Some of the most important international health policy documents have called for greater integration of public health and primary care, including the 1978 *Alma-Ata Declaration on Primary Health Care* and the 1986 *Ottawa Charter for Health Promotion*.^{1,2} Despite these declarations of intent, in practice there are often many obstacles preventing improved integration of primary care and public health, such as differences in the ways the two sectors are organised and financed, as well as differences in education, culture and approach.

A new policy brief by the European Observatory on Health Systems and Policies examines what initiatives have been undertaken recently to improve integration of public health and primary care; which factors influence integration; what outcomes have been achieved;

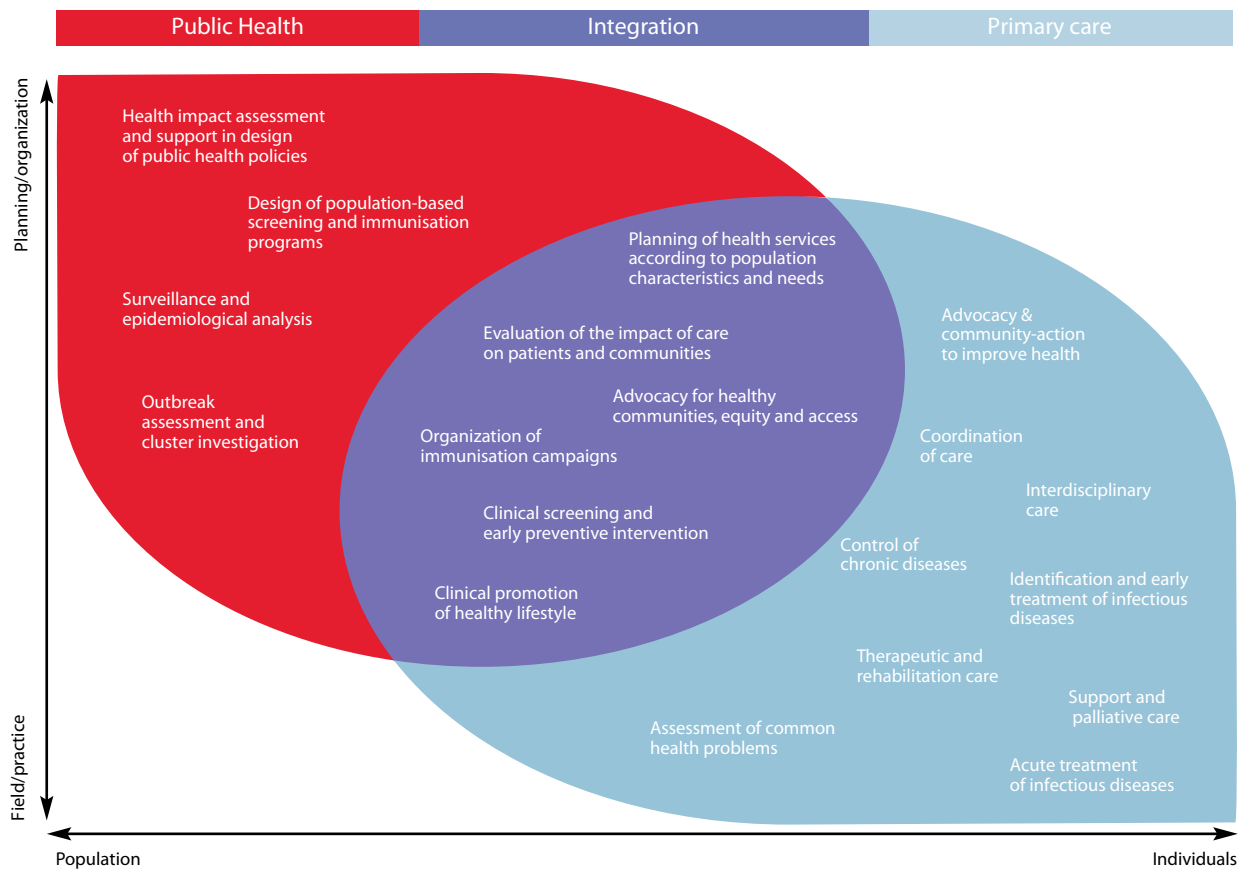
and what can be undertaken to increase the chances of achieving enhanced integration.³

Key terms: understanding public health and primary care

Although (or perhaps because they are) widely used, the terms “public health” and “primary care” can mean different things to different people and are worth clarifying.

One of the common definitions of “public health” is “the art and science of preventing disease, prolonging life and promoting health through the organised efforts of society”.⁴ Put differently, public health aims to improve the health of populations by keeping people healthy, improving their health or preventing the progression of disease. This can include a wide range of interventions, at both the population level and addressing individuals.

Bernd Rechel is Researcher, European Observatory on Health Systems and Policies, London School of Hygiene & Tropical Medicine, UK. Email: bernd.rechel@lshtm.ac.uk

Figure 1: Interaction between public health and primary careSource: ⁷

The terms “primary care” and “primary health care” are often used interchangeably.⁵ However, they derive from different assumptions and premises and carry different connotations. The term “primary care” originated in the United Kingdom, where in 1920 it was used to imply the regionalisation of health services; it was later used to denote first-point medical care.⁵

Today, primary care can be defined as “the first level of professional care [...], where people present their health problems and where the majority of the population’s curative and preventive health needs are satisfied”.⁶ In contrast, the term “primary health care” originated from the 1978 *Alma-Ata Declaration* and describes not only a level of care, but a much more comprehensive approach,⁵ emphasising universal coverage, accessibility, comprehensive care, disease prevention and health promotion, intersectoral

action, and community and individual involvement.⁴ As it incorporates some of the elements of public health, the term “primary care” seems to be preferable when discussing its relation to public health.

Interaction of public health and primary care

The complex interaction between public health and primary care is illustrated in Figure 1. The figure highlights that some functions are more clearly situated in one of the two domains, while others belong to both of them. Screening and immunisation, for example, as well as interventions to support healthy lifestyles, are public health functions that are nowadays commonly provided in Europe in primary care, while surveillance, planning and evaluation are public health activities that can improve primary care.^{7 8} There is a need for both

types of approaches and the closer they are interlinked, the more integrated services will be.

“ the identification of relevant factors at the systemic, organisational and interpersonal levels is very useful

Interventions to improve the integration of primary care and public health

The integration of primary care and public health can cover a wide range of activities, including community engagement and participation, health promotion, health education, prevention activities, chronic disease management, screening, immunisation and communicable disease control, information systems activities, development of best practice guidelines, conducting needs assessments, quality assurance and evaluation, and professional education.¹² One way of categorising interventions is to group them into five broad categories that follow Lasker's models of Medicine and Public Health Collaborations¹³ and the adaptation of these models by Shahzad, et al.¹⁴ However, these categories are not mutually exclusive and interventions can belong to several categories.

1. Coordinating health care services for individuals

Coordinating health care services for individuals is a core strategy for promoting cross-sectoral collaboration between clinical care and public health.¹⁵ Interventions can include: (1) coordination of clinical services with community services, whereby clinical services such as prevention, diagnosis and treatment or rehabilitation are combined with services such as counselling, outreach and social programmes; (2) bringing personnel to existing practice sites to provide individual-level support services to patients; and (3) establishment of 'one-stop' shop centres, where clinical and community-based professionals are brought together at one site (co-location), organised around the needs of local populations. Examples interventions in Europe include the health promotion centres that have been set up in all primary care centres in Slovenia (see Box 1).

2. Applying a population perspective to clinical practice

The second model of enhanced integration between primary care and public health involves applying a public health lens to primary care.¹⁶ This can involve the following types of interventions: (1) using and sharing population-based information

Box 1: Health promotion in Slovenia's primary health care centres

Health promotion centres in all 58 primary health care centres across Slovenia have, since 2002, taken on a major role in providing lifestyle interventions against key risk factors. Between 2013 and 2016 new approaches in primary prevention were developed and piloted. Activities in pilot projects were focused on three major goals: 1. development of a community approach; 2. assuring equity-focused health care; 3. development of an integrated health promotion centre. Health promotion centres integrated previously dispersed activities and introduced multidisciplinary teams. This resulted in increased competencies of staff, higher quality of services and higher visibility of health promotion activities in local communities.

Source: ¹²

(e.g. about prevalent health problems, health risks within the community, and preventive services for particular patient groups) to enhance clinical decision-making; (2) using population-based strategies, such as community-wide screening, case finding and outreach programmes, to direct patients to medical care; and (3) using population-based analytic tools, such as clinical epidemiology, risk assessment, cost-effectiveness analysis, to enhance practice management, for example, by informing decisions about practice site locations, service provision at each site, practice staffing patterns, or the need for patient education programmes.

3. Identifying and addressing community health problems

The third model of enhanced integration between primary care and public health involves using data obtained in primary care in support of public health.

4. Strengthening health promotion and disease prevention

The fourth model comprises interventions that adopt a population-based approach and strengthen health promotion and disease prevention through: (1) education (e.g. on risky behaviours or environmental issues); (2) advocacy (e.g. for health related laws or regulations, or for disadvantaged groups); (3) initiatives targeted at improving community health.

5. Collaborating around policy, training and research

This category comprises interventions such as influencing health system policy; engaging in cross-sectoral education and training; as well as conducting cross-sectoral research.

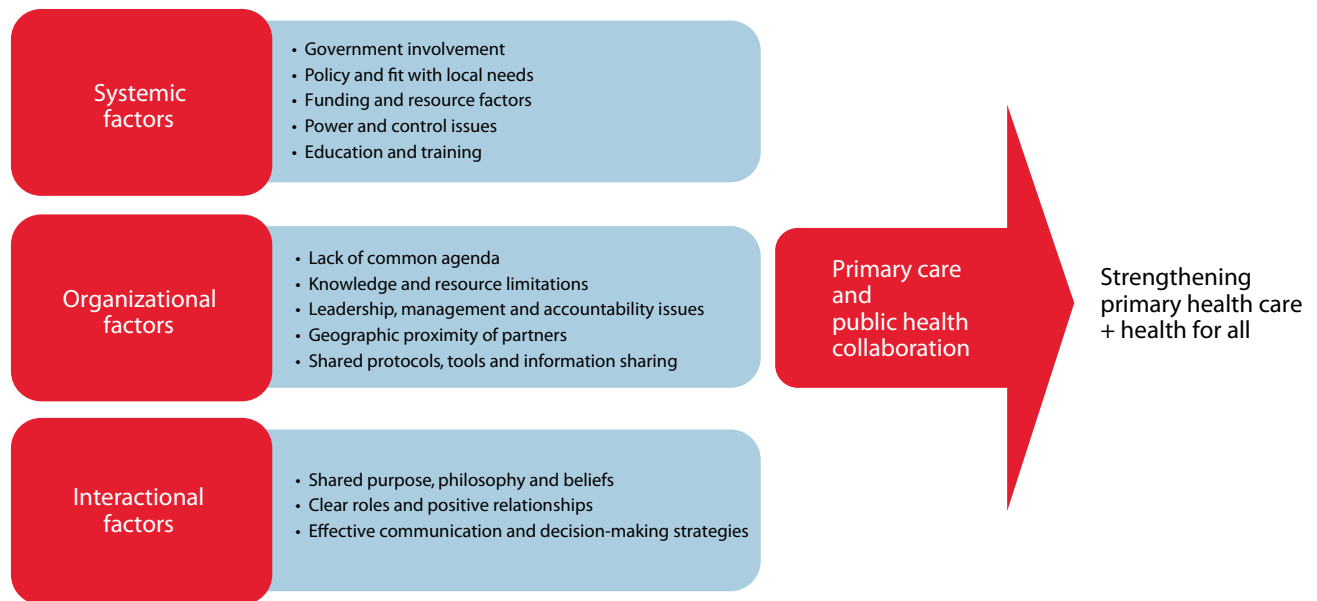
Factors facilitating the collaboration between public health and primary care

Many hallmarks of successful collaboration between primary care and public health will be the same as successful collaboration more broadly.¹⁷ A scoping literature review of collaboration between primary care and public health published in 2012 and covering 114 studies distinguished between systemic factors, organisational factors and interactional factors that support collaboration (see Figure 2).¹⁸

Systemic factors relate to the environment outside of the organisation where the collaboration takes place. They include governmental involvement, policy and fit with local needs, funding and resource factors, power and control issues, and education and training.

Organisational factors relate to conditions within the organisation. They include lack of a common agenda, knowledge and resource limitations, leadership, management and accountability issues, geographic proximity of partners, and shared protocols, tools and information.

Finally, **interpersonal (or "interactional") factors** relate to interactions between team members. They include having a shared purpose,

Figure 2: Factors influencing collaboration between public health and primary careSource: ¹

philosophy and beliefs, clear roles and positive relationships, and effective communication and decision-making strategies.

These factors are broadly in line with the principles of successful integration of primary care and public health identified in the influential report published in 2012 by the Institute of Medicine (see Box 2).

Conclusion

The five principles pointed out by the Institute of Medicine as being essential for successful integration of primary care and public health remain highly relevant: a shared goal of population health improvement; community engagement; aligned leadership; sustainability; and the sharing and collaborative use of data and analysis. While the identification of relevant factors at the systemic, organisational and interpersonal levels is very useful, their relative importance and interactions remain poorly understood. This means that it is difficult to point to the essential factors needed for collaboration to work in practice. However, they still provide useful guidance and illustration, keeping in mind the need to adapt them to local circumstances, in particular the ways that primary care and

Box 2: Institute of Medicine's principles of successful integration of primary care and public health

In 2010, the Institute of Medicine in the United States formed a Committee on Integrating Primary Care and Public Health. In their influential report published in the same year,¹ they identified five principles as being essential to successful integration of primary care and public health:

- a shared goal of population health improvement;
- community engagement in defining and addressing population health needs;
- aligned leadership that: bridges disciplines, programmes and jurisdictions to reduce fragmentation and foster continuity; clarifies roles and ensures accountability; develops and supports appropriate incentives; and has the capacity to manage change;
- sustainability, key to which is the establishment of a shared infrastructure and building for enduring value and impact; and
- the sharing and collaborative use of data and analysis.

public health are organised, financed and delivered and the specific health needs of populations.

References

- ¹ WHO. Declaration of Alma-Ata, International Conference on Primary Health Care, Alma-Ata, USSR, 6–12 September 1978. Geneva: World Health Organization, 1978.
- ² WHO. Ottawa Charter for Health Promotion. Geneva: World Health Organization; 1986.

³ Rechel B. How to enhance the integration of primary care and public health? Approaches, facilitating factors and policy options. Copenhagen: World Health Organization (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies), 2020.

⁴ Acheson D. Public health in England. Report of the Committee of Inquiry into the future development of the public health function. London: HMSO, 1988.

- 5** Felix-Bortolotti M. Part 1 – unravelling primary health care conceptual predicaments through the lenses of complexity and political economy: a position paper for progressive transformation. *J Eval Clin Pract*. 2009;15(5):861–7.
- 6** Boerma W, Kringos D. Introduction. In: Kringos DS, Boerma WGW, Hutchinson A, Saltman RB (eds) *Building primary care in a changing Europe*. Copenhagen: World Health Organization (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies), 2015: 27–40.
- 7** Levesque J, Breton M, Senn N, Levesque P, Bergeron P, Roy D. The interaction of public health and primary care: functional roles and organizational models that bridge individual and population perspectives. *Public Health Reviews* 2013;35(1):1–27.
- 8** Tyszko PZ, Nitsch-Osuch A, Minko M, Kanecki K. Primary health care tasks in implementing the main operations of public health. *Family Medicine and Primary Care Review* 2016;18(3):394–7.
- 9** Martin-Misener R, Valaitis R, Wong ST, et al. A scoping literature review of collaboration between primary care and public health. *Prim Health Care Res Dev* 2012;13(4):327–46.
- 10** Lasker R, Committee on Medicine and Public Health, New York Academy of Medicine, Abramson D. *Medicine & Public Health: the Power of Collaboration*. New York: Center for the Advancement of Collaborative Strategies in Health, the New York Academy of Medicine, 1997.
- 11** Shahzad M, Upshur R, Donnelly P, et al. A population-based approach to integrated healthcare delivery: a scoping review of clinical care and public health collaboration. *BMC Public Health* 2019;19(1):708.
- 12** Petrič V-K, Maresso A. Slovenia. In: Rechel B, Maresso A, Sagan A, et al. (eds) *Organization and financing of public health services in Europe: Country reports*. Copenhagen: WHO Regional Office for Europe (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies), 2018:109–22.
- 13** Booth M, Hill G, Moore MJ, Dalla D, Moore MG, Messenger A. The new Australian Primary Health Networks: how will they integrate public health and primary care? *Public Health Res Pract* 2016;26(1):e2611603.
- 14** Institute of Medicine. *Primary Care and Public Health: Exploring Integration to Improve Population Health*. Washington, DC: National Academies Press, 2012.

Serbia: Health system review

By: V Bjegovic-Mikanovic, Milena Vasic, Dejana Vukovic, et al.

Copenhagen: World Health Organization, 2019
(on behalf of the Observatory)

Freely available for download: <https://tinyurl.com/ObservatoryHiTs>

This analysis of the Serbian health system reviews recent developments in organisation and governance, health financing, health care provision, health reforms and health system performance. The health of the Serbian population has improved over the last decade. Life expectancy at birth increased slightly in recent years, but it remains around 10 years below the average across European Union countries. Some favourable trends have been observed in health status and morbidity rates, including a decrease in the incidence

of tuberculosis, but population ageing means that chronic conditions and long-standing disability are increasing.

Health system reforms since 2012 have focused on improving infrastructure and technology, and on implementing an integrated health information system. However, the country lacks a transparent and comprehensive system for assessing the benefits of health care investments and determining how to pay for them.



TOWARDS EQUAL ACCESS TO HEALTH SERVICES IN SERBIA

By: Vesna Bjegovic-Mikanovic, Milena Vasic, Dejana Vukovic, Janko Jankovic, Aleksandra Jovic-Vranes, Milena Santric-Milicevic, Zorica Terzic-Supic and Cristina Hernández-Quevedo

Summary: Serbia has a comprehensive universal health system with free access to health care, but there are inequities in the utilisation of health services. Some vulnerable groups, such as those living in poverty or Roma people in settlements, have more barriers in accessing health care. Financial constraints are the main reason for unmet needs, in particular for the less educated and the poorest. Although citizens are generally satisfied with public and private health care services, a significant number of patients are on waiting lists. Therefore, reaching equal access to health services should be one of the leading health policy goals.

Keywords: *Universal Health Coverage, Health Inequalities, Financing, Serbia*

Introduction

Access to health care and persistent inequalities in health due to socioeconomic conditions are key policy issues faced by countries in the WHO European Region. There is increasing concern that progress regarding health systems' performance has reversed in some countries because of the economic crisis, and reducing inequalities in health and inequities in access remains high on the political agenda.

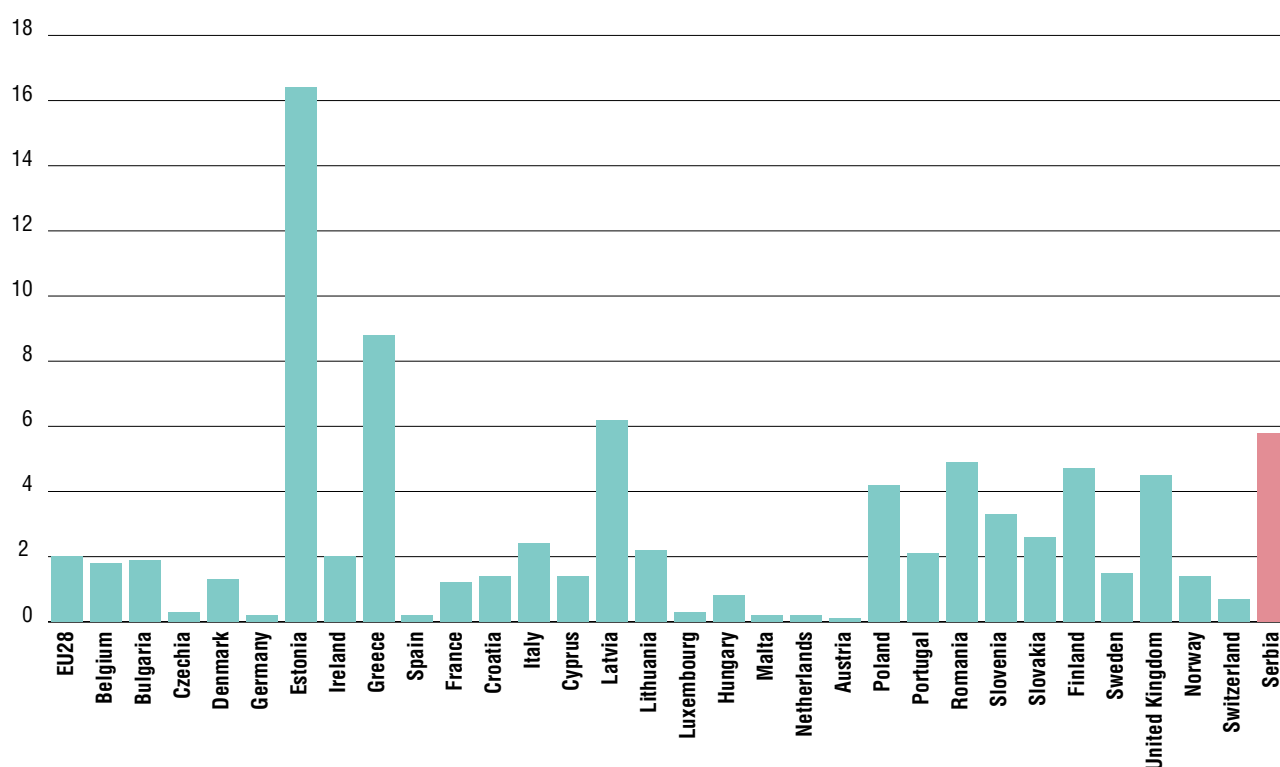
Serbia is no exception. Since 2000, significant progress has been made in the development of health policy in the country, and this has translated into favourable trends in health status and morbidity rates, such as a decrease in the incidence of tuberculosis and an increase in life expectancy at birth (although it remains five years below the average across European Union (EU) countries).^{1 2} However, barriers to health care remain, which increase inequalities in health status across socioeconomic groups.

Financial barriers to access persist and good health is enjoyed by the better-off

Serbia has a comprehensive universal health system with free access to health care services at the primary level. There are, however, inequities in the utilisation of health services, with some vulnerable groups such as people living in poverty, and Roma people in settlements, experiencing more barriers in accessing adequate care. In 2018, 5.8% of the Serbian population reported unmet needs for medical care due to cost, travel distance or waiting lists, well above the EU28 average of 2.0% and much higher than in neighbouring countries such as Bulgaria (1.9%), Croatia (1.4%), and Hungary (0.8%), but closer to those reported in Romania (4.9%) (see Figure 1).

Vesna Bjegovic-Mikanovic is Full Professor, Dejana Vukovic is Full Professor, Janko Jankovic is Professor, Aleksandra Jovic-Vranes is Professor, Milena Santric-Milicevic is Professor and Zorica Terzic-Supic is Professor, Centre School of Public Health, University of Belgrade, Belgrade, Serbia; Milena Vasic is Associate Professor, Institute of Public Health of Serbia "Dr Milan Jovanovic Batut", Belgrade, Serbia; Cristina Hernández-Quevedo is Research Fellow, European Observatory on Health Systems and Policies, London School of Economics and Political Science, London, UK. Email: bjegov@med.bg.ac.rs

Figure 1: Self-reported unmet needs for medical care in EU countries and Serbia (due to cost, travel distance or waiting lists) in %, 2018



Source: ²

“Some vulnerable groups have more barriers in accessing adequate care”

Financial constraints are reported to be the main reason for unmet needs for medical care, with those with lower educational attainment and the poorest being more likely to report them. The percentage of people that forewent medical care due to lack of financial resources in 2018 was higher in Serbia (3.1%) than the average across EU Member States (1.0%) and in neighbouring countries.² According to the latest National Health Survey in the country, in 2013, women (33.1%), the lower educated (35.9%), and the poorest (40.1%) were significantly more likely not to be able to meet their health needs.³ Additional analysis is needed to estimate

other obstacles in addressing unmet needs for medical care (i.e. geographic, cultural and informational).

Long waiting times also impede the accessibility of health services in Serbia. Although the National Health Survey (2013) shows that citizens are generally satisfied with public and private health care services, a significant number of patients who underwent treatment in 2013 had to go on a waiting list.³

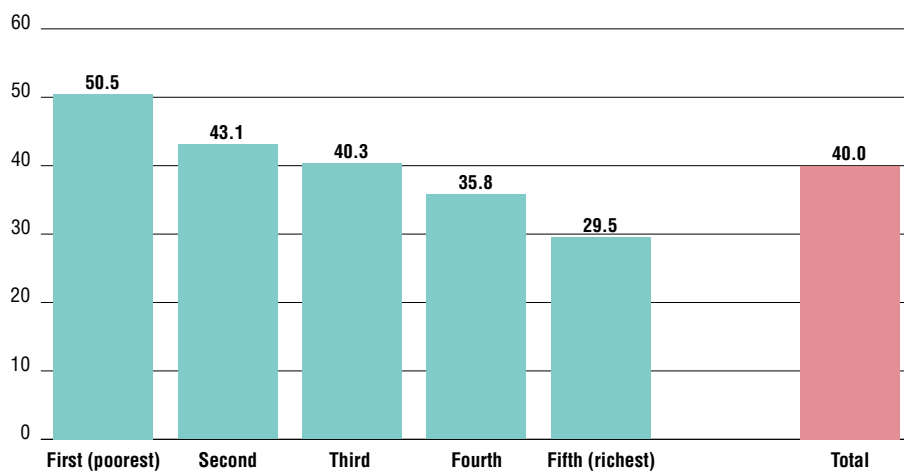
Regarding health inequalities, several studies show a clear association between sociodemographic determinants and health status in Serbia, and they confirm the existence of socioeconomic inequalities in morbidity.^{4, 5} Compared to people with higher levels of education, the lower educated have a 4.5 times higher chance of reporting poor health status. The unemployed, economically inactive individuals, and the most deprived people are also more likely to report poor self-perceived health than employed persons and those in the highest income group.⁴ Women, people with basic or lower levels of education and those in the lowest

wealth index quintile are more likely to report having a chronic disease or long-standing health issue (see Figure 2). The high prevalence rates for chronic disease risk factors such as smoking, alcohol consumption and hypertension are concentrated among men, individuals with low income and people with lower educational level, which contributes to health inequalities.⁶

National initiatives have targeted health inequalities and access to the health system

Recent reforms aimed to improve the performance of health care institutions in Serbia in order to address regional inequalities and disparities in the accessibility of health care services.⁷ The main reform in service delivery introduced the concept of the “chosen doctor” in primary care in 2005 with the Health Care Law, which was further supported by the 2019 Health Care Law. The “chosen doctors” are general practitioners (GPs) or specialists in general medicine, specialist paediatricians, specialist gynaecologists, and dentists.

Figure 2: Population in Serbia who reported having some long-term disease/health problem by wealth index quintile (%), 2013



Source: ⁸

Box 1: Interventions to improve health and access to health care for the Roma population in Serbia

Roma in Serbia are more than twice as likely as non-Roma to report poor health.⁹ Infant mortality and under-five mortality rates in Roma settlements (12.8 and 14.4 per 1,000 live births in 2014¹⁰) are more than two times higher compared to the national average in 2018 (5 and 5.5 per 1,000 live births).⁹ Also, smoking prevalence among Roma is higher than in non-Roma communities. A study conducted in 2010 by the United Nations Population Fund among 1,000 respondents living in Romani settlements showed that 53.8% of Roma are smokers, which is significantly higher than in the general population (34.7%).⁹

In the field of health, interventions to reduce inequalities are directed to reducing the differences in general health conditions between the Roma and the rest of the population through: a) the provision of quality health care to Roma, especially to children and women, of preventive care and social services under the same conditions under which they are available to the rest of the population; b) the inclusion of qualified Roma in health programmes (Roma health mediators) that affect their community, wherever possible (based on the Strategy for Social Inclusion of Roma for the period 2016–2025).¹⁰ The introduction of Roma health mediators responsible for linking Roma with primary health care providers presents an example of good practice in Serbia. The impact of this intervention is already visible in the reduction of infant and under-five mortality in the Roma population.¹¹ Furthermore, the life expectancy of Roma has improved, vaccination coverage among children has been increased and the majority of Roma men and women have been covered by mandatory health insurance.

The reform process also facilitated the set-up of counselling services both for vulnerable groups of the population and specific diseases such as diabetes. In practice, counselling services addressed a range of health risks and behaviours (e.g., nutrition, physical activity, substance use, prevention, mental health).¹²

National initiatives aiming to identify and reduce inequalities in health in Serbia started with the adoption of the 2003 Poverty Reduction Strategy. The main goal of this intersectoral strategy was to reduce poverty by half between 2003 and 2008.⁹ In 2009, the government established the Social Inclusion and Poverty Reduction Unit (SIPRU) mandated to strengthen

government capacities to develop and implement social inclusion policies based on good practices in Europe. The SIPRU provides support to the government to coordinate, monitor and report on efforts in the field of social inclusion. Successful interventions to reduce health inequalities have been implemented, including social welfare and health (particularly for vulnerable groups, i.e., Roma, people living with disabilities, migrants, and people living in poverty), education, economic development and employment, and human rights (for details see: <http://socijalnoukljucivanje.gov.rs/en/>).

The European integration process – the main mechanism for leading a dialogue on the priorities of Serbia in the field of social policy and employment – is contributing to the reduction of inequalities in health.⁹ However, although the formal start of Serbia's EU accession negotiations was on 21 January 2014, Chapter 28 on health has still not been opened in the negotiation process. The Employment and Social Reform Programme (ESRP) was officially launched in September 2013 by the government and covered the issues of the labour market and employment, human capital and skills, social inclusion and social welfare, and pension and health systems, with a specific focus on tackling high youth unemployment. More recently, the most relevant cross-sector strategies which tackle social inclusion and, hence, inequalities are the 2013 Strategy for Prevention and Protection against Discrimination, the 2016 Strategy for Social Inclusion of Roma for the period 2016–25, and the 2009 National Strategy for Improving the Position of Women and promoting Gender Equality.¹³ Successful interventions linked to the Roma population in Serbia have also been implemented (see Box 1).

Improvements in prevention may lead to better performance of the health system

The leadership and governance of the health system are focused on improving health and reducing health inequalities in the Serbian population.¹⁴ For that purpose, all self-government authorities in Serbia (158 in total) are expected to establish municipal health councils as multidisciplinary bodies to support

health.¹³ This policy has recently been adopted (2018) and its implementation is pending.

Broad, comprehensive, health promotion and disease prevention strategies take into consideration the many risk factors and determinants of ill health, which disproportionately affect already vulnerable groups, often leading to cases of multiple and cumulative disadvantages. In other words, health inequalities are an important dimension of prevention and promotion; it remains a fundamental objective for targeted strategies to tackle health inequalities and under no circumstance exacerbate them.¹⁴

“National initiatives are in place to increase access to the health system”

In the area of preventive services, while investments supported by European projects have improved cancer treatment, national screening rates are still very low. The problem appears to be that the level of investment in organised screening programmes is still too low, and consequently, implementation and response remain insufficient. Stepping up prevention efforts to deal with lifestyle factors such as tobacco use, alcohol consumption and obesity will also be essential going forward to help improve health more generally and to contribute to reducing health inequalities.

Conclusions

Serbia has a comprehensive universal health system with free access to health care services at the primary level, but inequities in the utilisation of health services persist, with vulnerable groups being disproportionately affected. Financial constraints are the main reason for unmet needs for medical care, which are reported more frequently by the lower educated and the poor. Although citizens

are generally satisfied with public and private health care services in the country, waiting lists challenge their prompt access to health care.

It is expected that Serbia will continue to develop policies focused on reducing barriers to accessing health care and improving the efficiency of the health system, supported by international organisations and in the context of Serbia's continuing EU accession negotiations.

References

- ¹ Bjegovic-Mikanovic V, Vasic M, Vukovic D, et al. Serbia: Health system review. *Health Systems in Transition*, 2019. Available at: <http://tiny.cc/HiTs>
- ² Eurostat. Statistical database. Luxembourg: European Commission. Available at: <http://ec.europa.eu/eurostat/data/database>
- ³ Ministry of Health. *Results of the National Health Survey of the Republic of Serbia 2013*. Belgrade: Ministry of Health of the Republic of Serbia, 2014. Available at: <http://www.batut.org.rs/download/publikacije/2013SerbiaHealthSurvey.pdf>
- ⁴ Jankovic J, Janevic T, von dem Knesebeck O. Socioeconomic inequalities, health damaging behavior, and self-perceived health in Serbia: a cross-sectional study. *Croat Med J* 2012;53(3):254–62.
- ⁵ Janevic T, Jankovic J, Bradley E. Socioeconomic position, gender, and inequalities in self-rated health between Roma and non-Roma in Serbia. *Int J Public Health* 2012;57(1):49–55.
- ⁶ SIPRU web site. Belgrade, Social Inclusion and Poverty Reduction Unit of the Government of the Republic of Serbia, 2018. Available at: <http://socijalnoukljucivanje.gov.rs/en/>
- ⁷ SORS – Statistical office of Serbia and UNICEF. *2014 Serbia multiple indicator cluster survey (MICS) and 2014 Serbia Roma settlements cluster survey, final reports*. Belgrade: Statistical office of the Republic of Serbia and UNICEF, 2014.
- ⁸ The World Bank. International comparison program database, world development indicators. Washington: the World Bank Group, 2020. Available at: <https://data.worldbank.org/>
- ⁹ UNFPA. *Istraživanje stanja zdravlja u romskim zajednicama. Pristup Roma uslugama zdravstvene zaštite* [Research on the health status in Roma communities. Roma access to health care services]. Belgrade: United Nations Population Fund, 2010.
- ¹⁰ Official Gazette. *Strategija za socijalno ukljucivanje Roma i Romkinja u Republici Srbiji za period od 2016. Do 2025 godine* [Strategy for Social Inclusion of Roma for the period 2016–2025]. *Official Gazette RS* (26/2016), 2016.
- ¹¹ Jovic-Vranes A, Bjegovic-Mikanovic V. Health and health status of children in Serbia and the desired Millennium Development Goals. *Southeastern European Journal of Public Health* 2015;4(1).

¹² CEVES. *Kakvo nam je zdravlje? Sistem indikatora za društveni dijalog o zdravlju i zdravstvenom sistemu Srbije* [How is our health? The system of indicators for social dialog about health and health system of Serbia]. Belgrade: Centre for Advance Economic Studies, 2017. http://ceves.org.rs/wp-content/uploads/2017/12/Kakvo-nam-je-zdravlje_Sistem-indikatora-za-dru%C5%A1tveni-dijalog.pdf

¹³ Official Gazette. *Strategija javnog zdravlja* [Public Health Strategy]. *Official Gazette RS* (61/2018), 2018.

¹⁴ European Commission's DG SANTE. *State of Health in the EU: Companion Report 2019*. Luxembourg: Publications Office of the European Union, 2019.

NORWAY'S HEALTHCARE COMMUNITIES ARE SET UP TO BUILD BRIDGES BETWEEN HOSPITALS AND PRIMARY CARE

By: Ingrid Sperre Saunes, Anna Sagan and Marina Karanikolos

Summary: In 2012, the Coordination Reform was introduced in Norway to improve coordination between municipalities that organise primary care and the central government that organises specialised care. In 2020, a local governance reform is being implemented, and some municipalities and regions are being merged into larger entities. “Healthcare Communities”, a new partnership between hospitals and their surrounding municipalities, are being established to improve planning and development of services, as well as contribute to national planning. However, improving coordination between primary and specialist services may prove challenging, notably due to the way in which they are governed.

Keywords: Centralisation, Governance, Partnership, Care Coordination, Norway

Health care organisation and governance in Norway

Norway's health care system is organised at two levels.¹ Broadly speaking, the central government is responsible for specialist care and the municipalities are responsible for primary care.

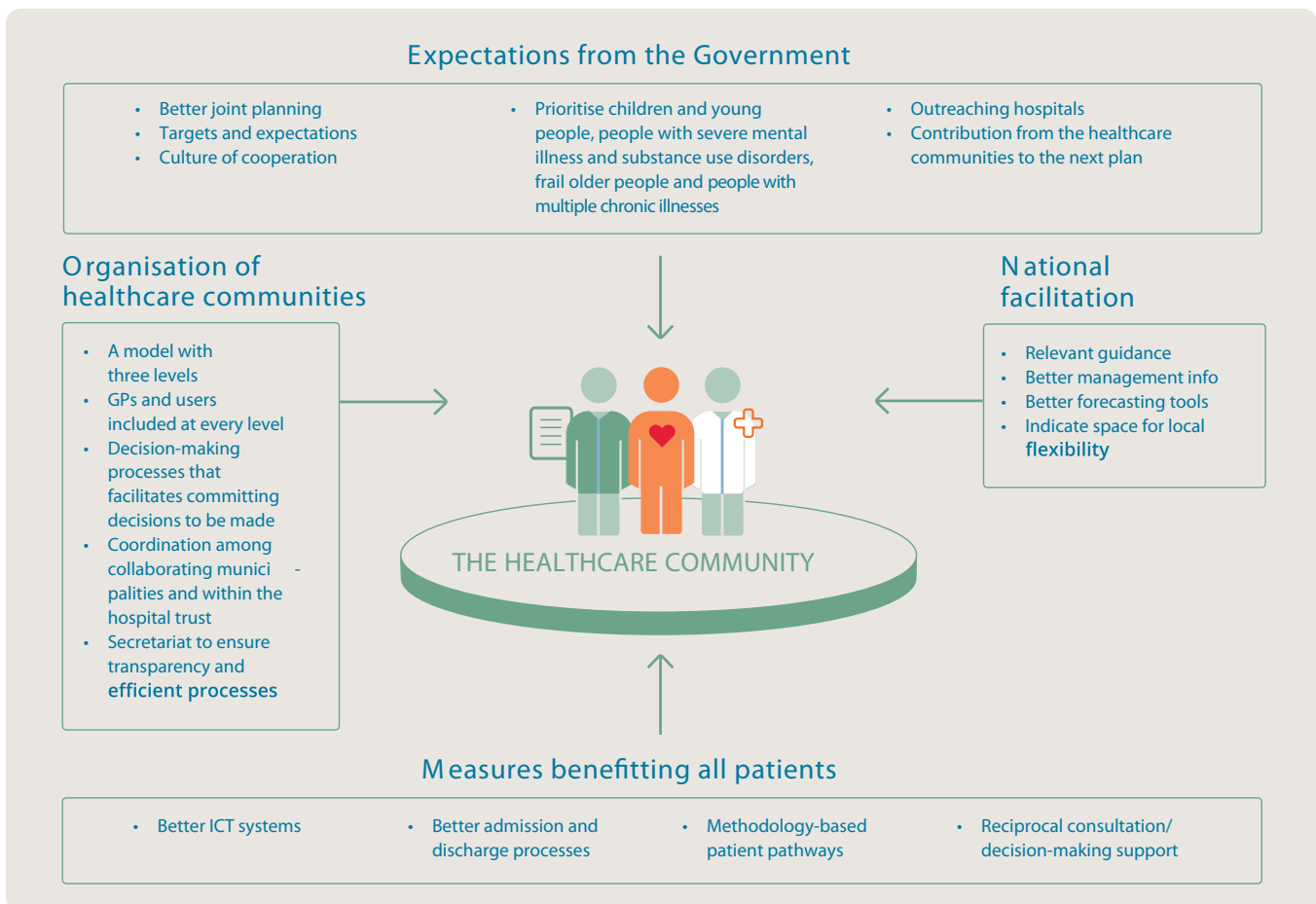
Between 1969 and 2002, hospital care in Norway was the responsibility of the counties. In 2002, the central government took over this responsibility and established regional health authorities (RHAs), which own and govern hospitals. Over time, 85 hospitals have merged into 20 health trusts. Each health trust is an independent legal entity, consisting of one or more hospitals with a joint administration and governance. Municipalities became responsible for

primary care in 1982, a responsibility that gradually expanded to include other services, such as environmental health services, and services for older people and people with disabilities. The majority of GPs are private practitioners contracted by the municipalities.

Municipalities have traditionally enjoyed a great deal of freedom in organising health services without a direct command and control line from the central authorities. However, in recent years this freedom has been gradually challenged by an increasing amount of regulation on how these services should be delivered and governed. Much of the focus of these regulations has been on improving coordination between the municipalities

Ingrid Sperre Saunes is senior advisor, Department of Health Services Research, Norwegian Institute of Public Health, Oslo, Norway; **Anna Sagan** is Research Fellow, European Observatory on Health Systems and Policies, London School of Economics and Political Science, London, UK; **Marina Karanikolos** is Research Fellow, European Observatory on Health Systems and Policies, London School of Hygiene and Tropical Medicine, London, UK. Email: Ingrid.Saunes@fhi.no

Figure 1: Measures to promote coordination of health and care services set out in the Health and Hospital Plan 2020–2023



Source: ¹ Illustration: Gjerholm design AS Reproduced with permission. Note: ICT is Information and communications technology.

and the RHAs and was part of the broader Coordination Reform implemented from 2012.¹

Another focus was on improving quality of care and patient safety. The Municipal Health and Care Act (2011),² which is a principal component of the Coordination Reform, gave the Directorate of Health – an agency under the Ministry of Health – the sole responsibility to develop, disseminate and maintain national clinical guidelines. Over the past decade, the Directorate has developed over 400 guidelines for general practitioners, local health centres, nursing homes, hospitals and other services.

In 2017, the regulation on “leadership and quality improvement in the health services” instructed the Directorate of Health to work systematically towards

ensuring that all processes of planning, implementation, evaluation and corrective measures to improve quality and safety were in place across all levels of services.

“foster a culture for cooperation between the hospital and municipal sectors

In parallel to these developments, since 2014 there has been a reform aimed at improving administrative efficiency, which has merged counties into larger entities and reduced the number of municipalities. In January 2020, 19 counties were merged into 11, and the number of municipalities was reduced from 429 to 356.

The Coordination Reform has proved challenging to implement

According to the Municipal Health and Care Act (2011), each municipality must ensure that its population has access to health care services and that they are provided in a coordinated manner by health care personnel who have the necessary competences.³ As part of this Act, the municipalities must establish formal contracts with the hospitals to

ensure appropriate and coordinated care for patients with complex care needs. These and other changes created a degree of uncertainty about responsibilities over the financing and organisation of care.

These challenges were reflected in the 2015 white paper ‘The Primary Health and Care Services of Tomorrow’.¹⁴ This report discussed the range and complexity of the tasks for which municipalities were responsible and identified greater demands on municipal capacity and expertise. The white paper acknowledged that new organisational solutions that recognise the existing challenges should be developed in order to improve coordination between primary and specialised care.

Introducing Healthcare Communities as a bridge between primary and specialised care

In October 2019, 19 Healthcare Communities (*helsefjellskap*) were established as an organisational solution to address the challenges described above. Each Healthcare Community consists of a partnership between a health trust and the municipalities within the region covered by this health trust. By organising themselves as a Healthcare Community the health trust and municipalities agree to develop and plan services together as equal partners. Healthcare Communities are responsible for ensuring a common understanding of targets and expectations from the central government for the municipalities it covers, and for joint planning between these municipalities and between municipalities and health trusts to achieve these targets. As such, Healthcare Communities report to the RHAs, which in turn report to the central government.

In November 2019, the government included the new Healthcare Communities in the Health and Hospital Plan 2020–2023 (see Figure 1), which communicates the government’s strategic vision for the development of health and care services.¹⁵ According to this Plan, Healthcare Communities are expected to foster a culture for cooperation between the health trust and municipal sectors by working out solutions that suit local needs. They are also intended to serve as an instrument of outreach support for

hospitals in the delivery of specialised services close to service users’ homes. Their focus should be on the needs of the following population groups: (i) children and young people; (ii) people with multiple chronic illnesses; (iii) people with severe mental illness and substance use disorders; and (iv) frail older people. The intention is to promote better continuity of care between hospitals, primary care and care delivered in patients’ homes, as well as enhancing primary care provider’s contact with hospitals. It is also a bridge between private providers (GPs) and the public hospital sector.

The government recommends that the Healthcare Communities are organised at three levels (see Figure 2):

- The *partnership meeting* is an annual forum where the strategic direction of the community is confirmed. It provides an opportunity for the high-level representatives from political and administrative arenas in the municipalities to meet with representatives from the hospital boards and executives from the health trusts. The purpose of this meeting is to set local priorities and ensure their common understanding by establishing a local framework.
- The *strategic cooperation committees* have the responsibility to develop strategic directions and actions plans for the Healthcare Community as well as to manage challenges and make necessary decisions. These committees are formed from administrative and specialist managerial staff from the health trusts and the municipalities in their respective regions. Their role is thus to prepare the agenda for the partnership meetings as well as to implement national and local frameworks and regulations through an action plan for the local geographical area.
- *Clinical collaboration committees* are the forum for health care professionals, who collaborate on the development of common procedures and service models for the municipality. The scope for their work is set by the strategic cooperation committee.

Healthcare Communities are expected to be operational by the end of 2020. It

is hoped that they may be the answer to a more efficient use of health care resources, including the health workforce, particularly in smaller municipalities and more rural areas. However, assessment of the results of this complex reform, which aims to integrate care across geographical, administrative and political boundaries, will require a comprehensive approach.

“
Healthcare
Communities are
expected to be
operational by
the end of 2020

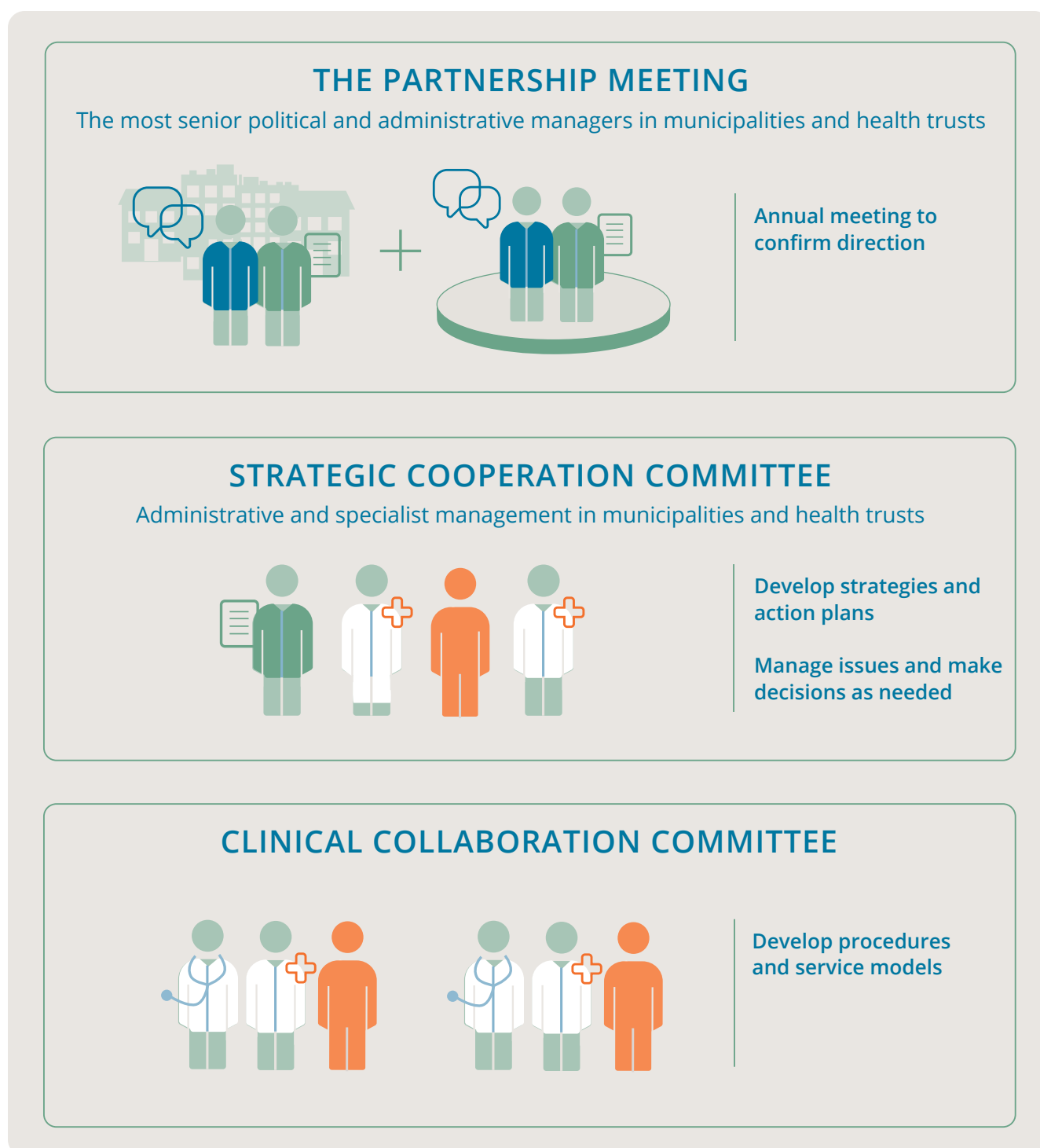
Discussion and conclusions

Stewardship and governance of the new Healthcare Communities involves balancing central and local governance and professional boundaries within a local network. In order for the Healthcare Committees to function well, a series of adjustments to regulations and governance are necessary. For example, the municipalities’ task of conducting work on improvement of quality- and safety- mechanisms, as well as planning, implementation and evaluation of these, overlap with the same role foreseen for the new Health Communities. With this overlap of responsibility, municipal decision-making becomes dependent on local coordination, not only with other municipalities, but also with hospitals, which are governed by the state.

Legislation on information sharing, financing schemes and management data need to be adjusted to support Healthcare Communities. In early 2020, there are plans to develop activity-based funding for patient pathways, as well as to increase the use of private specialists and to decentralise specialist care. For hospitals to deliver care in the communities an increased delegation of responsibility to local hospitals is foreseen, which might indicate larger autonomy from the RHAs.

Figure 2: Distribution of work in Healthcare Communities

Users and GPs participate at all levels



Source:  Illustration: Gjerholm design AS Reproduced with permission.

In order to support the operation of Healthcare Communities, the government aims to provide relevant guidance, improved ITC, information (e.g. on patient safety, quality and economic indicators)

for management and forecasting tools for secretariats and committees, as well as to indicate the degree of local flexibility. Forecasting tools aim to inform relevant competency building, availability

and recruitment needs of health care personnel. The model is expected to lead to an increased amount of skill-sharing between the hospitals and the local health care services.

By extending and formalising cooperation between the hospitals and the municipalities through Healthcare Communities, this may foster a decentralisation of services. It is an ambiguous model, as the Directorate of Health becomes more involved in the support and guidance for the Healthcare Communities, and the local health trusts and municipalities may gain influence on future health policies. Reporting is through the RHAs towards the central administration, which is a new line of accountability for the municipalities.

Healthcare Communities seem to represent a new set of governance, building on existing connections and formalising networks at the local level. It remains to be seen whether these changes will increase the local autonomy of health trusts and municipalities, or increase the central government's influence on local health policy.

References

- 1 Saunes IS, Karanikolos M, Sagan A. Norway: Health system review. *Health Systems in Transition* 2020;21(5). Available at: <http://tiny.cc/HiTs>
- 2 Norwegian Ministry of Health and Care Services. *Act 2011-06-24-30 on municipal health and care services etc.* (Municipal Health and Care Services Act), 2011.
- 3 Norwegian Ministry of Health and Care Services. *White Paper No. 26 (2014–2015). Report to the Storting.* Summary: The primary health and care services of tomorrow – localised and integrated, 2015.
- 4 Norwegian Ministry of Health and Care Services. *National Health and Hospital Plan 2020–2023.* Summary, 2019. Available from: <https://www.regjeringen.no/contentassets/95ec808f0434acf942fca449ca35386/en-gb/pdfs/stm201920200007000engpdfs.pdf>

Norway: Health system review

By: I Sperre Saunes, M Karanikolos, A Sagan

Copenhagen: World Health Organization, 2020
(on behalf of the Observatory)

Freely available for download: <https://tinyurl.com/ObservatoryHiTs>

This analysis of the Norwegian health system reviews recent developments in organisation and governance, health financing, health care provision, health reforms and health system performance. Norway is among the wealthiest nations in the world, with low levels of income inequality. Norwegians enjoy long and healthy lives, with substantial improvement made due to effective and high-quality medical care and the impact of broader public health policies. However, this comes at a high cost, as the Norwegian health system is among the most expensive in Europe, with most financing coming from public funds. Yet there are several areas requiring substantial co-payments, such as adult dental care, outpatient pharmaceuticals, and institutional care for older or disabled people.

Recent and ongoing reforms have focused on aligning provision of care to changing population health needs, including adapting medical education, strengthening primary care and improving coordination between primary and

specialist care sectors.

There has been an increasing use of e-health solutions, and information and communication technologies. Improvements in measuring performance and a more effective use of indicators is expected to play a larger role in informing policy and planning of health services.



PATIENT SAFETY AND MEDICAL LIABILITY IN ITALY

By: **Fidelia Cascini**, **Mariangela Contenti**, **Giada Scarpetti**, **Federico Gelli** and **Walter Ricciardi**

Summary: The World Health Organization estimates that one in ten patients in high-income countries is harmed while being treated in a hospital setting. The 2017 law on patient safety and medical liability in Italy aims to improve the safety of care and provide more structured regulation for the organisational, insurance and medico-legal/judicial fields. An assessment of the implementation of the law shows that progress has been uneven: the level of implementation of legislative provisions varies by region, and decrees on insurance coverage for liability are lacking. Further engagement from regional and national institutions is required.

Keywords: *Patient Safety, Medical Liability, Hospital Care, Italy*

Introduction

In 2019 the World Health Organization (WHO) declared September 17th as Patient Safety Day, thus raising awareness of patient safety as a global priority.¹ In the same year, Italy celebrated two years since the introduction of Law No. 24/2017 on patient safety and medical liability, also known as “Gelli Law”. A survey conducted by the Fondazione Italia in Salute in March 2019 provided an opportunity to assess the implementation status and impact of the law two years after its introduction.² The survey included two questions: 1) were the reforms adopted? and 2) what were the effects of the reforms’ implementation?

Evidence related to this survey was gathered through desk research, as well as interviews with six stakeholders, in particular Chief Executive Officers or General Directors of different regions and public organisations. The classification of results was based on two criteria: a) the field of application of the law, which

is divided into organisational, insurance and medico-legal/judicial; and b) the level of jurisdiction, which is divided into national, regional and local.

Overcoming the fragmentation of organisational requirements remains challenging

Two years after the introduction of the law, one of the main consequences concerns responsibilities in the organisational field at the national and regional levels.

Article 3 of the law established the National Observatory on Best Practices for Patient Safety (*Osservatorio Nazionale per le buone pratiche sulla sicurezza in sanità*) at the Italian National Agency for Regional Healthcare Services (*Age.na.s*). The Observatory collects information annually about risks, adverse events, incidents and controversy for public and private providers through the Regional Centres for the management of healthcare risk (*Centri regionali per la gestione del*

Fidelia Cascini is Senior Researcher, Department of Life Sciences and Public Health, Catholic University of the Sacred Heart, Rome, Italy; **Mariangela Contenti** is Expert in Healthcare Systems Management, Fondazione Italia in Salute, Milan, Italy; **Giada Scarpetti** is Research Fellow, Department of Health Care Management, Berlin Institute of Technology, Germany; **Federico Gelli** is an Italian Politician, Fondazione Italia in Salute, Milan, Italy; **Walter Ricciardi** is Full Professor, Department of Life Sciences and Public Health, Catholic University of the Sacred Heart, Rome, Italy. Email: fidelia.cascini1@unicatt.it

rischio sanitario) through a web-based unified procedure. The Observatory uses SIMES, the Information System for the Monitoring of Errors in Healthcare (*Sistema Informativo per il Monitoraggio degli Errori in Sanità*), which has several functions, including identifying prevention measures and monitoring of best practices. The activity of monitoring best practices is organised by Age.na.s, through a national annual tender; after its publication, Age.na.s receives all the best practices concerning the thematic priorities of the tender itself, validated by regions.

The Observatory took office in March 2018, with six working groups responsible for different tasks (see Box 1), who share their progress during quarterly plenary meetings.⁸

According to the law, the Observatory should be continuously updated about adverse events and health incidents occurring in the national territory, with this information reported by Regional Centres for the management of health care risk (*Centro regionale per la gestione del rischio sanitario*). These Centres were also introduced by Law No. 24/2017 with the aim of increasing the level of knowledge of care safety and improving the homogeneity of prevention measures and management of health care risk at the national level. However, this legislative provision was only integrated within the guidelines for the establishment and functioning of these centres by the Health Commission of the Conference of Regions two years later. The Regional Centres should receive information directly from public and private health care providers.

Two years after the introduction of the law, the Italian landscape remains fragmented

In response to the first question of the survey (has a centre for the management of healthcare risks and patient safety been established?), the analysis of institutional sites by region shows a fragmented landscape (see Figure 1): in 13 regions relevant legislation or an explicit acknowledgement of a previous law for the establishment of a Regional Centre exists (in green in Figure 1), while none was found in five regions (in red in

Figure 1). The two remaining regions (in orange in Figure 1) report intermediate situations where the Centre is not formally established, but there are organisations that partially perform its function.

With regards to the second survey question, the level of publicly available information on management of health care risk on Regional Centres' websites was analysed. The aim was to evaluate what information was available for citizens, and if they could understand the functioning level of Regional Centres, identify the reference standards and reach the competent coordination authority. Following some pre-defined criteria of accessibility, clearness and completeness, we classified the results from 0 to 5, where 0= no accessibility (null); 1= only office contact details are present (mediocre); 2= presence of unintentional and obsolete information (insufficient); 3= information only partially organised (decent); 4= accurate and well-organised information (good).

“the analysis of institutional sites by region shows a fragmented landscape

The resulting scenario, (see Figure 2) shows greater variation by region than that observed in the first survey question.

At the local level, i.e. health districts, compliance to the regulation is also rather limited. Law No. 24/2017 states that citizens should have access to information on health care providers and insurance policies or similar measures (article 10), compensation paid for health care incidents (article 4) and risks and adverse events in the form of an annual report (article 2). Furthermore, these instructions have been included in guidelines, written in October 2017 by the Conference of Regions and the

Box 1: National Observatory on Best Practices for Patient Safety working group tasks

- 1) creating an updated glossary, identifying and classifying information sources and indicators;
- 2) elaborating guidelines for the prevention and management of health care risk and for the monitoring of best practices;
- 3) identifying training needs and indicators for monitoring and guidelines for education of health care staff;
- 4) defining strategies and programmes for international and European exchanges;
- 5) creating models for the management of controversy with reference to medico-legal aspects;
- 6) organising communication modes for best practices.

Autonomous Provinces. Nevertheless, the system of classification and management of information according to the law across the various health districts appears highly fragmented. For example, only certain regions require public providers to publish an Annual Plan of Risk Management, containing part of the above-mentioned information. Two years after the law came into force, the latest published reports about health care risk are still: 1) the monitoring of health care incidents reports, performed by Age.na.s in 2015; and 2) the monitoring of sentinel events, produced by the Ministry of Health in 2012.

Another aspect of great relevance in the national organisational field considered by Law No. 24/2017 is the establishment of a National System for Guidelines (*Sistema Nazionale per le Linee Guida* – SNLG) at the National Institute of Health (ISS). The SNLG is the central authority in charge of studying, writing and making guidelines available and it is the only point of access for professionals and health care providers, managers, policymakers and

Figure 1: Map of the presence of Regional Centres for the management of health care risk as of 31 March 2019, two years after the introduction of Law No. 24/2017



Source: Authors' own

interested users. Through the National Center for Clinical Excellence, Quality and Safety of Care (*Centro Nazionale per l'Eccellenza Clinica, la Qualità e la Sicurezza delle Cure*), the ISS acts as guarantor of the guidelines' development process by Medical Associations and Technical-Scientific Associations. The ISS identified the path for integrating the guidelines in the SNLG and defined the instructions to write the guidelines, which have to be evaluated by the SNGL before their publication. Meanwhile, the Ministry of Health has selected 335 accredited medical associations and technical-scientific associations for the development of guidelines.

The limited progress on obligatory insurance requires attention

The law also concerns insurance, with article 10 mandating insurance coverage (or, alternatively, a similar form of guarantee) for public and private health care providers and for health professionals.

The law refers to the definition of minimum insurance requirements, as well as to the protocol of data flow, and surveillance and control, that have to be regulated through specific executive decrees. Although two years have passed, the fate of these decrees is still uncertain, leaving the field of medical-malpractice still lacking rules and with concerning statistics.

The issue of health care incidents is an area of concern and shows alarming data for Italy. 'Incidents' is defined as any compensation request for damages and/or any launch of legal action for civil liabilities, reported by the insurance company or managed by firms. A recent report from Marsh⁵ identified 20,947 reported health care incidents in 42 public health care providers, in the period 2004–16. The median cost per incident was over €88,000, which represents a cost of over €900 million to the Italian health system across the period analysed.

In our analysis we considered incidents in the period from 2004 to 2016, updated (through changes or status confirmation) throughout the year 2017. The majority of incidents (45.1%) were linked to surgeries, followed by the field of maternal and child health (13.8%) and internal medicine (12.1%). The emergency department, compared to previous editions, is affected to a lesser extent (10.6%). This represents a change from the previous Marsh report,⁵ where orthopaedics and traumatology came in first followed by general surgery, emergency department, and obstetrics and gynaecology.

health care incidents is an area of concern and shows alarming data for Italy

Marsh has also developed a system of specific indicators of risk rates and insurance values, which estimated the total insurance risk rates for insurance companies to range from: 1.1 per 100 administrative employees, 6.5 per 100 doctors, 2.8 per 100 nurses, 1.3 per 1000 hospitalisations.⁶ Accordingly, the insurance values for the same sample have been estimated to be: €943 per administrative employee; €5,659 per doctor; €2,434 per nurse; and €113 per hospitalisation. Both the risk rates and the insurance values consider the skill mix and specialisations of the public health care providers analysed in this report. Therefore, they cannot be extended to providers with a different distribution of medical, administrative or nursing staff, nor to highly specialised health care organisations.

Steps have been taken to provide a better structure for the juridical and medico-legal field

Law No. 24/2017 also deals substantially with the matter of health care professional liabilities and the related themes of fault

Figure 2: Map of the level of availability and clarity of information on regional health care institutions websites concerning the management of health care risk and patient safety



Source: Authors' own

(article 6), classification of the kinds of liability for the health care providers or professionals (article 7) and possible recovery actions like compensations (article 9).

The law also introduced an Experts and Technical Consultants Register (under article 15). In cases of health care professional liability, the law establishes the institution of a panel of experts composed of specialists of the clinical branch of the specific case, enlisted in specific registers created at District Courts and uniformly regulated across the whole Italian territory. On 25 October 2017, a Deliberation of the VII Commission of the Superior Council of Magistracy (*Commissione del Consiglio Superiore della Magistratura – CSM*) adopted shared standards for the revision and record-keeping of all District Courts registers and of the Experts and Technical Consultants Registers. After the deliberation, various agreements have been reached among CSM, the Forensic

National Council, and the Federation of the Boards of Physicians (protocol agreement of 11 April 2018) and Nurses (supplemental agreement of 19 September 2018), in addition to integrative agreements with the federations of pharmacists, psychologists, biologists, chemists, physicists and veterinarians (6 February 2019). We deduce the common intent to unify and regulate the selection and record-keeping criteria of the professional registers at courts, so that they can be balanced on a national scale.

Two years later, the implementation of the law reflects the heterogeneity of the Italian health system

The evaluation of the status of implementation of Law No. 24/2017 two years after its introduction highlights great differences among Italian regions. This once more demonstrates the different speed at which the Italian health system develops and operates throughout the country. Some regions have adopted,

improved, integrated and, in some cases, even anticipated the position of the legislator, while other regions have not yet acted despite the passage of time.

Law No. 24/2017, that aims to improve the safety level of care and to manage disputes for health care professional liabilities, needs attention from institutions, both at a national and regional level. It is therefore important that policy makers and leaders start to think of Italy as a single National Health System, so that the effects of reforms can produce concrete benefits.

References

- World Health Organization. World Patient Safety Day. Web Page. Available at: <https://www.who.int/news-room/campaigns/world-patient-safety-day/2019>
- Cascini F. *L'applicazione della Legge 24/2017: prime risposte di un percorso di ricerca*. [The implementation of Law 24/2017: first answers from a research path]. *I Quaderni della Fondazione Italia in Salute* 2019;1:18–34.
- Labella B. *L'osservatorio nazionale delle buone pratiche sulla sicurezza nella sanità e le altre iniziative promosse da Agenas: obiettivi raggiunti e prospettive future*. [The National Observatory on Best Practices for Patient Safety and other initiatives promoted by Agenas: achieved objectives and future prospects]. *I Quaderni della Fondazione Italia in Salute* 2019;1:62–70.
- Marsh. Report *medmal-sintesi: Studio sull'andamento del rischio da medical malpractice nella sanità italiana pubblica e privata*. [Study on trends of risks in medical malpractice in the Italian public and private healthcare] 9th edition, 2018. Available at: https://www.simlaweb.it/wp-content/uploads/2018/12/Medmal_EP_2018_sintesi.pdf
- Marsh. Report *medmal-sintesi: Studio sull'andamento del rischio da medical malpractice nei clienti sanitari pubblici Marsh*. [Study on trends of risks in medical malpractice among Marsh public health clients] 8th edition, 2017. Available at: http://www.panoramasanita.it/wp-content/uploads/2017/06/Medmal_EP_2017_SINTESI.pdf

NEW PUBLICATIONS

How to enhance the integration of primary care and public health? Approaches, facilitating factors and policy options

By: B Rechel

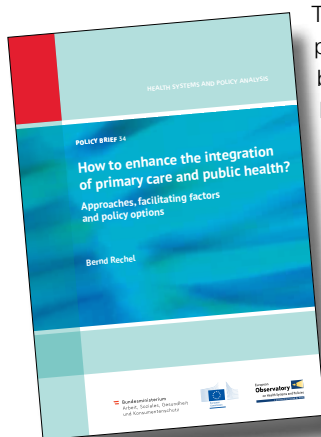
Copenhagen: World Health Organization 2020 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies)

Observatory Policy Brief 34

Number of pages: 30; **ISSN:** 1997-8073

Freely available for download: <https://apps.who.int/iris/bitstream/handle/10665/330491/19978073-eng.pdf?ua=1>

In most European countries primary care performs some public health functions, while public health can help to make the provision of primary care more effective.



This policy brief explores how primary care and public health can be brought together to improve the health of patients and populations. It describes the types of initiatives that have been undertaken; provides examples of such initiatives in Europe and beyond; and summarises the factors that can help to enhance or hinder the integration of primary care and public health. Further, it argues that there is a large overlap of activities between public health and primary care.

Organisational models of primary care that are conducive to integration with public health are identified and the key systemic, organisational and interactional factors that can facilitate integration between the two domains are described.

Contents: Key Messages; Executive Summary; Introduction; Defining key concepts; How to improve the integration of primary care and public health?; Factors facilitating the collaboration between public health and primary care; Discussion and conclusions; References; Appendix: Search strategy and results.

Screening: When is it appropriate and how can we get it right?

By: A Sagan, D McDaid, S Rajan, J Farrington, M McKee

Copenhagen: World Health Organization 2020 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies)

Observatory Policy Brief 35

Number of pages: 24; **ISSN:** 1997-8073

Freely available for download: <https://apps.who.int/iris/bitstream/handle/10665/330810/19978073-eng.pdf?ua=1>

Technological and other scientific advances have made it possible to screen for ever larger numbers of molecules and see inside the human body with a level of detail that was once unimaginable. Where there is good evidence that detecting a condition early will, overall, be beneficial for those who are screened, then it may be appropriate to design and implement a formal screening programme. However, just because something can be done does not mean that it should be done as screening may bring benefits as well as harm.



In this brief, the authors start by explaining the core components of a screening programme, highlighting that, while seemingly simple, putting together all elements of a screening programme is very complex. They then ask when screening should be done, emphasising the continued relevance of Wilson & Jungner's screening principles. In addition, they examine the pressures to implement screening and, where screening is inappropriate, suggest ways to

reduce it. When screening is appropriate, evidence is presented on how to achieve optimal results. This brief is an essential reading for anybody involved in the decisions on screening or its provision.

Contents: Key messages; Executive summary; Why this brief?; A systematic approach to screening; When is screening appropriate?; Supporting implementation of appropriate screening programmes; The way forward; References.

HSPM COUNTRY NEWS

The Observatory's Health Systems and Policy Monitor platform provides systematic descriptions of country health systems and features up-to-date information on ongoing health reforms and policies. See individual country pages for these news items and more: <http://www.hspm.org>



Compiled by Gemma Williams based on recent reform logs.

Belgium: The implementation of a new law on quality practice in health care

To improve the quality of care in Belgium, a new law on the quality of practice in health care has been elaborated and is expected to come into force in 2021. This law contains measures to help ensure the quality and safety of care for patients. Among the measures introduced by this law, there is an obligation for health care providers to maintain a “dynamic portfolio” that demonstrates their participation in continuing education and other activities in their field of expertise. The law also contains measures concerning minimum security conditions for certain high-risk interventions (e.g. the obligation to be transferred or have an emergency procedure in case of complications) and legally reinforces participation in out-of-hours services for almost all health practitioners where relevant. Some provisions of this law have been challenged before the Constitutional Court, for example the obligation for certain practitioners to participate in out-of-hours services and limitations to professional information that may be communicated to the public.

Estonia: Government invests in primary care IT development

The Estonian Government is investing €435,000 for an analysis on how to improve primary care information technology (IT) systems. Currently, primary care IT systems are mainly developed by the private sector, which has led to multiple software solutions that are often incompatible with public health care information systems. The goal of the analysis is to determine an IT solution that would be more user friendly and help physicians in their everyday work. Based on this analysis, the long term plan is to develop a new IT platform by 2023 which would be suitable for team based care in larger primary care centres and improve coordination with other health and social care providers. The majority of funding (€326,252) originates from European Union Structural Funds that are intended to modernise or re-build primary health care centres. The remaining costs will be covered by the state.

France: Training in medically underserved areas to improve access to care

Starting in November 2021, medical students in general practice will have to spend at least six months of their last year of post-graduate training in ambulatory care settings. These out-of-hospital training places will be primarily offered in medically underserved areas (MUAs). This measure is part of the new Health Law voted in June 2019 (“Ma santé 2022”), which aims, as part of its main objectives, to improve access to community-based care. MUAs currently represent one of the key concerns regarding health care access in France, affecting 18% of the French population.

This measure, adopted by a large majority of senators, adopts a number of financial incentives encouraging doctors to work in MUAs. Despite intense debates and criticism from physicians, which led to a reduction in the mandatory training time from one year to six months, the measure will be extended to other medical specialties over time.

Italy: Payment at result for the introduction of revolutionary CAR-T immunotherapy

In August 2019, the Italian Medicine's Agency (AIFA) inserted Kymriah, Novartis' CAR-T immunotherapy, within the country's budget for innovative oncological drugs. An estimated 600 patients per year (paediatric patients and young adults up to 25 years of age diagnosed with acute lymphoblastic leukaemia, and adults with diffuse large B-cell lymphoma, whose first two lines of systemic therapy were not effective) could be eligible for treatment. The new reimbursement scheme, known as “payment at result”, is also novel: treatments will be reimbursed to providers in three lump-sums: one at the beginning of treatment, one after 6 months and one after 12 months only in case of remission. This method aims at rewarding appropriateness of treatment. In November 2019, AIFA approved a second CAR-T therapy, Yescarta, by Gilead, which will follow a similar reimbursement scheme with payments at 6, 9 and 12 months from first administration. Currently, eight centres have been certified to administer CAR-T therapy; however, each region is currently working on additional authorisations.

Lithuania: New exemptions from user charges for people on low incomes

From July 2020, people with low incomes who reached retirement age or have a disability will be exempt from user charges for prescribed reimbursed medication. The exemption threshold is based on 95% of the minimum sustenance level in the preceding year (€176 per single person, or €251 per household in 2019). These groups were selected for exemption because, according to 2017 data on population income, people in retirement and disabled people were the groups at the highest risk of poverty and need for medical care.

Currently, the only exemptions from user charges for prescribed medicines are:

- full reimbursement for medicines used to treat selected diseases (tuberculosis, schizophrenia, cancer, epilepsy etc.);
- and b) selected medicines for patients

belonging to certain vulnerable groups (full reimbursement for children and severely disabled adults and 50% reimbursement for people in retirement and adults with moderate disability). Even in the case of full reimbursement, everyone still needs to cover the difference between the retail and reimbursement price of medication. The new policy is also expected to cover the latter charge.

Malta: Joining European Reference Networks

European Reference Networks (ERNs) are networks involving health care providers across Europe. They aim to tackle complex or rare diseases and conditions that require highly specialised treatment and concentrated knowledge and resources. There are 24 ERNs, covering a range of thematic areas including bone disorders, childhood cancer and immunodeficiency.

In Malta, Mater Dei Hospital (MDH) has been designated as a National Coordination Hub (NCH) for ERNs by the Superintendent of Public Health (SPH). The SPH is the competent authority set by law to perform this designation (Legal Notice 304 of 2018). On the basis of its NCH designation, MDH will be the 'link' for Malta with all 24 existing ERNs. The designation was communicated to the EU Commission, the Board of Member States and the Coordinators of each of the 24 ERNs in early July 2019. An ERN Coordination Unit is being set up at MDH. Over the next few months this unit will coordinate the establishment of a bilateral agreement between the hospital and each ERN.

Portugal: List of foods and drinks subject to advertising restrictions

Following implementation of Law No.30/2019 on restrictions to advertising of unhealthy food products for children under 16 years of age, the Directorate General of Health has issued a list of foods and drinks characterised by high calorific value, sugar content, salt content and fats, which jeopardise a healthy diet. The selection of drinks and foods took into consideration WHO recommendations according to the WHO Regional Office for Europe Nutrient Profile Model. The list

contains a total of 18 groups of products that include, among others, juices, milk, vegetable drinks, dairy, ready meals, bread and bread-based products. For each group, a maximum threshold for saturated fats, added sugar, salt, trans-fats and calorific value (in Kcal) per 100g of product is defined. All products above this threshold are considered unhealthy and advertising and consumption should therefore be restricted according to the terms defined under Law No.30/2019.

Romania: New measures introduced to improve access to health care services

In July 2019, the government approved several changes to the Framework Contract – the legislative document issued every two years that regulates provision of health services within the social health insurance system. These measures aim to improve access to statutory services and are in line with the National Health Strategy 2014–2020. They include:

(1) Introduction of a document (issued by the family doctor) confirming pregnancy to facilitate access to the basic services package for uninsured pregnant women during the prenatal and postpartum periods; (2) Extension of the validity of family doctor referrals to specialists, laboratory or palliative services for patients with chronic conditions, from 60 to 90 days; (3) Extension of the list of services that can be provided by day care units of hospitals; (4) Increasing the number of home care days covered within the benefit package from 90 days over the period of 11 months to 180 days

Slovakia: Implementation of National Cancer Screening Programmes

In 2018, Slovakia established a national cancer strategy. The aim of the strategy is to reduce cancer incidence and improve the survival and quality of life of cancer patients. The first measures introduced in 2019 included a pilot project for colorectal cancer screening and the definition of quality standards of mammography centres (licensed by the Ministry of Health). During the year, population screening programmes for cervical and breast cancers were also

introduced. The pilot on colorectal cancer included an invitation letter with a home-testing kit. The retention rate during the first 6 months was 30% (the proportion of the population who undertook colorectal cancer screening was roughly 20% for 2018). Based on a health technology assessment (HTA) of colorectal cancer screening, if the screening rate reaches 50%, there will be €1.6 million in immediate savings for health insurance companies and €16 million savings for public finances.

Spain: New National Plan for Alzheimer's disease

The Spanish Government and the autonomous communities approved a 2019–23 National Plan for Alzheimer's disease and other dementias in the last Inter-territorial Council (14 October 2019). More than 400,000 people live with Alzheimer's disease in Spain and this figure is expected to double in the coming decades as life expectancy increases. The National Plan aims to reduce the impact of Alzheimer's disease for patients, their families and caregivers and has been developed following the WHO directives and the Global Action Plan on the public health response to dementia 2017–25.

The National Plan has four lines of action: changing society's vision of the disease to prevent stigmatisation or discrimination; placing the patient at the centre of health and social care by developing health promotion policies and informing health professionals about risk factors, early detection, and appropriate treatments; tackling the rights and dignity of patients and caregivers by improving services, support and benefits; and, finally, encouraging research, innovation and knowledge.



COVID-19 Health System Response Monitor

The World Health Organization Regional Office for Europe, the European Commission, and the European Observatory on Health Systems and Policies are working on a timely initiative to systematically monitor health system responses to the COVID-19 pandemic.

<https://www.covid19healthsystem.org>

The COVID-19 Health Systems Response Monitor is an innovative platform which will collect and organize up-to-date information and enable cross-country analyses and comparisons of responses to the pandemic, as well as mapping wider public health initiatives, across the European region.

By combining this unique approach with links to important websites and essential data relevant to the pandemic and its impact, the COVID-19 Health Systems Response Monitor will be a key resource for policymakers and those responding to the crisis.

