Patient access schemes for high-cost cancer medicines: Good in theory, difficult in practice

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created by the pharmaceutical industry to allow access to expensive cancer drugs—can be fraught with administrative problems, meaning that money does not reach the parts of the UK National Health Service that it should, if at all. The issues are discussed in a Comment in the February edition of The *Lancet Oncology*, written by Steve Williamson, Northumbria Healthcare NHS Foundation Trust Pharmacy, North Tyneside Hospital, North Shields, UK.

Some new cancer drugs have been deemed too expensive and not cost effective by the UK's National Institute for Clinical Excellence. In response, drug companies have created PAS—in which they offer discounts or rebates to the UK National Health Service (NHS), so that patients can access these drugs. For example, in some schemes the NHS will pay for the cost of the drug if the patient responds, while the drug company will pay for it if the patient does not respond. In the NHS, cancer medicines are supplied to patients in hospital provider trusts, who are then reimbursed for the cost of the medicine from the patient's local primary care trust (PCT).

The UK Government's House of Commons Select Committee on Health has raised 'serious concerns about the effectiveness of risk-sharing schemes where they place the burden of proving the success of the scheme on the NHS and not on pharmaceutical companies.'

In response to these concerns, the British Oncology Pharmacy Association undertook a questionnaire-based research project to assess the effect of PAS for cancer medicines on front line NHS staff; to identify problems with current schemes and gain feedback on how the schemes are working in the real world; and to identify aspects of a good scheme. The specific drug schemes examined were erlotinib for lung cancer, sunitinib for renal-cell cancer or gastrointestinal stromal tumour, bortezomib for multiple myeloma, and cetuximab for advanced colorectal cancer.

Data were collected from 31 NHS hospital trusts, including 756 patients entered in PAS that were in operation in the UK for at least 12 months between 2007 and 2009.

The research showed that in 47% of cases, refunds received by hospital provider trusts for two of the most common PAS (sunitinib and bortezomib) were not being passed on to the PCT, meaning that the purchasers were paying full price for the drug(s). This means there is a risk that the purchasing PCT will not accept PAS if they are not receiving the refund. The research also showed a need for flexibility in processing claims, and that 90 days should be allowed.

Almost three-quarters of responders said they could not manage PAS without paying staff to co-ordinate the schemes—as such, this could prevent future schemes being implemented. There was no consensus over which of the schemes was best or worse, although the two schemes linked to measurement of a clinical response, cetuximab and bortezomib, showed a trend towards being the worst.

The erlotinib scheme was the simplest to administer, needing an average of 17•5 min of staff time per patient episode. Sunitinib needed 19 min, bortezomib 37•5 min, and cetuximab 45 min. The research also found that minimum effect on capacity and minimum requirement for

registering patients were considered the most important factors for a good scheme.

The success of many schemes was found to depend on communication between the doctors managing the patient and the pharmacists managing the scheme. This was highlighted as a problem with the bortezomib scheme, where every missed claim due to inadequate communication results in a loss of £12 000.

There seems to be much frustration with PAS and a desire to see improvements to the way the NHS supports the implementation of these schemes. The formation by NICE of a dedicated body, the Patient Access Scheme Liaison Unit, to coordinate these schemes is seen as a positive step. Almost three quarters of respondents thought a set of nationally approved standard templates for PAS, to allow manufacturers to select a familiar off-the-shelf scheme, would be beneficial.

Williamson concludes: "Staff may spend time manually tracking patients, retrospectively adjusting stock control systems, and ensuring financial systems account for the true cost of the drug. The variations between the different schemes add to this complexity. When considering the use of PAS, organisations must consider investing in staff to implement and manage these schemes."

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