Quarterly of the European Observatory on Health Systems and Policies

EUROHEALTH

incorporating Euro Observer

RESEARCH • DEBATE • POLICY • NEWS

› The changing role of nursing

Volume 22 | Number 1 | 2016

European Observatory on Health Systems and Policies
a partnership hosted by WHO

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: info@obs.euro.who.int
http://www.healthobservatory.eu

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 European Observatory on Health Systems and Policies is a partnership between the World Health Organization Regional Office for Europe, the Governments of Austria, Belgium, Finland, Ireland, Norway, Slovenia, Sweden, the United Kingdom and the Veneto Region of Italy, the European Commission, the World Bank, UNCAM (French National Union of Health Insurance Funds), London School of Economics and Political Science and the London School of Hygiene & Tropical Medicine.

Design and Production: Steve Still

ISSN 1356–1030

LSE Health

Eurohealth is available online http://www.euro.who.int/en/who-we-are/partners/observatory/eurohealth and in hard-copy format.
Sign up to receive our e-bulletin and to be alerted when new editions of *Eurohealth* go live on our website:
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

If you want to be alerted when a new publication goes online, please sign up to the ***Observatory e-bulletin:***
http://www.lse.ac.uk/lsehealthandsocialcare/publications/eurohealth/eurohealth.aspx

Back issues of *Eurohealth* are available at: http://www.euro.who.int/en/who-we-are/partners/observatory/eurohealth

CONTENTS

List of Contributors

Linda H. Aiken • Center for Health Outcomes and Policy Research, University of Pennsylvania, USA

Janet E. Anderson • Florence Nightingale Faculty of Nursing and Midwifery, King's College, London, United Kingdom

Diāna Arāja • Department of Pharmacy, Ministry of Health, Latvia

Louise Barriball • Florence Nightingale Faculty of Nursing and Midwifery, King's College, London, United Kingdom

Luk Bruyneel • Leuven Institute for Healthcare Policy, University of Leuven, Belgium

Reinhard Busse • Department of Health Care Management, Berlin University of Technology, Germany

Jonathan Cylus • European Observatory on Health Systems and Policies, UK

Paul De Raeve • King's College London and European Federation of Nurses Associations (EFN), Belgium

Gilles Dussault • Institute of Hygiene and Tropical Medicine, Nova University of Lisbon, Portugal

Josep Figueras • European Observatory on Health Systems and Policies, Belgium

Tamara Hervey • School of Law, University of Sheffield, England

Tom Keighley • independent health care consultant, United Kingdom

Keili Kõlves • Medicines and Medical Devices Division, Estonian Health Insurance Fund, Estonia

Claudia Leone • Florence Nightingale Faculty of Nursing and Midwifery, King's College, London, United Kingdom

Diana Ognyanova • Department of Health Care Management, Berlin University of Technology, Germany

Willy Palm • European Observatory on Health Systems and Policies, Belgium

Martin McKee • European Observatory on Health Systems and Policies, UK

Ellen Nolte • European Observatory on Health Systems and Policies, UK

Anne Marie Rafferty • Florence Nightingale Faculty of Nursing and Midwifery, King's College, London, United Kingdom

Edith Schippers • Minister for Health, Welfare and Sport, The Netherlands

Walter Sermeus • Leuven Institute for Healthcare Policy, University of Leuven, Belgium

Ruth Young • Florence Nightingale Faculty of Nursing and Midwifery, King's College, London, United Kingdom

Britta Zander • Department of Health Care Management, Berlin University of Technology, Germany

EDITORIAL

There is no doubt that the role of nurses has been changing over the past few decades, not only in terms of their evolving clinical and managerial responsibilities but also in terms of their education and training. These processes have been affected in many ways by developments at the European level, not least through directives on the free movement of professionals, as well as the mutual recognition of professional qualifications.

In this Spring issue, Zander et al. kick off the **Observer** section by outlining the main findings of a wide-ranging and multi-country study on the current European nurse workforce and how the work environment and qualifications impact on retention rates, job satisfaction and patient care. Delving more deeply into the theme of nurse workforce migration, Leone et al. cast light on the complex combination of factors that shape the debate on the current imbalance of nurse supply and demand across European Union Member States. The authors use the United Kingdom and Portugal as illustrative case studies on the impact of increased mobility caused by some countries targeting others to fill their nursing vacancies.

Next, De Raeve and colleagues analyse whether European enlargement provides an opportunity for the nursing profession to gain traction on policy change. They report on findings related to the robustness of EU compliance mechanisms and the degree to which the nursing leadership is engaged in agenda setting and policy-making. This section rounds off with an article by Keighley, who explores how policy-making at the European level focused primarily on the free movement of professionals, harmonisation of training, and mutual recognition of education and training standards has resulted in a largely unplanned new European framework for nurse education and training. The author notes that this process has not always taken stock of the specific policy priorities of nurse representative groups.

In our **International** section, Edith Schippers, Minister for Health, Welfare and Sport in the Netherlands, discusses the three health priorities for the 2016 Dutch presidency of the EU, all of which have a strong cross-border dimension. In his article on the implementation of the Directive on patients' rights in cross-border health care, Palm discusses the reasons why patient mobility remains quite low and highlights how national variations in transposition, interpretation and transparency have created persistent hurdles. Completing this section is an article by Hervey assessing the claims made by the health policy community on the impact of European Union health law. Her detailed assessment is presented through the lens of four themes: consumerism; rights; equality, solidarity, and competition; and risk.

Finally, in the **Systems and Policies** section Arāja and Kõlves explain how Managed Entry Agreements (MEAs) have been employed in Estonia, Latvia and Lithuania as one of a number of tools designed to make new medicines available to patients, while at the same time safeguarding the financial sustainability of the health system. This is followed by an article critiquing the health system rankings of the Health Consumer Powerhouse by Cylus et al.

Our **Monitor** section features two new studies on strengthening health system governance and on making sense of European Union health law, while the normal round up of news brings you the latest on health policy developments around Europe.

We hope you enjoy the Spring issue!

Sherry Merkur, Editor
Anna Maresso, Editor
David McDaid, Editor

Cite this as: *Eurohealth* 2016; 22(1).

THE STATE OF NURSING IN THE EUROPEAN UNION

By: Britta Zander, Linda H. Aiken, Reinhard Busse, Anne Marie Rafferty, Walter Sermeus and Luk Bruyneel

Summary: The current European nursing workforce crisis is exacerbated by nursing shortages in most countries. Measures will need to be adopted to maintain a healthy and satisfied nurse workforce, to attract new nurses and to guarantee high quality care. The Registered Nurse Forecasting (RN4CAST) project aimed to study how features of work environments and nurse workforce qualifications impact on nurse and patient outcomes by confirming, in a large European setting, the core logic of previous US research. The results confirmed previous findings and highlighted the important role of nurses in providing safe patient care and pave the way for a renewed discussion on the direction of nursing's future in Europe.

Keywords: *Nurse Workforce Strategies, Nurse Work Environments, Nurse Education, Patient Safety, RN4CAST*

Acknowledgment: This research received funding from the European Union's Seventh Framework Programme (FP7/2007–2013, Grant Agreement No 223468).

Britta Zander is Research Fellow and **Reinhard Busse** is Professor and Head of the Department of Health Care Management, Berlin University of Technology, Germany; **Linda H. Aiken** is Professor and Director at the Center for Health Outcomes and Policy Research, University of Pennsylvania, USA; **Anne Marie Rafferty** is Professor at the Florence Nightingale School of Nursing and Midwifery, King's College, London, United Kingdom; **Walter Sermeus** is Professor and Program Director and **Luk Bruyneel** is a post-doctoral researcher at the Leuven Institute for Healthcare Policy, University of Leuven, Belgium.
Email: britta.zander@tu-berlin.de

Introduction

Organisational features of nursing care, from better patient-to-nurse staffing ratios to supportive work environments and better educated nurses, are associated with improved nurse wellbeing and better patient outcomes. In the United States, this evidence has emerged over the past three decades through numerous research programmes and has fuelled debates about the direction of nursing's future. Several high-profile policy and advocacy initiatives have been launched to achieve safe nurse staffing and improved work environments, such as mandated safe nurse staffing ratios and the Magnet Hospital Accreditation Programmes for excellence in nurse work environments. In Europe, there is limited evidence of a similar large-scale uptake of these findings. Since nursing shortages threaten almost all European countries, measures need to be adopted to maintain a healthy and satisfied nurse workforce, to attract new nurses and to guarantee high quality care.

Until recently, the limited policy impact of the existing evidence on the important role of nurses in providing safe patient care was attributed to the evidence base being mainly from North America. The first European study published in 2007[1] confirmed the US findings and was followed by a Belgian study in 2009.[2] Additionally, the Registered Nurse Forecasting (RN4CAST) study was able to scale up evidence to a multi-country context, confirming in a large European setting the core logic of previous US research. As a result, good nursing workforce strategies are now associated in Europe with improved patient outcomes. Moreover, the RN4CAST findings have

paved the way for a renewed discussion on the professional profile of nursing in Europe.

Research on nursing workforce strategies in Europe

The RN4CAST study (2009–2011) aimed to study how features of work environments and nurse workforce qualifications impact on nurse retention, job satisfaction and burnout among nurses and on patient outcomes. Related to this last measure, the study looked at how nurses could enhance the performance of health care organisations and health itself. The consortium brought together researchers from sixteen countries: twelve participating European countries (Belgium, England, Finland, Germany, Greece, Ireland, the Netherlands, Norway, Poland, Spain, Sweden and Switzerland), three from outside Europe (China, Botswana and South Africa) while leading researchers from the US co-directed the consortium, providing guidance from study design to analysis. Drawing on previous experience of the 'International Hospital Outcome Study', wherever possible, a pool of well-known and extensively-validated tools, supplemented with recent measures that are important to evaluate nurses' roles in patient care were used. Details are described in depth elsewhere[3] but it is appropriate to provide a short overview of the design to convey the scale and scope of RN4CAST.

'Nurses' were defined in each country as those meeting the EU definition of trained and licensed nurses according to Directive 2005/36/EC. The nurse survey consisted of 118 questions, containing the Practice Environment Scale of the Nursing Work Index (PES-NWI) and the Maslach Burnout Inventory (MBI) and included information on the quality of their work environment, burnout, job satisfaction, quality of care, nurse staffing levels and demographics. It was completed by 33,659 medical-surgical nurses working in 488 hospitals across the twelve European countries. To measure patient satisfaction and nursing related experience with their hospital stay, patient experience data were obtained for 11,549 patients in 217 hospitals in eight countries (Belgium, Finland, Germany, Greece, Ireland, Poland, Spain and Switzerland). The patient survey included questions about communication with nurses and doctors, responsiveness of hospital staff, pain management, communication about medicines, discharge information, cleanliness and quietness of the hospital environment, overall rating of the hospital and willingness to recommend the hospital to friends and family. Additionally, hospital discharge abstract datasets were collected to calculate the impact of nursing care on patient outcomes. All countries except Germany, Greece and Poland had the required data available in a format that allowed cross-country comparisons. For the nine countries and the selected hospitals 3,987,469 patient records were collected using ICD-10 data in five countries and ICD-9-CM data in four countries.

> 20–50% of nurses intended to leave their current job

Findings

The study results showed large differences throughout Europe.* More than 25% of nurses were dissatisfied with their job; however, dissatisfaction varied dramatically across the twelve European countries and sources of dissatisfaction varied as well. No country was immune from nurses' negative work perceptions and 30% of nurses reported burnout. In spite of these seemingly high levels of dissatisfaction and burnout, fewer than 1 in 4 nurses in all countries, except Greece (40%) and Ireland (28%), reported being dissatisfied with their choice of nursing as a career. Nonetheless, between 20–50% of nurses in every country intended to leave their current job in the next year and of those that expressed such intentions, about 9% (varied from 5% to 17% between countries) indicated that the job they would seek would be outside of nursing due to features of the work environment such as poor nurse-physician relationships, leadership, participation in hospital affairs and burnout.[5]

The number of patients per nurse during day-shifts estimated in the different countries ranged from roughly four or five patients per nurse in Norway, the Netherlands, Switzerland and Sweden to nine or ten per nurse in Belgium, Greece, Poland, Germany and Spain. In fact, each additional patient per nurse increased the likelihood of nurses reporting burnout, job dissatisfaction and intention to leave within the next year. Supporting these staffing ratios, the majority of nurses in most countries also reported that there were not enough nurses or adequate support services to provide good patient care. The effect of the work environment was generally stronger than the specific staffing effect which emphasises the need to strengthen the work environments of nurses. In contrast, an important finding of the study was that almost every country under study had one or more hospitals that nurses ranked as having good work environments. However, hospital quality, safety and staff retention problems were common in all countries.

The role of nurses in providing safe patient care

The percentages of patients who gave high overall ratings to their hospital ranged from 35% in Spain to close to 60% in Switzerland, Finland and Ireland. Patients were less satisfied with their hospital stay in those hospitals with worse nurse work environments whereas patients in hospitals with better work environments were more likely to rate their hospital highly and to recommend it. The same applied for patients in hospitals that had higher percentages of burnt out or dissatisfied nurses and more patients per nurse (that is, increased nurse workload).[6]

Using data from 422,730 patients aged 50 or older who underwent common surgery (orthopaedic surgery, vascular surgery, general surgery), it was demonstrated that increasing a nurses' workloads by

* An RN4CAST special issue published by the *International Journal of Nursing Studies* in 2013 provided a descriptive report about the RN4CAST results and the state of hospital nursing practice in Europe (see Ref 4).

one patient increased the likelihood of mortality by 7%. Furthermore, the results suggested that having a better educated nurse workforce (that is, every 10% increase in nurses with Bachelor degrees) reduced the likelihood of mortality by 7%. These associations imply that patients in hospitals in which 60% of nurses had Bachelors degrees and nurses caring for an average of six patients would have almost 30% lower mortality than patients in hospitals in which only 30% of nurses had Bachelors degrees and nurses cared for an average of eight patients.[7]

Methodological progress

The RN4CAST study not only confirmed US findings, but also provided significant methodological progress. Several RN4CAST studies analysed in detail the concept of missed nursing care, which pertains to omission of necessary nursing care.[8,9] The thinking was that missed nursing care reflects the process of care and was defined as necessary nursing activities that were missed due to lack of time. Thirteen nursing care activities related to direct physical care and monitoring, planning and documenting care and psychosocial care were defined. Nurses were asked to indicate whether activities that were necessary were left undone due to a lack of time during their most recent shift. Across European hospitals, the most frequent nursing care activities left undone included 'Comfort/ talk with patients' (53%), 'Developing or updating nursing care plans/care pathways' (42%) and 'Educating patients and families' (41%). It was also shown that those tasks which were more likely to have negative consequences for patients (e.g. pain management or medication on time) were missed less frequently than those tasks with less immediate or direct effects (e.g. psycho-social). Furthermore, the results showed that less care was omitted in hospitals with more favourable work environments, lower patient to nurse ratios and lower proportions of nurses carrying out non nursing tasks frequently. In addition, it was shown that the effect of poorer nurse staffing on more care left undone diminishes with an increasing proportion of university-educated nurses.[10]

Summary and policy implications

The RN4CAST study generated a large evidence base of nurse workforce issues across European health systems, which was unique regarding data on the number and qualifications of nursing staff, the quality of working environments, burnout rates, job satisfaction rates and intention-to-leave rates. High variability in nurse workforce issues was found across Europe. In summary, RN4CAST strengthened the belief that improvements can be made at an incremental rate if policy-makers and human resources managers acknowledge that nursing workforce strategies are modifiable properties of a health care organisation in its mission to provide excellent patient care. The study followed-up with a wide range of capacity building and knowledge dissemination activities, providing resources to bolster future health workforce strategies.

> increasing a nurse's workload by one patient increased the likelihood of mortality by 7%

The current European nursing workforce crisis is exacerbated by nursing shortages in most countries and by the increasing numbers of patients admitted to hospital. Measures will need to be adopted to maintain a healthy and satisfied nurse workforce, to attract new generations of nurses, to sustain the workforce of nurses wishing to retire early or remain longer in the job and to have nurses working part-time due to dissatisfaction return to full-time status. These measures go beyond only increasing staffing levels. Levers for improving the quality of patient care include investing in a better educated nurse workforce and improving work environments.

Two take home messages for policy-makers include: 1) significant improvements in work environments can be a relatively low cost lever and effective approach to achieving the greatest value for investments in nurse staffing because it strengthens the nurse workforce through better working conditions, which will attract new nurses and avoid high turnover rates; and 2) comprehensive planning and forecasting methodologies are needed that account for increases in the dependency of the population on the health system due to demographic change.

EU policy makers can also look to findings from other recent European projects where RN4CAST has contributed, i.e. the Joint Action of Health Workforce Planning and Forecasting (2013–2016)† and a study on effective recruitment and retention for health workers (2014–2015).‡

In addition, the study conclusions that nurse qualifications are related to patient mortality can influence further decision making on the European nursing qualification structure which is positioning nurse education at the Bachelor degree level (see also the article by Keighley on nursing education in this issue). While countries have made progress, there is still great diversity and differences in the pace with which they have sought to transform their nurse training systems from being vocationally-based to academically-based. Moreover, some countries lack clinical career paths that are necessary to motivate advanced education (e.g. Sweden) while others do not differentiate between the roles of higher educated and intermediate educated nurses in practice (e.g. the Netherlands, Belgium).

Lastly, evidence on the variability of patient-to-nurse ratios in European hospitals has created momentum in several national policies not to lower their nurse staffing ratios in times of austerity. In England, safe nurse staffing ratios in adult patient wards in acute hospitals have been recommended by the National

† http://healthworkforce.eu/

‡ http://ec.europa.eu/health/workforce/policy/recruitment/index_en.htm

Institute for Health and Care Excellence (NICE) since July 2014, partly based on RN4CAST evidence.

> European evidence on the economic value of nursing remains scarce

Strengthening health systems through nursing

The work of the consortium continues to gather momentum. Some other countries are replicating the RN4CAST study (Portugal in 2013; Cyprus and Italy, currently underway). The US, Germany and Belgium are collecting data in 2015/2016 to provide a longitudinal perspective. Thus, the work of RN4CAST continues with the common objectives of highlighting the importance of nursing in improving patient outcomes and promoting and improving the situations for nurses in their countries. Future initiatives will aim to model the complexity of nursing workforce strategies in an intervention in order to assess the optimum level of production. Such initiatives are expected to provide more steering in developing workforce strategies as well as to allow the building of a business case, because European evidence on the economic value of nursing remains scarce.

Further reading

A comprehensive overview of nurses' situations in fourteen European countries (the original twelve RN4CAST countries plus Lithuania and Slovenia) is due to be published in autumn 2016.[11] The book will place the RN4CAST findings into context by elaborating for each country the organisation of the health system, nurse education and regulation, the structure of nurses' work and the composition, deployment, career structure, planning mechanisms, as well as mobility of nurses. Further, thematic chapters will focus on the contribution of nursing to health care systems, nurse education, workforce planning, migration, and regulation.

References

1 Rafferty AM, Clarke SP, Coles J, et al. Outcomes of variation in hospital nurse staffing in English hospitals: cross-sectional analysis of survey data and discharge records. *International Journal of Nursing Studies* 2007;44(2):175–82.

2 Van den Heede K, Lesaffre E, Diya L, et al. The relationship between inpatient cardiac surgery mortality and nurse numbers and educational level: analysis of administrative data. *International Journal of Nursing Studies* 2009;46(6):796–803.

3 Sermeus W, Aiken LH, Van den Heede K, et al. Nurse forecasting in Europe (RN4CAST): Rationale, design and methodology. *BMC Nursing* 2011;10:6.

4 Aiken LH, Sloane DM, Bruyneel L, Van den Heede K, Sermeus W, RN4CAST Consortium. Nurses' reports of working conditions and hospital quality of care in 12 countries in Europe. *International Journal of Nursing Studies* 2013;50(2):143–53.

5 Heinen MM, van Achterberg T, Schwendimann R, et al. Nurses' intention to leave their profession: a cross sectional observational study in 10 European countries. *International Journal of Nursing Studies* 2013;50(2):174–84.

6 Aiken LH, Sermeus W, Van den Heede K, et al. Patient safety, satisfaction and quality of hospital care: cross sectional surveys of nurses and patients in 12 countries in Europe and the United States. *British Medical Journal* 2012;344:e1717.

7 Aiken LH, Sloane DM, Bruyneel L, et al. Nurse staffing and education and hospital mortality in nine European countries: a retrospective observational study. *The Lancet* 2014;383(9931):1824–30.

8 Ball J, Murrells T, Rafferty AM, Morrow E, Griffiths P. "Care left undone" during nursing shifts: associations with workload and perceived quality of care. *BMJ Quality and Safety* 2014;23(2):116 – 25.

9 Ausserhofer D, Zander B, Busse R, et al. Prevalence, patterns and predictors of nursing care left undone in European hospitals: results from the multicountry cross-sectional RN4CAST study. *BMJ Quality and Safety* 2013 Nov 10.

10 Bruyneel L, Li B, Ausserhofer D, et al. Organization of hospital nursing, provision of nursing care and patient experiences with care in Europe. *Medical Care Research Review* 2015; 72(6):643–64.

11 Rafferty AM, Busse R, Zander B, Bruyneel L, Sermeus W. *The contribution of nursing to heath system performance: A European perspective.* Copenhagen: European Observatory on Health Systems and Policies, 2016 Forthcoming.

United Kingdom: Health system review

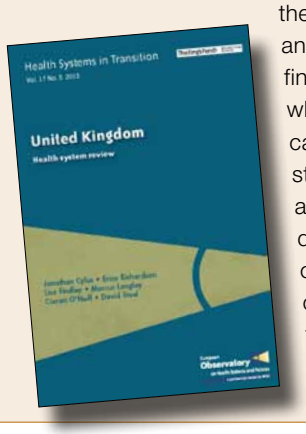
By: J Cylus, E Richardson, L Findley, M Longley, C O'Neill and D Steel

Copenhagen: World Health Organization 2015 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies).

Number of pages: xxvii + 125 pages; **ISSN:** 1817-6127

Freely available for download at: http://www.euro.who.int/__data/assets/pdf_file/0006/302001/UK-HiT.pdf?ua=1

The United Kingdom spends less on health compared to many other Western European countries, yet the national health services function remarkably well overall. Many health outcome measures, such as amenable mortality, have improved in recent years due in part to public health initiatives and a general emphasis on improving the quality of care. However, the marked reductions to health and social care budgets since the financial crisis call into question whether the United Kingdom can continue this progress. As it stands, health inequalities remain and the gap between the most deprived and the most privileged continues to widen, rather than close, despite universal access that is mostly free at the point of use.



NURSE MIGRATION IN THE EU: A MOVING TARGET?

By: Claudia Leone, Ruth Young, Diana Ognyanova, Anne Marie Rafferty, Janet E. Anderson and Gilles Dussault

Summary: The nursing profession is the most numerous and increasingly mobile element of the health workforce. Imbalances of nurse supply and demand across the EU/EEA are generating challenges for policy-makers and managers. Increasing mobility within the EU/EEA has been caused by countries targeting others within the region to fill nursing vacancy posts, although the number of nurses is finite. Data from two studies on migration to the English National Health Service are analysed to provoke a more informed debate on the increasing complexity of migration in the current EU/EEA agenda and the possible consequences for the supply of the nursing workforce.

Keywords: *Nurses, Nurse Shortages, EU/EEA mobility, Portugal, England*

Acknowledgement: The study upon which this article is based draws from a study funded by The Foundation for Science and Technology, UK PhD Grant SFRH / BD /94301 / 2013.

Claudia Leone is a PhD candidate, **Ruth Young** is Reader in Health Policy Evaluation, **Anne Marie Rafferty** is Professor and **Janet E. Anderson** is Senior Lecturer at the Florence Nightingale Faculty of Nursing and Midwifery, King's College, London, United Kingdom; **Diana Ognyanova** was Research Fellow at the Department of Health Care Management, Berlin University of Technology, Germany at the time of writing this article; and **Gilles Dussault** is Professor of International Public Health and Biostatistics at the Institute of Hygiene and Tropical Medicine, Nova University of Lisbon, Portugal. Email: claudia.leone@kcl.ac.uk

Introduction

A message consistently emerging from the literature on health systems is their increasing vulnerability to workforce fluctuations.[1] Mobility is one factor with the potential not only to determine how health services are organised, planned and delivered within a health system, but also to generate imbalances in supply and demand from region to region.[2,3] This is particularly the case in the European Union and European Economic Area (EU/EEA), where mobility is facilitated by the principle of freedom of movement.

The nursing profession is the most numerous, and increasingly mobile, element of the health workforce.[4] Recognition of this for the quality and effectiveness of care is gaining increasing traction with policy-makers and managers. Cross-border migration within the EU/EEA is seen as having a significant but largely unmeasured effect.[5] The real challenge posed by increasing mobility is the implications it has for workforce planners. In contrast to non-EU flows, which can be controlled through immigration regulations, there are no formal monitoring mechanisms between EU/EEA countries and very few certainties regarding the pattern, destination and length of stay for EU nationals.

In England, recent reports confirm that the nursing shortage persists across the whole country, across all types of health care organisations and all areas of practice,[6] leading most National Health Service (NHS) organisations to become increasingly active in recruiting nurses in other EU countries, such as Portugal, to fill vacancies.[6] In what follows, we attempt to provoke a more informed debate on the need to recognise the increasing complexity of factors affecting migration in the current EU/EEA agenda and the possible consequences, intended and unintended, for the supply of the nursing workforce. We use material from two European studies: data from Portugal

newly added to the RN4CAST dataset[2] and the PROMeTHEUS series,[5,7,8] from which data are being gathered in a book on nursing from the EU Observatory on Health Systems and Policies.[9]

Firstly, we map the current nursing shortage and the most common policy responses in England. Second, we present data that show the changing and complex nature of mobility trends. Third, we emphasise the impact on Portuguese nurses. Finally, we consider the implications for sending and receiving countries.

National shortages

England, as a traditional destination for health professionals from inside and outside the EU,[5] can showcase the ongoing shifts in mobility patterns within the EU/EEA. Like many other industrialised countries in the region, England has remained an attractive option for nurses looking for work opportunities abroad. PROMeTHEUS and earlier studies[5,7] suggest that the most attractive "pull" factors are: the greater opportunities for professional development through postgraduate education available in the UK; the English language; and geographical proximity to the rest of Europe.

However, despite the increasing flows of foreign nurses, there is evidence that poor staffing levels and vacancy rates in the NHS are a persistent problem. There are no official figures on how many nurses the system is currently short of, but according to recent data from an NHS Trusts survey, national vacancy rates run at 10%. Ninety three percent of Trusts are reporting shortages, of which 72% are hard-to-fill vacancies (i.e. vacant for more than three months).[6] Overall, the current situation is one of a national nursing shortage.

Concerns about the consequences of these vacancy rates have been mounting, particularly since the effects on quality of services and on mortality rates have been highlighted.[2] Organisational and policy responses, such as using agency/temporary nurses, return-to-practice campaigns and increased adult nurse training numbers, have been put in place in an attempt to address current vacancies and projected severe shortages. However, all these responses either promise results in the long term (e.g. the results of increasing training places will be visible from 2020 onwards[9]) or rely on strategies that have no assurance of being more than just a temporary stop-gap to manage shortages. As NHS organisations are in urgent need of a larger pool of nurses, many have become more active in recruiting nurses in EU/EEA countries.[6]

Changing patterns of mobility

International practices in England have included specially-arranged recruitment fairs in several countries. Until a few years ago, the most common destinations were the Philippines and India.[5,7] But in recent years, large pools of low-paid and unemployed nurses in EU/EEA countries which were most severely affected by the economic crisis, such as Portugal, Spain and Italy, have been serving as the target for many trusts in need of skilled nurses. Registration data showed that in 2014–15, a total of 8,183 internationally recruited nurses joined the Nursing & Midwifery Council (NMC) register to work in the UK; 7,518 (92%) from within the EU/EEA and 665 (8%) from outside the EU/EEA.[10] Recent policy reports also found that 93 NHS Trusts (63% of all respondents in a survey) have actively recruited from outside of the UK in the last 12 months: 62% of these have targeted recruitment activity only in EU/EEA countries during the same period, mainly in Italy, Spain and Portugal.[6] Data specifically about Portugal,[2] showed that the number of Portuguese nurses registered with the NMC increased from 250 to 1,211 from 2010 to 2013, which represents an estimated five-fold increase. Early findings of ongoing research* suggest that Portugal became the second biggest source of recently recruited foreign nurses after Spain in the same time period.

But the mobility of health professionals has always had a dynamic and changing nature, particularly evident in periods of major economic or geopolitical change.[5] Despite the reliance on these EU/EEA focused recruitment flows, there is little empirical research on the impact of these flows on health care organisation, and more importantly, on their duration, to inform workforce planners. According to many organisations, throughout 2014–15 the pool of available nurses (potential new recruits) from within the EU/EEA was found to be smaller than in previous years.[6] As vacancy rates spread, more organisations (and countries) are led to join the search for nurses through European recruitment drives. However, the stock of nurses from EU/EEA countries is finite,[6] and the number of recruiters has been growing.

Many factors may account for the changing patterns of migration trends.[5,7] First, EU nurses are exercising their rights of free movement underpinned by Directive 2005/36/EC and its updated version in 2013 (2013/55/EU[11]) on the recognition of professional qualifications. Second, changes in policies regarding immigration and professional registration have a clear impact on the number of professionals from non-EU countries. Such changes include monthly limits on secured restricted certificates of sponsorships (RCoS) and the decision to exclude or include nursing in the Shortage Occupation List (SOL). Following the decision to first exclude nursing from the SOL in early 2015, many organisations were unable to secure RCoS for nurses from out of the EU/EEA, slowing down their recruitment.[6] Since December 2015 (and at least until planned a review in spring 2016), nursing is back in the SOL, which seems likely to impact on the directional flow of recruits from non EU/EEA countries once again. Finally, recent amendments to the 2005/36/EC Directive on professional qualifications, such as the agreement to introduce language competency controls for professions, has consequences for patient safety and needs to be considered as well.[11] The impact of these language checks remains to be seen but it is likely to further reduce the pool of EU/EEA nurses, as has been the case for the medical profession when the General Medical Council introduced this requirement in 2014.[6]

* This article outlines part of the background of an ongoing PhD study on the implication of EU-nurse (Portuguese) Recruitment for NHS organisations in England.

Tension between national interests and EU policy

According to EU regulations, it is the responsibility of individual countries to decide how their services are delivered, how treatment or care is paid for, and, most importantly for us here, how or which health staff are trained and deployed, where and in what numbers. This is defined by the principle of *subsidiarity* of the EU.[11] However, since free movement is a reality, it has become obvious that health services and the development of the health care workforce within Member States cannot be understood without also considering the broader EU-level legislative changes that are being driven by economic and geopolitical factors.[7]

Drivers of health workforce shortages, such as demographic changes in the population and in the health professions, and increasing demand for care have been abundantly reported.[3,5] Yet, shortages are also generated by policies and austerity measures at the national[6] and European levels. Both have influences that may limit recruitment, replacement and retention to meet savings and to address particular concerns around mobility (e.g. language competency).

From this, what is clear is that EU/EEA recruitment is not a strategy that can be considered reliable or sufficient on its own to address workforce problems. Even if it serves the national interests of receiving countries, such as England, it is unlikely to solve skill shortages as it does not focus on the issues that led to the present situation. It also fails to foster the principle of solidarity and cooperation between EU/EEA countries, as the pulling power of some countries may weaken the possibility of others to retain their remaining workforce.[5,7]

Towards more helpful debates

Mobility patterns between Portugal and England are relevant to the broader EU situation on account of the characteristics they share with other sending and receiving countries in the region. Countries such as Portugal, but also Spain and Italy, have well-educated, newly-qualified and experienced nurses motivated to work within their profession but unable to find employment, as their national health systems are unable to absorb them.[5] This is not due to lack of need but due to lack of funds and/or sector reform restrictions. In other countries such as England and Germany, organisations have unfilled posts and are willing to pay high rates for temporary nurses, assuming also recruitment and travel costs to attract professionals from abroad.

One way of starting to tackle these labour market deficiencies is to recognise and document the complexity of factors influencing migration. Those which, on balance, are losing their nurses to other countries need to understand what measures they can implement to keep more health workers at home and/or encourage and benefit from return migration. Data from PROMeTHEUS, RN4CAST,[2,8] and more recently from an EU commissioned Recruitment and Retention study,[7] help to address that information gap by exploring the importance of workforce management and working environments for nurse retention. PROMeTHEUS studies[5] showed that relying on the expectation that nurses gain additional skills, competencies and experiences abroad to be applied back when they return is short sighted. In practice, experience in another European country may not always be seen as compatible or even relevant to a nurse's home country.[5] This might explain why these studies found that nurses stay in their new country much longer than they expected, and some permanently.

For those on the receiving end, the logical solution would be to move to a position of greater self-sufficiency. They could also do more to engage with sender countries to encourage and facilitate re-integration for returners. Bilateral agreements, institutional collaborations and exchange programmes are some examples of options proposed in the literature.[5]

Overall, the primary aim has to be to ensure that the individual patient experience is safe and of high quality. But health providers also need to be assisted to obtain maximum value from employing EU/EEA nurses and nurses themselves need to be empowered and assisted to gain the maximum benefits from moving to another EU/EEA country.[7] This will be possible only through closer policy articulation between organisations, and national and European authorities.

Conclusions

Nurses will not stop moving to, from, and within Europe. However, in the current context, the scale and impact on the workforce and on health systems are raising concerns. Policy-makers and managers need to respond both within particular countries and at the EU/EEA level. Countries receiving health workers from abroad need to work towards achieving greater self-sufficiency while also helping professional and employer organisations to provide migrants with support to integrate them effectively into the workforce. Those losing their nurses to other countries need to understand what measures they can take to avoid uncontrolled and undesired outflows and how to benefit from return migration.[6]

The focus of most of this will have to be on the interaction between policy and organisational levels and on the workplace itself. It is important not only to maximise the contribution of these highly qualified professionals to either sending or receiving health systems, but also to reinforce one of the founding principle of the EU/EEA, which is for individuals to deploy their skills and qualifications where they choose. Data from recent studies are already sufficient to provoke a more informed debate about the need to recognise the increasing complexity and tension between national interests and EU policies in the current EU/EEA agenda and the possible intended and unintended consequences on workforce planning and management of the nursing workforce across Europe.

References

1 Glinos IA. Health professional mobility in the European Union: Exploring the equity and efficiency of free movement. *Health Policy* 2015;119:1529 – 36.

2 Leone C, Bruyneel L, Anderson JE, et al. Work environment issues and intention-to-leave in Portuguese nurses: A cross-sectional study. *Health Policy* 2015;119:1584 – 92.

3 Kreutzen M, Dussault G, Craveiro I, et al. Recruitment and retention of health professionals across Europe: A literature review and multiple case study research. *Health Policy* 2015;119: 1517 – 28.

EU ACCESSION: A POLICY WINDOW FOR NURSING?

By: Paul De Raeve, Anne Marie Rafferty and Louise Barriball

Summary: European enlargement provides an opportunity for the nursing profession to gain traction on policy change but our research demonstrates that the European Commission mechanisms to process compliance need to be robust and designed to deliver such change. These opportunities also increase when the nursing leadership operates across a united front and articulates its agenda with a clear political voice. In addition to a united leadership, we argue that nursing needs support from civil servants and EU officials so that it can influence the EU accession policy agenda relating to nursing and shape successful policy outcomes.

Keywords: *Acquis Communautaire, EU Accession, Nursing Leadership, Stakeholder Engagement, Taiex, Health Policy*

Introduction

European enlargement has been the subject of extensive investigation in a wide range of policy areas.[1] However the impact of European Union (EU) enlargement upon one of the largest health professions, nurses, has been largely neglected in health policy research. European institutions are currently halting EU enlargement although there are Commission negotiations and preparations with five candidate countries: Albania, the former Yugoslav Republic of Macedonia, Montenegro, Serbia and Turkey, Bosnia and Herzegovina, Kosovo, Georgia and Ukraine are potential candidates. Becoming an EU Member State entails working towards a well-functioning democracy with stable institutions and the rule of law being guaranteed, with human rights and the protection of minorities being legally guaranteed and respected in practice.[2] In addition to these political requirements, membership of the Union requires a functioning market economy and the capacity to cope with competitive pressures and market forces within the Union.[3]

Acquis Communautaire

The EU accession process consists of negotiations between national governments and the European Commission with the aim of aligning national legislation with the European Directives set out in the *Acquis Communautaire*. The Acquis comprises several chapters reflecting the broad sectors of EU responsibility, including Chapter 3, incorporating the free movement of "nurses responsible for general care" (Directive 2005/36/EC, recently modernised by Directive 2013/55/EU). This Directive includes the recognition of

4 Kingma M. *Nurses on the move: migration and the global health care economy*. NY: Cornell University Press: Ithaca, 2006.

5 Buchan J, Wismar M, Glinos IA, Bremner J (eds). *Health professional mobility in a changing Europe New dynamics, mobile individuals and diverse responses*. Copenhagen: WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies, 2014. Available at: http://www.euro.who.int/__data/assets/pdf_file/0006/248343/Health-Professional-Mobility-in-a-Changing-Europe.pdf

6 NHS Employers. *NHS registered nurse supply and demand survey – findings*, 2015. Available at: http://www.nhsemployers.org/case-studies-and-resources/2016/01/2015-nhs-registered-nurse-supply-and-demand-survey-findings

7 Young R, Weir H, Buchan J. Health professional mobility in Europe and the UK: a scoping study of issues and evidence. *Research Report produced for the National Institute for Health Research Service Delivery and Organisation Programme,* 2010.

8 Zander B, Blumel M, Busse R. Nurse migration in Europe – Can expectations really be met? Combining qualitative and quantitative data from Germany and eight of its destination and source countries. *International Journal of Nursing Studies* 2013;50(2):210 – 8.

9 Rafferty AM, Busse R, Zander B, Bruyneel L, Sermeus W. *The contribution of nursing to heath system performance: A European perspective*. Copenhagen: European Observatory on Health Systems and Policies, 2016. Forthcoming.

10 The Royal College of Nursing (RCN) 2015 International Recruitment 2015. The Royal College of Nursing, London. Available at: https://www2.rcn.org.uk/__data/assets/pdf_file/0007/629530/International-Recruitment-2015.pdf

11 European Commission. Modernisation of the Professional Qualifications Directive – frequently asked questions. Brussels: Commission for the European Communities, 2013. Available at: http://europa.eu/rapid/press-release_MEMO-13-867_en.htm

Paul De Raeve is King's College London PhD and Secretary General of the European Federation of Nurses Associations (EFN); **Anne Marie Rafferty** is Professor of Nursing Policy, **Louise Barriball** is Professor of Healthcare Education, Florence Nightingale Faculty of Nursing and Midwifery, King's College London, United Kingdom. Email: efn@efn.be

professional nursing qualifications, and transposing the minimum requirements of the Directive relating to the minimum entry level of general education; the full educational programme of 4600 hours; a minimum one third of the educational programme being theoretical and at least 50% being spent on clinical training on a full-time basis. Most importantly, new Article 31, sets out eight competencies and makes it clear who is a general care nurse according to EU Legislation. As the nursing profession is one of the most mobile professions in the EU, compliance with the European Directive on Mutual Recognition of Professional Qualifications (MRPQ) is key for patient safety and quality of care[4,5] and protecting the individual nurse willing to move within the EU.

TAIEX

The compliance policy process for EU membership is supported by the European Commission's Technical Assistance and Information Exchange (TAIEX) peer reviews and capacity building seminars. Taiex is the instrument responsible for all technical assistance elements in relation to preparations for the application of the *Acquis*. Peer reviews are the main mechanism for determining whether adequate administrative infrastructure and capacity are in place to ensure full implementation of the Acquis and they also pinpoint areas that require further strengthening. The Taiex capacity-building seminars are therefore largely demand driven, facilitating the delivery of appropriate tailor-made expertise. The peer review reports tend to be an important source of information for the Commission's comprehensive monitoring reports upon which political leaders from the European Commission, the European Council and the European Parliament make informed decisions on progress towards compliance with the Acquis.

Lessons can be learned from the Romanian and Croatian EU accession process. The main criteria for selecting Romania and Croatia relate to their historical and political contexts, their different positions within the EU accession process – especially timing and the stage reached in the overall accession process at the time of the study – and the different levels of development of nursing as a profession.

Nursing after Ceausescu and Tito

The starting point at which the Romanian and Croatian nurse leaders entered EU accession differed from economic and political perspectives. While Croatian nurse leaders lived through a well-functioning free market economy but had to endure a terrible Balkan War, the Romanian nursing leadership found itself in a collapsed economy, inefficient state institutions, a highly politicised and unaccountable judiciary and public administration, corruption, political apathy and mistrust. Although Romania and Croatia differed on the political and economic EU membership criteria, the status of nursing education post-communism was quite similar: nursing education at the secondary level was located within vocational and technical schools and as such, 'nurses' were called medical assistants.

Romania and Croatia both share the legacy of a Soviet-influenced health care system, based on the hospital-focused Soviet Semashko model, including informal payments.[6] Moreover, the nursing profession in both cases shared similar conditions and mind-sets from the post-communist conservative regime ensuring that nursing education continues to be medically dominated. This position was exacerbated by the perception of policy-makers that it was not necessary to develop the nursing profession and health care system by transitioning to higher education. The contextualisation of Romanian and Croatian nursing education history within the wider political and policy context indicates that the minimum requirements, as set out in the Directive 2005/36/EC, were not met prior to EU accession.

Case studies

We explored two case studies, Romania and Croatia, of nurse leadership engagement in the EU accession policy-making process and the extent to which EU accession provided a policy window to advance a professional agenda. A comparative two – stage case study approach was adopted within an ethnographic, multi-method design involving qualitative interview and documentary analysis, exploring the mechanisms used by the Commission to process compliance and the degree to which the nursing leadership was able to capitalise upon the opportunity to formulate and implement a professional agenda and achieve policy goals in both cases.[7]

> "one of the most mobile professions in the EU

Findings

The findings relate to the robustness of the EU compliance mechanisms and the degree to which the nursing leadership engaged in agenda setting and policy-making. Three policy mechanisms were identified which were used to reach compliance with the Acquis: the Commission's comprehensive monitoring reports, the Taiex peer review reports, and the Taiex capacity-building seminars. Findings suggest that these three policy mechanisms were not robust enough to deliver successful legislative outcomes, although the comparison of Romania and Croatia showed that the Taiex capacity-building seminars enabled the nurse leadership to influence the process to gain capacity building funds in the case of Croatia to put a plan in place to upgrade nursing education. Nevertheless, findings indicate that the Taiex peer review and capacity building mechanisms were too weak for the recommendations to be picked up by the Commission's comprehensive monitoring reports, signed off by politicians in the three European Institutions: European Commission, European Parliament and Council of Ministers.

Commission Comprehensive Monitoring Reports

Based on the study findings, it transpired that compliance with Directive 2005/36/EC was not a major priority for governments, further weakening the

capacity of the Commission's comprehensive monitoring reports in EU accession negotiations to upgrade nursing education. The case study findings show that the comprehensive monitoring reports failed to ensure that recommendations for compliance were carried through to align with legislative change. Non-implementation was not an impediment to closing chapters of the Acquis and therefore no sanctions were applied. As such, it can be argued that the Commission's comprehensive monitoring reports were not well designed for multi-level governance and, consequently, are not sufficiently robust to respond to the nursing education challenges prior to EU accession.

> "EU compliance mechanisms were unable provide traction

Government's lack of preparation

Similarly, although the Taiex peer review reports pinpoint areas requiring further attention, the recommendations do not tend to be an important source of information for the Commission's comprehensive monitoring reports. These reports are important since they form the basis upon which EU political leaders make informed decisions. As both cases show, Chapter 3 of the Acquis was provisionally closed, although there was no evidence of the Taiex recommendations having been addressed adequately. Rather, the Taiex peer review reports were treated as a negotiation tool between the government and the Commission, with minor engagement of stakeholders and specifically, no engagement with the nursing leadership in formulating solutions to address the Taiex recommendations. The weaknesses in nursing education identified in the Taiex peer review reports were not addressed due to the government's lack of readiness and attitude towards upgrading nursing workforce competencies towards EU standards (Directive 55).

Although the Taiex recommendations could have a political impact on the negotiations, government reluctance to acknowledge non-compliance with the EU Directive 36/55 criteria impacted negatively on the development of the nursing profession in both cases.

Consequently, nurses in Romania and Croatia are still called medical assistants (not nurses) and therefore face problems accessing free movement in the EU based on MRPQ.[8] These challenges have remained unresolved as the Romanian and Croatian national governments see the Acquis as a potential exit route for nurses lured by better working conditions in other EU Member States. Both governments agreed with the Commission that they would install a new nursing education curriculum at university level in compliance with Directive 2005/36/EC, from the date of entering the EU, leaving the existing secondary school level nursing workforce in non-compliance. It can be argued that this represents a missed opportunity for a predominantly female profession to develop their skills and competencies and hence promote their ability to move within the EU on the basis of MRPQ. Romanian and Croatian nurses will move in the EU, but not as nurses benefiting from the mutual recognition regime, potentially impacting negatively on the national and European workforce composition.

Capacity building

Finally, the third mechanism, the Taiex capacity building seminars, addressing the weaknesses set out in the peer review reports, can be extremely helpful in bringing stakeholders together, facilitating a better understanding of how to transpose Directive 55 into national legislation and how to address the challenges set out in the Taiex peer review reports. However, requesting funds from the EU for nursing implied admitting there was a problem to be fixed. This failure to demand EU financial support seems to have missed a major policy window opportunity to bring together relevant stakeholders to design new national nursing legislation in compliance with the European Directive. The nursing leadership was severely constrained in raising agreed challenges to their ministry officials since they recognised that moving Taiex recommendations up the political agenda itself was reliant on the goodwill of civil servants negotiating EU accession itself. Therefore, the imperative to drive the process through may have militated against the nascent nurse leadership being able to influence the uptake of the Taiex peer review recommendations and the capacity building seminars. Furthermore, ministries did not seize the opportunity to upgrade the nursing workforce. Indeed, there are signs of a residual intention to block free movement by some ministries in order to retain the nursing workforce which otherwise would migrate as a consequence of Directive 2005/36/EC (DIR 2013/55/EU).

Unified voice in agenda-setting

It can therefore be argued that EU compliance mechanisms were unable to provide the necessary traction to move from legislative endorsement to legislative implementation through lack of governmental commitment and stakeholder engagement.[9] However, although these mechanisms acted as a barrier to effective compliance, the leadership of the nursing community (e.g. professional association, nursing regulator, nursing union, chief nursing officer) were not mobilised to work together or provide a united voice in agenda-setting or framing professional and legislative outcomes. With respect to the leadership needed to engage in the EU accession policy process, the evidence suggests that the nursing leadership was imbued with the culture of the Communist regime in which nurse leaders' interests, their patterns of interactions and subordinate roles in policy design set the level of compliance with Directive 2005/36/EC (DIR 2013/55/EU). Consequently, a persisting cultural legacy maintains nursing education at the secondary level. Nevertheless, a strong strand of opinion supporting the development of nursing as a profession at university level is emerging and growing, with the potential to consign vocational training to the past.

Medical-dominated Soviet Semashko model

Findings suggest that the nursing profession's overall capacity to influence the policy process was weakened by challenges in harnessing a unified

and coordinated position in relation to influencing the political agenda. Conflicting agendas between nursing leaders left leverage for politicians pursuing their own agendas and responsibility for acceptance of the legislative and professional outcomes in the hands of civil servants, mainly physicians and lawyers. It is equally possible that nurse leaders were marginalised from the process since they had little track record of operating within the complex politico-legal environment of the EU. The nursing leadership's divided positions seemed to undermine nursing leaders in seizing EU accession as an opportunity to move nursing towards a position of being part of the European Single Market, benefiting from free movement. Nursing is the most mobile profession and each nurse in principle should be able to benefit from the unique mutual recognition regime in the EU.

Credentialing rivalry

Finally, evidence suggests there was rivalry between the respective ministries of education and of health in which newly created agencies, governmental departments and committees fragmented the mutual recognition credentialing process. Rivalry over responsibility for the recognition of credentials between the ministries reflected the tensions within the nursing community, each trying to maintain their own influence and control over the recognition of professional qualifications, thereby constraining the future professional development of the largest occupation in the health sector. It can be argued that the power differentials and rivalries between ministries as well as the structure of the nursing leadership weakened the nursing advocacy efforts and helped to explain why the nursing leadership was unable to capitalise upon the EU accession policy window.

Conclusions

Based on the above findings, it can be concluded that EU accession was not a destination but rather a starting point for nursing education to comply with European standards as set out in Directive 2005/36/EC (DIR 2013/55/EU). The failure of the nursing leadership to achieve successful legislative and professional outcomes at national level in compliance with EU nursing education standards relates to inherited policy; the political context of the Communist regime; the weakness of the Commission's mechanism to achieve compliance; and the lack of unity within the nursing leadership community in setting a joint professional agenda. It is clear that the process itself, in its initial phase, militated against engagement for a complex mix of reasons. Therefore, it can be argued that EU accession was an important starting point for stimulating nursing leadership advocacy work in Eastern European countries, such as Romania and Croatia, and for providing some exposure to the mechanisms of process compliance. However, the Comprehensive Monitoring and Taiex peer review were weak levers to hold back EU membership when targets were not met. The Taiex capacity building seminars, if properly used, could be a tool to build the capacity of the nursing leadership to design an advocacy strategy to address critical gaps in the future.

Finally, the findings form part of the wider argument that nurses need to increase their engagement in multi-level governance and political decision-making processes at all levels of the policy system.[10] [11] The study findings provide evidence that the lack of multi-level and lateral governance[12] – as a system involving different institutions and stakeholders with diverging views and perceptions – impacts negatively both on the policy process and the outcomes achieved. Leadership becomes the key driver for successful policy outcomes but needs to be harnessed according to a coherent strategy designed to modernise EU accession mechanisms and align that leadership to achieving policy consensus between the key state and non-state actors.

References

1 Börzel TA. Policy Change in the EU's Immediate Neighbourhood. A Comparison in Practice, co-edited with Katrin Böttger. Baden-Baden: Nomos, 2012.

2 Morlino L, Sadurski W. *Democratisation and the European Union. Comparing Central and Eastern European post-communist countries*. London: Routledge, 2010.

3 Hillion C. EU Enlargement. In Evolution of EU Enlargement Policy. Academia, 2011: 188.

4 De Raeve P. Nurses' Voice in the EU Policy Process. Kluwer, 2011.

5 Keighley T. *European Union standards for nursing and midwifery: Information for accession countries*. Copenhagen: WHO Regional Office for Europe, 2009.

6 Gaal P, McKee M. Informal Payment for Health Care and the Theory of INXIT. *International Journal of Health Planning and Management* 2004;19(2):163–78.

7 Baillie L. Ethnography and nursing research: a critical appraisal. *Nurse Researcher* 1995;3(2), 5–21.

8 Maciejewski M. Freedom of Establishment, Freedom to Provide Services, and Mutual Recognition of Diplomas, European Parliament, 2012.

9 Fagan A, Sircar I. Compliance without governance: the role of NGOs in environmental impact assessment processes in Bosnia-Herzegovina. *Environmental Politics* 2010;19(2).

10 Weston MJ. Strategies for Enhancing Autonomy and Control Over Nursing Practice. *OJIN: The Online Journal of Issues in Nursing* 2010;15 (1):2.

11 Aiken LH, Clark SP, Sloane DM, et al. Effects of hospital care environment on patient mortality and nurse outcomes. *Journal of Nursing Administration* 2008;38:223–29.

12 Underdal A. Strategies in international regime negotiations: reflecting background conditions or shaping outcomes? *International Environmental Agreements* 2012;12(2):129–44.

IS THERE AN EU FRAMEWORK FOR NURSE EDUCATION?

By: Tom Keighley

Summary: This article explores the unplanned way in which a framework for nurse education has emerged within the European Union. Using the reform of Directive 2005/36/EU and its subsequent amendment (2013/55/EU) as the lens for this exercise, certain issues worthy of further examination emerge. Among them are the likely impact of the Professional Card, a competency-based EU-wide nurse education programme, and what the mechanisms will be for exercising the delegated acts. The article concludes with observations about current policy making and its implications both for Member States and accession countries.

Keywords: *Nurse Education, Nurse Qualifications, Mutual Recognition, Free Movement, EU Policy*

Introduction

The immediate answer to the question in the title is no, as there is no European Union (EU) competency to create such a framework for nurse education; but this is an oversimplification. The nursing profession, the single largest workforce in the EU, is subject to numerous EU policy structures and processes, not least those designed to ensure workforce free-movement, harmonisation of training, and mutual recognition of education and training standards. Other policy developments, especially in public health, education and consumerism, also influence nurse education, with the current initiative on Active and Healthy Ageing being an example. This requires nurses to participate more actively in patient adherence to medical prescriptions, initiating falls prevention programmes, improving assessment skills in levels of frailty and functional decline, and developing more integrated health care delivery. The picture, therefore, is of a complex matrix of influences all impacting on nurse education and practice while focusing on other EU policy concerns. Inverting the image, and seeing nurse education as a major component of policy delivery within the EU opens a different perspective on the relationship between the ways that the workings of the EU both impacts on nurse education and is dependent on it for the successful delivery of many of the health and consumer related initiatives.

This article will briefly describe developments in nursing education and mutual recognition of professional qualifications, as well as identify the key legislative and non-mandatory influences, determined both within the EU and external to it, but applied within its policy framework. Finally, the adoption of a competency-based approach to nurse education within the EU context will be addressed.

Acknowledgement: This article is based on a chapter in the forthcoming study: Rafferty AM, Busse R, Zander B, Bruyneel L, Sermeus W. *The contribution of nursing to heath system performance: A European perspective*. Copenhagen: European Observatory on Health Systems and Policies.

Tom Keighley is an independent health care consultant.
Email: nurprc@nursing.u-net.com

A legal-base for nurse education

The enactment of the sectoral directives in 1977 brought closure to a nursing initiative pursued for over twenty years.[1,2] It instituted a mechanism for both mutual recognition of qualifications in general nurse training and the regulation of nursing practice. Over the next twenty years, there were several amendments, especially the agreement on the balance between theory and practice in the training programmes. Further, there were advisory documents on cancer, palliative care, public health and care of older people to act as a backdrop to the development of training programmes, leading to a separate form of recognition which permitted the free-movement of specialist nurses.[3] An attempt in the late 1990s to move over to a competence-based approach to training failed but further revisions of the directives resulting in Directive 2013/55 finally achieved that goal.[4]

> moving to competency-based education

Non-mandatory, and not specific to nurse education, but deeply influential on how nurse education has developed across the EU, are the European Qualification Framework (EQF) and the European Credit Transfer and Accumulation System (ECTS). These have determined the academic level of nurse training that is professionally desirable (EQF level 6) and the duration of training (180 credits). This structuring has enabled a shift of nurse education from mono-technical schools and colleges into higher education university settings. The move has been contended by numerous governments and remains a controversial development, especially in German speaking countries and some of the EU accession and recently acceded countries in Central Europe. In these countries, the combination of state-level decisions about the status of different occupations and the appropriate level of associated education has previously precluded nursing from integration into higher education.

EU policy making can move in step with non-EU bodies, and so influence the framework for nurse education as well. The Bologna Process to increase compatibility between European higher education systems is one example, while the World Health Organization (Europe),[5] the International Labour Organisation on health and safety at work,[6] and the International Council of Nurses[7] have all issued reports and advisories which have influenced the content and shape of nurse education in recent years.

The current situation

The revision timetable for Directive 2005/36/EU slipped considerably and in doing so illuminated the tensions between first order intentions (improving the flexibility of the workforce and associated free-movement at a time of financial crisis) and the wish of the nursing profession to see major improvements in the nature of nurse training. Some decisions have been pushed through despite great concerns about their deliverability. These include the Professional Card, the development of competency-based education, and the creation of delegated acts.

The Professional Card, issued to all nurses in the EU since 18th January 2016, contains details of their education and registration. While a worthy idea, it does not address the complexity of the mutual recognition process, with several hundred regulatory organisations in which recognition can be checked and the lack of resources (both human and IT) in many countries to ensure such a card is kept up-to-date.

Article 31 of Directive 2013/55/EU lays out in broad detail the nature of the competencies to be adopted in nurse education. These competencies have been developed in great haste to meet the deadlines for the issuing of the Directive and have not been tested. Further, they have not been examined to determine how a person emerging from a programme designed around such competencies will integrate into the multi-disciplinary arena that constitutes modern health care delivery. More importantly, the competencies have been developed in the knowledge that many countries do not have the faculty to teach such competency-based programmes or the clinical arenas to provide the associated training and permit subsequent practice. Of greatest concern must be questions about quality of care and patient safety, issues not of concern in a directive focusing on free-movement of the workforce but which could be affected by the over-rapid development of the competencies.

Delegated acts are a new phenomenon. They are a mechanism to enable the revision of course content and approval of education developments without requiring a revision of a complete directive. This is a mechanism that will apply primarily to the Annexes of the directive and circumvent the delays that reforms have experienced in the past. While this is a positive development, it is still unclear quite how they will operate.

The policy debate on nurse education has been invigorated by the discussions about the revision of the directive. In many countries in Western Europe, this is the first time in over a decade that governments have had to address the framework of nurse education actively and to encounter how this is seen both by the professions in their own countries as well as the responses of other countries. The challenge, however, remains the same, and that is how to have a policy debate about nurse education in the EU when the decisions about it are made secondary and some cases tertiary to higher-level policy decisions. There is increased awareness in the Commission and amongst MEPs about issues like gender challenges implicit in decisions about nurse education and concerns about patient safety and quality of care. However, the focus now needs to turn to whatever mechanisms can be agreed to draft and implement specific competencies in line with the Directive, as well agreeing the revision mechanisms to keep the Directive up-to-date while being applied in a harmonised fashion across the EU.

Challenges for accession countries

The stream of countries still preparing to accede to the EU presents particular challenges for nurse education. Turkey, Montenegro, the Former Yugoslav Republic of Macedonia, and Albania

are all working to achieve conformity with the EU directives. In nursing, this requires not only the reform of nurse education, but also fundamental changes to education at high school level and the re-classification of professions with all that that entails in terms of remuneration and social recognition. It is the area of reform that has caused a focus to develop on opportunities for women and their right to education. In particular, adopting the EU directives that apply to nursing has shone a lens on the historic communist types of education which even now have not been fully reformed.

The major policy challenge for much of the EU and the accession countries when developing nurse education is how to generate the professional space to permit comprehensive and autonomous nurse practice to be delivered. The lack of integrated policy for nurse education highlights the problem. The lack of negotiation with key stakeholders, like doctors and national law makers, jeopardises the development of a competence-based education system. The resistance to such developments limits the opportunities for women accessing higher education when it was not open to them in their nation's previous educational systems. In positive terms, the development of the EU directives on professional qualifications has resulted in the creation of regulatory structures which, as a by-product, have not only improved patient safety and quality of care, but also enabled nurses to engage more fully with the decision-making concerning their career paths. In so doing, this process has assisted in addressing the internal democratic deficits in countries.

Conclusions

No single policy or strategy has been determined and pursued within the EU on nurse education and training. Indeed, given the diversity of decisions and influences it may come as a surprise to some that such a framework has emerged. The consequences of this are multiple. It means that there is no particular focus within the European Commission structures whereby nurse education matters can be discussed or facilitated. Moreover, no mechanism exists for the Commission to work with Member States on matters concerning the training of nurses, unless this relates to free movement of nurses. It has been a source of great frustration to the nurse associations and their representatives at a European level that this cannot happen, even when consensus exists that such discussion would aid all concerned. Despite creating a common platform mechanism in Directive 2005/36/EC, which could have been used for the reform of nurse education, no attempt was made between 2007 (when the Directive became active) to 2012 to use it. Therefore, from the perspective of nurse associations, it seems fair to conclude that seeking specific policy direction for nurse education within European Commission procedures is currently not a fruitful exercise.

However, decisions both within the EU and in organisations that relate to it have created a *de facto* policy framework which has demonstrated an evolutionary capacity over time. What has emerged is a process of validation, some of which is embedded in law and some within voluntary 'good practice' frameworks which have reformed the nature of nurse education and training in the last two decades and looks set to continue to do so. While the stimuli for this have emerged from a concern about creating a skilled and sophisticated workforce equipped for the coming decades, and to ensure ease of movement between national borders, nurse educationalists in particular have reshaped delivery mechanisms and course structures to a profound degree. So effective has it been that accession countries aspire to imitate this in their reform proposals to the European Commission, even when the requirements exceed the legal requirements for accession to the EU.

Further, because nursing is considered to be one of the liberal professions, nurses have rights of individual establishment meaning that irrespective of what national governments, trade unions or nurse associations may wish in attempting to ensure conformity amongst practitioners, individual nurses have the right to practice based on their training and the recognition of their qualifications. Thus, it would be fair to state that examination of this implicit policy framework is rich territory for those who wish to look in detail at the stimuli for change in nurse education and training and the drivers behind the aspirations and outcomes expressed in nursing forums and publications cross the EU.

References

1 European Economic Community. Council Directive 77/452/EEC of 27 June 1977 concerning the mutual recognition of diplomas, certificates and other evidence of the formal qualifications of nurses responsible for general care, including measures to facilitate the effective exercise of this right of establishment and freedom to provide services. Luxembourg.

2 European Economic Community. Council Directive 77/453/EEC of 27 June 1977 concerning the coordination of provisions laid down by Law, Regulation or Administrative Action in respect of the activities of nurses responsible for general care. Luxembourg.

3 European Economic Community. Council Directive 89/48/EEC of 21 December 1989 on a general system for the recognition of higher-education diplomas awarded on completion of professional education and training of at least three years' duration. Luxembourg.

4 European Parliament and Council. Amending Directive 2005/36/EC on the recognition of professional qualifications and Regulation (EU) No 1024/2012 on administrative cooperation through the Internal Market Information System ('the IMI Regulation') (Text with EEA relevance). *Official Journal of the European Communities,* L354, 132 – 170.

5 World Health Organization Regional Office for Europe. *European strategic directions for strengthening nursing and midwifery towards Health 2020 goals*. Copenhagen, WHO Regional Office for Europe, 2015.

6 International Labour Organisation. *Occupational Safety and Health,* 2016. Available at: http://www.ilo.org/safework/lang-en/index.htm

7 International Council of Nurses. *The Code of Ethics for Nurses – Revised*. Geneva, ICN, 2012.

THE NETHERLANDS EU PRESIDENCY ON HEALTH

By: Edith Schippers

Summary: With several other pressing policy areas dominating the agenda of the Netherlands Presidency of the European Union, health issues still feature as valuable areas of focus. Building on the work of previous presidencies, the three main priorities of the current presidency are antimicrobial resistance, timely access to innovative medicines for patients at sustainable prices, and food product improvement, all of which have a clear cross-border dimension and require European cooperation. Through various targeted initiatives, such as conferences, roadmaps and facilitating mechanisms for improved coordination and cooperation among Member States, the Netherlands Presidency aims to bring action on these health priorities to the next level.

Keywords: *The Netherlands EU Presidency, Health, AMR, Access to Medicines, Food Product Improvement*

Introduction

In times when the European Union (EU) is experiencing serious turmoil, the Netherlands has taken over the Presidency of the Council of the European Union for the first half of 2016. The priorities for this presidency are innovation, growth and jobs, asylum and migration, robust financial policies and a common European approach to climate and environmental issues. A brief glance through the newspapers gives an idea of what other issues – e.g. terrorism and the referendum in the United Kingdom – might require our attention as well. In this scheme of things, health and health policy might almost seem like a minor issue, and in the recently published working programme of the European Commission, health plays a modest role as well. However, many health challenges require European cooperation to find the best solutions. Therefore, the Netherlands has put together an ambitious but realistic agenda for health.

Legislative agenda

At the request of many Member States and the European Parliament, the Netherlands Presidency, first and foremost, wants to bring the legislative agenda in Brussels a step forward. High on this agenda are the regulations on medical devices and in vitro diagnostics. These regulations aim to improve the system for market access of medical devices and in vitro diagnostics, while respecting the balance between innovation and safety. Because these proposals contain stringent rules of a highly technical nature, it has taken the Council a long time to find a solid basis for starting negotiations with the European Parliament. It is the ambition of the Netherlands to reach an agreement between the Council and the European Parliament before the end of its presidency term. Challenging issues are questions regarding the regulation of high-risk devices and how to balance innovation and safety aspects. Other

Edith Schippers is Minister for Health, Welfare and Sport, The Netherlands.
Email: r.a.driece@minvws.nl

issues are the reprocessing of single-use devices, liability of economic operators and requirements with regard to the use of genetic tests.

Three Presidency priorities

Besides the legislative agenda, the Netherlands Presidency aims to follow up on important issues on the European agenda as addressed by previous presidencies. The three health issues it has chosen as priorities under its programme are: antimicrobial resistance, timely access to affordable medicines for patients, and food product improvement. These three issues all have a clear cross-border dimension, in which European cooperation is essential.

Antimicrobial resistance

First, when it comes to the pressing topic of antimicrobial resistance (AMR), the numbers are telling. Every year 25,000 Europeans die due to untreatable bacterial infections.[1] Although we see a growing awareness both at a European and global level, it often turns out to be difficult to put this awareness into action. Furthermore, it is essential to understand that the solution to this problem should not only be sought in the health sector. Other sectors are important as well, in particular the veterinary sector.

The only effective approach is the *One Health* approach because without the commitment of both the human health and the veterinary world, the problem of AMR cannot be solved. To facilitate this approach, the Netherlands proposes close cooperation between the health and veterinarian sectors, for a One Health approach at the EU-level. In line with this approach, the Netherlands aims at securing firm political commitment to binding agreements for prudent use of antibiotics in veterinary medicines, including a ban on the use of antibiotics which are critically important for human health. To establish this political commitment, a joint ministerial meeting for both ministers of Health and ministers of Agriculture was organised in February, and the issue will be discussed further in relation to draft Council Conclusions.

During the conference there was broad political support for a new EU action plan with measurable targets for the reduction of AMR. In addition, all Member States should work on national plans with measurable targets. The Netherlands suggested at the conference that a peer-review mechanism should be set up in the EU to monitor progress on implementation of AMR action plans and to identify ways to better support each other with this implementation.

When it comes to the development of new antibiotics, alternatives and diagnostics, many good instruments and initiatives are already in place. However, the results of these are often inadequate. At the conference it was acknowledged that we need a more focused European research agenda and commitment of all partners to further support the implementation of these initiatives.

Finally, there is a common understanding that it is important to present one clear and common EU position regarding AMR in different international forums, such as the UN General Assembly. Together with the other measures, this will hopefully bring European cooperation on AMR to the next level.

Timely access to affordable medicines for the benefit of patients

Secondly, following up on the Italian and Luxemburg presidencies, the Netherlands would like to put the topic of timely access to affordable and innovative medicines for patients on the European agenda. Medicines play a crucial role in the lives of millions of people in the EU: they cure people, give chronically ill people a chance to lead an active and productive life, and patients with severe illnesses have gradually obtained a better quality of life and an increasing chance of survival. Recently, remarkable advances have been made in this field. However, these developments come at a cost: prices of new innovative pharmaceutical products have dramatically increased, while on the other hand, more and more medicinal products come to the market for smaller groups of patients. It should be our overall goal to make innovative medicines available to severly ill people, while ensuring the sustainability of our health care systems. Our focus is threefold: 1) optimising flexible market authorisation mechanisms under the right conditions; 2) facilitating voluntary cooperation in the field of pricing, and 3) analysis and discussion about unintentional and undesired incentives in the EU market access legislation.

1) Flexible market authorisation mechanisms

Obviously it takes time before medicines receive a marketing authorisation, often up to ten years. Patients are calling for faster access, also for products that cater for smaller patient groups and therefore cannot follow the current phases of clinical trials. Therefore, in our view, it is necessary to explore ways for better use of flexible marketing authorisation mechanisms. This involves focusing on the right (essential) products, better alignment of market access and reimbursement criteria in order to speed up the time-to-patient, and also early interaction with payers.

2) Voluntary cooperation regarding pricing

The second focus is on how to counter the ever increasing prices of medicines. The fragmented position of individual Member States reduces their leverage when it comes to countervailing the power of pharmaceutical companies in the European market. This power comes with the lack of competition for many new innovative products because there are no or hardly any alternatives for these medicines.

It may be clear that exorbitantly high medicine prices put a lot of pressure on health care systems. The affordability of health care systems is at stake. One of the key ingredients in this respect is improving the checks and balances between governments and the pharmaceutical industry. The Netherlands EU presidency would like to address how countries can voluntarily work together at a strategic level – but also in practical terms – on the issue of pricing, to restore the balance between the public interest and the interest of the private sector in the pharmaceutical market. Joint 'horizon scanning', sharing information on prices and price setting between countries, or even shared price negotiations could be a good start to ensure sustainable health care systems, now and in the future.

3) Undesired and unwanted incentives in EU market access legislation

Thirdly, existing and 'built in' incentives in the EU market access legislation are meant to promote innovation. The question is, however, whether instead they disturb the balance between innovation and availability on the one hand, and costs on the other. To stimulate industry and other parties to develop medicines, including for specific rare diseases or small patient groups, additional incentives, such as data protection, supplementary protection certificates and market exclusivity for orphan drugs, were created. These incentives have proven to be successful in terms of new products coming onto the market. However, there is a downside, as these incentives lead to high-price products that affect countries' health budgets. In the Netherlands' opinion, it is therefore urgent to discuss whether the current incentives are still in balance or lead to too many unintended and unwanted effects.

Food product improvement

The third priority under the Netherlands presidency is food product improvement. As is well-known, health is interconnected with eating habits. An unhealthy diet increases the risk of non-communicable diseases like diabetes, cardiovascular diseases and obesity. However, even if people try to eat healthily, they often risk consuming too much salt, sugars and saturated fats, as processed food products contain too much of these ingredients. Food product improvement can be/is an important instrument for countering the rise of non-communicable diseases and making the healthy choice the easy choice. The call for improved food products also offers opportunities for innovation.

Fortunately, many Member States are already taking action at a national level and several food business operators have started to improve their products. These trends are encouraging. However, the food business is in essence a cross-border business. The lack of a harmonised approach undermines the level playing field and hampers product innovation. As a first step towards more concerted action, the Netherlands organised a Conference on Food Product Improvement on 22 February 2016. At this conference, a joint Roadmap for Action,[2] was supported by Member States, trade and industry organisations and NGOs. The Roadmap should lead the way towards stronger concerted action. The results of the conference will be shared with the informal Health Council in April 2016.

Additional health policy concerns

Apart from these three main priorities, there are a few other health concerns that will be addressed during the EU presidency. One of these is dementia. Since the French presidency in 2008, successive presidencies have made dementia a priority. The Netherlands would like to continue the European collaboration in this field. The time is right to combine the numerous activities in every Member State into an integrated approach to tackle all aspects of the challenge that dementia poses. Member States should work together in research into the cause, cure and prevention of dementia, and share best practices on how to include people in the early stages of dementia in society for as long as possible. Other topics that will be touched upon during the Netherlands presidency are ehealth and the safeguarding of qualifications of medical professionals in cross-border settings.

The next level

To conclude, as noted, health may not be in the top three of all the challenges the EU currently faces, but there are enough important health issues that require and deserve our collective European attention. The Netherlands believes that with its presidency's health agenda pressing issues will be brought to the next level, which is necessary to improve and safeguard the health of all European citizens.

References

1 European Commission. *AMR: a major European and global challenge. Fact Sheet.* Available at: http://ec.europa.eu/dgs/health_food-safety/docs/amr_factsheet.pdf

2 Ministry of Health, Sport and Welfare. *Roadmap for Action on Food Product Improvement.* Available at: https://www.rijksoverheid.nl/documenten/formulieren/2016/02/22/roadmap-for-action-on-food-product-improvement

France: Health system review

By: K Chevreul, KG Brigham, I Durand-Zaleski and C Hernández-Quevedo

Copenhagen: World Health Organization 2015 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies).

Number of pages: xxvii + 218 pages, **ISSN:** 1817-6127

Freely available for download at: www.euro.who.int/__data/assets/pdf_file/0011/297938/France-HiT.pdf?ua=1

While the French population is largely satisfied with the health system, the overall state of health in France is mixed. Health inequalities across socioeconomic and geographical groups are much larger in France than in most other European countries. The rising cost of health care also remains a challenge for the health system, with public financing of health care expenditure among the highest in Europe. While the latest health reforms aim to address these challenges, long-term care reform efforts have thus far failed to identify a sustainable financing mechanism to meet this large and growing need.

THE CROSS-BORDER CARE DIRECTIVE: IMPLEMENTATION STATUS

By: Willy Palm

Summary: The first report on the operation of the Directive on patients' rights in cross-border health care shows mixed results. So far, patient mobility remains quite low in general, which may partly reflect limited motivation among European Union (EU) citizens to travel for care. However, it also relates to two other factors. First, despite several measures to improve information, many patients remain unaware of their rights. Second, Member States seem to limit the reimbursement of cross-border health care through imposing administrative requirements, applying unjustified low reimbursement rates or maintaining elaborate systems of prior authorisation. The European Commission is committed to enforce full compliance of the Directive.

Keywords: *Cross-border Care, Patients' Rights, Directive 2011/24/EU, European Commission*

Transposition status

The Directive on the application of patients' rights in cross-border health care came into force on 24 April 2011.[1] It was the result of a long process, initiated by a series of consecutive rulings of the Court of Justice since 1998 about how the fundamental principle of free movement of services would directly apply to the case of reimbursing medical treatment purchased in another Member State.[2] This Directive was meant to clarify the conditions under which cross-border health care is covered by the statutory health system of affiliation, but also what rules would apply to ensure patient safety and good quality health care (**see Figure 1**).

Member States had until 25 October 2013 to transpose the Directive into national law. Up to this date the European Commission assisted Member States – through country visits and workshops – in finding the best ways of transposition, taking into account the specific context of each health system. After the deadline it launched infringement proceedings against 26 Member States for late or incomplete transposition of the Directive. Since then all Member States seem to have complied with the obligation of transposition, the clearest sign being the creation of National Contact Points (NCP) which are meant to inform patients' about the conditions under which they can receive health care in another Member State. However, this does not mean that

Willy Palm is Dissemination Development Officer, European Observatory on Health Systems and Policies, Brussels, Belgium. Email: wpa@obs.euro.who.int

Member States have transposed the Directive correctly. The Commission is now pursuing a compliance check, which could lead to a new series of infringement procedures against certain Member States.

A recent report on the operation of the Directive, released by the European Commission in September 2015 (and which must be issued every three years from now on), already gives an indication of the variation in which Member States have translated and implemented the different elements of the Directive.[3] Despite clear anomalies in some cases, in its report, the Commission carefully refrains from naming and shaming the Member States who are overstepping their discretionary power, so as not to jeopardise the legal force of the possible infringement proceedings for non-compliance that may be launched against some of these countries.

Obstacles to reimbursement

The first and primary objective of this Directive was to facilitate access to cross-border health care by clarifying patients' rights to statutory coverage in line with the jurisprudence of the Court of Justice. The general principle set by the Directive is that any treatment provided by a registered health provider in another Member State should be reimbursed according to the same tariffs and conditions as the one applying in the state of affiliation. Clearly, the margins for Member States to limit reimbursement for cross-border health care or to impose additional conditions were narrowed significantly. In essence, any restriction would need to be justified by so-called "overriding reasons of general interest" and should prove to be proportionate and necessary with regard to this objective. In addition, such measures should be notified to the Commission.

In practice, several Member States seem to stretch their discretionary power (**see Table 1**). The Commission provides several examples of additional administrative requirements that patients need to fulfil: document the medical necessity of a particular treatment abroad (UK), provide a sworn translation of foreign invoices (Bulgaria) or even a certification of all documents by the local consular official (Greece). Although Member States are in principle allowed to uphold a gatekeeping system for accessing specialised care (if it can be objectively justified), the Commission seems to question the practice in several Member States that the referral should be provided by the general practitioner with whom patients are registered in their country. Furthermore, at least four Member States seem to apply a lower reimbursement rate for cross-border care, the same as the one they apply for private or non-contracted providers in their country. Already in 2013, the former Health Commissioner Tonio Borg stated in a response to a question from a Dutch MEP, Ria Oomen-Ruijten, that such practices would constitute a disincentive for patients to use their rights to cross-border health care and would need to be justified.

The report also demonstrates that several Member States are still maintaining comprehensive prior authorisation systems, whereas the Directive curtailed Member States' power to make the reimbursement of cross-border care subject to prior authorisation. Such a condition can essentially only apply for more complex forms of treatments, i.e. health care that is subject to planning requirements and involves either overnight hospital stay or the use of highly specialised and cost-intensive medical infrastructure or equipment. Member States are expected to specify these categories and to publicly state for which health care services prior authorisation is still needed. However, most Member States have essentially copy-pasted the criteria of "overnight stay" and "highly specialised care" into their national legislation without really specifying what categories of treatments are covered under one or the other. Those countries that actually provide more detailed lists of treatments, vary considerably in scope. Some specify the services (out-patient and in-patient) for which prior authorisation is still needed, whilst others apply broad categories and basically exclude all cross-border in-patient care from unconditional reimbursement under this Directive. In this context, another element of confusion occurs when certain medical interventions could be treated as day-cases in one Member State but not in another. As this criterion of "overnight stay" is part of the reimbursement rules, prior authorisation could only be justified if the treatment would require it in the home state. However, according to the Commission, some Member States instead refer to what is the standard in the Member State of treatment.

As was also confirmed by an evaluative study undertaken on behalf of the Commission,[4] it is often not clear for patients when they actually need to ask for prior authorisation, and even when

Figure 1: Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (objectives and constitutive elements)

Source: W Palm

Table 1: Conditions for reimbursement of cross-border health care under Directive 2011/24/EU

Scope of prior authorisation				Member States applying a lower reimbursement rate	Member States requiring a 'domestic' referral for reimbursing claims
In all circumstances	*No or unclearly defined list* (1)	*Clearly defined list* (2)	*Never* (3)		
CY	AT, BE, BG, DE, DK, EL, ES, FR, IE, IT, LU, PL, SI	HR, HU, LV, MT, PT, RO, SK, UK	CZ, EE, FI, LT, NL, SE	AT, DE (4), FI, NL	IE, MT, IT, EE, LT, LV, RO, SK, SI, PL

Source: Author's own analysis based on information drawn from the National Contact Points (February 2016).

Notes: (1) This means that the scope as defined in the Directive is not further detailed, or only partially (in several instances the criterion of "overnight stay" remains unspecified); (2) This does not necessarily mean that the scope as defined is in conformity with the principles of necessity and proportionality; (3) Some countries still preserve the legal possibility of introducing prior authorisation and defining its scope at a later stage; (4) Germany applies a 5% reduction as an administrative fee to process claims.

there are lists interpreting them usually requires some degree of medical expertise. This is why patients may still have to contact their NCP or their health insurer to get additional clarification. Apart from the persistent lack of transparency, most Member States seem to forget that extensive systems of prior authorisation can only be justified if they prove to be necessary and proportional for achieving objectives of general interest, such as maintaining financial balance and universal access to quality health services within their health system as well as ensuring patient safety and public health. Given the extremely low number of requests for prior authorisation (see '*Low patient flows*' section) this seems to be hardly the case. One country (Cyprus) even continues to request prior authorisation in all circumstances (except for one specialist consultation per patient once a year). Only six countries no longer require any prior authorisation for the reimbursement of any type of medical treatment under this Directive. But even in those countries, prior authorisation is still needed when patients seek planned health care under the traditional – and often more advantageous – route of the Social Security Coordination Regulation 883/2004, which guarantees reimbursement according to tariffs of the state of treatment.*

* The EU social security coordination framework, which is enshrined in this Regulation that was revised in 2004, has for decades ensured access to health care outside the state of affiliation for migrant workers, their family members and finally all statutorily insured citizens. It applies in parallel to the Directive and in general it offers better financial protection since patients are covered *as if they were insured in the Member State of treatment*, whereas under the Directive they are only reimbursed afterwards according to the applicable tariffs of their home state.

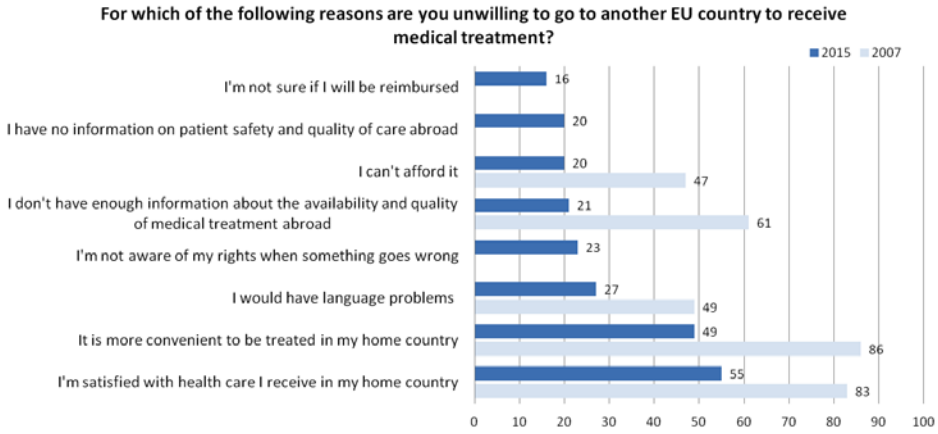
Low awareness among patients

The complexity of the legal situation, with two distinct reimbursement regimes for cross-border care (the Directive and the Regulation), as well as the national variations in transposition, interpretation and transparency, make it extremely difficult for patients to understand their rights and make use of them. Despite the efforts and provisions in the Directive to ensure good information about patients' rights and entitlements as well as procedures for accessing them, a *Eurobarometer* study published in 2015 revealed that only 17% of respondents felt they were well-informed about their rights to treatment in another Member State (compared to 49% in their own country).[5] In fact, only 57% seemed to know that they had a right to reimbursement for care received in another Member State. Less than one in three knew that they could use a medical prescription in another Member State. A key instrument for filling this knowledge gap was the establishment of NCPs in each Member State to enable both outgoing and incoming patients to make use of their rights. However, only one in ten seems to be aware of their existence. This also correlates with the low activity level of the NCPs so far, as was shown by the evaluative study and other sources. Most information is drawn from NCP website visits, less from telephone, email or face-to-face contacts.

Furthermore, questions have been raised about the quality of information provided and its usefulness for patients to make informed decisions around seeking treatment in another Member State. The uncertainty surrounding cross-border care not only relates to patients' entitlements to reimbursement but also to the availability and kind of health care they can expect to find abroad, as well as the quality and safety standards that apply there. Indeed, even more than the financial uncertainty, people are put off by the lack of information about the availability, quality and safety of treatment abroad and the insecurity about what might happen when something goes wrong (**see Figure 2**). While quality is also one of the main motivations for patients to seek care abroad, reliable, comparative and systematic information on provider performance seems to be the most wanted but also least available. The NCPs mainly provide generic information, often just links to legal or policy documents on quality and patient safety, and only a few provide more practical and detailed information on individual providers.

The European Patients' Forum, which between 2013 and 2015 organised a series of regional consultations with national patients' organisations on the implementation of the Directive, has also named the variable quantity and quality of information made available to patients as one of the main challenges for its success. To this end, it also calls for a closer and more systematic involvement of patients' organisations to ensure that the information provided meets patients' needs.[6] Another study requested by the European Commission, which looked at the NCP websites, suggested that next to more detailed information on providers, a review system should be created similar to those used on travel and hotel websites, where patients could post reviews about their experiences with health care providers in different countries.[7]

Figure 2: Eurobarometer survey results on patients' reasons for not using cross-border health care, 2007 and 2015



Source: Eurobarometer 2015 and 2007

Low patient flows

The Commission report also tries to give an indication of the actual patient flows resulting from the operation of this Directive. The data provided cover the year of 2014, the first year after the transposition of the Directive. Considering the late compliance of most Member States, the remaining obstacles with reimbursement and the low level of awareness it is not surprising that the observed numbers are quite low. Of those countries that were able to provide data on the operation of the Directive in 2014, six (Austria, Bulgaria, Cyprus, Estonia, Greece and Portugal) made no reimbursement at all. Most reimbursements were recorded in Denmark (over 31,000). In 17 Member States still using prior authorisation under the Directive only 560 requests were received, of which 360 were authorised. This is rather insignificant compared to patient flow data under the Social Security Regulations: over 30,000 prior authorisation requests and 1.6 billion claims processed in 2013 (incl. unplanned care).

Perhaps most puzzling is that after all these years the Commission is still not in a position to provide an accurate picture of patient flows, mainly because in several cases the data that should be provided by Member States are either not available or not sufficiently aggregated. The Directive did not really include a clear obligation for Member States to systematically keep and share this kind of data. In a report in 2014 the Commission described the current situation as "a dearth of statistical data on cross-border healthcare", which does not allow policy makers to properly monitor and assess the financial impact of the application of the Directive on the Regulation.[3] However, the report also suggested that if Member States wanted to maintain a prior authorisation system under the Directive they would need considerably improved data to demonstrate that such systems meet the overall requirements of proportionality.

So far, nothing seems to suggest that the Directive may have increased or further stimulated patient mobility in the EU. The 2015 Eurobarometer survey even showed a slight decrease in the general willingness to travel for care compared to the initial survey conducted in 2007: on average 46% of respondents were averse to the option of cross-border care, with the highest share in France (78%) and the lowest in Malta (10%). In addition, Eurostat's European Core Health Indicators (ECHI) database confirms the picture of low patient mobility showing that only an average of 2.9% of people discharged from hospital were non-residents, with only Luxembourg (10.3%) and Malta (5.8%) above that level.

Conclusion

Despite the obvious benefits for patients, only few patients seem to use the rights under the Directive. Nevertheless, the real impact of the Directive should not only be measured in numbers. In fact, the legal framework was never meant to encourage patients to seek health care abroad, but rather to facilitate it in case there was a real need or a true desire for it. Meanwhile, under the Directive's chapter that stimulates cross-border cooperation in the field of health care, important things are happening that will produce practical and useful outcomes for patients, such as the creation of European Reference Networks to better treat patients with complex or rare conditions. This, together with the pressure on Member States to improve transparency and information, to attach importance to patient safety and quality as well as to patients' rights in general, will also turn out to be beneficial for domestic patients.

References

1 For a more detailed overview see: Peeters M. Free Movement of Patients: Directive 2011/24 on the Application of Patients' Rights in Cross-Border Healthcare. European Journal of Health Law 2012;19:29–60. DOI: http://dx.doi.org/10.1163/157180912X615158

2 Palm W, Wismar M, van Ginneken E, et al. Towards a renewed Community framework for safe, high-quality and efficient cross-border health care within the European Union. In Wismar M, et al. (eds.) Cross-border health care in the European Union Mapping and analysing practices and policies. World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2011: 23–46. Available at: http://www.euro.who.int/__data/assets/pdf_file/0004/135994/e94875.pdf

3 Commission report on the operation of Directive 2011/24/EU on the application of patients' rights in cross-border healthcare, 4 September 2015, COM(2015) 421 final. Available at: http://ec.europa.eu/health/cross_border_care/docs/2015_operation_report_dir201124eu_en.pdf

4 Evaluative study on the cross-border healthcare Directive (2011/24/EU), Final report, 21 March 2015. Available at: http://ec.europa.eu/health/cross_border_care/docs/2015_evaluative_study_frep_en.pdf

5 Patients' rights in cross-border healthcare in the European Union, Special Eurobarometer 425, May 2015. Available at: http://ec.europa.eu/public_opinion/archives/ebs/ebs_425_en.pdf

6 European Patients Forum. Cross-border healthcare: is it working for patients across the EU?, Conference Report, 13 July 2015. Available at: http://www.eu-patient.eu/globalassets/events/2015-ceu-cbhc/20150917-cbhc_report_final_external.pdf

MAKING SENSE OF EUROPEAN UNION HEALTH LAW

By: Tamara Hervey, University of Sheffield

Summary: Health policy communities make many claims about the EU's health law, often from a position that EU law is 'bad for health'. In an extended analysis, Hervey and McHale have assessed these claims. This article summarises some of their key findings. Overall, while the *strong* version of each claim is not borne out, once we immerse ourselves in the details of law in its policy contexts, a *weaker* version may well be defensible.

Keywords: *European Union Health Law, Consumerism, Rights, Equality, Solidarity, Competition, Risk*

Introduction

For nearly 20 years, Jean McHale and I have been researching the European Union's (EU) health law. During that time, we have heard many claims about EU health law from health policy communities. In our latest publication *European Union Health Law: Themes and Implications*,[1] one of the things we do is to assess those claims. We do so through four themes: consumerism; (human) rights; equality, solidarity, and competition; and risk.

One claim is that EU law treats health products and health services as essentially the same as any consumer product available in the European market. Patients essentially become consumers, subject to rules such as *caveat emptor*, even if they are protected by law from at least some products and services that would harm their health. Notions of a professional ethic of care, or provision of public service, are consequently fundamentally undermined, because EU health law understands the relationships between doctors and their patients through the lens of **consumerism**.

Second, it is claimed that, if patients' rights become essentially consumer rights, the recognition of *health* **rights** as human rights is diminished in EU health law. EU health law involves consumerisation of health care, so it enhances individual patient autonomy and patient choice. But that means that the collective 'right to health care' (despite appearing in the EU's own Charter of Fundamental Rights) is not sufficiently protected in EU health law which works to strengthen individual claims to health care resources as claims of right.

EU health law involves more patient choice. But that increased choice weakens the position of national health care systems. They seek to provide care for all equally, on the basis of need, with limited resources, predominantly funded either by taxation or through social insurance.

Tamara Hervey is Jean Monnet Professor of EU Law, University of Sheffield, England.
Email: t.hervey@sheffield.ac.uk

7 Impact of information on patients' choice within the context of the Directive 2011/24/EU of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, August 2014. Available at: http://ec.europa.eu/health/cross_border_care/docs/cbhc_information_patientschoice_en.pdf

8 Report from the Commission to the Council and the European Parliament compliant with the obligations foreseen under Article 20(3) of Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare, 3 February 2014, COM(2014) 44 final. Available at: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52014DC0044&from=EN

The fundamental basis of health care in European contexts is solidarity. National arrangements for health care provision in EU countries involve monopoly, or near monopoly, of providers of health care services. Looking at health systems as markets, EU health law scrutinises such behaviour and the concentration of market power through mergers of health care providers. EU health law is moving health care systems towards market-based models of regulation. Therefore, it is claimed that EU health law challenges, disrupts, or even destroys, those fundamental bases on which national health systems are organised, as well as their underlying ethos. EU health law is ill-equipped to balance **equality** and **solidarity** with fair and effective **competition**.

Finally, we hear both the claim that the EU is *too strict* in its regulatory approach to **risk** (i.e. is significantly more risk-averse than, say, the USA) and that it is *not strict enough*. Firms operating in the EU are said to be saddled with competitive disadvantage when seeking to compete globally. Innovation in European health industries is hampered, stifling economic growth. Patients waiting for a treatment for their currently incurable conditions have to wait longer than they should. Alternatively, it is claimed that pre- and post-market controls of health care products, such as pharmaceuticals, bio- or nano-technology products, and especially medical devices are insufficiently stringent to protect vulnerable patients. On the other hand, it is also claimed that when it comes to other products that are or may be harmful to health, such as tobacco, food, alcohol, EU health law is too permissive.

Our overall findings are that, while the *strong* version of each claim is not borne out, once we immerse ourselves in the details of law in its policy contexts, a *weaker* version may well be defensible. Here is some of the detail. Readers are welcome to consult the indicated book chapters for a more in depth discussion of individual points.

Consumerism

Most *health products* (and medical devices now coming into line) are not treated in the same way as other consumer products available in the European market (see Chapters 5, 11, 12, 13, 14, 17 of *European Union Health Law*). Prior marketing authorisation applies, involving oversight of research, development, and manufacturing, as well as post-market surveillance. The ways in which EU health law treats health products or services as requiring special legal regimes are incomplete: some products that are, or may be, especially harmful to health (such as pharmaceuticals, products derived from human blood, tissue, or cells, and tobacco) are the subject of EU-level legislation which aims, at least in part, to mitigate those potential dangers (Chapters 12, 13, 14, 17, 18). But the regulation of others (such as food or alcohol) is left more to the discretion of Member States (Chapters 15 and 18).

EU law treats *health services* quite distinctly from the way it treats general consumer services (Chapters 4, 6, 7, 8, 9, 10, 17). Overall, there is little EU-level regulation of health services *per se* – the organisation and delivery of such services within national health systems is a matter for national law. EU health law does not conceptualise patients entirely within a consumerist perspective (Chapters 4, 5, 7 and 8) and particularly, where treatments are ethically controversial, EU health law leaves significant discretion to national regulatory settlements (Chapter 4).

EU law touches upon regulation of health professions, and where it does so, it understands the relationships between health professionals, the national health (insurance) systems within which they operate, and the patients for whom they care, through a service-provider/receiver model, which is grounded in consumerism. But again, the scope of EU law is limited, and national approaches based on a professional ethic of care, patient protection and safety, or provision of public service, remain in place (Chapters 6 and 10).

Rights

EU law on patients' rights incorporates the human right to health. At present, the implications are more symbolic than real, but emergent interpretations of EU citizenship rights may alter this position over time (Chapter 8). EU law also understands patients' rights in at least three other ways: patients' rights as a distinct legal category; the social security entitlements of migrant workers; and rights of patients to consume services in the EU's internal market. In particular, the latter is more related to consumer rights than to fundamental human rights.

Where it opens access to health care across borders in the EU, EU health law enhances patient choice, and patient autonomy. These concepts are related to the human rights to privacy and dignity. But specific legal entitlements are very difficult to enforce as human rights in EU law, not least because of the significant national discretion accorded to the interpretation and implementation of relevant human rights provisions. Thus, national health care systems are unlikely to be significantly affected by EU health law on human rights (Chapters 4, 7, 9–11).

The impact of competition and choice

Monopolistic or near-monopolistic national arrangements for providing health care may be subject to EU law which controls abuse of such concentrations of market power. But important exceptions apply to the application of EU competition law to health institutions. EU health law recognises health as a special type of service: although it falls within the ordinary rules of competition, state aids and public procurement law, many important exceptions to those rules apply in health contexts (Chapters 9, 10, 11).

It is important to point out that nothing in EU health law moves health care systems towards market-based models of regulation, although if national systems do so through political choice, EU law may have the effect of *de facto* preventing or impeding a return to a less market-based system (Chapters 9, 10, 11).

Where individual patients enforce rights to consume health services within the EU's internal market, EU health law supports patient mobility and the right to individual freedom of choice. The arrangements of national health systems are subject to scrutiny where they constrain such freedom. As a minimum,

their rules concerning access to medical treatment must comply with principles of individual assessment of patient needs, non-discrimination on grounds of nationality, and judicial reviewability (Chapters 4, 5). These aspects of EU health law have the potential to affect the solidarity-based provision of health care within EU countries – increased choice for some patients implies reduced choice for others, because health systems have limited resources. In addition, consumer autonomy in patients implies a reframing of doctor-patient relationships, suggesting changes to the way health professionals relate to the health systems within which they offer services (Chapter 6). The reconfiguring of health care relationships has positive implications for patient choice and autonomy, and potentially negative implications for equality and access to health care according to professionally assessed patient need. Where an individual patient enforces an entitlement under EU law to access medical treatment in another EU country, in circumstances where their home country has not authorised that treatment, the professional assessment of their medical need which underpins that access looks more like gatekeeping to access a personal choice, than gatekeeping within a system that seeks to deploy limited resources fairly.

But where *legal persons* (companies) seek to rely on the rules of the EU internal market to trade across borders in ways which disrupt national health systems, we see a different pattern emerging. In areas most integrated within the operation of national health systems, including social insurance provision, hospitals, laboratories and blood centres, EU law operates under a 'light touch' approach, which allows countries to justify national institutional arrangements, provisions and practices which on their face breach EU free movement or competition law (Chapters 9, 10). Furthermore, matters such as the pricing of pharmaceuticals within health systems, which operates through nationally negotiated settlements, have, by and large, not been disrupted by EU law (Chapter 11).

At a systemic level, EU health law's increased patient choice has much less of an effect than is often supposed on the delivery of health care through systems that are organised on the basis of solidarity. Solidarity-based systems are predominantly funded either by taxation or through social insurance. They seek to secure equality of access to health care according to need. Any effects of EU law are indirect only, because countervailing aspects of EU law prevent patient choice, or other actions of market participants, from 'unravelling' national health systems (Chapters 4–6; 9–11).

Regulation and risk

It is unclear whether EU law results in competitive disadvantage for European health industries which seek to compete globally, and consequent impediments to innovation in such industries, and to economic growth. From the point of view of patients who hope for novel medical treatments to become available, it may be good news that EU law on clinical trials and pharmaceuticals is centrally concerned with ensuring that products reach the market (Chapters 12–14).

Many have associated EU law with a precautionary approach to risk regulation, favouring on balance the risks of harm to patients against freedom to run a business. But others take the view that EU law is no more restrictive of industry or capital than any other legal system. This is especially so of the restrictions EU health law imposes (or, rather, it is argued does not impose) on the global pharmaceutical industry (Chapters 12, 13, 17, 18).

When it comes to assessment of risk in EU health law, medical devices regulation is an outlier, but will almost certainly not remain so (Chapter 14). Comparatively speaking, EU health law does not have a light touch approach to regulation of pharmaceuticals, bio- or nano-technology products, products involving human blood, tissue or cells, or of whole human blood or plasma, or human organs (Chapters 12–14). On the contrary, EU law requires significant and detailed pre- and post-market control of these things.

Some other products which are or may be harmful to public health are also subject to detailed EU legislation, for instance on labelling, restrictions on advertising, and composition rules. EU law on tobacco is the example of most complete health-focused legislation; food is subject to some detailed EU law aimed at health protection; EU alcohol law leaves significant national discretion (Chapters 15, 18). Nonetheless, EU law has secured at least some significant improvements in public health.

Conclusion

There is more to EU health law than free competition and under-regulated market choice. Furthermore, EU internal market and competition law are used to support a range of objectives other than economic efficiency and free trade in a narrow sense. EU health law also promotes social and ethical goals. Over-generalised statements about the effects of EU law on health systems, patients, health professionals, and public health should be seen for what they are: too simplistic. A deeper understanding of EU health law recognises both the potential threats to health implicit in the dynamics of EU law, but also the potential benefits and advantages.

References

1 Hervey T, McHale J. *European Union health law. Themes and implications*. Cambridge: Cambridge University Press, 2015.
Available at: http://www.cambridge.org/us/academic/subjects/law/european-law/european-union-health-law-themes-and-implications?format=HB

MANAGED ENTRY AGREEMENTS FOR NEW MEDICINES IN THE BALTIC COUNTRIES

By: Diāna Arāja and Keili Kõlves

Summary: Managed entry agreements (MEAs) have become a topical issue due to the increasing cost of new medicines and the presence of significant uncertainty at the time of making reimbursement decisions. There are uncertainties about clinical and economic evidence, fair prices and budget impact, as well as about the eligible patient population. Innovative solutions are needed to make new medicines available to patients and to ensure the long-term financial sustainability of health care systems. This article outlines the use of MEAs in Estonia, Latvia and Lithuania as part of their pharmaceutical policy arsenal to improve access to new medicines.

Keywords: *Managed Entry Agreements, Reimbursement, Pharmaceutical Policy, Estonia, Latvia, Lithuania*

Introduction

A Managed Entry Agreement (MEA) is an arrangement between a manufacturer and a payer/provider that enables access to coverage/reimbursement of a health technology subject to specified conditions. These conditions can be either financial or health outcome-based, and different types of MEAs exist for each of these two groups. These arrangements can use a variety of mechanisms to address uncertainty about the performance of technologies, to reduce uncertainty around the clinical effectiveness and/or cost-effectiveness of a technology in real life, to limit the budget impact of a new technology, or more generally, to manage the adoption of technologies in order to maximise their effective use.[1]

The most common features of MEAs across European countries are Price-Volume Agreements (PVAs) (39.2% of total MEAs), followed by requirements for data collection (29.2%), limited access to eligible patients (13.0%), conditional continuation (5.6%), payment by result (5.4%), discounts (4.6%), dose price time cap (2.2%) and price match (0.8%).[2] MEAs are often used for high-cost patented drugs for which there is limited evidence of effectiveness in a non-controlled environment and of long-term effects.[2]

Effective pricing, reimbursement and rational use of medicines are goals of all three Baltic States, along with facilitating access to new medicines. Within this context Estonia, Latvia and Lithuania share similar reimbursement systems, namely:

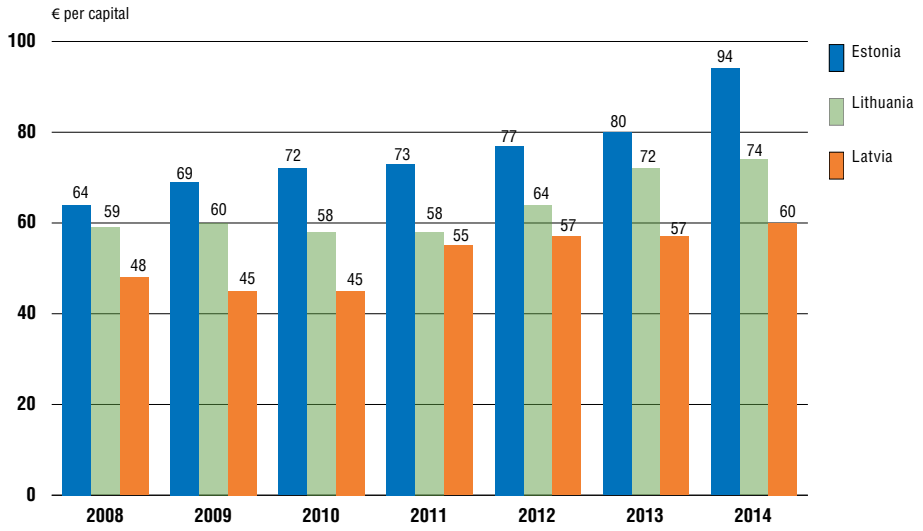
Diāna Arāja is Acting Director of the Department of Pharmacy at the Ministry of Health, Latvia and **Keili Kõlves** is Head of the Medicines and Medical Devices Division at the Estonian Health Insurance Fund, Estonia.
Email: Diana.Arajs@vm.gov.lv

- Medicinal products are reimbursed on the basis of the diagnosis.
- Reimbursement rates are divided according to the character and severity of the disease.
- There are positive lists of the medicines and medical devices that are reimbursed.
- Medicinal products are reimbursed in accordance with reference prices and individual agreements, if these exist.
- Since 2002, the *Baltic Guidelines for Economic Evaluation of Pharmaceuticals* have been used to perform pharmacoeconomic evaluation.[3]

However, the state budget resources allocated for the reimbursement system are different in the Baltic countries (**see Figure 1**). In Latvia, this amount is significantly lower than in neighbouring countries.

In the following sections, we provide an outline of the reimbursement systems in Estonia, Latvia and Lithuania and the use of MEAs to help meet their pharmaceutical policy goals.

Figure 1: State budget resources allocated for the reimbursement of expenditures for the acquisition of medicinal products and medical devices intended for out-patient medical treatment in Estonia, Latvia and Lithuania (€ per capita), 2008–2014



Source: Ref. [4]

Estonia

The health insurance system in Estonia covers the costs of health services provided to the insured population to prevent and cure diseases, finances the purchase of medicinal products and medical devices, and provides temporary sick leave benefits for the employed.[5] Only medicines included in the Estonian Health Insurance Fund's (EHIF) Positive List of medicines or in the List of Health Services are reimbursed. However, there are special reimbursement mechanisms (reimbursement on a named patient basis) available for medicinal products without a marketing authorisation in Estonia.

Medicinal products are reimbursed based on reference prices and price agreements (where these exist); in other cases, reimbursement is based on the product's retail price. Price setting is incorporated into the decision-making procedure for reimbursement. The country's internal reference pricing system to determine the reference price for out-patient medicines was launched in January 2003 and involves grouping pharmaceuticals on the basis of active ingredients (Anatomical Therapeutic Chemical (ATC) classification ATC-5 level), pharmaceutical form and route of administration.

At the manufacturing level, there is statutory pricing (after negotiations) for reimbursable pharmaceuticals. The procedures for setting a manufacturer's prices differ depending on whether the pharmaceutical is an innovative or a generic product. There are specific criteria for the reimbursement of generics: the price of the first generic has to be 30% lower than the price of the primary authorised product on the market, the prices of the generics that follow have to be 10% lower and starting from the fifth generic the price should not be higher than the fourth. The statutory price levels are set according to the prices of the product in three reference countries (Latvia, Lithuania and Slovakia). If applicable, and if similarity is proven, the prices of pharmaceuticals with similar effects are also compared.

If the price of a pharmaceutical is too high, price negotiations with the manufacturer are started. Pricing decisions for out-patient medicines are made by the Minister of Health and Labour, who receives advice from a Pharmaceutical Committee and pricing decisions for in-patient medicines are made by the Estonian Government after receiving a proposal from Estonian Health Insurance Fund.

Acceptable cost-effectiveness of medicines is a priority to ensure equal access among patients. In Estonia, there are several options to help achieve an acceptable price level, including:

- Confidential discounted wholesale prices agreed between the Ministry of Social Affairs (MoSA) and the Marketing Authorisation Holder (MAH).
- Cost sharing agreements (since 2014).
- Risk sharing agreements (since 2014), including performance-based MEAs, which have been introduced in recent years for a number of indications (**see Table 1**).

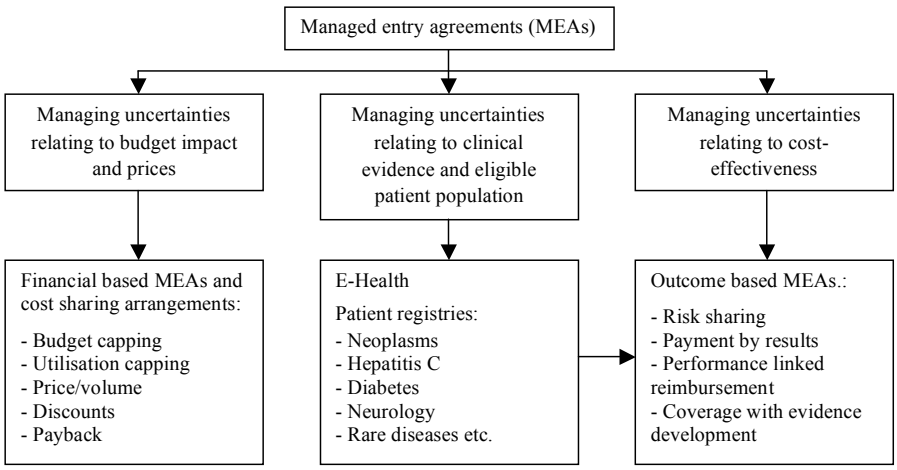
The MoSA website contains summaries of the reference prices and price agreements, including all the prices of reimbursed out-patient medicines. The reference prices of in-patient medicines are available in the List of Health Services. However, confidential risk or cost-sharing information is not publicly available. Moreover, discounts/rebates are not defined in legislation but within price agreements.

Table 1: Performance-based and cost-sharing MEAs in Estonia, based on indication

International Non-Proprietary Name (INN)	Indication	Managed entry agreement
Brentuximab	Lymphoma	Performance-based
Mifamurtide	Osteosarcoma	Performance-based
Telaprevir	Hepatitis C	Performance-based
Goserelin	Prostate cancer	Cost-sharing
Triptorelin	Prostate cancer	Cost-sharing
Bevacizumab	Lung cancer	Cost-sharing
Bevacizumab	Ovarian cancer	Cost-sharing
Dabrafenib	Melanoma	Cost-sharing

Source: Ref [6]

Figure 2: Existing and potential MEAs in Latvia



Source: Authors' own.

Latvia

Reimbursement procedures in Latvia allow patients to acquire medicines and medical devices, with the state completely or partially covering acquisitions through national budget funds. Reimbursement is determined by the type of disease and the degree of severity.[7] In order to include a medicinal product on the positive list, the MAH submits a written application to the National Health Service (NHS) containing clinical information (a summary of the clinical trial evidence, indications, patient target groups, etc.) and pharmacoeconomic information (in accordance with the *Baltic Guidelines for Economic Evaluation of Pharmaceuticals*). Decisions are based on medical assessment and economic evaluation.

The main elements in the pricing system are as follows[7]:

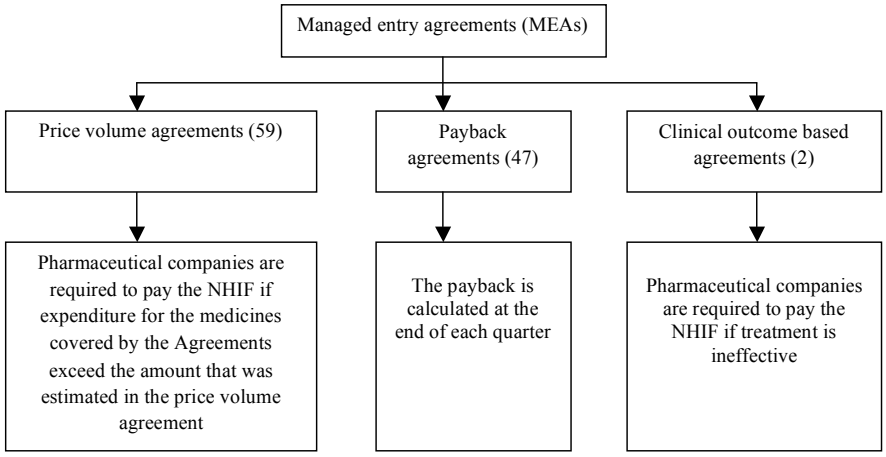
- External reference pricing: the price of a medicine cannot be higher than the third-lowest price (manufacturer/wholesaler) found in the Czech Republic, Denmark, Romania, Slovakia and Hungary and cannot exceed the prices in Estonia and Lithuania.
- Internal reference pricing (for medicines with the same International Non-Proprietary Name (INN) or the same pharmacotherapeutic group) was introduced in 2005: the price must be at least 30% lower for the first generic/biosimilar medicinal product, 10% for the second and third, and 5% for further applications. The reference price for medicines with the same (equal) therapeutic efficacy is determined based on the price of the cheapest medicine in the reference group (originator or generic).
- Clinical and cost-effectiveness pricing: data comparison of Incremental Cost-Effectiveness Ratio (ICER) per life year/quality adjusted life year (QALY) with corresponding data for medicines already included in the positive list.
- MEAs: individual agreements between the NHS and MAHs, such as price-volume agreements, were introduced in October 2012 as well as the possibility to cover patients' co-payments (who receive reimbursement through individual compensation).

Although the reimbursement system in Latvia operates under more limited financial resources than its neighbours (**see Figure 1**), a wide spectrum of financial tools has been implemented in the reimbursement system and further measures are being investigated. MEAs, which are just one of these tools, limit the uncertainties that exist with the introduction of new medicines with regard to clinical and economic evidence, fair price and budget impact as well as eligible patient population (**see Figure 2**).

Currently, Latvia uses financial-based MEAs most frequently. For example, taking into account the fixed annual budget allocation for the reimbursement system, a claw-back scheme was implemented for the period 2011–12, whereby MAHs, depending on their market share, had to partly compensate the NHS if the annual medicines budget was exceeded. The claw-back system has been re-introduced in 2016 under certain conditions e.g. if the sales of specific medicines or medical devices – included in List B (non-interchangeable items), that have been reimbursed for at least three years – increase more than 10% from the previous period (except where an MEA is signed).[7]

The number of MEAs has grown over the years and in 2015 there were 29 price-volume agreements, four payback agreements and one pay-for-performance agreement in force. From 2016, outcome-based MEAs will increase in prominence, including in treatment monitoring of Hepatitis C with innovative medicines and applying payment by results, based on patient registry data.

Figure 3: Types of MEAs between the NHIF and the pharmaceutical industry in Lithuania, 2015



Source: Ref [4]

The policy goal of MEAs is to encourage the entry of new medicines onto the market. At same time, there are some risks for countries, like Latvia, with low purchasing power:

- New innovative medicines initially are launched in countries with high purchasing power and their prices are set according to the purchasing power of the wealthiest European Union (EU) countries.
- Confidential agreements can decrease competition on the prices of innovative medicines.
- Agreements for confidential discounts are mostly influenced by the external price reference systems, which exist in almost all EU countries, and significantly decrease the transparency of pricing as they hide real prices.

Lithuania

Lithuania's health care system serves the entire population, and all permanent residents are required to participate in the compulsory health insurance scheme. Compulsory health insurance provides a standard benefits package for all beneficiaries. Medicines prescribed by a physician are reimbursed according to a positive list.[5]

Outpatient pharmaceuticals are reimbursed according to a list of defined diseases, with the reimbursement category depending on the severity of the disease. Criteria for inclusion to the positive list are the product's budgetary impact, therapeutic value and pharmacoeconomic value.

The main pricing mechanisms used for reimbursed medicines in Lithuania are[4]:

- External reference pricing: prices levels are compared with eight reference countries (Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Poland, Slovakia and Romania) and 95% of the average price in reference countries is used to calculate the base (reimbursed) price.
- Internal reference pricing and clustering: on the basis of INN, pharmaceutical form (e.g. soft, solid, injectable), method of use, purpose and method of release of active substance. Interchangeable pharmaceuticals with a different INN (since 2010) can be clustered according to therapeutic effect, indication of reimbursement, presentation form and age groups of patients.
- Generic pricing: the first generic has to be priced 50% below the originator, while the second and third generics must be priced at least 15% below the first generic to be reimbursed (until 2014, the pricing levels were 30%, 10% and 10% below, respectively). If the INN is produced by four or more producers, the most expensive medicinal product cannot exceed the price of the cheapest one by more than 30%.
- MEAs: individual agreements between the National Health Insurance Fund (NHIF) and MAHs were introduced in 2007 and their numbers have increased in recent years from 20 MEAs in 2010 to 60 in 2013 to 108 in 2015. MEAs take the form of price-volume agreements, payback agreements and clinical-outcome based agreements (**see Figure 3**).

The largest number of MEAs are signed for Antineoplastic and immunomodulating agents (group L of the ATC) (47.6% of total MEAs), followed by the Nervous system (N) (9.5%), Alimentory tract and metabolism (A) (8.6%), Blood and blood forming organs (B) (8.6%), Antiinfectives for systemic use (J) (7.6%), Cardiovascular system (C) (4.8%), Respiratory system (R) (4.8%), Systemic hormonal preparations (excluding sex hormones and analogues (H) (3.8%), Musculo-sceletal system (M) (2.9%), Sensory organs (S) (0.9%) and Various (V) (0.9%).[4]

References:

1 WHO Regional Office for Europe. *Access to new medicines in Europe: technical review of policy initiatives and opportunities for collaboration and research*. Copenhagen: World Health Organization, 2015. Available at: http://apps.who.int/medicinedocs/documents/s21793en/s21793en.pdf

2 Ferrario A, Kanavos P. *Managed entry agreements for pharmaceuticals: the European experience*. Brussels: European Medicines Information Network (EMINET), 2013. Available at: http://eprints.lse.ac.uk/50513/

3 *Baltic Guidelines for Economic Evaluation of Pharmaceuticals* (Pharmacoeconomic Analysis). Available at: http://www.ispor.org/peguidelines/source/Baltic-PE-guideline.pdf

4 *Materials for the twelfth Baltic Policy Dialogue*. Organised by the World Health Organization in collaboration with the Ministry of Health of the Republic of Latvia in partnership with the European Observatory on Health Systems and Policies. Riga, 2015.

5 Estonian State Medicines Agency, Latvian State Medicines Agency, Lithuanian State Medicines Control Agency. *Baltic Medicines Statistics 2010 – 2012*. Tartu: ESAM, 2013. Available at: https://www.zva.gov.lv/doc_upl/BS_2013.pdf

6 Estonian Health Insurance Fund. *Managed entry agreements applied in Estonia*. Riga, 2016.

7 Regulation No. 899 of the Cabinet of Ministers of the Republic of Latvia. *Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medicinal Devices Intended for Out-patient Medical Treatment*. 31 October 2006, with amendments. Available at: http://www.likumi.lv/doc.php?id=147522

OPINION

WHAT, IF ANYTHING, DOES THE **EURO HEALTH CONSUMER INDEX** ACTUALLY TELL US?

By: Jonathan Cylus, Ellen Nolte, Josep Figueras and Martin McKee

Since 2005, the Health Consumer Powerhouse has produced its annual Euro Health Consumer Index,[1] ranking European health systems according to their performance[2] on a host of indicators around (i) patient rights and information, (ii) accessibility, (iii) outcomes, (iv) range and reach of services, (v) prevention and (vi) pharmaceuticals. In its most recent iteration, the United Kingdom ranked only 14th of 35 countries studied. This is in stark contrast to the assessment by the Commonwealth Fund just a year before, in which the UK was rated as the best performing health system among a set of high-income countries in 2014.[3]

While we understand the excitement surrounding health system rankings, we caution against over-interpreting them and, especially, the Euro Health Consumer Index which, as we will show, is especially problematic.

Arbitrary scores are given to indicators

The index is constructed by scoring performance in the five areas listed above as good (3), intermediary (2) or not-so-good (1), based on arbitrary cut-off points. Consequently, countries with similar performance will receive very different scores if they are just on either side of the cut-off point. For example, Poland scores not-so-good on "equity of health care systems" because only 69.6% of health care is publicly funded. Yet Slovakia receives an intermediate score as it achieves 70.0% (a whopping 0.4 percentage points more). Switzerland earns a "good" score on this measure, despite its high levels of deductibles and out-of-pocket spending as a share of total expenditure that is twice the EU-15 average, along with high levels of unmet need compared to other countries and many peer-reviewed studies concluding that the Swiss financing system is regressive.[4]

The point system does not reflect what matters to citizens

There is no obvious logic in how many points are allocated to each indicator. For example, all health outcomes indicators are worth a total of 250 points, while accessibility is worth 225 points. Yet there are more outcome indicators (8) than accessibility indicators (6), so that the maximum score on any given accessibility metric (e.g. waiting time) will be higher than on an outcome metric (37.5 compared to 31.25 points). Thus, not only do abortion rates and cancer survival carry the same weight (since both are considered health

Acknowledgement:
Reprinted by permission of *The BMJ*. Originally published online on 9 February 2016.

Jonathan Cylus, Ellen Nolte, Josep Figueras and **Martin McKee**, European Observatory on Health Systems and Policies, Brussels and London. Email: j.d.cylus@lse.ac.uk

outcomes) but an outcome indicator like cancer survival counts less than an accessibility indicator like direct access to a specialist.

This seemingly indiscriminate approach to allocating points also means that countries can accumulate similar points by prioritising different issues, even if these are unlikely to be seen as equivalent by citizens, had they been asked. For example, a hypothetical country coming last on cancer survival and infant deaths earns approximately 10.4 points for each indicator (out of a possible 62.5 total points) leaving around a 41.6 point deficit. Rather than investing in improving these outcomes, it could just compensate for this simply by abolishing gatekeeping, since allowing direct access to a specialist can gain 37.5 points), which may[6] or may not[7] improve outcomes on these measures.

There is no apparent basis for selecting the indicators

Lastly, the indicators are a strange mix of trends over time and cross-sectional rankings. For example, heart disease and stroke deaths are measured as changes over time, whereas hospital-acquired infections use the most recent data point, penalising countries showing substantial improvements, such as the United Kingdom where the percent of hospital-acquired infections being resistant has fallen from 21.6% in 2010 to 13.8% in 2013. Others, such as Estonia, have seen this figure increase by 2.8 percentage points in the same period (from an admittedly low level, at just 3.5% in 2013) but still receive the maximum points.

Conclusion: We should just ignore the findings of the Euro Health Consumer Index

While many other health systems rankings that have been widely criticised, such as the 2000 World Health Report, these are far more transparent, methodologically, than the Euro Health Consumer Index. Yet, there is no "right" way to rank health systems, or any other complex system for that matter. Choices must be made regarding the indicators to be assessed and the values to attribute to them. However, the notion that we can (or should!) rank health systems based on a single measure that seemingly haphazardly combines indicators that have been "scored" what seems to be at random is debatable. Composite indices conceal what is actually going on in health systems, and offer little guidance for policymakers who want to improve the performance of their system.

Although the report accepts that its results are not "dissertation quality" and must be treated "with caution" it draws inappropriate conclusions about the superiority of one system versus another one, leading to uninformed recommendations and assertions that display limited understanding of health systems. This is patently irresponsible.

There is great potential for countries to learn from each other through careful comparison but the Euro Health Consumer Index's use of poorly constructed composite indices of uncertain origin is unlikely to inform any evidence-based policy development.

References

1 Euro Health Consumer Index 2015. Available at: http://www.healthpowerhouse.com/files/EHCI_2015/EHCI_2015_report.pdf

2 Watson R. Netherlands tops European healthcare index. *BMJ* 2016;352:i538. Available at: http://www.bmj.com/content/352/bmj.i538

3 Davis K, Stremikis K, Squires D, Schoen C. Mirror, mirror on the wall: How the performance of the US health care system compares internationally. New York: Commonwealth Fund, 2014. Available at: http://www.commonwealthfund.org/~/media/files/publications/fund-report/2014/jun/1755_davis_mirror_mirror_2014.pdf

4 De Pietro C, Camenzind P, Sturny I, et al. Switzerland: Health system review. *Health Systems in Transition* 2015;17(4):1–288. Available at: http://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits/full-list-of-country-hits/switzerland-hit-2015

5 The world health report 2000 – Health systems: improving performance. Geneva: World Health Organization, 2000. Available at: http://www.who.int/whr/2000/en/

6 Hawkes N. The role of NHS gatekeeping in delayed diagnosis. *BMJ* 2014;348:g2633. Available at: http://www.bmj.com/content/348/bmj.g2633

7 Olesen F. Re: The role of NHS gatekeeping in delayed diagnosis. 27 April 2014, Available at: http://www.bmj.com/content/348/bmj.g2633/rr/695920

Luxembourg: Health system review in brief

By: F Berthet, A Calteux, M Wolter, L Weber, E van Ginneken, A Spranger

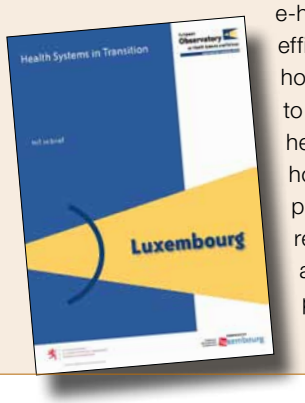
Copenhagen: World Health Organization 2015 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies).

Number of pages: 18

Freely available for download at: www.euro.who.int/__data/assets/pdf_file/0006/287943/Mini-HiT_Luxembourg-rev1.pdf?ua=1

The Luxembourgish health system has the highest per capita health spending in purchasing power parity amongst European countries and lacks capacity to train health personnel, with shortages in some specialty care, which also necessitates a generous policy towards receiving care abroad.

Reforms in 2008 and 2010 have targeted these challenges by establishing a single health insurance fund envisioned to play a stronger role in cost-containment and introducing e-health. There is also room for efficiency gains, especially in hospital care. Current reforms aim to implement a national structured health information system for hospital services, which is a prerequisite to further announced reforms such as the introduction of a diagnosis-related groups based payment system.



NEW PUBLICATIONS

Strengthening health system governance: better policies, stronger performance

Edited by: SL Greer, M Wismar and J Figueras

Maidenhead: Open University Press, 2015

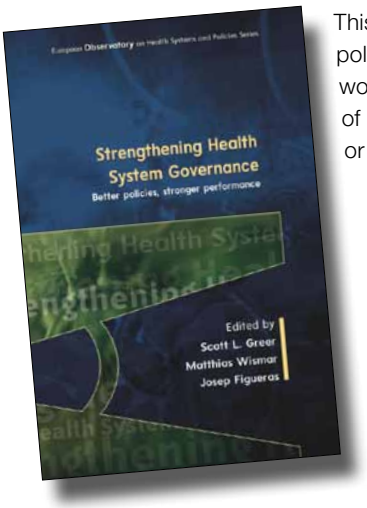
Number of pages: xiv + 272; **ISBN:** 978 0 3352 6134 5

Available for purchase at: http://www.mheducation.co.uk/9780335261345-emea-strengthening-health-system-governance-better-policies-stronger-performance

This book provides a robust framework that identifies five key aspects of governance, distilled from a large body of literature, that are important in explaining the ability of health systems to provide accessible, high-quality, sustainable health: transparency, accountability, participation, organisational integrity and policy capacity. Part 1 of this book explains the significance of this framework, drawing out strategies for health policy success and lessons for more effective governance:

- transparency, accountability, participation, integrity and capacity are key aspects of health governance and shape decision making and implementation;
- there is no simply good governance that can work everywhere: every aspect of governance involves costs and benefits, and context is crucial;
- governance can explain policy success and failure, so it should be analysed and in some cases changed as part of policy formation and preparation; and
- some policies simply exceed the governance capacity of their systems and should be avoided.

Part 2 explores eight case studies, applying the framework to a range of themes.



This book is designed for health policy-makers and all those working or studying in the areas of public health, health research or health economics.

Ensuring innovation in diagnostics for bacterial infection: implications for policy

Authors: C Morel, L McClure, S Edwards, V Goodfellow, D Sandberg, J Thomas and E Mossialos

Copenhagen: Observatory Studies Series No. 44, 2016

Number of pages: xvi + 317; **ISBN:** 978 92 890 5036 4

Freely available for download at: http://www.euro.who.int/__data/assets/pdf_file/0008/302489/Ensuring-innovation-diagnostics-bacterial-infection-en.pdf?ua=1

The inappropriate use of antibiotics is a primary cause of the ongoing increase in drug resistance amongst pathogenic bacteria.

The resulting decrease in the efficacy of antibiotics threatens the ability to combat infectious diseases. Rapid, point-of-care tests to identify pathogens and better target the appropriate treatment could greatly improve the use of antibiotics, yet few such tests are available or being developed, despite the rapid pace of medical innovation. Clearly, something is inhibiting the much-needed development of new and more convenient diagnostic tools.

This study delineates priorities for developing diagnostics to improve antibiotic prescription and use, in order to manage and curb the expansion of drug resistance. It calls for new approaches, particularly in the provision of diagnostic devices, and, in doing so, outlines some of the inadequacies in health, science and policy initiatives that have led to the dearth of such devices. The authors make the case that innovation is clearly and urgently needed, not only in the technology of diagnosis but also in public policy and medical practice to support the availability and use of better diagnostic tools.

This book explores the complexities of the diagnostics market from the perspective of both supply and demand, unearthing interesting bottlenecks: some obvious, some more subtle. It calls for a broad, multifaceted policy response, and an overhaul of current practice, so that the growth of bacterial resistance can be stemmed.

NEWS

International

EU launches new European Medical Corps to respond faster to emergencies

On 15th February the EU launched the European Medical Corps to help mobilise medical and public health teams and equipment for emergencies inside and outside the EU. Through the Corps, EU Member States and other European countries participating in the system can make medical teams and assets available for rapid deployment before an emergency strikes – thus ensuring a faster and more predictable response. The medical corps could include emergency medical teams, public health and medical coordination experts, mobile biosafety laboratories, medical evacuation planes and logistical support teams.

The framework for the European Medical Corps is part of the EU Civil Protection Mechanism's new European Emergency Response Capacity (otherwise known as the 'voluntary pool'). So far Belgium, Czech Republic, Finland, France, Luxembourg, Germany, Spain, Sweden and the Netherlands have already committed teams and equipment to the voluntary pool.

Humanitarian Aid and Crisis Management Commissioner Christos Stylianides said that "the aim is to create a much faster and more efficient EU response to health crises when they occur. We need to learn the lessons from the Ebola response; a key difficulty was mobilising medical teams".

More information on the European Medical Corp at: http://europa.eu/rapid/press-release_MEMO-16-276_en.htm

European Framework for Action on Mental Health and Wellbeing

The Final Conference of the Joint Action on Mental Health and Wellbeing (JA MH-WB), held in Brussels on 21–22nd January 2016, presented the opportunity to discuss progress made over the past three years and to hold a debate on the European Framework for Action on Mental Health and Wellbeing, the most important outcome of this initiative.

According to situational analyses made by the Joint Action, significant advances have taken place in Europe in public mental health in recent years. Yet, important challenges remain to be effectively addressed and in most countries mental health policies have not been fully implemented. Enhanced efforts and new strategies are, therefore, needed to improve the implementation of policies aiming at the provision of essential mental health care for the most prevalent mental disorders and the development of preventive and promotion interventions. Thus, the European Framework for Action on Mental Health and Wellbeing has five main objectives:

1. Ensure the setup of sustainable and effective implementation of policies contributing to promotion of mental health, prevention and treatment of mental disorders.
2. Develop mental health promotion and prevention programmes through integration of mental health in all policies and multi-sectoral cooperation.
3. Ensure transition to comprehensive mental health care in the community, emphasising the availability of mental health care for people with common mental disorders, coordination of health and social care for people with severe mental disorders, as well as integrated care for mental and physical disorders.
4. Strengthen knowledge, the evidence base and good practice sharing in mental health
5. Partnering for progress.

More information on the conference at: http://www.jamhwbfinalconference.admeus.net/

The Framework document and other publications for the joint action are available at: http://www.mentalhealthandwellbeing.eu/publications

ECOFIN ministers agree to consider health and care issues, particularly in the Euro area

In Brussels on 11th February Economic and Finance Ministers agreed that it would be important to make public spending more efficient to enhance the Euro area's potential for economic growth. They agreed to further discuss specific areas of public spending. The Eurogroup will pay particular attention to investment, health care and ageing-related expenditure at upcoming Eurogroup meetings. The discussion was based on a study conducted by the European Commission to assess the composition, efficiency and effectiveness of the euro area's government expenditure in fields such as education, health care, and research and development.

More information at: http://www.consilium.europa.eu/en/meetings/eurogroup/2016/02/11/

Superbugs: curb use of today's antibiotics, and develop new ones, urge MEPs

The European Centre for Disease Control (ECDC) recently warned that bacteria in humans, food and animals continue to show resistance to the most widely-used antimicrobials. Scientists say that resistance to Ciprofloxacin, an antimicrobial that is critically important for the treatment of human infections, is very high in Campylobacter, thus reducing the options for effective treatment of severe foodborne infections. Multi-drug resistant Salmonella bacteria continue to spread across Europe.

To fight the growing resistance of bacteria to today's antibiotics, the use of existing antimicrobial drugs should be restricted, and new ones should be developed, said Environment and Public Health Committee MEPs on 17th February. In a vote on draft plans to update an EU law on veterinary medicines, they advocated banning collective and preventive antibiotic treatment of animals, and backed measures to stimulate research into new medicines.

The objectives of the legislative proposal on antimicrobials are interlinked. It aims to increase availability of veterinary medicinal products; reduce administrative burdens; stimulate competitiveness and innovation; improve functioning of the internal market; and address the public health risk of antimicrobial resistance (AMR). The revised law would empower the European Commission to designate antimicrobials which are to be reserved for human treatment.

"The vote is a big step forward for animal health and the fight against antibiotic resistance. With these new rules, we can better circumscribe and control the use of antibiotics in farm animals and thus reduce the risk that potential resistances will emerge. The text will also help to improve the availability of medicines and drive innovation forward, so as to expand the therapeutic arsenal available to vets. I welcome the broad consensus on this report, which should promote public health and consumer protection", said lead MEP Françoise Grossetête (EPP, FR). Her report was approved by 60 votes to two.

Veterinary medicines must not under any circumstances serve to improve performance or compensate for poor animal husbandry, say MEPs, who advocate limiting the prophylactic use of antimicrobials (i.e. as a preventive measure, in the absence of clinical signs of infection) to single animals and only when fully justified by a veterinarian. Metaphylactic use (i.e. treating a group of animals when one shows signs of infection) must be restricted to clinically-ill animals and to single animals that are identified as being at a high risk of contamination, in order to prevent bacteria from spreading further in the group, they say.

MEPs urge farm animal owners and keepers to use stocks with suitable genetic diversity, in densities that do not increase the risk of disease transmission, and to isolate sick animals. To encourage research into new antimicrobials, MEPs also advocate incentives, including longer periods of protection for technical documentation on new medicines, commercial protection of innovative active substances, and protection for significant investments in data generated to improve an existing antimicrobial product or to keep it on the market.

In a separate vote, the committee approved by 53 votes to three a report by Claudiu Ciprian Tănăsescu (S&D, RO), amending another law to reflect the fact that centralised marketing authorisation for veterinary medicinal products is being decoupled from that for medicines for humans. Both reports are being debated and will be put to a vote during the March/April plenary sessions in Strasbourg.

More information on the report and proposed amendments at: http://tinyurl.com/zbwuago

EPFPSU: European and national policies must strengthen public health care systems

How can Europe ensure good quality health care for all and counter increasing pressures brought about by under-investment and lack of cooperation amongst different health care systems? This question was a central theme of the European Federation of Public Service Union's (EPSU) standing committee for health care and social services (HSS) that met on 16 February. Some 60 representatives from 25 countries took part in the meeting.

A special focus was given to challenges facing health care unions in Romania and Bulgaria. Against a backdrop of a continuing exodus of trained health care workers to wealthier parts of Europe, the meeting noted that unions struggle to build up a stable trade union membership base that could more effectively address these challenges. Many participants mentioned difficulties with ensuring safe and adequate staffing levels in health care. The EPSU consider that trends regarding the privatisation, marketisation and commercialisation of health (and social) care run counter to the need to increase funding in public systems and to step up coordination and cooperation of polices across Europe to ensure universal access to high quality healthcare. They affirmed their belief that well-funded and democratically controlled health care systems are extremely efficient when compared to these where market forces are allowed to play too big a role.

More information at:
http://www.epsu.org/a/12042

Informing policy for young people's health

On 15th March the 2016 edition of the WHO Health Behaviour in School-aged Children (HBSC) study was published. The report *'Growing up unequal: gender and socioeconomic differences in young people's health and well-being'*, covers the 2013/2014 survey on the demographic and social influences on the health of almost 220,000 young people in 42 countries and regions in the WHO European Region and North America.

The report is the latest addition to a series of reports on the HBSC study: a WHO collaborative cross-national study that has provided information about the health, well-being, social environment and health behaviour of 11-, 13- and 15-year-old boys and girls for over 30 years. Young people described their social context (relations with family, peers and school), health outcomes (subjective health, injuries, obesity and mental health), health behaviour (patterns of eating, tooth brushing and physical activity) and risk behaviours (use of tobacco, alcohol and cannabis, sexual behaviour, fighting and bullying). For the first time, the report also includes items on family and peer support, migration, cyberbullying and serious injuries.

The report and further information are available at: http://tinyurl.com/zh77dmp

Warning on TB elimination in Europe

The eighth report launched jointly by ECDC and the WHO Regional Office for Europe indicates that, despite notable progress in the past decade, tuberculosis (TB) is still a public health concern in many European countries. An estimated 340,000 Europeans had tuberculosis (TB) in 2014, corresponding to a rate of 37 cases per 100,000 population.

The organisations warn that although new TB cases decreased by 4.3% on average between 2010 and 2014, high rates of multidrug-resistant (MDR) TB and TB in vulnerable populations, such as the homeless, drug and alcohol abusers and migrants from countries with high numbers of cases of TB continue to challenge TB elimination.

"One quarter of all 480,000 patients sick with MDR-TB globally were in the European Region in 2014. This alarmingly high number is a major challenge for TB control," stated Dr Zsuzsanna Jakab, WHO Regional Director for Europe. "The most vulnerable groups, including poor and marginalised populations and migrants and refugees, are at greater risk of MDR-TB. Because of their living conditions, TB is often diagnosed late, and it is harder for them to complete a treatment course. If we really want to eliminate TB from Europe, no one must be left behind."

"Some social circumstances or lifestyles may make it more difficult for people to recognise the symptoms of TB, access health care services, follow treatment or attend regular health care appointments. We need to find tailored interventions for such vulnerable people, which can include outreach teams or directly observed treatment," commented ECDC Acting Director Dr Andrea Ammon.

Tuberculosis surveillance and monitoring in Europe 2016 is available at:
http://tinyurl.com/zuq9ewc

National

France: Work organisation challenged by psychosocial risks

The most recent publication of the SUMER survey focuses on psychosocial and organisational risks, investigated using workplaces stress models developed by Robert Karasek and Johannes Siegrist. The initial results indicate that job strain impacts more on women because of their lower job autonomy and opportunity to shape the work they do, for example the pace of work.

Administrative staff, unskilled, trade and service workers are more often reporting to be "tense", due to a combination of strong psychological demands with low decision latitude. Men who exercise functions predominantly occupied by women are most affected by the lack of recognition of their work.

The health care sector is particularly exposed to psychosocial risks. In contrast, working in direct contact with the public was found to be a protective factor, provided that there is no tension with the public; of the 75% of workers who were reportedly in contact with the public by phone or in person, 10% reported such tensions. Exposure to psychosocial risks was also found to increase the risk of occupational accidents and absenteeism, especially for men who report a lack of recognition.

The SUMER survey is a unique survey based on interviews of occupational physicians with workers who undergo health surveillance and has been carried out in three waves (1994, 2003 and 2010). It covers a broad range of risks, including chemical, biological, physical and organisational risk factors. The next survey is currently in preparation.

The report is available in French at:
http://tinyurl.com/jox65sr

UK: New sugar tax on soft drinks announced

The UK Minister of Finance, George Osborne, has announced in his annual budget statement to Parliament that a new sugar tax on soft drinks that will come into effect from 2018. A levy will have to be paid by the drinks industry. It will provide an incentive to cut the amount of sugar in drinks. The industry may decide instead to raise the prices of their products.

Drinks with 5 grams (g) of sugar per 100 millilitre (ml) will incur an £0.18 (€0.21) per litre levy and drinks with 8g or more per 100ml will incur a £0.24 (€0.27) per litre levy. Given that soft drink cans contain 330ml of liquid, drinks in the upper band could be 8p (€0.09) more expensive per can, a small bottle could be 12p (€0.14) more and a 1.75-litre bottle could cost around 40p (€0.45) more. Natural fruit juices with no added sugar, as well as milk-based drinks, will be exempt from the tax.

Gavin Partington, Director General of the British Soft Drinks Association said that they were "extremely disappointed by the Government's decision to hit the only category in the food and drink sector which has consistently reduced sugar intake in recent years – down 13.6% since 2012. In contrast Professor John Ashton, President of the UK Faculty of Public Health (FPH) warmly welcomed the announcement.

"This measure is supported by a majority of the public and sends a clear signal to industry that the public's health is a key part of the economic recovery. FPH congratulates the government for accepting the strong, evidence-based argument that this will have a positive effect on the lives of the population."

Mr Osborne said that the tax would raise an estimated £520m a year to spent on sport in primary schools. The devolved administrations in Northern Ireland, Scotland and Wales will have to decide how to spend their share of the proceeds.

UK: Healthier in the EU group established

The United Kingdom government's decision to hold a referendum on European Union (EU) membership has generated much, largely uniformed, debate. One important issue is the impact of the EU on health and health policy in the UK. A new grassroots movement, Healthier in the EU, has been launched, with the goal of correcting misconceptions that are circulating. Its advisory board has some of the UK's leading health professionals, including a former Scottish Chief Medical Officer, President of the Royal College of Physicians, and Chief Executive of the NHS in England, as well as experts in EU law and health policy, nursing, and the editor of the Lancet. The organisation's website includes statements by health professionals on the importance of the EU for the NHS and public health, ranging from the obvious, such as sharing of expertise on rare diseases, biomedical research, and the ability of British patients to obtain access to care throughout Europe, to the less obvious, such as how UK health professionals were able to achieve concerted European action to restrict the use of medicines in executions in the USA.

More information at: http://healthierin.eu/

Additional materials supplied by:
EuroHealthNet Office
67 rue de la Loi, B-1040 Brussels
Tel: + 32 2 235 03 20
Fax: + 32 2 235 03 39
Email: r.rollet@eurohealthnet.eu

10th ANNIVERSARY

OBSERVATORY VENICE SUMMER SCHOOL 2016

Primary care: innovating for integrated, more effective care

24–30 July 2016
Isola di San Servolo,
Venice, Italy.

Theme and objectives

A one-week intensive course aimed at senior and mid-level policy makers, civil servants and professionals steering primary care services and those looking at strengthening care, its continuity and integrative functions within and beyond the health system.

Building on participants' own knowledge and expertise, the School will:

- Systematise and interpret **primary care reform innovations** and their implementation;
- Provide tools to assess the **performance** of primary care systems;
- Explore a series of innovations that can help to **strengthen effectiveness**;
- Address how integrative and integrated primary health care systems can **serve whole populations, including vulnerable groups**;
- Address the **integration** between health care, public health and social services;
- Provide **evidence-based country experiences** of different systems and innovative models of primary care;
- Review **how provider payments and incentives** can ensure primary care fulfills its potential and works effectively with other sectors.

Approach

The School will equip participants to:

- Investigate different organisational models for delivering primary care (including public and private provision);
- Coordinate different professionals with an appropriate skill mix to best meet patients' needs;
- Apply tools, frameworks and different approaches to better support and integrate different population groups, including persons in vulnerable situations;
- Use technological innovations and information system developments to support more effective primary care and better integration;
- Empower patients and make primary care the guide which advises patients in their path through the health system, and supports them in exercising choice and accessing the right services in the right settings at the right time;
- Integrate public health services into primary care.

How to apply

Submit your CV and application form before **31 May 2016**.

Summer School's fee: €2,200 (including teaching material, accommodation, meals, social programme, and transfers between the airport and the island upon arrival/departure).

More information and on-line application on our website:
www.theobservatorysummerschool.org

WE AWAIT YOU IN VENICE!

Organised by the European Observatory on Health Systems and Policies, the Veneto Region of Italy, the European Commission and the World Health Organization.

REGIONE DEL VENETO

follow us on twitter

European Observatory on Health Systems and Policies
a partnership hosted by WHO