Improving efficiency of allocating public funds to pharmaceuticals: A pilot study in the Kingdom of Saudi Arabia

Khaled A Al Hussein, Ali S Al Akeel and Jim Attridge

Summary: The optimal management of the allocation of limited public health funds across the growing diverse range of modern medicines is a challenge faced by both high and middle income countries. The context of this study is one in which reform strategies aim to accelerate patient access to the best available medicines, within the context of a well-managed and efficient budgetary regime. Critical in this regard is a concern to better match the usage patterns of medicines with changing patterns of disease prevalence in the local population. A second key aim is to manage the costs of established products more efficiently by the wider usage of less expensive generics in order to release funds to cover the cost of newer innovative products. In this article we report the results of a pilot study in the Kingdom of Saudi Arabia in which a model has been developed for both recording and analysing past data on allocations across different classes of medicines and its use as a predictive tool to consider the potential consequences of choosing alternative priorities for future expenditure. We then explain how using the information from it informed strategic decisions on policy reforms to achieve these objectives.

Keywords: Funding medicines, allocation model, Saudi Arabia, pilot study

Management of national pharmaceutical expenditures
There is an extensive international literature upon approaches to the effective and efficient management of health expenditures and more specifically effective cost management approaches to the pharmaceutical sector. In developed countries within the Organisation for Economic Cooperation and Development (OECD), in Europe and beyond, a wide range of demand and supply side forms of regulation or interventions have been adopted.1–4 Table 1 provides a summary of regulatory or negotiating policy instruments and models adopted across world markets with varying degrees of success.

OECD and Middle Income Countries (MIC) face the same essential challenges in allocating public health system funds to medicines. Over many years a steady stream of new modern medicines have offered improved outcomes in many disease areas, which at times has driven up expenditure on medicines faster than either health care expenditure generally or

Table 1: Regulatory and negotiating policy instruments for medicines

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<td>Pharmacoeconomic studies</td>
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growth in national Gross Domestic Products (GDP). Although the most recent data suggest this era may be coming to an end, two fundamental decision-making challenges remain:

- What proportion of total health care should be spent on medicines in any given national context or timeframe?
- Within the expenditure on pharmaceuticals what criteria or principles should be applied to decide how best to allocate it between different disease areas and classes of medicines?

The first of these questions has been the subject of international benchmarking studies which have identified two general trends. Firstly, as might be expected, average levels of national expenditure increase over the range US$ 50–400 per capita spend in proportion to increasing GDP per capita (at Purchasing Power Parity, PPP) over the range US$5,000–40,000, reflecting affordability limits. Less obvious is a trend in which the proportion of total health care expenditure attributable to medicines falls from as high as 30% at the lower end of the GDP range to 10% at the upper end. Considerable variations in national patterns of expenditure make it less clear why this is the case, although prima facie it would appear to reflect not so much excessive expenditure on medicines in less affluent countries, but a substantial under-expenditure on other services, notably primary care and uptake of modern technologies in hospital settings.

We report here our experience of a pilot study in the public sector in Saudi Arabia to develop and explore the use of a relatively simple model into which historic annual volume and value data can be entered. This may be of interest to other health care systems currently seeking to establish or upgrade their decision making processes in this area.

Health care and medicines in Saudi Arabia

The Kingdom of Saudi Arabia is one of the largest countries in the Middle East with a population of twenty-five million of which approximately six million are foreign nationals. It is a relatively ‘young’ population with 40% under fifteen years of age and only 3.5% over sixty-five. Health care is provided free for all Saudi citizens and expatriates working in the large public sector. The Ministry of Health (MoH) is the largest provider of services, covering 62% of all in-patient care; other governmental agencies and the private sector provide the remainder, at 20% and 17% respectively. The MoH is also responsible for administering a regional system of preventive and primary care centre services; the latter acting as the ‘gate-keeper’ for access to the hospital sector. Since the 1970s a series of five year plans have greatly improved both the quality and national coverage of services. Widening free access to services to all social classes and geographical regions, whilst upgrading the technological basis of the medical infrastructure continue to be the core objectives. Currently there are ambitious plans to build up to two thousand new primary care centres and to increase the hospital bed stock with a network of fifty strategically located five-bed hospitals to meet the demand of a growing population.

Funding and provision of prescription medicines

Medicines are funded by the MoH largely on a ‘global budget’ basis for the hospital sector. The balance of hospital expenditure on medicines, at 25–30% of total expenditure, is relatively high in the OECD/MIC range outlined above. It lies in a similar range to the new EU member states of Eastern Europe. The cornerstone of policy is the principles outlined in the WHO Guidelines for Drug Policy. The prime criteria are to ensure:

- fair and equitable access to medicines for all sections of the community,
- efficient allocation of health care funds and other resources, and
- that the pattern of expenditure on medicines is constantly reviewed and updated to meet the changing patterns of diseases and health needs.

In a situation of growing demand for modern medicines, good data and analysis to identify potential areas for cost savings in respect of older products, thus creating ‘headroom’ for expenditure on new products, is a key feature of the system.

An expenditure model

A model has been developed to analyse actual expenditures on medicines using the internationally accepted Anatomical Therapeutic Classification (ATC) system. In this pilot phase the model has been populated with MoH statistics for the years 2004 and 2005. Individual medical products are identified by their registered trade names, pharmaceutical forms, dose levels and pack sizes and data taken from the annual national health statistics data base. The model covers 77 ATC classes, which are subdivided into three sub-groups;

- G1 Products for life threatening diseases,
- G2 Products for essential medicines for important diseases,
- G3 Products for less essential diseases.

The data base consists of a universe of 613 products, for which the following metrics have been included:

- Pack sizes prescribed and dispensed
- Number of units purchased
- Price per unit
- The date at which the product was first introduced into the market.

The use of the G1–G3 classification has international precedents. For example, the French Haute Autorité de Santé (HAS) price and reimbursement system uses this conceptual distinction, both in classifying new products according to their degree of innovative added value and as a basis for determining percentage patient copayment levels. We recognise that this way of classifying disease states and treatment classes involves value judgements and difficult choices for border line cases and therefore should be treated with some caution.

We have used the dates of product introduction into the market to classify products according to ‘age’ into the following four categories:

Y1 Products introduced between 1999–2004 (0–5 years old),
Y2 Products introduced between 1993–1998 (5–10 years old),
Y3 Products introduced between 1987–1992 (11–15 years),
Y4 Products introduced prior to 1987 (15+ years).

This segmentation of expenditure based upon product age groups, Y1–Y4, offers a fairly crude way of distinguishing the most recent innovative products from those that are long-established. In broad terms groups Y1 and Y2, products up to ten years old would, more or less equate to products which were patented, on the assumption that of the normal twenty year patent life the first ten years is consumed by the research and development (R&D) process, leaving only about ten further years for the marketing phase. Beyond ten years in a
competitive market there will be increasing levels of brand generic competition, which will both erode prices down to much lower levels and fragment the market for any given molecule, between the originators brand and competing generics.

In Saudi Arabia, in line with many other markets, the generic industry sector is becoming an established feature of supply side competition, where there are a steady flow of new product entrants, which are both brand generics and minor product variants, such as new formulations, dosage forms and combination products.

To summarise, this model provides a base case analysis of expenditures which can be interrogated using three key product characteristics; the ATC level 3 or 4 class to which it belongs, the severity of the disease for which it is used (G1, G2, G3) and its age (Y1, Y2, Y3, Y4) and at all levels of aggregation from individual product, to ATC level 3 and 4 classes, to higher levels of aggregation for specific disease states and total expenditure levels.

The model has a facility to undertake simulations of the impact upon annual expenditure of the following alternative strategies, using the following parameters:

- Selective reimbursement of ATC classes or product sub groups
- Variable levels of patient co-payment
- Price changes at the individual market, product class or ATC disease sector level
- Unit/volume changes.

The base case analysis
The results of the base case analysis for MoH Hospital expenditure for the year 2005 focus attention upon three dimensions:

(a) Expenditure by disease/therapeutic area category
(b) Expenditure by therapeutic class and age of products
(c) Relative unit prices between therapeutic classes and age categories.

Expenditure by therapeutic category
Figure 1 shows the spread of expenditure across the three categories of disease, G1, G2, G3, used in the model. The Figure shows, as we would expect, that the majority of the expenditure (>70%) is spent on the more serious life threatening diseases. However, it is notable that there are substantial levels of expenditure on the less essential medicines. Also a more detailed analysis of this G3 category at the ATC therapeutic class level shows that the two largest components are vitamins and cough/cold remedies. In category, G2, there are a wider range of therapeutic areas and product classes represented, of which anti-infectives and analgesics are major components.

MoH expenditure by product age
The volume consumption as a function of age is summarised in Figure 2, which clearly shows that expenditure is dominated (70.2%) by products that have been in the market for more than fifteen years and that products which entered the market in the most recent five years accounted for only 3.6% of the total. Surprisingly there is little evidence of incremental increase in the percentages on the intermediary 5–10 year and 10–15 year categories, which are also low.

Figure 3 shows the same analysis in value terms with a total expenditure for the year 2005 of $185m. On the basis that inevitably newer products, particularly the newest market entrants, are likely to be substantially more expensive than the older categories this shows the expected, less pronounced gradation in the increase in expenditure as the product classes age i.e. 15% for 0–5 years; 21% for 5–10 years; 25% for 10–15 years; and 33% for products 15+ years. A more detailed analysis of the products in the 0–5 year old category showed that of the 15%, 9.4% were originator brands of innovative products and 5.7% were other brands or generics sold by local or international generic companies.

This base case analysis suggests that even
though for 2005 expenditure was well focussed upon serious life threatening diseases, most of the medicines being used had been in the market for at least ten years (84% by units; 64% by value).

We have also examined the ratio between expenditure on chronic as opposed to acute disease states and as a function of the diseases categories G1–G3, as shown in Figure 4. Overall, as one might expect, the share attributed to acute conditions falls from $75m (55%) for life threatening diseases to $10.6m (35%) for essential diseases and to a negligible level for less essential diseases. However, the share held by chronic conditions, at $61m (45%) of the life threatening diseases, appears to be high in a hospital setting and would perhaps merit further investigation at lower ATC class levels.

We have also analysed average unit prices, based upon the age segments, Y1–Y4. The prices of medicines in the less than five years old group, the newest products, at an average of US$25.7 were considerably more expensive than those in the oldest category, at an average of US$3.26 (15 year+). However the intermediate categories 5–10 years old at US$9.99 were actually lower than the 10–15 year category at US$13.0. This result suggests that in this latter category there are some anomalies and a lack of competition in some classes.

Simulation Analyses

This model has considerable potential for examining a wide range of options to address questions as to what might be the impact of alternative new funding approaches or provision policies for different disease states and product types. These could include market price structures, selected price increases or decreases, limits on indications and patient categories and patient co-payment schemes. In this initial phase we have focussed upon examining alternative reimbursement strategies. We have evaluated the possible cost saving potential of introducing some form of graduated patient co-payment scheme, in which medicines for life threatening diseases, G1, would continue to be 100% reimbursed, serious diseases, while G2 would require a small co-payment and category G3 would have substantial co-payments. This analysis suggested there might be some scope within the expenditure for G3 products to achieve savings of around 17–27% per annum.

Discussion

We have reviewed Saudi Arabian policies on the reimbursement, purchasing and deployment of prescription medicines in the publicly funded hospital sector. The aim has been to ensure that investment in medicines reflects changing patterns of disease incidence and prevalence in the relevant population and to develop a strategy for improving access to innovative medicines at reasonable prices, whilst also making the best use of less expensive older generic ones.

Saudi Arabian policies have focused upon a selected combination of these measures in the past, most notably international price comparison (external reference pricing against a basket of thirty other countries) and internal reference pricing on a product class basis. In more recent times a policy of selective price reductions has been adopted on a class by class or individual product basis, with a particular concern for sales growth and budget impact criteria. Another important principle has been to discriminate based upon pack value, whereby price reductions may be applied to all packs which have a price above a given fixed value. Pricing and admission of products to reimbursement has recently begun to focus upon health technology assessments of relative added value within
competitive existing products.

The following represent the main findings from our analysis of Saudi Ministry of Health purchases for hospitals in 2005.

1) Of the total hospital expenditure of $185m, the majority, $135m (73%), is allocated for treating serious life-threatening conditions which are normally treated in a hospital setting.

2) Of the total expenditure, $118m (64%) was spent on products that had been in the market for more than ten years, which would be predominantly patent expired products and brand generic copies.

3) Spending on the Less Essential Diseases category constituted only 10% of total expenditure, but notably this category contained significant levels of expenditure on products normally associated with the retail or ‘Over the Counter’ (OTC) sectors, such as vitamins, topical creams and cough and cold remedies.

4) Expenditure on chronic conditions, such as asthma, hypertension and hypercholesterolemia, which can be precursors to acute episodes that require hospitalisation, do not appear to be consistent with broader national epidemiological data on the disease burden and treatment patterns for these conditions.

5) As only 9.4% of total expenditure is currently attributable to newer innovative products **prima facie** scope may exist to improve outcomes through a higher allocation of funds in this area. This is particularly critical for treating life-threatening diseases which are still treated in large part with ‘older/off patent’ drugs; the exception being for cytostatic and psychotropic products, where innovative products are more widely used.

6) Older off-patent drugs are priced relatively highly compared to recently introduced versions of the same drugs, suggesting that lower purchase prices could be achieved.

**International Comparisons**

It is difficult to find comparable data to assess how the situation in Saudi Arabia compares with other countries. In Table 2 we show a limited set of comparative market shares of products up to five years old for selected European countries, which further differentiates between innovative originator products and brand generic, generic or copy products.

We recognise that national environments vary greatly in terms of the health care funding and provision systems and the priority given to different disease areas.11 Furthermore these countries are all undergoing dynamic change in regulation of access, prices and reimbursement and supply side competitive structure. There is considerable variation in uptake rates for innovative products at one end of product life cycles and the extent to which effective generic competition occurs at patent expiry at the other.

Thus, a country such as the UK has a long tradition of being slow to embrace new products and over recent years has developed a highly competitive off patent generic market. Hence in Table 2 the 0–5 year share of originator products is relatively low at 9.7%, whereas the share of new generic entrants over this period at 9% is high compared to other countries. In contrast, in France, Italy and Spain shares held by originator products in the first five years are much higher, reflecting more rapid diffusion of innovative products, but underdeveloped generic markets. This latter situation is now changing rapidly.11

Even within the newer EU middle income states of Central and Eastern Europe (CEE) there is considerable diversity in the situation. Hungary having a liberally regulated market shows a relatively high uptake of new products, contrasting sharply with Poland, where over this time frame there were strong regulatory barriers to reimbursing innovative new products and many delays in the administrative procedures resulting in an abnormally low figure.

Similarly we need to be cautious in interpreting the results for Saudi Arabia. The data cover the hospital market which is under the direction of the MoH, whereas the EU data cover both the retail and hospital sectors. The analysis of expenditure on chronic versus acute therapies suggests that maybe in the Saudi Arabian context, hospitals play a more significant role in distributing chronic therapies on an ambulatory basis that would normally be distributed through primary care and retail pharmacies in EU countries. Despite these limitations we would make the following observations on Table 2:

(i) By EU country standards the Saudi market appears to be less dynamic, in that for products less than five years old the share of the market appears to be relatively low both for innovative originator and other brand and generic entrant products.

(ii) The lower innovative product uptake may be because the Saudi product sample is skewed towards the acute hospital sector and hence the impact of major new classes of primary care product categories, such as statins or atypical antidepressants which have shown high growth during these years, will have been less prominent than in the EU.

(iii) It may also be that formal price controls limit the incentive for new generic companies to enter the market and compete solely on the basis of price. An effect widely observed in southern European markets.4,11

(iv) The low uptake of innovative new products, at a level very similar to that in the UK, may reflect the same combination of ‘therapeutic conservatism’ by clinicians combined with budgetary constraints.

**Conclusions and further development of this type of model**

In the context of Saudi Arabia we see considerable potential to extend the use of this model by:

(i) Extending data collection in future years to build up a better understanding of ‘cause and effect’ relationships between policy changes and market outcomes.

(ii) Prospective studies of the likely impact of new technological advances in medicines, notably biologic products.

(iii) As part of the new primary care network development the model could aid decisions as to which products are supplied via ambulatory care services at hospitals and which should be delivered and funded through primary care services.

(iv) At a lower level of aggregation, versions of the model could be developed for individual general and specialist hospitals. Expert formulary committees could input assessments of the clinical and cost-effectiveness of new products and examine the budgetary consequences of alternative strategies for patient access.

(v) Evaluate the benefits and costs care in selectively adopting patient co-payment contributions to medicines.

More generally many MICs are now upgrading their management systems for pharmaceuticals in response to the growing importance of health care expenditure as a proportion of total public expenditure.
Historically decision-making has been driven by medical need tempered by short-term perceptions of affordability. From both of these perspectives the quality of decision-making has been severely limited by a lack of epidemiological and cost data to understand trends in both need and cost patterns, as a basis for formulating medium-term strategies. In consequence, decision-making processes for medicines often rely heavily upon arbitrary annual budget increases and ad hoc, short-term cost containment interventions on prices or access to reimbursement to deal with frequent over-expenditures. In order to move forward toward systems based upon medium-term strategic plans, rather than a succession of short-term tactical responses, progress is needed on three fronts:

(a) A major increase in investment in epidemiological data and cost data collection, taking advantage of modern information technology and communication technologies.
(b) The development of planning models which can accommodate this data at various levels of aggregation.
(c) More sophisticated ‘trade-off’ models which improve the overall efficiency of allocating limited funds.

This pilot study has achieved a substantial step forward in Saudi Arabia in bringing together improved data collection systems under (a) in a decision-making model under (b). Clearly the further widespread adoption of this model and population of it with longer trend data sets will provide a sound platform for initiatives under (c) involving appropriate forms of health technology assessment (HTA).

Currently many MICs appear to be embarking upon ambitious reforms adopting the more advanced concepts of HTA under (c), without paying adequate attention to putting in place the necessary systems and infrastructures at levels (a) and (b). We would therefore commend the development of this type of model in Mic involved in this transitional process, as part of the progression to achieving a better service for patients by improving the balance between the funds available for innovative new products and the optimal use of the cheapest available generic versions of older ones.

Table 2: International comparison of value share (%) of total medicines market by product type and age category.

<table>
<thead>
<tr>
<th>Country</th>
<th>Share (%) of originator brands 0–5yr old</th>
<th>Share (%) of all other brand generics 0–5yr old</th>
<th>Share (%) of products over 5yr old</th>
<th>Comment</th>
</tr>
</thead>
<tbody>
<tr>
<td>SAUDI ARABIA*</td>
<td>9.4</td>
<td>5.7</td>
<td>84.9</td>
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<tr>
<td>MAJOR EU**</td>
<td></td>
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<tr>
<td>Spain</td>
<td>18.5</td>
<td>7.5</td>
<td>74.0</td>
<td>High uptake of new products – weak generic competition</td>
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<tr>
<td>Italy</td>
<td>13.2</td>
<td>6.4</td>
<td>80.4</td>
<td>As above</td>
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<tr>
<td>France</td>
<td>13.5</td>
<td>7.8</td>
<td>78.7</td>
<td></td>
</tr>
<tr>
<td>Germany</td>
<td>10.6</td>
<td>12.6</td>
<td>76.8</td>
<td>High growth in generics</td>
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<tr>
<td>UK</td>
<td>9.70</td>
<td>9.00</td>
<td>81.3</td>
<td>Low innovation uptake -mature generics market</td>
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<td>NORTH EU</td>
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<td></td>
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<td>Norway</td>
<td>19.1</td>
<td>8.4</td>
<td>72.5</td>
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<tr>
<td>Belgium</td>
<td>18.8</td>
<td>6.6</td>
<td>74.9</td>
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<tr>
<td>Denmark</td>
<td>18.1</td>
<td>10.8</td>
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<td>Netherlands</td>
<td>14.5</td>
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<td>Sweden</td>
<td>12.9</td>
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<tr>
<td>Finland</td>
<td>10.6</td>
<td>6.4</td>
<td>83.0</td>
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<td>CENTRAL/EASTERN EUROPE</td>
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<tr>
<td>Hungary</td>
<td>13.1</td>
<td>9.0</td>
<td>77.9</td>
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<tr>
<td>Czech Republic</td>
<td>11.8</td>
<td>14.9</td>
<td>73.3</td>
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<tr>
<td>Poland</td>
<td>5.3</td>
<td>15.8</td>
<td>78.9</td>
<td>Very limited access to innovative products</td>
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Source: EU data from EFPIA
* Saudi Arabian data is the MoH (hospital sector) for 2005
** EU country data includes both hospital and primary care retail distribution data for 2003
Belarus: developments in primary care

Valentin Rusovich and Erica Richardson

In order to maintain the provision and access to health care services following independence, Belarus has pursued a policy of incremental health care reform. Consequently, the Belarusian health care system bears many of the same features as the Soviet Semashko system which the republic inherited in August 1991. However, the primary care sector in Belarus is one area of the system which has seen more change in the last decade. In common with health systems across Europe, primary care services have been expanded in response to rising health care costs and the need to develop better ways of caring for people with long term conditions. Evidence from around the world suggests that primary care services are more technically efficient than hospital in-patient services and health systems that have a greater primary care orientation have better aggregate health outcomes as well as better access and equity.

Shifting the focus from secondary to primary care involves a broad package of measures, such as enhancing the prestige of primary health care, shifting resources away from secondary to primary care and strengthening the gatekeeper role of primary health care practitioners. However, reforms designed to increase the primary care orientation of established health care systems can be very challenging to implement in practice as their success is contextually dependent.

Primary care reforms in Belarus

Primary care in Belarus has been in transition since the late 1990s as the country has experimented with different models of organizing services. The successful piloting of per capita resource allocation in Vitebsk oblast (region) led to the nationwide roll out of new financing mechanisms for primary health care from 2000 and the implementation of per capita financing for services from 2004. Reforms in health care financing have aimed to improve efficiency in the system by moving away from input-based financing mechanisms to reduce excess capacity in the hospital sector thereby releasing extra resources for primary care services. The Concept on the Development of Health Care in the Republic of Belarus 2003–2007 was envisaged as a document which would guide the health care system to a new model in which primary care would become the main priority and resources would be allocated to it accordingly. The aim was to improve the technical efficiency of the health system as a whole and reverse worrying demographic trends in the country related to the rapid ageing of the population and the burden of premature mortality. As a result there has been significant investment in order to improve both the quality and accessibility of primary care services in rural areas, namely a significant expansion in the number of primary care facilities and capital investment to improve the state of repair of 113 rural health care facilities. This capital investment has been accompanied by a significant investment in the retraining of primary care doctors working in rural areas as general practitioners.

Organisation of primary care services

As a result of these reforms, there is now a dual primary health care system in Belarus: a system of general practitioners in rural areas and on the outskirts of some cities and the maintenance of the traditional Semashko polyclinic system in urban areas. All primary care facilities are state owned and financed and controlled by Regional Health Care Departments. In remote rural areas primary care services are provided

References


Valentin Rusovich is National Professional Officer Communicable Diseases (Tuberculosis), WHO Country Office, Belarus.

Erica Richardson is Research Officer, European Observatory on Health Systems and Policies and Research Fellow, London School of Hygiene and Tropical Medicine.