"End-of-Life" Drug Policies in the UK, Australia and Germany

The ongoing rise in pharmaceutical spending in industrial countries is primarily due to higher spending on expensive new treatments for cancer and rare indications like HIV/AIDS. In the case of cancers, the gains in life expectancy come at a very high price. For the United States, Fojo and Grady (2009) estimate that for new cancer treatments the cost of surviving an additional month is $80,000. Extending the life of all 550,000 Americans that die of cancer annually by one year would, by this estimate, cost $440 billion – with none of the patients being cured.

Governments are trying to cope with this challenge of balancing entitlement to the best possible care and upholding the financial sustainability of healthcare systems.
This article summarizes a recent paper by Chalkidou, Lopert, and Gerber (2012) that describes the institutional arrangements for access to costly end-of-life treatments in the UK, Australia, and Germany.

United Kingdom

In the UK, drugs that satisfy the comparative clinical and cost-effectiveness requirements of the National Institute for Health and Clinical Excellence (NICE) are available free under the National Health Service (NHS). Many new end-of-life treatments, however, do not meet NICE's criterion of purchasing an additional quality adjusted life-year (QALY) at £20,000-£30,000. Instead, cost estimates for new renal cancer treatments, for instance, amount to £70,000-£170,000 per QALY. In response to public pressure for a more generous coverage policy for terminal cancer treatments, the UK government has introduced a number of exceptions to NICE's rules.

NICE's End-of-Life Guidance permits the violation of its cost-per-QALY threshold if the costly treatment is limited to a small, terminally ill patient population and if there is robust evidence for the treatment to extend life expectancy by at least three months compared to the current NHS treatment. The current Conservative Government has also put in place the Cancer Drugs Fund. The fund, financed separately from the NHS, aims to make cancer drugs available regardless of cost-effectiveness considerations. Its financial sustainability, however, is in question, as is the legitimacy of limiting exemptions from cost-effectiveness requirements to cancer treatments. Another instrument to improve access to costly end-of-life care is patient access schemes. Here the NHS reaches an agreement with pharmaceutical companies to pay for treatment only for those patients for whom the treatments work in that they increase life-expectancy so much as to meet NICE cost-effectiveness criteria.

Despite these exceptions, 30 percent of cancer drugs remain non-reimbursable due to a lack of clinical or cost-effectiveness. To address this issue, the UK government aims to add "value-based pricing" to NICE's standard criteria to determine NHS coverage: from 2014, it seeks to negotiate with manufacturers the prices for all new drugs and thereby reaches prices that better represent "broader societal benefits, disease severity, and the degree of innovation represented by the new therapy".

Australia

In Australia, the Pharmaceutical Benefits Advisory Committee (PBAC) undertakes comparative clinical and cost effectiveness analysis to make recommendations to the federal Pharmaceutical Benefits Scheme (PBS) on whether or not to list a new drug on the national formulary. If on the formulary a drug can be purchased at a subsidized price. The final listing decision is with the Ministry for Health and Ageing. The Ministry, however, cannot turn around a non-positive PBAC recommendation.

While cost is a factor in PBAC's analysis, there is no cost-threshold as at NICE. Instead, comparative clinical effectiveness is crucial: new, costly medicines only qualify for subsidization if they represent a clinically significant improvement in effectiveness or reduction in toxicity.

With its flexible approach to cost-effectiveness, PBAC has no particular process for assessments of end-of-life drugs. Instead, certain assessment criteria like the availability and effectiveness of alternatives, total cost projections, and the affordability at non-subsidized prices here gain particular importance. In addition, a "rule of rescue" permits recommendation of costly but effective medicines for rarely occurring serious or fatal diseases for which no other treatments exist. With PBAC's rather generous assessment standards, the rule of rescue is, however, rarely applied.

To strengthen financial sustainability, PBAC can recommend restricting indications for the use of expensive treatments – for instance, a new drug can be recommended as part of a stepped or last-line therapy when no other treatment has helped. Alternatively, subsidized access is limited to highly targeted patient groups for which there is clear evidence of comparative clinical effectiveness. Australia also employs risk sharing arrangements similar to the UK's patient access schemes. For instance, rebates apply when total annual expenditure on a treatment exceeds a cap negotiated between government and industry.

Germany

Under the German Statutory Health Insurance (SHI) system that covers 90 percent of the population, all effective prescription drugs become part of the benefit package, excluding so-called life-style drugs. Effectiveness assessments are carried out by the Federal Joint Committee (FJC), a self-governing board comprising of representatives of the national association of SHI funds, ambulatory care physicians, hospitals, and nonvoting patient representatives. New drugs enter the market at industry-set prices. To contain costs, the FJC can determine reference groups of drugs of similar effectiveness. SHIs then only reimburse to reference-price, with patients having to cover the difference to the listing price out-of-pocket. To inform its reference-group decisions, the FJC refers to unbinding comparative effectiveness studies undertaken by the Institute for Quality and Efficiency in Health Care (IQWiG). IQWiG has also recently been commissioned to carry out comparative cost-effectiveness analysis to provide additional guidance for SHI reimbursement policies.

An additional cost-containment instrument was introduced in early 2011. Since then, manufacturers must provide comparative effectiveness analyses as a precondition for market entry. If the new drug offers no additional benefit over existing treatments it enters a reference group. If it does, its price is negotiated with the association of SHI funds. If the parties reach no agreement within six months, a central board of arbitration determines a price with reference to international prices.

At the moment, no specific policy that regulates access to expensive end-of-life treatments is in place in Germany and uncertainty about IQWiG's future path in comparative clinical and cost-effectiveness methodology prevails. In 2005, the High Court ruled it unconstitutional to deny patients access to care that bears at least a remote chance of cure or discernible improvement in the course of the disease in the case of a life-threatening disease. Still, with the increase in pharmaceutical spending being largely driven by expensive patent-protected drugs, Germany is under pressure to develop a coherent, transparent, and ethical reimbursement policy for costly end-of-life treatments.

As value for money becomes an increasingly important concept in healthcare policies across the world, the stance towards end-of-life care remains an important field of public debate: what legitimates appropriating more funds per QALY to end-of-life care than to other, more cost-effective measures to save lives? Who should decide on such prioritizations and what would a legitimizing methodology look like? And what incentives does a shift in preference towards end-of-life treatments bear for research in the pharmaceutical industry?

S.N.

References

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