Strengthening child health and health services

- Primary care for children
- Child public health in Europe
- Child and adolescent mental health services
- Prescribing for children
- Men’s health and primary care
- Electronic patient summary guidelines
- Out-of-pocket spending on drugs in Estonia
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Because children are not just small adults, efforts to improve their health and the relevant health services they use must be tailored accordingly. Each stage of early life – from infancy to adolescence – has distinct illnesses, developmental issues and challenges. Furthermore, children rely on their families and other caregivers to identify and manage any ill health and are particularly sensitive to the effects of social conditions. This issue of Eurohealth aims to draw attention to the challenges of child health and health services in Europe, and to strengthen our understanding of the challenges facing European Member States and health systems in this regard.

In their overview of the Eurohealth Observer section, Wolfe and McKee address the current state of child health in Europe, focusing on the changing burden of disease and the impact of the social determinants of health. Based on evidence gleaned from their large study in this area, they put forward recommendations for strengthening child health services and systems based on a whole systems approach.

In the case study articles, the crucial role of primary care and the different models by which child health services are delivered in Europe is examined by Thompson et al. Next, Tamburlini and colleagues discuss the need for multi-sectoral and multi-disciplinary approaches to translate into action strategies aimed at tackling the social determinants of health, as well as nutrition, parenting, early literacy and lifestyles. Kaltiala-Heino, Crowley and Kraemer show the variation across Europe in the funding of child and adolescent mental health services, as well as in training and availability of services and experts. Finally, McKee addresses the issue of prescribing medicines for children – many of which often have only been evaluated on adults – and presents new incentives to industry for evaluating medicines in children.

In the Eurohealth International section, the unnecessarily poor state of men’s health in Europe compared to that of women is exposed by Baker and Banks. They highlight some reasons why this has occurred, and provide some thoughtful ways forward for improving men’s use of primary care services. On a different note, the European Directive on the application of patients’ rights in cross-border health care is having wide-ranging effects, also in e-health initiatives. Maarseveen and Thorp discuss how the newly adopted guidelines on the European patient summary dataset aim to be the first step in Member States eventually being able to develop structured electronic patient summaries which are transferable across borders when a patient requires care from a health professional abroad.

In Eurohealth Systems and Policies, Habicht and colleagues examine pharmaceutical reimbursement policies in Estonia since the onset of the economic crisis. They emphasise new policies to encourage doctors to change their prescribing habits, which in part has helped to reduce out-of-pocket payments.

Eurohealth Monitor presents a new book on European Child Health, which documents some alarming variations in child health outcomes between countries and provides a wealth of information should you be interested in further exploring the themes of our Observer section. Additionally, a new policy summary on Promoting health, preventing disease makes the economic case for investing in tackling the major risk factors.

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STRENGTHENING CHILD HEALTH AND HEALTH SERVICES IN EUROPE

By: Ingrid Wolfe and Martin McKee

Summary: Child health in Europe has improved dramatically in recent decades and child survival is better than ever. However, all countries are struggling to adapt to changing health needs and demands, while facing mounting pressures to improve quality and contain costs. Some countries are managing to deliver substantially better gains in child health than others, offering opportunities for shared learning. Children are especially vulnerable, and the policy choices made by European governments have profound effects on their health, well-being, and development. A comprehensive strategy for European child health requires changes in professional practice, planning, and child health policy.

Keywords: Children, Child Health, Health Services, Health Systems, Health Strategy

A snapshot of child health in Europe

While improvements in child health are very evident, particularly in terms of reduced mortality rates, the disease burden profile for children in Europe is changing considerably and factors such as poverty and other social determinants of health have a strong impact on children’s quality of life and the risk factors they face.

Death in childhood

Mortality rates across Europe have dropped dramatically over the past few decades, so more children than ever survive into adulthood. However, rates in some countries have improved more than others, something that is apparent from calculating how many children would survive if all countries could match the best performing country. Across the EU27 countries, there would be over 12,000 fewer child deaths per year if every country had the same death rate as Sweden (see Table 1).

The changing burden of disease

The health problems that affect children are changing. Fewer children die from infectious diseases, while chronic conditions such as asthma and diabetes are becoming ever more important. Young people are increasingly exposed to the risk factors for chronic diseases, obesity, smoking and alcohol, while their continuing risks of cancer, injuries, and mental health problems are often inadequately recognised.
Social determinants

Differences in access to resources affect the lives and risks of death for children and young people. The more unequally that wealth is shared within a society, the more babies and children die. Political choices on economic policy and social protection are crucially important for the health and well-being of children and families. This is apparent from looking at the numbers of children living in poverty, or who are at risk of poverty and social exclusion (see Table 2). Some countries choose to protect the young whereas others have adopted policies that disproportionately disadvantage children and young people. For example, in Sweden poverty and social exclusion affect all age groups about equally, whereas in the United Kingdom, the young are at greater risk.

There are other ways in which policy choices can differentially protect or harm vulnerable children. As shown in Table 3, deprivation among migrant families in Sweden is similar to the rate in the overall population, whereas in Spain migrant families fare worse than the general population. Similarly, the deprivation rate for children living in households where no parent is in paid employment is three times higher in Spain than it is in Sweden.

Child health services and systems

The variation between countries reveals disturbing levels of unfairness. However, it also presents opportunities, since the best-performing countries show us what to aim for – what it is possible to achieve. And they can help us to learn how to do better and, as discussed above, what could be achieved if all countries performed as well as Sweden.

The reasons why some countries achieve better child health are complex, but include both the capacity to act – for example, financial resources – and the political will to do so, such as social spending, generosity of family policy, environmental safety policies, and high quality equitable health care. Although there have been tremendous successes in child health across Europe, in many regards the responses of health systems to evolving health and social needs have been too little and too late. National policies for children’s health have too often focused on individual short-term issues, while paying inadequate attention to the underlying problems, thereby preventing meaningful and sustainable change. The consequences of health system failures to meet needs adequately include suboptimal health outcomes, unnecessary variation in quality of care, inefficient, inconvenient services, and ultimately failure to realise children’s full potential health and development. We believe that a system-wide transformation will be required to secure the health of Europe’s children.

There are three broad explanations why children’s health systems are not delivering optimal health and development. First, there is a mismatch between children’s health needs and the services and systems that should be ready to meet those needs. Why? The answers include a failure to adapt to the shifting burden of disease, accumulating evidence on effective models of health care delivery, and advances in paediatric medicine.

Children with chronic diseases, long-term conditions, mental ill health, and...
disabilities require new models of care. Services for children with long-term conditions are too often fragmented, deliver poor quality, are inconvenient and sometimes even unsafe. A key problem in some countries is that health services are still hospital-centric and there are professional, financial and organisational barriers to multidisciplinary care models. Consequently, children with chronic conditions must fit around systems driven by the need to respond, inefficiently, to urgent care needs.

Second, we are failing to maximise children’s health gain and well-being. The results are sadly inevitable: high rates of preventable non-communicable diseases, vulnerable children who do not receive the support they need to thrive, and widening gaps between rich and poor families. Child health should be about more than preventing illness and treating it when it happens. It should be about building good health and enabling children to reach their full potential.

Third, there is a failure to realise the rights-based approach to child health that underpins the United Nations Convention on the Rights of the Child (UNCRC), to which each European country has agreed.

Recommendations

A whole systems approach is needed to deliver the scale and scope of changes needed to strengthen child health systems in order to meet the present and future health needs of Europe’s children. A comprehensive strategy requires action in practice, plans, and policy (see Box 1).

Practice

Primary care is at the core of children’s health care. However, it is important to ensure that there are sufficient expert professional skills available at the first point of contact, while maintaining the traditional family and person-centred approach of primary care. Tensions between generalism and specialism characterise many countries’ attempts to improve everyday health care for children. There is no simple “one size fits all” solution. It is important to be clear about which services need to be delivered in a hospital, and which do not. Hospitals are not needed to provide care for children with minor or common conditions, where sophisticated technology is not required, and where local access is an advantage. Moreover, hospitals are not needed for most care for children with long-term conditions and chronic diseases who need carefully planned multidisciplinary teams of professionals to care for them.

A renewed focus on primary care is needed. A team of professionals working
together could provide a good balance between access and expertise for medical, mental health, social care, and other specialties, and should enable the majority of children’s health care to be provided in primary care.

A comprehensive chronic care model is needed to improve prevention and care for children and young people. Medical, psychological, nursing, social, educational, and other services are needed for children with chronic conditions. In addition, policies in the wider health system are needed to reduce risk, enhance resilience, and improve quality of life. A holistic comprehensive chronic care model is linked closely to the philosophy of primary care, and developing an effective chronic care model and improving first contact care for children are closely related. For example, problems in one area worsen those in the other; if acute services are excessively and inappropriately used by children with minor illness, there is inadequate resource available for chronic care services. And because those providing first contact care often function as gate-keepers to the rest of the health care system, problems arise if the system does not work efficiently. Thus, solving problems at the first point of contact with health care will allow more time and resources for planned team-based care including, crucially, services for chronic conditions, both physical and mental. Progress in child health care depends on resolving the problems in every-day paediatric practice.

Table 3: Child deprivation in at risk groups, EU27, Norway and Iceland

<table>
<thead>
<tr>
<th>Country</th>
<th>Deprivation rate for children lacking two or more items</th>
<th>Deprivation rate for children living in single parent families</th>
<th>Deprivation rate for children living in families with low parental education (none, primary and lower secondary)</th>
<th>Deprivation rate for children living in households (no adult in paid employment)</th>
<th>Deprivation rate for children living in migrant families</th>
</tr>
</thead>
<tbody>
<tr>
<td>Austria</td>
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<td>16.9</td>
<td>19.2</td>
<td>40.7</td>
<td>17.9</td>
</tr>
<tr>
<td>Belgium</td>
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<td>20.0</td>
<td>26.7</td>
<td>40.4</td>
<td>19.6</td>
</tr>
<tr>
<td>Bulgaria</td>
<td>56.6</td>
<td>76.0</td>
<td>89.6</td>
<td>85.2</td>
<td>–</td>
</tr>
<tr>
<td>Cyprus</td>
<td>7.0</td>
<td>34.3</td>
<td>22.6</td>
<td>54.1</td>
<td>14.4</td>
</tr>
<tr>
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<td>29.7</td>
<td>59.5</td>
<td>50.0</td>
<td>18.8</td>
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<tr>
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<td>10.1</td>
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<td>22.3</td>
<td>29.4</td>
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<td>16.6</td>
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<td>6.8</td>
<td>2.5</td>
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<td>20.5</td>
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<td>23.8</td>
<td>35.6</td>
<td>42.2</td>
<td>16.7</td>
</tr>
<tr>
<td>Greece</td>
<td>17.2</td>
<td>24.3</td>
<td>50.8</td>
<td>–</td>
<td>42.2</td>
</tr>
<tr>
<td>Hungary</td>
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<td>47.3</td>
<td>74.5</td>
<td>64.4</td>
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</tr>
<tr>
<td>Iceland</td>
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<td>3.9</td>
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<td>3.6</td>
</tr>
<tr>
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<td>Lithuania</td>
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<td>54.7</td>
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<td>31.5</td>
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<tr>
<td>Luxembourg</td>
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<td>5.0</td>
</tr>
<tr>
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<td>7.8</td>
</tr>
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<td>4.1</td>
<td>5.9</td>
<td>14.6</td>
<td>3.4</td>
</tr>
<tr>
<td>Poland</td>
<td>20.9</td>
<td>42.6</td>
<td>61.0</td>
<td>46.8</td>
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<tr>
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<td>37.9</td>
<td>73.6</td>
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<td>Romania</td>
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<td>92.4</td>
<td>95.8</td>
<td>–</td>
</tr>
<tr>
<td>Slovakia</td>
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<td>23.1</td>
<td>83.8</td>
<td>78.8</td>
<td>–</td>
</tr>
<tr>
<td>Slovenia</td>
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<td>17.3</td>
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<td>43.6</td>
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<td>19.3</td>
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</table>

Source: Ref 6
Health care and public health are part of a continuum and each is necessary for the other to produce and promote health in individuals and in populations. Social determinants of health have a direct effect on health services, and health services are an important determinant of health in children and young people. Public health policies can promote health through education and improving social determinants. Clinicians treat disease but also deliver preventive health care. A public health approach to planning, delivering, evaluating, and improving health care can help improve the quality and equity of health care and health.

Integrating services is a key policy focus in many European countries. Integration takes two broad forms. Vertical integration combines services that traditionally work in a hierarchical way. So cooperation between primary and secondary care can help achieve a better balance between access and expertise. Horizontal integration, across sectors such as health and social care, is particularly important for children with specific needs, including long-term conditions, mental health problems, or children who are particularly vulnerable for social reasons. Integration is also needed at the point of transition between children’s and adults’ health services, which is often a time when problems occur. Although effective integration is a common goal, all countries have struggled to achieve progress. Key lessons from countries such as the Netherlands and Sweden include the need for supportive policy and incentives to cooperate and work together.

A transformation in the child health workforce will be required to achieve many of the changes necessary to strengthen children’s health services and systems. At present there is a lack of comprehensive comparable data on child health professionals in Europe, and little reliable evidence on safe numbers of staff for population size or health need. Training programmes often lack evidence to support them. Health professionals must go beyond the acquisition of skills and knowledge, develop abilities to mobilise knowledge, to reason critically, and participate as fully engaged team members in health systems.

**Plans**

Health services are often shaped by historical and cultural influences, and by current patterns of service use, not by a rational and comprehensive assessment of population health needs. The current way of planning services helps create a mismatch between need and provision that was discussed previously, and there are other unintended consequences. Children and their parents frequently fail to use services as intended by those who designed them. For example, parents in many countries often seek non-urgent care directly from emergency departments. Poorly planned services also affect families of children with chronic disease or complex conditions, who frequently report unsatisfactory care experiences, such as multiple appointments in different locations on different days. A public health service based on a geographically defined population should have population level data, be able to assess health and health service needs, anticipate changing health and social care needs, and shape services to match needs.

But we still lack a detailed understanding about how to deliver health care to optimal effect. There is growing recognition that we need a deeper understanding of the conditions within which a health system operates, defining the factors that promote improvement in child health, and understanding of how to drive improvements in quality of care and health outcomes. But improving health care depends on having reliable data. Child health indicators are needed to measure the quality of care, and the effects of policy on health and health services. Comprehensive, reliable, and comparable indicators of health and disease, of services and systems, that could be used across Europe, would strongly enhance research capability and drive progress in improving European child health.

However while research can give us information on current patterns of health, it is much more difficult to anticipate what needs to happen in health systems in future years. Far-sighted policy-making is needed to prepare for changes in health, to be ready to exploit new knowledge about how and why diseases happen, and implement appropriate technological developments. This will require new thinking on predicting and modelling health trends.

**Policy**

Despite improvements in health care for children, child health could be much better. Many countries have failed to deliver the health gains that others have achieved and stark inequities remain within countries too. Child health is shaped by a balance of risk and protective factors. The conditions in which children are born and live depend on a wide range of material, psychosocial, environmental and behavioural factors. So the risks of disease and the underlying social determinants that underlie these conditions can only be addressed with a comprehensive, coordinated, and sustained policy response. A health dimension in all policies is needed.

Better knowledge about what works in child health policy is urgently required. A concerted effort is needed to develop capacity in child health services, systems and policy research, and improve knowledge brokering to help translate research into policy.

Accountability in health systems is frequently promised but rarely delivered. An effective accountability mechanism should ensure that the voices of children are heard and that policy-makers fulfil their commitments. A framework for monitoring, reviewing, and remedying processes is needed. Countries could agree indicators for child health services and create monitoring organisations with responsibility for collecting and analysing data. A national child health oversight mechanism reporting to the government executive or legislature should make recommendations for action, with an accountable body responsible for ensuring change.

Sustained political will is needed to make all these things happen. Policy-makers must translate the knowledge that intervening effectively early in life helps build the foundations for a productive and healthy life into policies.

The UNCRC reminds us of the moral imperative to improve children’s lives...
and health. A rights-based approach to child health services articulates the values we should aspire to by recognising that health exists in a social and environmental context, that children live and grow up in a world that could be so very much better. The challenge for child health in the 21st century is to develop health systems and cross-cutting health policies that are more responsive to child and family health needs. This will be crucial to shape, promote, and protect this generation and the next.

References


Summary: Primary care is fundamental to children’s health systems but remains an underdeveloped resource. There are important gaps in knowledge about systems, services and the workforce for children’s primary care. While core attributes of a primary care model for children are generally agreed, it is clear that urgent care dominates at the expense of care for chronic conditions. The steadily increasing rates of chronic diseases in children mean that this is a significant threat to population health, and to health system sustainability. Urgent action is required to strengthen primary care systems for children to safeguard their health, and that of future generations.

Keywords: Children’s Primary Care, Acute Care, Health Workforce, Child Chronic Diseases

The foundation of health systems

Primary care is widely accepted as the backbone of modern health care systems. Countries with well-developed primary care systems provide higher quality and more cost-effective care than those with a more specialty-based service. Primary care provides individual level and population-based care, strives to deliver continuity of care and considers patients in the context of their family and social environment. Primary care concurrently emphasises biomedical and patient-centred care and encourages shared decision-making.

The models and systems that have emerged set many countries in Europe apart as world leaders in primary care. However, the role of primary care in most European countries is evolving. These disparate models of primary care also provide a ‘natural laboratory’ to develop and adapt different models of care and to learn from each other. Moreover, as cost containment becomes increasingly important for economic recovery in Europe, the cost effectiveness of different primary care models may be key to maximising Europe’s competitive advantages globally.
Table 1: Key aspects of primary care for children

| Systems | Choice available for parents in selecting type of primary care clinician: In some countries there may be no choice, e.g. in the UK all children are registered with a General Practitioner (GP), whereas in Germany parents may have a choice about registering with a GP or primary care paediatrician (although there are financial incentives for parents to register with a GP).

| Extent of coordination of care between primary care and secondary care or specialists: Some countries have established a more integrated care model (e.g. Sweden), with cooperation and coordination between general and specialised services. Integrating primary and specialist care can involve the same physical location (i.e. co-location) of services, shared clinical pathways and protocols or guidelines, information system/medical record-sharing, referral systems and pathways or urgent/acute management.

| Services | Range of clinical services provided: This can include acute and chronic conditions, preventive care, e.g. well-child checks, immunisations, mental health, sexual health clinics, and adolescent health services, which can vary between countries.

| Acute care or after-hours care: Care for acute health problems arising during or after normal working hours, including acute medical and surgical problems and acute trauma, is provided variably ranging from specific out-of-hours services to individual doctors looking after their own patients.

| Workforce | Type of medical clinician responsible for providing the majority of care: This can be predominantly GPs (e.g. The Netherlands, UK) or paediatricians (e.g. Italy), or combinations.

| Doctor-to-population ratios: Range widely across Europe, from as few as 112 children per primary care doctor (France) to 341 per primary care doctor (The Netherlands). This variation may arise from economic, geographical or historical factors.

| Primary care team working: The extent to which primary care doctors work in isolation, or with various other members of a primary health care team involved in the care of children, including nurses, dieticians, community organisations, social workers, school nurses, etc.

Source: Ref

Primary care for children

Primary care for children is provided in different ways throughout Europe, and there are often variations within the same country. Key aspects that characterise primary care models are shown in Table 1. These different models have emerged partly for historical and cultural reasons but objectively comparing quality of care among the different systems of children’s primary care across Europe is important to improve services. A better understanding of which delivery models and processes of care offer the best experience, outcomes and cost effectiveness is urgently needed. Unfortunately, there is little evidence currently to support such comparisons. Better indicators for measuring quality of care are needed, including more research to evaluate and compare systems. Only then will policy-makers be able to make fully informed decisions about finding or adapting the best model for a given context (or identifying characteristics that may be part of an ‘ideal’ model).

Training doctors for primary care

Across Europe, primary care systems involve doctors (GPs and/or paediatricians), nurses (either specialist children’s or general nurses), or combinations of different types of providers. GPs and paediatricians undergo different types of training, of varying duration. Yet there is scarce evidence to inform best-practice in training, and guidelines are set by professional bodies with a diversity of requirements and interests to consider. The challenge in GP training is to fit in enough paediatric training while learning about all the other age groups and disease areas. Moreover, training is often hospital-based and may be of limited relevance to primary care practice. However, in some countries there may be no requirement for GPs to receive specialist training in community-based paediatrics at all. For example, only 6 of 27 countries surveyed in Europe provide paediatrics training as part of postgraduate education for general practitioners. On the other hand, paediatricians receive almost all of their training in hospital settings and thus may be poorly equipped for the challenges of providing care for children in primary care settings.

The lack of reliable evidence about the duration, content and format of child health professional training makes it difficult to know how to shape education programmes to best serve the interests of children and young people. Standardising training requirements across Europe is one way forward, and some Europe-wide professional bodies have made recommendations for paediatric training. But more important is gathering evidence for what training is needed and how to provide it, tailored to each country’s specific context and needs.

There is now greater awareness of the need to provide adequate training, and in some countries the length of GP training has increased. There have also been calls for a shared training programme (at least for periods of training) that both GPs and paediatricians would share to try to improve the appropriateness of training for both.

Common clinical problems in primary care for children

The reasons why children and parents seek care in the community are fairly consistent between countries. Acute infections are the most common reason, particularly those of the respiratory tract and ear, nose and throat, followed by chronic conditions such as asthma and eczema. However, immunisations, developmental checks, and other routine services are also common.

Across many countries in Europe there has been a steady increase in primary care use in recent decades, and in some (e.g. England) there has been a concurrent increase in emergency department attendances and unplanned hospital admissions. In England, there has been a 28% increase in emergency hospital admissions in children from 1999 to 2010, mostly for acute infections. This is somewhat paradoxical since significant improvements in public health, immunisations, and nutrition have, on the whole, made infectious diseases less common and less serious.
The rising demand for acute services in England, and presumably in other countries (though less well documented) has drawn resources away from the steadily increasing rates of chronic diseases in children and young people. This presents a serious threat to the future health of the population, and to the sustainability of the health system.

**Urgent access to primary care**

Acute but often minor illnesses and injuries are perhaps the most common aspects of primary care for children. By their nature, these problems are fairly urgent and often occur outside normal working hours – nights or weekends. Fortunately, most urgent care for children can be delivered safely in the primary care setting, provided the services available to parents have certain core attributes (see Table 2). However, there are many different ways in which these services are provided across Europe: driven by health service needs, parent demands, work-life balance of staff, and even social pressures.

The large number of different models that have emerged in Europe illustrate tensions between often competing demands for access, continuity of care, high quality, and cost containment. This is particularly so for access to acute care out-of-hours, where there may be a mismatch between the demands that parents may have (accessible, high quality, minimal cost, continuity) and what realistically can be provided. Across Europe there has generally been a shift from more individual-based care (e.g. where a child’s family doctor or paediatrician might provide on-call care), to cooperative models where groups of primary care providers share out-of-hours work, perhaps from a centralised location; telephone advice services; emergency departments; and walk-in or urgent care centres.

The main challenges in urgent primary care services for children include: increasing parental expectations for access to care; the need for coordination between primary care and other services; signposting and education for parents to seek the ‘right care at the right time and right place’; increasing the skills and technology in primary care for enhanced diagnosis and treatment; and the need to minimise costs.

**Long term conditions in children**

Primary care is ideally suited to be the major provider for prevention, early detection, and ongoing management of children with chronic diseases.

There are distinct differences between chronic conditions in children and adults, so it can be helpful to consider them in different ways, and according to the optimal primary care involvement. First, children with common conditions such as asthma or eczema are predominantly managed in primary care, perhaps with occasional consultation with specialists. Second, in cases where children have less common chronic diseases, such as epilepsy or type-1 diabetes, specialists usually provide the majority of care. Third, there are children with complex chronic conditions and co-morbidities, such as severe cerebral palsy, who may have a complex array of health and social care providers. Finally, are those children with risk factors for chronic diseases, such as hypertension, obesity or impaired glycaemia which are now emerging but which are unlikely to cause illness for many decades. There is potential to deliver substantial population health gain by ensuring that sufficient resources are dedicated to this area of growing need.

**Preventive services in primary care**

One of the core functions of primary care for children has traditionally been providing preventive services, and across Europe there is wide variability in terms of the scope of services offered. Common to all systems is immunisation under childhood programmes, but they
Table 3: Future issues in models for delivering primary care for children in Europe

- **Integration**: fostering cooperative delivery of services for children within the primary care team, between primary care and community services (e.g. social services); and between primary care and specialists.
- **Reducing costs**: or at least minimising the rate of increase of health care costs for primary care for children; disinvesting in inefficient or outdated practices; and reducing inappropriate specialty referrals and admissions.
- **Workforce**: identifying the ideal balance of skill-mix, training and access, between paediatricians, GPs, nurses, and other types of clinician.
- **Balancing choice**: for types and location of providers, with workforce availability and costs of services, and increasing expectations of parents and children.
- **Supporting research**: to evaluate current systems of care and new models for delivery.

Source: Ref

can also include scheduled check-ups, health promotion activities, and active surveillance. However, beyond this there is wide variability in what services are offered and by whom.

A survey of 29 European countries found that the mean number of clinical visits for well-child check-ups was 14.7, with a range from 5 to 30. In terms of who provides these services, again there is variation in the type of clinician, working alone or in teams; different forms of promoting access for particular high risk groups of children and parents; and whether services are organised at clinic level or at regional or national level.

Across Europe there is broad consensus that the vast majority of preventive services should be provided as close as possible to where children and their parents reside. Usually this means as part of primary care or community health care services. There is also agreement over the need to expand the type and age range of preventive services beyond growth, development and vaccination in early ages, to incorporate prevention for rapidly growing health problems in children and young people such as obesity, lifestyle-related illnesses and mental health conditions.

**Future issues and priorities**

There are several issues to address in order to improve primary care services for children in the future (see Table 3).

**Next steps**

We propose several immediate steps for adapting and improving primary care for children in Europe.

**Reflect the changing epidemiology of child health**: Primary care for children has become overwhelmed with providing acute care, and to a lesser extent screening and preventive care services. These have dominated research, health care policy, and practice in most countries. Yet countries have failed to adapt to the major epidemiological changes affecting children. It is critical now to change this approach, and tackle head on the rise in chronic conditions, particularly non-communicable diseases and mental disorders which will increasingly dominate children and young people’s health and well-being, and impact hugely on adult health.

**Improve chronic disease management**: While the management of chronic diseases in adults has changed and adapted over recent decades to become more effective, for children there has been little change. While there will not be a ‘one size fits all’ system for children in primary care, there are excellent models from adult primary care that could be adapted to children. These are all likely to include elements of collaborative working, increased decision support, more sophisticated information systems, support for children and their carers, longitudinal systems, and effective methods to identify and modify risk factors for chronic diseases.

**Shift resources away from acute care**: It is simply not possible to continue to keep providing more and more acute care at the expense of all other components of primary care for children. The paradoxical situation of improved overall health yet rising acute hospital admission rates must be addressed. There must be better ways of supporting parents at home and with community resources that fit their needs for accessibility and quality of care.

**Workforce and training**: It is now also timely to design an evidence-based training for health care professionals to provide optimal primary care for children, ideally working across professional boundaries. However, many health systems and training programmes are strongly entrenched in medical cultures in each country, so it may be more realistic to identify new and better ways for health care professionals to work together, and clarify the training needed to provide safe and effective team-based primary care for children.

**Quality of care indicators**: Without robust quality markers it is difficult to compare different systems of primary care across Europe, so a Europe-wide agenda to develop, validate and then use quality markers is essential in order to be able to learn lessons from each other.

**Research gaps**: There are major deficits in the current body of research which could be used to inform policy decisions and clinical care for children in primary care settings. Identifying where the gaps are, and refining and prioritising these for research funding at the EU and national level has occurred, but needs to be translated into research funding decisions.

Fortunately, many EU countries now have excellent infrastructure to support research in primary care and the primary care child health research workforce is growing. What is needed now is sustained investment and political will to strengthen children’s primary care research as a foundation for delivering sustainable health gain through the years.
By: Giorgio Tamburlini, Mitch Blair and Ingrid Wolfe

**Summary:** An overview of child health status, determinants and policies in Europe indicate the risk of a slowing down in positive health gains and an increase in inequities. Strategic directions towards improved and equitable outcomes in child health and development include: taking a comprehensive approach; giving priority to tackling disadvantage; and stronger investment during the early years.

To address threats, child public health approaches need to embrace multi-sectoriality and multi-disciplinarity and focus on the known links between social determinants and factors such as nutrition, parenting, early literacy and lifestyles. Europe-wide efforts to address research gaps, implement scientific evidence and share best practices are needed.

**Keywords:** Child Public Health, Early Exposures, Social Determinants, Public Policies

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**Key concepts and relevance to society**

Child public health is about understanding how the health and development of children are influenced by the family, community and societal environments and how they can be improved by public policies and by coordinated interventions carried out at population level. Child public health responds to the principles of new public health: a strong basis on scientific evidence, a multidisciplinary and multi-sector approach, an equity lens, and an emphasis on participation. It has a very important added value in being the starting point of a life-course approach to population health: from conception until late adolescence/early adulthood. What happens to the embryo, the foetus, the newborn baby, the infant and the child has a profound impact on health, development and well-being in subsequent life stages and throughout the life-course.

The early years of life represent a golden opportunity to improve the health of the whole population and the development of the whole of society. In fact, it has been shown that investments in the earliest periods of life pay the greatest dividends to families and to societies. There is a second “window of opportunity” for preventive intervention in adolescence which can alter life-course trajectories, especially in securing healthy lifestyles, mental health and well-being.

For these reasons, child public health is, and should be, viewed as the quintessence of public health. Unfortunately, although economics, neuroscience, education science and epidemiology have produced increasing evidence to justify the notion that focusing on the early years is in the best interests of everyone, most policy-makers and many public health...
experts still find it difficult to capture the implications of this evidence and translate it into public policies and interventions.

In this article, we outline some strategic directions to move towards improving family, community and societal environments for children. This discussion is based on a snapshot analysis of current trends and future scenarios of child and adolescent health in Europe, and on our understanding of how different factors, including public policies, act and interact during the early years of life to determine child health and development outcomes.

**Shifting burden of disease and lost opportunities for development**

In Europe more children than ever are surviving, and the diseases and disabilities they suffer from are changing. The burden of disease in the 0–18 age group has shifted from infants and children to newborn babies and adolescents and from infectious diseases to disabilities and non-communicable diseases (NCDs). Congenital malformations and diseases, cancer and injuries are responsible for an increasing proportion of childhood deaths. Mental health problems and developmental disorders appear on the rise everywhere. [2] [3] [4] [5] [6]

**Inequities in child health and developmental outcomes**

The burden of morbidity, mortality and poor cognitive and emotional development is unevenly distributed across countries and within countries. Socioeconomic gradients have been described in many European countries in mortality and morbidity, in pregnancy outcomes, in developmental outcomes, in school performance, and in most risk conditions, from adverse housing conditions to living near a road with heavy traffic. Resources like day-care and green areas are less common in disadvantaged areas, particularly in cities. [2] [6]

In this respect, it is particularly worrying that in most countries in Europe, poverty among children is higher on average than among the population as a whole, and that, as a consequence of the economic crisis, poverty levels have significantly increased, even doubled in some Mediterranean countries.

Children, particularly those belonging to low-income and migrant households, are particularly vulnerable to the consequences of economic crises. Many families, especially those with disabled members, single-parents and especially single-mother and migrant families, experience a decline in living standards and develop coping strategies which typically include shifting to cheaper food and reducing expenditure on health and education, including day-care. The stress of economic insecurity and reduced public spending in health, education and welfare systems add to pre-existing deprivation and psychosocial difficulties to produce a variety of adverse outcomes among children and adolescents, including intergenerational adverse effects, and causes immense suffering and huge societal costs. In Europe, an important proportion of children cannot develop their potential for a satisfactory and productive life due to the consequences of poverty, social exclusion and adverse family circumstances such as poor education, mental ill health, domestic violence and neglect, and to insufficient access to quality day-care, and lack of support for parenting as well as early literacy development. [2] [6]

**Future scenarios**

Policy development requires foreseeing the future at least as much as understanding the past. Knowing in what direction the main determinants of health are moving is crucial for informing effective policies, including prioritising investments. Within the European Commission (EC) funded RICHE (Research into Child Health in Europe) project, a preliminary exercise to identify these trends showed a likely further increase in risk factors and conditions such as premature birth, low birth weight, obesity, unhealthy health styles and in chronic conditions such as obesity, mental health disorders, cancer and other non-communicable diseases. Developments in information and communication technology (ICT) and social networks will play an even greater role in influencing the lifestyles of new generations. We need to understand this and other rapidly changing environmental influences on human development. Due to the persistent effects of the economic crisis, the proportion of children living in poor families is increasing, with significant adverse effects on the health and well-being of children and young people. Finally, current policy developments include trends towards increasingly restrictive welfare policies, and unmet gender (e.g. women’s access to labour market) and civil rights (e.g. access to health services of children from “irregular” migrant parents) issues in many countries. Taken all together, prospects for child health may not be as favourable as they have been over the past decades, and inequalities will likely be increasing. However, an important factor will be the attention that international and national authorities will devote to policies that may directly or indirectly improve the conditions in which children live and grow up, and particularly those of the most disadvantaged.

**Gaps in Europe-wide policies and research**

While some European countries provide significant financial support
to families with children in order to fight child poverty and assist parents with childcare responsibilities, in others fiscal redistribution policies are lacking, and social protection is insufficient, with the result that ill health and loss of developmental opportunities strike heavily among children from the most disadvantaged population groups. With respect to the implementation of public health policies in different areas, including pregnancy, childbirth and child health, a recent assessment showed that their implementation has varied enormously among European countries. While evidence-based policies still need to be implemented to tackle well-known challenges such as maltreatment and obesity, both of which will have immense consequences for a substantial proportion of the population for many years to come, new issues emerge, such as the profound and still incompletely known cognitive and emotional implications of the pervasive use of digital devices, of which the rapidly increasing cases of internet-addiction represent just the top of the iceberg.

The RICHE project, a response to an EC call to better understand and to identify gaps in European child health research, found a number of poorly addressed issues. A very critical area was found to be mental illnesses and developmental disorders in terms of the increasing incidence and insufficient access to services. A critical finding of the project has been that there is a great deficit in applying what is known in terms of effective interventions and that there is surprisingly little implementation research in child health.

Critical windows of vulnerability and opportunity for action

Child health is important not only because of its immediate consequences for the child, but also because of its long-term effects on population health. Research in recent decades shows that many diseases and conditions that arise in childhood, and even much later along the life-course, may have causes that start prenatally and in the earliest years of life. Exposure to inadequate nutrition, to chemical and physical pollutants, to social and psychosocial adverse conditions, to infectious or other harmful agents or processes, may interfere with early organ and system development, disrupt metabolic pathways, modify disease susceptibility and have profound effects on outcome at birth, on health during infancy and childhood, and throughout the entire life. There is a growing body of evidence showing that there are periods of child development, primarily the first two to three years and, to a lesser but still very important extent, adolescence, when such exposures can have particularly pronounced effects. Windows of vulnerability coincide with windows of opportunity for promotion of protective factors and practices and for prevention of risk.

Fourth, to address old and emerging threats, traditional public health approaches need to embrace the complexity of multi-sectoriality and multi-disciplinarity and to take advantage of improved understanding of the causal pathways linking distal determinants to intermediate factors which play a key role in the earliest years, such as nutrition, parenting and early education (see Figure 1).

Finally, there is an urgent need for Europe-wide efforts to address research gaps, implement scientific evidence on effective interventions and public policies, and to share and scale-up best practices.

A two-pronged approach is needed

To move in this direction, a two-pronged approach is needed.

Governments and international agencies should take responsibility for the impact on new generations of macroeconomic, fiscal and welfare social policies and of public policies addressing the social, economic and cultural determinants of health. As the experience of some countries, particularly Northern ones, has shown, redistributive policies can help to overcome social inequalities that might lead to disadvantage, reduce inequalities and improve health and development outcomes. Government policies that can influence child health and well-being include fiscal policies and family benefits that decrease child poverty; increased provision of services such as day-care which have impact on education and employment; social inclusion policies such as those for migrant families and their children; and environmental protection and legislation to improve lifestyle choices, such as nutrition, substance use, and physical activity. The Health-in-All policies principles should inform multi-sector child health plans.

The health sector should be aware of its unique potential to reach all families and communities from pregnancy, and even before conception, and should use it to ensure that children’s exposure to risk factors is reduced and protective factors are enhanced.
Home visiting programmes, for example, are able to ensure both health promotion and risk reduction through universal and early contacts and to provide enhanced services and links with other sectors for families and children. They have been shown to improve health and developmental outcomes for children as well as well-being and parenting skills, and the investment pays off with substantial economic returns through reduced health and social costs and improved societal cohesion and productivity. One of the challenges for Europe is the ageing workforce in the child health field and the urgent need to ensure replacement by a competent and multidisciplinary workforce. The traditional dichotomy separating health services for the individual child from the population-focused child public health service should be overcome through stronger links among services and improved public health training and practice of all practitioners involved in child health.

Conclusions

Improving children’s personal and collective circumstances is a moral imperative and also presents the greatest opportunity to improve the health of a population. The World Health Organization’s (WHO) European Region needs to confirm its role at the forefront of child health policies by increasing investments in knowledge generation, policy implementation and international collaboration. The establishment of a European Observatory on Child Health, conceived as a network of institutions collaborating on data collection, research, exchange of information and best practices, may provide an ideal environment to inform and advocate child public health policies in the future.

The commitment to improving child health needs to come not only from sectors of the government or civil society but requires inter-sectoral and inter-country collaboration as well as the participation of local communities.

International institutions and agencies have a clear mandate to foster this process. In 2014, WHO will deliver a new Child and Adolescent Health Strategy and, first Greece and then Italy–two countries that have been severely hit by the economic crisis–will lead the European Union through their presidencies. These represent two great opportunities to develop policies that, both directly and indirectly, can provide equitable opportunities for health and development to all European children.

References

CHILDREN AND YOUNG PEOPLE’S MENTAL HEALTH SERVICES

By: Riittakerttu Kaltiala-Heino, Rose Crowley and Sebastian Kraemer

Summary: Child and adolescent mental health disorders are common and contribute excessively to the disease burden in developmental years. They impair quality of life and acquisition of social, educational and vocational skills and threaten economic productivity and social cohesion. Consequences are seen and effective prevention and treatment takes place not only in health but also in the social, educational and criminal justice systems. There is wide variation across Europe in funding of child and adolescent mental health services as well as in training and availability of services and experts. Early interventions to prevent these disorders need to be applied systematically, and the effect of interventions needs to be evaluated across sectors.

Keywords: Mental Health, Mental Disorders, Children, Adolescents

Introduction

Emotional or behavioural disorders affect one in five young people, and mental health conditions are a major contributor to the disease burden in childhood and adolescence. Issues range from young children with emotional disorders to adolescents with psychosis or those who self-harm or misuse substances. The detection and management of such a variety of disorders requires the integration of paediatric and psychiatric input with education and welfare services.

Mental disorders directly impair quality of life and threaten the acquisition of social, educational and vocational skills during crucial periods of childhood and adolescent development. This has lifelong consequences for individuals and, on a wider scale, threatens countries’ economic productivity and social cohesion. The majority of major adult mental health disorders have their roots and onset during childhood and adolescence. Failure to address these disorders results in significant costs to the health, social and criminal justice systems in adult life, which could be avoided by effective prevention and treatment.

What is mental health?

Mental health is more than the absence of a mental illness. The World Health Organization (WHO) defines it as ‘a state of well-being in which the individual realises his or her own abilities, can cope with the normal stresses of life, can work productively and fruitfully, and is able to make a contribution to his or her community.’ This makes it difficult to compare countries’ spending on mental health, as health services per se account for only a small proportion of efforts to tackle broader societal forces (poverty,
social exclusion etc.) known to increase children’s risk of developing mental health disorders. A great deal of such conditions in children and young people is concealed behind social problems, such as crime, drug abuse, homelessness, violence, educational failure and bullying. These phenomena are, in turn, strongly associated with early disruption or breakdown in attachments with parents and other caregivers.

**Workforce and funding**

The provision of a comprehensive child mental health service requires, firstly, adequate numbers of suitably trained specialist providers (like child psychiatrists and psychologists); and secondly, sufficient skills among those most likely to first detect the disorders (such as paediatricians, GPs, teachers and social workers). There is great variation across Europe in training and availability of specialists in child and adolescent (C&A) psychiatry, and in mental health-related training of paediatricians and primary care physicians.

Comparing the budget available for child mental health services between countries is complicated by wide variation in funding streams. In many countries, mental health service budgets are decided independently at regional or federal level from their general allocation for health care, with surprisingly little aggregate data available. Analysing spending within the health service will also fail to take into account the varying proportions of education and social care budgets that are spent on preventive programmes for child mental health. Significant numbers of projects are funded by non-governmental organisations, frequently with little coordination between these and various government sectors. Despite these limitations, the worrying conclusion from the WHO ATLAS survey was that, globally, ‘there is a universal absence of parity between adult and child mental health services’⁹ In 25 countries from the WHO European Region, only 77% had any specific programme for child mental health, and for 29% of countries, out-of-pocket payments were still the second most common means of financing mental health care.

**Assessing the challenges: needs and trends**

The most significant mental health disorders in children and adolescents include depressive and anxiety disorders, post-traumatic stress disorder (PTSD), attention deficit hyperactivity disorder (ADHD), autism spectrum and conduct disorders, and from adolescence onwards, substance use, eating disorders and psychosis.

Little methodologically-sound, comparable information is available on detailed epidemiology of mental disorders among European children and adolescents. At the severe end, suicide rates among young people are available for most European countries in the WHO mortality database, with suicide being the third leading cause of death worldwide among those aged fifteen to nineteen. Even if mortality rates also include deaths from overdose and anorexia nervosa, they may still underestimate the impact of mental ill health, as disorders also increase risk-taking behaviour and accidental injury. Service use figures will underestimate the problem, as many disorders will go unrecognised or untreated, for reasons related to stigma, economic barriers, gaps in service provision and inconsistent referral pathways.⁹ Surveys among young people, parents and teachers can give a more comprehensive picture, including untreated and sub threshold disorders. Examples of large European surveys are Child and Adolescent Self – harm in Europe,⁵ the WHO HBSC survey, the National Health Interview and Examination Survey in Germany, and the School Health Promotion Survey in Finland.

Inequality is a major contributor to young people’s mental health disorders,⁸ as are familial problems and traumatising experiences. Children who are taken into care by child welfare authorities and immigrant children form special risk groups. Variation over time in these risk factors may influence mental health epidemiology in children and adolescents.

**Child mental health care: the European experience**

The ‘Child Health Services and Systems in Europe’ (CHSSE) questionnaire explored differences and similarities in services for child and adolescent mental disorders through case vignettes. Six key areas of variation and some examples of good practice were highlighted.

**Professionals and services**

The respondents to CHSSE identified those primarily responsible for treatment of C&A mental health disorders as being psychiatrists (4 countries), paediatricians (2), combination of the two (2) and psychologists/social workers (1). In the UK, the patient’s condition partly determines this; many behavioural disorders fall within the remit of community paediatricians, while affective or psychotic disorders would be managed by C&A psychiatrists. In Finland, patient age is the major determinant: child psychiatrists provide care for pre-pubertal children and adolescent psychiatrists for those aged 13 to 18 (in outpatient care up to 21).

There is great variation in who manages adolescent substance misuse, from child psychiatrists or adult psychiatrists specialised in substance abuse to paediatricians. In Italy, adolescent substance abuse is a subset of adolescent medicine; in France and Finland, it is treated as a part of substance abuse in general (adult services); in Austria, there is a combination of the two. In Poland, patients under-16 are admitted to children’s wards and those who are older to specific toxicology wards for adults. It is unlikely that the overall health needs of adolescents at varying stages of development will be met by being seen wholly within adult services.

**Inpatient care**

A particular challenge in caring for children and adolescents is lack of suitable inpatient facilities. Many young people are treated for psychiatric conditions in less than ideal settings, such as adult psychiatric units or general paediatric wards.

In Finland, legislation stipulates that adolescent psychiatric inpatient care should be separate from that of adults, while in France there are designated beds for adolescents in adult psychiatric wards.
In Scotland, there has been a drive to strengthen existing inpatient adolescent facilities, in response to a 2004 report on psychiatric inpatient facilities.\textsuperscript{3} In this respect, psychiatry was earlier to recognise the importance of dedicated adolescent units than other paediatric specialties. In the UK, there is greater political pressure to keep under-18s out of adult psychiatric wards than there is to provide comprehensive mental health care in paediatric settings, where many young people in crisis alongside those with chronic or unexplained medical conditions are likely to be admitted.\textsuperscript{7}

Pathways to care

CHSSE highlighted the importance not only of primary care physicians but of education and social services in identifying and referring C&A mental health disorders, particularly Attention Deficit Hyperactivity Disorder (ADHD).

Delays between problem recognition and specialist assessment are common, predominantly due to a lack of available specialist services. In Norway, the child is guaranteed to be seen within ten days by a C&A psychiatrist, and treatment initiated within 90 days if a preliminary ICD-10 diagnosis is reached. In Finland, the Ministry of Health and Social Affairs developed priority rating tools for all specialties in 2004, to guarantee equal access to specialist level services across the country. In C&A psychiatry, patients presenting with disorders with severity scoring over a defined cut-off are guaranteed assessment within six weeks from referral, then treatment within three months. In England, NICE has produced guidance on the referral and management of depression, ADHD, autistic spectrum and conduct disorders with a four-tier hierarchy of referral, ranging from primary care to extremely specialised services.

Age range

Age boundaries between C&A and adult services form three distinct problems in Europe. Firstly, a gap is created in services when C&A services only treat up to 16 years but adult services refuse to admit under 18 year olds. Secondly, even if adult services should treat all conditions from age 18, they may have limited skills in some typical C&A mental health disorders, such as ADHD, autistic spectrum disorders or even eating disorders. Thirdly, as few young people actually transition to independent living at age 16–18, adolescent psychiatric services might better meet the psychological needs of 18–23 year olds than adult services.

Early intervention services

Ante – and perinatal factors, such as maternal depression, anxiety and psychosocial stress, negatively influence children’s development and mental health.\textsuperscript{8} This damage could be prevented with coordinated ante – and postnatal care between maternity, primary care and mental health workers.

A positive development was identified from Finland where maternity and child health clinics are increasingly being modified to become ‘family welfare clinics’ (preventive services with emphasis on family welfare, the father’s role, and psychosocial factors in addition to children’s physical health), in parallel with similar extension of school health examinations to emphasise ‘psychosocial wellbeing of the child and her/his family’.

Future challenges

There is a need to promote child mental health knowledge within paediatrics, primary care, education and welfare services. Treatment approaches combining specialist level services with primary care and paediatric care could then be established.

It is of outmost importance to determine whether the established usefulness of community treatment in adult mental health will be replicated in the paediatric population. To date, there is scant evidence from randomised controlled trials (RCTs) to judge whether better outpatient care could reduce the need for inpatient care in C&A psychiatry.\textsuperscript{8} In the absence of RCT data, prospective multicentre audits should be carried out.

School – based programmes are likely to prove of particular importance, reaching a far greater proportion of the population than any intervention based within child psychiatry. One systematic review identified 28 school-based programmes that reduced depressive symptoms.\textsuperscript{9} Another systematic review supported the use of parent training and child social skills training to prevent conduct disorder and universal school-based cognitive behaviour therapy programmes to reduce anxiety.\textsuperscript{10}

The effect of policies in many sectors on C&A mental well-being needs to be recognised. For example, paid parental leave in the first year of life not only reduces child mortality \textsuperscript{3} but also promotes child development and mental health. Integrated perinatal prevention remains patchy and without powerful champions\textsuperscript{11} but a number of recent policy documents embed mental health provision firmly within broader social policy and emphasise the importance of school health. These include the 2007 WHO Forum ‘Social cohesion for mental well – being among adolescents’, the ‘Mental Health Action Plan for Europe’, and the ‘European Pact on Mental Health and Well – being. The lack of existing comparative data in the region was addressed by the Child and Adolescent Mental Health in the Expanded European Union (CAMHEE) project,\textsuperscript{13} which collated information on existing services, identifying examples of best practice, and establishing knowledge networks to share them.

Economic evaluation of interventions needs to take into account long-term savings not only to the health service, but also to the education, social services and criminal justice systems. Social return on investment (SROI) analyses delineate the significant benefits to the child, family and state, across all sectors, that prevention and effective intervention for children’s mental health can provide.

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PREScribing FOR CHILDREN

By: Martin McKee

Summary: Every day, children throughout Europe are given medicines that have only been evaluated on adults, even though their effects and side effects may differ considerably and, in some cases, the children may be exposed to considerable risk. There are many challenges in evaluating medicines in children. These have been addressed by measures, initially in the USA but subsequently in the EU, that incentives manufacturers to evaluate the use of their drugs in children, with valuable extensions on patent life. However, so far, the response from industry has been quite limited.

Introduction

Children are not just small adults. Yet when they need medicine they are often treated as if they were, given drugs tested only on adults and without any additional evaluation. Typically, the only concession is to scale down the dose to take account of the child’s smaller body size. However, children differ in many ways beyond size; differences in metabolic pathways or side effects may differ considerably and, in some cases, the children may not be clear what the correct dosage should be, a situation not helped by the use of arbitrary divisions in guidance based on age. Moreover, adverse reactions are poorly understood, for its stability and bioavailability.

This poses a dilemma for paediatricians. Should they just make an arbitrary decision about what to use, in what dosage, based on rules of thumb? Or should they withhold a potentially life-saving treatment because it has not been evaluated formally for use in children? In practice they tend to do the former, engaging in what is termed off-label prescribing. Yet, when they do so, surveys indicate that a majority have concerns about the safety of what they are prescribing, even though they also believe that their decisions are the inevitable consequence of the situation they are faced with.

Keywords: Children, Paediatric, Medicines, Safety, Clinical Trials

* Bioavailability concerns drug absorption, specifically the fraction of an administered dose of unchanged drug that reaches the circulation.
Child-relevant clinical trials?

Superficially, the answer is simple. Drugs used in children should be evaluated on them and, if shown to be effective, then approved for use on them just as they are on adults. But there are many barriers to doing so. First, the number of children needing the medicine may be very small, requiring a trial involving a very large number of centres. Second, the paediatric market may be small, reducing the incentive for the pharmaceutical industry to conduct such trials. Third, in some countries, ethics committees may, erroneously, deny approval to trials simply because they involve children, failing to recognise that the consequence is the undeniably unethical situation in which children are given unevaluated medicines. They also fail to appreciate that parents are often very willing that their child participates in trials when the reasons are explained and when they trust the professionals involved. Finally, even when medicines are evaluated, manufacturers may choose not to seek approval for commercial or other reasons.

Measures enacted so far

Recognising that the current system is not working, in 1990 the European Parliament called for action by the European Commission. However, the USA moved first, with the Food and Drug Administration (FDA) introducing the concept of “pediatric exclusivity” in 1997. Manufacturers could be asked to conduct additional trials to ascertain effectiveness in children, either prior to the medicine being approved for adults or later, and in return be granted a six month patent extension. The success of the programme led to what had been a temporary provision becoming permanent, and to it being put on a compulsory rather than voluntary basis.

Europe then played a game of catch up, with a Regulation resembling the American legislation being enacted a decade later. Again, a manufacturer undertaking additional evaluation on children, undertaking a Paediatric Investigation Plan (PIP) is granted a patent extension of six months. However, recognising the rarity of many of the conditions for which children need new medicines, there is also provision for a further two year extension for what are called “orphan drugs”, where the condition involved is chronically disabling or life threatening and affects fewer than 5 per 10,000 people in the EU. Evaluations are coordinated with the FDA to avoid unnecessary duplication. The Regulation also requires the company holding a marketing authorisation with a new paediatric indication to place the product on the market within two years.

While these provisions relate to new medicines, there are many where the patent has already expired that may be effective in children but have not been evaluated as such. The manufacturer of such a medicine can apply for a Paediatric use Marketing Authorisation (PUMA), providing the medicine is intended solely for use in children. If successful, the manufacturer is granted eight years of data and ten years of market exclusivity. Funding for evaluation is available within the EU’s research programme. Finally, the Regulation established a European Network of Paediatric Research (Enpr-EMA) to link centres of excellence, enabling them to share protocols and maximise recruitment to trials.

The impact of current measures

So have all these measures had any effect? The evidence is mixed. There is some research showing that, even when paediatric formulations are approved and made available, off-label prescribing continues and may even increase. Medicines are being submitted for PIPs, but in many cases the Paediatric Committee of the European Medicines Agency (EMA) has asked for modifications to strengthen the methodology. By the end of 2012, the EMA had agreed 600 paediatric investigation plans, 453 (76%) of which were for medicines not yet authorised in the EU, with the remainder addressing new indications for patent-protected products or paediatric-use marketing authorisations. Since the Regulation came into force, 31 out of 152 new medicines (20%) have been authorised for paediatric use and, by the end of 2011, 72 new paediatric indications had been approved for previously authorised medicines. Concerns have, however, been voiced about the very small number of submissions in some areas such as pain relief and antibiotics.

The number of clinical trials on children has not increased, remaining steady at about 350 per year, although this is against a backdrop of an overall decline in trials, widely attributed to the bureaucratic workload imposed by the Clinical Trials Directive. The PUMA process has been especially disappointing, with only one authorisation being granted. However, there has been an increase in the number of trial participants aged under two years, who were previously very rarely included.

The one area where there has been clear progress has been in the creation of research networks, working to strengthen capacity and develop shared methodology. The European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA) was launched in 2009 and has met regularly since 2010. Furthermore, research has been made available for 20 off-patent substances, at a cost of €80 million.
Conclusion

In summary, it has taken a long time for the issue of prescribing for children to reach the policy agenda in Europe. Despite generous regulatory and financial incentives, the pharmaceutical industry has shown itself reluctant to do what is necessary to ensure that prescribing for children is safe and effective. While some progress is being made in preparing an environment that will support evaluation of medicines for children, there is still a long way to go.

References


New HiT on Malta

By: N Azzopardi Muscat, N Calleja, A Calleja and J Cylus

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This new HiT health system review on Malta discusses many achievements that have occurred in the health system since the last HiT report was published in 1999. Two key events in the past decade have contributed to the further development of the health system. Malta’s accession to the European Union in 2004 played an important role guiding new legislation in public health and health protection, while the construction of the new acute general hospital, Mater Dei Hospital, in 2007 was significant in shaping the flow of capital resources. Important reforms include the use of health technology assessment to define the benefit package, improvements in access to medicines through the Pharmacy of Your Choice scheme, and expansion of prevention and community-based services.

While Maltese citizens enjoy one of the highest life expectancies in Europe, the ageing of the population is already putting pressure on public finances. Current policies that are often geared towards hospitalisation and institutionalisation of older people are costly and contribute towards inefficient utilisation of resources. Successfully managing this issue will require strategic investments and efforts to shift care away from hospitals and into the community. The new National Health Systems Strategy under development will help to provide direction.
**Introduction**

The evidence for the unnecessarily poor state of men’s health across Europe is irrefutable. In the European region as a whole in 2011, average life expectancy at birth was 72 for men and 79 for women, a difference of seven years. Life expectancy at age 60 was another 19 years for men and 23 for women, a difference of four years. The gap in life expectancy between men and women is highest in Eastern Europe where, in 2010, average life expectancy at birth was 64 for men and 75 years for women, a difference of 11 years.

Of particular concern is the high level of premature mortality among men. There were 630,000 deaths among men of working age (15–64) in 2007 across Europe, of which about 198,000 were before the age of 50. By comparison, there were 300,000 deaths in women of working age and around 86,500 deaths before the age of 50. Recent improvements in the life expectancy at birth of men and women have mostly occurred at older ages; there has been little improvement in the high rate of premature death in younger men.

According to Michael Marmot’s review of social determinants and the health divide in the World Health Organization (WHO) European Region, men’s poorer survival rates reflect several factors: greater levels of occupational exposure to physical and chemical hazards; risk behaviours associated with male lifestyles (including smoking and hazardous levels of alcohol consumption); health behaviour paradigms related to masculinity; and the fact that men are less likely to visit a doctor when they are ill and to report the symptoms of disease or illness. A study of inequalities and discrimination in access to health care by the European Union Agency for Fundamental Rights also found that ‘women are generally more aware of their health status than men and are more frequent users of health care services’.

**Summary:** Men’s health across Europe is unnecessarily poor with twice as many men as women of working age dying each year. Men’s ineffective use of all primary care services is part of the explanation. This happens because men are reluctant to seek help and because, as yet, health services have not engaged with men effectively. The changes needed include changing services’ opening hours and difficult-to-use appointment systems, developing the role of pharmacies as a first point of contact for men with the health system, improving training for health professionals on men’s health issues and investing in better men’s outreach services.

**Keywords:** Men, Gender, Primary Care, Public Health, Policy
observed that ‘a major challenge is to engage with the many men who do not access health services’.6

The problem

Primary care services are currently a ‘no man’s land’ – they are used ineffectively by men. Men access the full range of primary care services – general practice, pharmacy, dentistry, optometry – less often than women. For example, in England, in 2008–9, women aged 15–80 years had significantly more consultations with general practitioners (GPs) than men; the biggest gap was in the 20–44 year age group.7 A study of middle-aged Lithuanians found that 54% of women and 41% of men attended dental check-ups habitually,8 while another study of the uptake of free eye tests in Scotland after their introduction in 2006 found that a larger proportion of women had their eyes tested both before and after. There was a significant increase in female utilisation after the change but no evidence of a change in male uptake.9

Of greater significance than the frequency of men’s uptake of primary care services is the impact of the way they use services on their health outcomes. Much of the evidence about this is anecdotal – based on the experience of health professionals and men themselves – but there is robust evidence from Ireland where a study of the excess burden of cancer on men found that they were diagnosed at a later stage than women for colorectal, lung and stomach cancers, as well as for malignant melanoma.10 Men’s delay in seeking help for mental health problems could also be part of the explanation for their much higher suicide rate. A Danish analysis based on almost 36 million GP contacts and 1.2 million hospitalisations in 2005 hypothesised that men’s lower use of GPs helped to explain their higher use of hospital services.11 Spanish men aged 60 years and over have also been found to visit medical practitioners and receive home medical visits less frequently than women but to be admitted more frequently to hospital.12

There are two main explanations for men’s less effective use of primary care services. The first is that the gender construct of masculinity inhibits help-seeking for health problems. Men are ‘supposed’ to be independent and invulnerable, strong and silent, stoical and self-reliant. Many men therefore do not feel comfortable admitting to a physical or emotional problem, whether that is to a partner, a friend or a health professional. Some men also find traditional health settings ‘too feminine’, especially community pharmacies which often have prominent displays of women’s beauty products.

Secondly, men’s reluctance to access services makes them less willing to overcome the many practical barriers they experience, especially the lack of extended opening hours (men are more likely than women to be in full-time work which can make it difficult for them to attend services provided only during ‘normal’ working hours). Men also seem more likely than women to be deterred by appointment booking systems and delays in seeing a clinician after an appointment has been made.

Some specific groups of men face additional barriers to accessing primary care. Men in low-paid occupations tend to have less flexible working hours and may lose pay if they take time off to attend an appointment. Men who have been recently released from prison, who are homeless, or who are Roma/Travellers or migrants find it harder to access a GP. Gay men are also deterred by experiences of homophobia from some practitioners.13 14

Responses

One possible response to the problem of men’s use of primary care is to point out that services are provided for whoever needs them and that it is therefore men’s own fault if they fail to make use of them. Blame may seem tempting but it leaves men at risk of unnecessarily poor health – with human and financial consequences for them and their families, communities and employers, as well as for health services and the wider economy. The financial costs of poor men’s health are difficult to quantify but one study has estimated that men’s premature mortality and morbidity costs the US economy US$479 billion (about €350 billion) annually.15

Blaming men is also unfair because their attitudes and behaviours are in large part socially determined. The pressures on men, especially on boys and young men, to confirm to gender stereotypes are difficult to resist for many. In addition, health and related services have been slow to respond to men’s needs. There is only one European country, Ireland, which has developed a national men’s health policy.

The European Men’s Health Forum (EMHF) has begun a long-term project to improve men’s use of primary care. The first stage was a roundtable event held in June 2013 where EMHF brought together the widest possible range of primary care professions from across Europe to identify the barriers to men’s effective engagement with services and, more importantly, how these could be overcome. The roundtable’s findings were discussed further at an EMHF workshop at the European Health Forum Gastein in October 2013. The next steps include discussions with the European Commission and other Europe-wide organisations, as well as with EMHF roundtables within individual states to support the development of primary care services that work better for men.

A number of potential solutions have already been identified and are summarised in Box 1. These are much more likely to be implemented if health systems – Europe-wide, national and local – make an over-arching commitment to tackle men’s health problems through a policy-led approach that leads to comprehensive action at all levels. In 2011, the European Commission published a detailed analysis of the state of men’s health in Europe but the report contained no recommendations for action.16 The EC Commission should now take a lead and produce a plan for tackling the deep-seated problems revealed by its analysis. Without that kind of focus and commitment, too many men, especially those in
disadvantaged groups, will continue to die too young from a major health inequality that is still all too often overlooked.

References


Box 1: Potential ways of improving men’s use of primary care services

- The practical barriers that deter men from accessing primary care must be addressed. These include limited opening hours, difficult-to-use appointment systems and, for pharmacy services especially, an emphasis on products and services for women. The solutions include greater use of digital technologies for making appointments and for information, advice and even some consultations, some consultations (see, for example, EMHF’s Your Prostate service: http://www.yourprostate.eu) extending opening hours beyond the ‘normal’ working day and making services feel more ‘male-friendly’.

- Pharmacies have a potentially significant role as a first point of contact with the health system. Community pharmacies are often more conveniently located for men, an appointment is not needed and they are often open for longer than general practice.

- Training for health professionals on men’s health issues is important. In the UK, training modules are now available for pharmacists and GPs but these are optional and not yet part of pre-qualification training; as yet, take-up is relatively low.

- There is a need for better outreach services. Taking services to where men are has been shown to be an effective strategy. The new EuroFIT project (http://eurofitp7.eu), which aims to improve men’s health through programmes delivered via football clubs, and ‘Men’s Sheds’ (http://menssheds.eu) are good examples of this approach. Workplaces, faith and leisure venues (such as clubs and pubs) provide other settings where men can be engaged.

- Men’s health literacy, including symptom awareness, should be improved. Possible actions include: better health education for boys at school; effective targeting of public health campaigns on heart disease, cancer, diabetes and other major conditions; and the production of health information in ‘male-friendly’ formats.

- More support for the development of men’s health champions and role models – including celebrities, health professionals and ‘ordinary’ people – who can influence health care policies and practices as well as men’s attitudes, knowledge and behaviours.

- Key transition points in men’s lives, such as becoming a father or retirement, present opportunities for engagement.

- More research is needed into men’s use of primary care services, including better evaluation and dissemination of initiatives to help develop and extend good practice.

- The main focus of work to improve men’s use of primary care services should be those groups of men with the worst health outcomes, including low-income men, migrants, gay men, homeless men, prisoners and offenders, and black and minority ethnic men.
GUIDELINES ON THE EUROPEAN PATIENT SUMMARY DATASET

By: Edwin Maarseveen and Jeremy Thorp

Summary: The Directive on patients’ rights in cross-border health care envisages high quality continuity of care across borders. This requires reliable exchange of patient information to support health professionals in their work. This article describes the development of guidelines for a patient summary dataset, focusing on emergency or unplanned care in a cross-border context. The guidelines were approved by the eHealth Network in November 2013 and will assist Member States by providing a common baseline for patient summaries at national level.

Keywords: Patient Summary, Dataset, Electronic Exchange, eHealth Network, Cross-border Care

Introduction

When travelling abroad a person may require the medical services in the country he or she is visiting. Since the need for medical assistance is likely to be unexpected, the health care provider might not be familiar with the medical history of the patient. This might have a negative effect on the quality of the treatment and can even be life threatening (for example, in the case of medication allergies). An electronic patient summary which is transferable across borders will increase the information available to the foreign health care professional. This will increase the quality of the care provided, especially when the data can be made available in a structured form and in the native language of the health professional.

The desired outcome of the guidelines is that Member States voluntarily commit to implement the patient summary dataset nationally and make it possible to share patient summaries across the European Union (EU). To achieve this, they must be able to identify what steps to take. These guidelines provide national health authorities, the information technology (IT) health industry, health providers and other stakeholders with a first blueprint of what Member States have agreed upon for the implementation of an electronic patient summary.

Cross-border directive and eHealth Network

The basis for this agreement between Member States is found in Article 14 of the Directive on the application of patients’ rights in cross-border health care. This article states that a network of “national authorities responsible for eHealth” shall be formed, and that this network should aim to “support and facilitate cooperation and the exchange of information among
Member States”. Specifically, the directive describes the three main tasks of the eHealth Network as follows: to

1. work towards sustainable economic and social benefits of European eHealth systems;
2. draw up guidelines on (a) a non-exhaustive list to be included in patients’ summaries and (b) effective methods for enabling the use of medical information for public health and research; and
3. support Member States in developing common identification and authentication measures.

The eHealth Network comprises Members designated by the 28 Member States and is co-chaired by Paola Testori Coggi, Director-General of DG Health and Consumers at the European Commission, and Clemens-Martin Auer, as the chair from the Member States (rotating). The eHealth Network convenes twice a year, and counts on the eHealth Governance Initiative (see www.ehgi.eu) to develop the products necessary for discussion in the eHealth Network. During the fourth meeting of the eHealth Network the guidelines on the electronic exchange patient summary were unanimously adopted.

**Aim of guidelines in eHealth**

Even though the specifications of these guidelines may be considered rather technical, the principal aim is broader. It is described in the Directive as “to achieve a high level of trust and security, enhancing continuity of care and ensuring access to safe and high-quality health care”.

The construction of the guidelines is strongly connected to real life situations, called “use cases” in the IT field. The patient summary is most useful when the health professional and patient do not share the same language, and no information has been previously requested or shared, as in unplanned encounters. The guidelines are therefore based on cases where a person travels abroad occasionally, and needs care unexpectedly. However, the patient summary can be useful in any clinical encounter and access will not be restricted to a particular situation.

The patient summary guidelines are not only important recommendations for policy advisors who work to improve their local, regional or national eHealth system. They should also lead to a higher trust of professionals and patients in these systems. In this respect, a reference must be made to the European eHealth Project called epSOS (www.epsos.eu). This large-scale pilot project designed and built a trusted service infrastructure that demonstrates cross-border inter-operability between electronic health record systems in Europe. Through the epSOS project, for the first time, it was possible for patients in Europe (when seeking health care in participating epSOS pilot countries) to have access to important medical data across borders. The expertise and experiences of the epSOS project were the foundation for the development of the guidelines.

**What do the guidelines contain?**

The adopted guidelines consist of a general part, containing the introduction and context, and a specific part, containing the official guidelines. The introduction and the context paragraphs focus on the scope, the legal basis and the use cases of the guidelines. They are intended to give readers background information about how the guidelines were constructed and their underlying rationale.

**Data in the patient summary**

The specific part of the guidelines focuses on the recommended dataset to be included in the patient summary, and a description of the organisational, technical and legal prerequisites. One of the most important articles in the guidelines is Article 6, which consists of a table containing the recommended data fields, their definition and comments. The dataset is divided in two parts, the first on the patient administrative data, and the second on the patient clinical data, as presented in Table 1.

**Table 1: Dataset parameters**

<table>
<thead>
<tr>
<th>Patient administrative data</th>
<th>Patient administrative data</th>
</tr>
</thead>
<tbody>
<tr>
<td>Identification</td>
<td>Alerts</td>
</tr>
<tr>
<td>Personal information</td>
<td>Medical history</td>
</tr>
<tr>
<td>Contact information</td>
<td>Medical problem</td>
</tr>
<tr>
<td>Insurance information</td>
<td>Medication Summary</td>
</tr>
<tr>
<td>Country</td>
<td>Social history</td>
</tr>
<tr>
<td>Patient summary</td>
<td>Pregnancy history</td>
</tr>
<tr>
<td>Nature of patient summary</td>
<td>Physical history</td>
</tr>
<tr>
<td>Author organisation</td>
<td>Physical findings</td>
</tr>
<tr>
<td></td>
<td>Diagnostic tests</td>
</tr>
</tbody>
</table>

Source: Ref14

### Table 1

<table>
<thead>
<tr>
<th>Dataset parameters</th>
<th>Patient administrative data</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Patient administrative data</strong></td>
<td></td>
</tr>
<tr>
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<td>Personal information</td>
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<tr>
<td>Insurance information</td>
<td>Medication Summary</td>
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<tr>
<td>Country</td>
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<tr>
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<tr>
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</tr>
<tr>
<td>Author organisation</td>
<td>Physical findings</td>
</tr>
<tr>
<td></td>
<td>Diagnostic tests</td>
</tr>
</tbody>
</table>

**Member States**
Each data-field in Table 1 can consist of multiple sub-elements. To provide an example, Table 2 shows the sub-elements included under the ‘Medical history’ field.

The guidelines allow the use of basic and extended datasets. The basic dataset is defined as a set of essential health information that needs to be sent from a clinical point of view in order to be able to deliver safe care to the patient. The information in the basic dataset must always be available. The extended dataset contains information which should be completed whenever possible.

### Organisational, technical and legal prerequisites

Besides the recommended dataset, the guidelines also describe the prerequisites necessary to enable cross-border exchange of patient summaries. This part contains guidance on terminologies and terminology standards, quality standards and validation, technical standards, testing, authorisation and identification, legal framework, as well as information about education, training and awareness raising. It is important to mention that these articles give a general description of the scope of the items, but do not contain detailed (technical) specifications. The eHealth Network agreed to do further work on these specifications.

#### Security and privacy

Security and privacy is another important part of the guidelines. How can the patient’s information be kept confidential, and how can access to such data be legal? Alongside rigorous security requirements, the basis for access to data is the specific consent of the patient. The guidelines propose that access to the dataset will be executed in an opt-in mode and through a two-step process in which (i) prior agreement by the patient is acquired in the country of affiliation, and (ii) specific consent is needed by the patient in the country of treatment. Access to data is allowed provided that the patient has granted consent in accordance with national law, and the purpose of access is to provide medical care for the patient.

### Main challenges

Director-General Paola Testori commented that ‘the adoption of these guidelines is a landmark agreement on EU cooperation on eHealth’. During the discussion in the eHealth Network it became clear that the adoption of the guidelines is also a starting point. The guidelines will have

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Table 2: Medical history field sub-elements

<table>
<thead>
<tr>
<th>VARIABLE (nesting level 1)</th>
<th>VARIABLES (nesting level 2)</th>
<th>VARIABLES (nesting level 3)</th>
<th>COMMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical history</td>
<td>Vaccinations</td>
<td>Contains each disease against which immunisation was given</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Brand name</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vaccinations ID code</td>
<td>Normalised identifier</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Vaccination Date</td>
<td>Date when the immunisation was given</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Problem Description</td>
<td>Problems or diagnosis not included under the definition of ‘Current problems or diagnosis’. Example: hepatic cyst (the patient has been treated with an hepatic cystectomy that solved the problem and therefore it is a closed problem)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Problem ID (code)</td>
<td>Normalised identifier</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Onset time</td>
<td>Date of problem onset</td>
<td></td>
</tr>
<tr>
<td></td>
<td>End date</td>
<td>Problem resolution date</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Resolution Circumstances</td>
<td>Describes the reason by which the problem changed status from current to inactive (e.g. surgical procedure, medical treatment, etc). This field includes “free text” if the resolution circumstances are not already included in other fields. Example: This field may already be included in others like Surgical Procedure, eg: hepatic cystectomy</td>
<td></td>
</tr>
<tr>
<td>Surgical Procedures prior to the past six months</td>
<td>Procedure description</td>
<td>Describes the type of procedure</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Procedure ID (code)</td>
<td>Normalised identifier</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Procedure date</td>
<td>Date when procedure was performed</td>
<td></td>
</tr>
</tbody>
</table>

Source: Ref 2
no meaning if Member States do not implement them. The implementation of the guidelines will take time and effort from both governments and stakeholders. The importance of the guidelines will differ per Member State, mainly because of the difference in the maturity of national eHealth systems.

Beside the practical work at national level, there are developments at EU level that will have a significant impact on the implementation of the guidelines. Two of the most important developments are the current discussions concerning data protection and electronic identification regulations. Both regulations have the possibility to make the implementation of the guidelines easier, and the services based on the guidelines better trusted. However, the less clear the regulations will be about the use of medical data and the possibility to use electronic identification in the field of eHealth, the more difficult the implementation of the guidelines will be.

Furthermore, the eHealth domain is rapidly evolving. Technical developments sometimes move faster than legislative processes can follow. Therefore, the agreements made at EU level on eHealth need to be updated regularly, taking into account the most up-to-date knowledge. The guidelines on the patient summary explicitly mention that it is an evolving document. However, tension will always exist between the wish to give clarity and direction to the health sector, and the desire to take into account new developments.

Conclusions

The guidelines on the patient summary dataset adopted by the eHealth Network (under the Directive on patients’ rights in cross-border care) show that EU eHealth cooperation is moving from discussing eHealth, to agreeing on specification. While the guidelines are significant, they are also just a starting point. There is a need to specify the further work as foreseen in the guidelines, and the guidelines need be updated, specifically taking into account developments on data-protection and electronic identification. A proper future evaluation of the use of the guidelines within the Member States should provide more information about their relevance on the deployment of eHealth services.

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New HiT on Norway

By: Å Ringard, A Sagan, I Sperre Saunes and AK Lindahl

Copenhagen: World Health Organization 2013 (acting as the host organization for, and secretariat of, the European Observatory on Health Systems and Policies)

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Norwegian citizens are fortunate to enjoy one of the highest levels of per capita health expenditure in the world. The level of public health care coverage is high (85%) and the health status of the population is very good. However, the satisfaction of people using health care services seems to be ‘only’ average compared to other OECD countries that spend less. Poor coordination of hospital care with other health services and long waiting times for elective care are the key reasons for dissatisfaction with the health system. While both of these issues have been on the policy agenda for a long time, the “coordination reform” has recently made a renewed effort to improve these two aspects of the system.

The Municipal Health and Care Act and the Public Health Act, enacted in 2011, are the cornerstones of the coordination reform. Their aim is to improve coordination between hospital care and other health services, especially in non-hospital settings. This should reduce pressure on overcrowded hospitals (the average bed occupancy rate in Norway is 93%) by reducing both the average length of stay and waiting times. At the same time, and separately from the coordination reform, increased attention is paid to quality of care and patient safety. The evaluation of the coordination reform is ongoing. Should it lead to improved coordination of care and a reduction in waiting times, it may well succeed in improving the satisfaction of Norwegian patients with the health care system.
ALLEVIATING HIGH OUT-OF-POCKET SPENDING ON DRUGS: PRACTICAL EXAMPLES FROM ESTONIA

By: Triin Habicht and Ewout van Ginneken

Summary: High pharmaceutical out-of-pocket payments, which generally have a detrimental effect on equity of access, have been a challenge in many countries. Notable improvements for patients without burdening the health budget can be observed in the Estonian example. Estonia uses a multifaceted approach that consists of: (1) stronger enforcement of International Nonproprietary Name (INN) prescribing and dispensing; (2) using e-Prescriptions to stimulate INN prescribing; (3) raising awareness among consumers; and (4) using feedback mechanisms coupled with personal visits and bonuses to change prescribing habits. However, improving rational drug use may not be enough to further alleviate high pharmaceutical out-of-pocket payments in the future. Additionally, countries should consider pricing policies and reimbursement rules.

Keywords: Pharmaceutical Reimbursement, Out-of-Pocket (OOP) Payments, Health System, Estonia, Estonian Health Insurance Fund (EHIF)

Introduction

Estonia spent 5.9% of its GDP on health in 2011. Health care is largely publicly financed (79.3%), mainly through earmarked payroll taxes. In 2011, private sources accounted for 19.2% of total expenditure on health care. The main share of private financing is related to dental care and pharmaceuticals. High pharmaceutical-related out-of-pocket (OOP) spending has been a longstanding concern in Estonia. Võrk et al. noted that not only 53% of average OOP expenditure relates to medicines, but that these expenditures are unequally distributed among different socio-economic groups. Indeed, even though expenditure of the richest households is more than twice that of the poorer households, the poorest cohort spent a much higher proportion OOP on medicines (84%) than the richest cohort (33%) in 2007. This may threaten access to medicines for poorer households.

Furthermore, Kanavos et al. found that Estonian patients faced an average 37% co-payment of the drug price for those drugs that are reimbursed by the Estonian...
Health Insurance Fund (EHIF) in 2008, up from 25% in 1997. This level of effective co-payment is higher than in most western European countries. The strong rise was likely the result of the reference pricing system, which was introduced in 2003 with the main objective to ration public spending on pharmaceuticals.

Pharmaceutical reimbursement

The pharmaceutical reimbursement system in Estonia is disease specific and there are two groups of diagnoses, classified on the basis of the severity of illness. The pharmaceuticals listed for the most severe diseases (i.e. diabetes, cancer) receive the full (100%) rate of reimbursement; pharmaceuticals for less severe chronic diseases (i.e. hypertension, asthma) are reimbursed on a 75% basis. A higher reimbursement level of 90% for disabled and retired individuals applies to the latter group, as well as for children aged 4–16 years. Children under four years of age receive 100% reimbursement for all pharmaceuticals listed. All other pharmaceuticals in the positive list are reimbursed at a 50% rate. A higher reimbursement level of 90% for disabled and retired individuals applies to the latter group, as well as for children aged 4–16 years. Children under four years of age receive 100% reimbursement for all pharmaceuticals listed. All other pharmaceuticals in the positive list are reimbursed at a 50% rate.

Curbing OOP spending

There are many reasons for high pharmaceutical co-payments, including the reimbursement and pricing policy, as well as relative prices for pharmaceuticals in the economy. However, the World Health Organization (WHO) recommended that priority ought to be given to mechanisms that could lead to a reduction of such co-payments by promoting rational drug use and cost-effective prescribing. This is supported by an analysis of the Estonian Health Insurance Fund (EHIF), which suggests that in the case of hypertension the level of cost-sharing could be reduced from its current rate of 42% to 24% if physicians prescribed on the basis of clinical cost-effectiveness criteria and patients chose the least costly alternative at the pharmacy.

Due to the financial crisis in 2008, the efficiency and sustainability of the health system became a priority. Moreover, the report “Responding to the challenge of financial sustainability in Estonia’s health system” recommended that the Ministry of Social Affairs and the EHIF should take urgent action to bolster their policy on the rational use of drugs. Therefore, since 2010 different measures have been implemented to tackle high OOP payments for drugs through the promotion of rational drug use.

First, the regulatory framework was strengthened to promote cost-effective choices by the patient. From 2005, prescribers were required to prescribe medicines by International Nonproprietary Name (INN). Exemptions are allowed if this is clinically justified and documented. Yet the requirement was poorly adhered to and four years later only about half of prescriptions were INN-based. Moreover, dispensing behaviour of pharmacies was largely unregulated. In April 2010 the requirement was strengthened by obliging pharmacies to offer the cheapest alternative to the patient presenting an INN-based prescription.

Second, Estonia introduced a digital prescription system, called ePrescription, in 2010. Doctors prescribe medications for patients using their computer software and forward an electronic prescription to the national database. The e-prescription is then immediately accessible in any pharmacy upon the patient’s request. In May 2011, just fifteen months after the launch, 84% of prescriptions were being issued digitally while in 2013 this proportion reached 97%. The e-prescription system requires that all prescriptions for branded drugs have to be justified directly on the prescription. This makes INN-based prescribing a more convenient and less burdensome alternative. As a result, the share of INN-based prescriptions increased rapidly from 50% in 2010 to 80% by the second half of 2013.

Third, patient awareness of costly medicines was relatively low. According to the annual population survey “Public opinion on health and health care”, only 38% of respondents who had purchased prescription drugs in 2010 were offered a choice of different products in the pharmacy. At the same time, 81% of the respondents consider it important that this choice is given. In September 2010, the EHIF started an awareness campaign with the slogan “the difference is in the medicine’s price” to empower patients to make more price aware choices in the pharmacy and to ask for an INN-based prescription from their doctor if it was not offered already. The main target group was the population over 40 years of age.

The first campaign phase, which lasted three months, was kicked off with a press conference that was extensively covered by the news media. After that, a broad range of outlets was used including articles, flyers, brochures, public debates, television commercials, as well as billboard ads. In the second, less intense campaign phase, the same messages and campaign materials were used and the TV campaign was repeated. In 2012, the campaign was renewed, keeping the underlying objective to empower patients to take a more active role in choosing equivalent medicines by price. The message for the new campaign was “same quality, lower price – it acts just as well”.

In 2013, the campaign was continued.

Fourth, the new e-prescriptions system created new opportunities for analysing data on prescribing behaviour in order to give feedback to health care providers.
Family physicians have been in general more committed to INN-based prescribing and have been important partners in the public awareness campaign. In 2012, the EHIF and the Society of Family Doctors agreed to include an indicator to gauge INN-based prescribing (share of INN-based prescriptions for high risk hypertension patients) in the family physician's quality bonus system (See Ref. 3 for more about the quality bonus system). The indicator has been collected since 2013, to be used in the bonus system starting in 2014. The results by doctor over the first six months of 2013 are already publicly available. On average, 85% of prescriptions were INN-based, yet about 10% of doctors had a share lower than 50% while some doctors had not prescribed INN drugs at all. In addition, all family physicians received feedback about their results, and EHIF visited family doctors with low scores to discuss the results and hopefully change their prescribing habits.

The hospital sector: next up?

In addition to family doctors, in 2013 INN-based prescribing and avoidable OOP payment data in 2012 were included in the EHIF’s feedback report for Hospital Network Development Plan hospitals. The indicator was disaggregated by specialties and enabled comparisons between nineteen hospitals. The share of INN-based prescriptions varied from 18% to 79% and avoidable OOP payment per prescription from €1.5 to €4.8. These observations point to considerable potential to also mitigate the pharmaceutical OOP burden for hospital patients. Since then, EHIF has discussed this variance with all hospital management and supervisory boards. The impact of these steps will first be analysed and further activities will be planned accordingly.

Results so far

The supervision of rational drug policies is a joint responsibility of the State Agency of Medicines (SAM) and the Health Board (HB). SAM monitors and supervises the operation of pharmacies (e.g. if medicines are available and at what cost) while the HB monitors prescribing practices. SAM has been regularly monitoring whether pharmacies adhere to the requirement to have available and to provide patients with the cheapest generic drug. In 2010, for 20% of INN drugs, an alternative below the reference price was not available in pharmacies. Since then this percentage has been improving and dropped to 3% in the first half of 2013. The annual population survey “Public opinion on health and health care” shows the effect of increased availability of cheaper alternatives on patients. Among those who had purchased prescription drugs in 2013, 61% could buy the most favourably priced option in the pharmacy, up from 38% in 2010.

In 2012, the HB conducted a survey to map the reasoning used by doctors when prescribing non-INN-based hypertension drugs. In half of the cases, the justification was that the patient was a long time user of the drug while for the other half it was the preference of the patient and/or doctor. Only in 2.3% of cases was the justification medically relevant. Given these poor results, the HB continued monitoring in 2013.

In 2011, Rüütel et al. concluded that it was too early to draw any conclusions regarding the effect of the changes on patient OOP payments on drugs. As of 2014, it seems evident that the measures described above have had a significant effect in reducing patient OOP payments for drugs, which have fallen from 38.6% of expenditure on EHIF-reimbursed medicines in 2007 to 32.1% in 2013 (see Figure 1). In absolute terms, cost sharing per prescription fell from €7.5 to €6.4 during the same period.

Lessons for other countries

High pharmaceutical OOP payments have been a challenge in many countries. This predominantly affects the newer EU member states where pharmaceuticals are relatively expensive and thus absorb a high proportion of total health expenditure. In particular, during the financial crisis, some governments chose to curb public spending on drugs by raising OOP payments. Yet probably more could be done to alleviate the effect on consumers by using more effective regulation. The Estonian approach gives valuable insights on how notable improvements for patients

![Figure 1: Out-of-pocket share of spending on EHIF-reimbursed medications](image-url)
can be made without greatly increasing the health budget, using a multifaceted approach that consists of: (1) stronger enforcement of INN prescribing both on the side of the prescriber and the pharmacy, (2) using e-Prescriptions that stimulate INN prescribing, (3) raising awareness among consumers of drugs, and (4) giving feedback to physicians on prescribing habits coupled with bonuses and, where necessary, follow up with a personal visit to change prescribing habits. It should be noted, however, that although this is a step in the right direction, OOP payments on pharmaceuticals remain comparatively high in Estonia. Improving rational drug use by changing prescribing habits may not be enough to further reduce high OOP payments in the long term; therefore, changes in other areas such as pricing and reimbursement will also have to be considered in the future.

References

### HiT on Estonia

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This analysis of the Estonian health system reviews recent developments in organisation and governance, health financing, health-care provision, health reforms and health system performance.

Without doubt, the main issue has been the 2008 financial crisis. Although Estonia has managed the downturn quite successfully and overall satisfaction with the system remains high, it is hard to predict the longer-term effects of the austerity package that was imposed in the country. The latter included some cuts in benefits and prices, increased cost sharing for certain services, extended waiting times, and a reduction in specialised care. In terms of health outcomes, important progress was made in life expectancy, which is nearing the European Union (EU) average, and infant mortality. Improvements are necessary in smoking and alcohol consumption, which are linked to the majority of avoidable diseases.

Although the health behaviour of the population is improving, large disparities between groups exist and obesity rates, particularly among young people, are increasing. In health care, the burden of out-of-pocket payments is still distributed towards vulnerable groups. Furthermore, the number of hospitals, hospital beds and average length of stay has decreased to the EU average level, yet bed occupancy rates are still below EU averages and efficiency advances could be made.

Going forwards, a number of pre-crisis challenges remain. These include ensuring sustainability of health care financing, guaranteeing a sufficient level of human resources, prioritising patient-centred health care, integrating health and social care services, implementing intersectoral action to promote healthy behaviour, safeguarding access to health care for lower socioeconomic groups, and, lastly, improving evaluation and monitoring tools across the health system.
In recent decades the health needs of children in Europe have changed. We see more chronic disease than ever before and persistent inequalities in health and wellbeing. However, despite increasingly sophisticated technology, the delivery of care and organisational structures of healthcare services have not evolved sufficiently to meet these challenges.

Taking a purposefully child-centric view this book aims to improve our understanding of children's health services across Europe. Focusing on ten Western European countries, the book combines primary and secondary research on children's health services and wider child health systems.

Drawing extensively on literature reviews, government data, clinical case studies and a questionnaire distributed to child health leaders, the authors identify the common themes that are contributing to child health across the European landscape. This book illustrates that European countries face many common challenges in their attempts to improve child health, and highlights the opportunities for learning from each other. The authors conclude this book with a strategy for improving the capacity of European health systems to drive improvements in health and equity. This book serves as a wake-up call to all those concerned with the well-being of Europe's children.

Contents: Child health in Europe: an overview, Primary care for children, Health services for children with long-term conditions and non-communicable disease; Transition from children's to adults' services; Child public health; Schools and the health of children and young people; Young people's health and health services; Mental health and behavioural disorders; Services for vulnerable and maltreated children; Prescribing for children in Europe; Comprehensive strategies for improving child health services in Europe.
**International**

**Health priorities of the Greek Presidency**

Health Minister Adonis Georgiadis presented the Greek Presidency’s priorities in the field of health before the members of the Committee on the Environment, Public Health and Food Safety of the European Parliament (ENVI) on 22 January 2014. Legislative priorities of the Greek Presidency will include issues related to medical devices, tobacco products, clinical trials, pharmacovigilance fees and the transparency directive.

Non-legislative priorities include the economic crisis and the impact on health care and health systems. This will be discussed at the Informal Health Council on 28–29 April in Athens and the Presidency will propose Council Conclusions on how European health systems coped with the financial constraints and the lessons learned, aiming at identifying best practices and highlighting key elements for the ideal package of policy measures to overcome the crisis and develop a recovery model. Another key priority focuses on migration and its implications on public health. Minister Georgiadis underlined the importance of close co-operation between Member States and the need for solidarity in addressing a common public health challenge for the EU Member States.

The minister noted that in the fight against non communicable disease that Greece will propose Council Conclusions on nutrition and physical activity aiming at promoting healthy lifestyle behaviours across the lifecycle. Greece will also place special attention on innovation in the health sector and eHealth solutions contributing to the sustainability and efficiency of health systems and in this respect the eHealth Forum 2014 will take place on 12–14 May in Athens aiming at driving the Digital Agenda forward.

For detailed information on the priorities of the Greek Presidency see: [http://www.gr2014.eu/Programme-Greek-Presidency-EU](http://www.gr2014.eu/Programme-Greek-Presidency-EU)

**Council confirms deal on the financing of reinforced pharmacovigilance**

On 19 February the Permanent Representatives Committee of the Council of the European Union (EU) approved a compromise agreed with the European Parliament on a draft regulation aimed at ensuring the funding of strengthened post-authorisation monitoring of medicines for human use (“pharmacovigilance”) conducted at EU level. It endorsed a compromise reached between the Greek presidency and representatives of the European Parliament and of the Commission on 12 February.

The EU rules on pharmacovigilance were reinforced in 2010 and also following the Mediator case in France in 2012. The agreement is expected to provide the means to finance the work of addressing safety concerns and maintaining high standards of quality, safety and efficacy of medicinal products. “The agreement is a great step towards the enhancement of public health, it secures the sustainability of the system while it is based on the principles of fairness and transparency”, said Greek Minister for Health, Adonis Georgiadis. In order to enter into force the draft regulation still needs to be formally approved by the European Parliament at plenary and by the Council once the text has been revised by the lawyer-linguists.


**New WHO analysis shows alarming rates of overweight children**

According to a new report published by the WHO Regional Office for Europe, being overweight is so common that it risks becoming a new norm in the WHO European Region. For example, up to 27% of 13-year-olds and 33% of 11-year olds are overweight. The country profiles made by the Regional Office give a bleak picture of nutrition, obesity and physical inactivity in the European Region’s 53 Member States. The profiles were launched at a conference in Athens at the opening event of for the Greek Presidency of the EU. Among 11-year-old boys and girls, the prevalence of overweight was highest in Greece (33%), Portugal (32%), Ireland (30%) and Spain (30%) and lowest in the Netherlands (13%) and Switzerland (11%). In 23 out of 36 countries, more than 30% of boys and girls aged 15 years and over are not getting enough physical activity. Among adults, women’s rates of insufficient physical activity range from 16% in Greece and 17% in Estonia to 71% in Malta and 76% in Serbia.

The country profiles on nutrition, physical activity and obesity are available at: [http://www.euro.who.int/en/health-topics/disease-prevention/nutrition/country-work](http://www.euro.who.int/en/health-topics/disease-prevention/nutrition/country-work)

**Employment, Social Policy, Health and Consumer Affairs Council (EPSCO Council)**

On 10 December 2013 the EPSCO Council adopted Conclusions on the reflection process on modern, responsive and sustainable health systems. The Council recommended Member States to assess the possible impact of health system reforms, including direct and indirect effects on health, population poverty, employment rates, productivity and competitiveness. The Council also recommends the Member States to establish and develop national policies and programmes on integrated forms of care and reshape fragmented delivery of health and social services.

The 16th European Health Forum Gastein (EHFG) explored the relationship between austerity policies and necessary innovations in health care systems in order to keep them resilient.

**Key Policy Findings**

- Resilient and innovative health systems require sustainable and patient-centred policies, a renewed commitment to Health in all Policies and tailor-made governance structures which follow the principles of transparency and accountability.

- Innovations needed to foster and promote resilient health systems have to be evidence based. They can be technological, social or organisational innovations and require innovative governance approaches.

- Innovative leadership and communication strategies are needed to display the values of health systems for a society. Health system reforms have to take economic and financial policies into account.

*For full details, see the Gastein Conference Report, 2013*

This year’s theme

Background: The cost of pharmaceutical care continues to increase in most OECD and emerging countries presenting decision-makers with significant challenges and dilemmas about its future sustainability. Among others, dilemmas relate to how new technologies can be covered and who is likely to benefit; what constitutes value for money in different settings and how can this be defined objectively; what evidence is required to make positive recommendations about coverage and how best to structure reimbursement decisions; how can we deal with uncertainty about the value of new medical technologies; and whether wise choices are made in the procurement of generic drugs in order to optimise the use of new technologies.

Objectives

The Summer School will build on participants’ own knowledge and expertise in pharmaceutical policies and coverage decisions and marshal the latest evidence on new developments to:

- Provide a state of the art account of novel strategies to optimise pharmaceutical policy decisions;
- Draw on a wide body of evidence to provide a range of concrete pharmaceutical policy options related to the assessment of new health care technologies, the risk-sharing in novel therapies and the procurement of off-patent drugs;
- Interpret how such policy options can be operationalised considering resource, infrastructure and technology constraints in different settings; and
- Draw practical policy and implementation lessons to deliver better decisions that will have a positive impact on population health given resource constraints.

Approach

The six day course combines a core of formal teaching with a participative approach that includes participant presentations, round tables, panel discussions and group work. It mobilises the latest evidence; a multidisciplinary team of experts; and the insights of key international organisations including WHO, the European Commission and relevant professional and governmental organisations.

Modules

The course is organised around three modules. Module 1 looks at what is the problem? Understanding the challenges facing pharmaceutical decision-makers. Module 2 addresses what can we do? The evidence on new developments in pharmaceutical policy, particularly for new technologies. Module 3 looks at how do we make it happen? Governing and implementing changes in pharmaceutical policies to optimise resources and coverage decisions. Participants’ experiences and practice will be central and they will share their perspectives, work in groups and develop a case study that cuts across themes. They will also be able to engage in political dialogue with senior policy makers and representatives of professional bodies.

Accreditation

The Summer School has applied to be accredited by the European Accreditation Council for Continuing Medical Education and as in past years hopes to count towards ongoing professional development in all EU Member States.

Applicants/participants

The Summer School is primarily aimed at senior to mid-level policy-makers although some more junior professionals will be included. All participants should be working in a decision-making or advisory institution that focuses on policy and management at a regional, national or international level. The cost is €1,950 and covers all accommodation and meals, the course, teaching materials, transfers to and from the airport and the social programme. Potential participants are asked to apply by 26 May 2014. Early applications are encouraged.

For more information and updates: www.observatorysummerschool.org