Personalised healthcare

Roche Australia (Pharmaceuticals) Policy Position

Summary

- Personalised healthcare (PHC) is based on using genetic and clinical information to help identify the optimal course of treatment for each patient.
- By improving the efficiency of drug development, reducing waste from ineffective or inappropriate treatments and optimising patient care, PHC may improve patient outcomes and deliver savings to the health system[1,2].
- However, PHC is highly complex and it has been difficult for systems for evaluating and reimbursing PHC solutions to keep pace. As a leader in PHC innovation, Roche wants to help develop appropriate processes and tools to deliver the promise of PHC in Australia.

Background

Personalised healthcare (PHC) is based on the observation that patients with the same diagnosis react to the same treatment in different ways. As a result of disease-related and disease-independent individual characteristics, a considerable number of patients receive treatment that is suboptimal for them; treatment that may cause adverse reactions in some cases. PHC has the potential to increase the efficacy and safety of treatments[1], building on our increasingly sophisticated understanding of differences among patients, the molecular basis of disease and how medicines work.

By taking the individual characteristics of patients and their diseases into account, PHC may:

- Help identify patients who are most likely to respond to a specific treatment, improving outcomes and the overall cost-effectiveness of care;
- Improve understanding of disease diversity and subtypes;
- Identify patients who are at increased risk of suffering from a certain disease and create opportunities for preventive measures before the disease develops; and
- Allow a faster, less burdensome and less expensive drug approval process by conducting trials on smaller patient subgroups qualified by specific biomarkers[1].

Roche position

Combining our strengths in pharmaceuticals and diagnostics, Roche is uniquely positioned to deliver PHC. Roche has the expertise in molecular biology and clinical research and the experience and tools of a large and successful diagnostic and pharmaceutical company in-house.

Roche is committed to entering into a dialogue with stakeholders about the value created by PHC solutions, being fully convinced that it has enormous potential to make healthcare better, safer and more cost-effective. In promoting development and application of PHC solutions:

- Roche makes sure that PHC solutions are adequately tested for efficacy and safety;
- Roche is committed to the education of healthcare professionals concerning PHC solutions, so that they are able to adequately inform patients about the opportunities and limitations; and
- Roche will contribute to the gathering of medical and economic data to provide further evidence that PHC adds value to the healthcare system.

However, the speed of innovation has meant that it is challenging for health systems to keep pace with the science. The 2015 Australian Senate inquiry into cancer medicines highlighted how a "one size fits all" approach to evaluation and reimbursement can delay access to care by patients[3]. The most urgent issues are:

- Delayed reimbursement for medicines targeted to small patient populations;
- Variations in access to molecularly-targeted medicines between different primary tumour sites (e.g. breast cancer vs stomach cancer); and
- A complex process for assessing medicines with companion diagnostics.

Targeted therapies that use companion diagnostic tests ("co-dependent technologies") can help maximise the benefits of treatment and minimise side-effects. Unfortunately, the time to access a targeted therapy is currently at least twice that for a medicine that does not require a genetic test[4]. While the principle of co-dependent assessment is valid, in practice the process may not be meeting community expectations around timely access. These challenges will only be exacerbated as PHC develops and treatments are further tailored to look at multiple genes or markers and different combinations of medicines.

A concern for payers and policy makers around PHC is that medicines developed for small populations (such as through genetic targets) may be more expensive per patient than traditional drugs for common diseases. Yet these may still represent value for money, as medicines can be targeted to patients with a high likelihood of response and low probability of adverse events. PHC may allow for the lower usage of ineffective therapies. It may also identify patients who would benefit equally from older, genericised treatments as from new medicines and it allows for care to be amended over time as we learn more about outcomes and targeting.

Further, PHC approaches to drug development may lead to more efficient trials and economies of scale that flow through to lower costs for payers. For example, cancer "basket studies" look at a patient group with a mix of tumour types but all with common genetics or biomarkers, rather than conducting studies in each tumour. However, such studies are not well understood by regulators and payers in Australia at present and Roche welcomes the opportunity to discuss how best to incorporate them into decision-making.

Evidence generation approaches other than randomised studies are also possible. The use of "Big Data" can track how medicines work in practice, allowing for targets to be re-evaluated and even identification of new markers and predictors. Real world evidence can also include non-clinical aspects of the value of medicines such as use of healthcare services, disability support, welfare and ability to work and pay tax. With proper use of data, medicines can be reimbursed in a timely way under "managed access" schemes, with value and cost re-evaluated as the full picture emerges.

Roche is committed to working with all stakeholders to identify solutions that will allow the promise of PHC to become a reality in Australia.

Further reference

Roche Position on Personalised Healthcare (Global policy)

This position paper was adopted by the Roche Australia (Pharmaceuticals) Leadership Team on 6 September 2016 and entered into force the same day.

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[1] US Food and Drug Administration. 2013. "Paving the Way for Personalized Medicine: FDA's Role in a New Era of Medical Product Development". Silver Spring

[2] Personalized Medicine Coalition. 2014. "The Case for Personalized Medicine". Washington DC

[3] Senate Community Affairs References Committee. 2015. "Availability of new, innovative and specialist cancer drugs in Australia". Final Report, Canberra

[4] Medicines Australia. 2014. "Submission to the National Commission of Audit November 2013". Canberra