lung, prostate, and urinary tract cancers, and higher rates of oesophageal, stomach, and gall bladder cancer and leukaemia.¹²

Reducing health inequalities has been the focus of policy. However, current strategies are based on the health needs of the general population. As the pattern of health need and causes of death differ for people with intellectual disabilities, most current policies and public health initiatives will widen rather than close the health inequality gap.

This is not the only group to experience health inequalities. For example, people from ethnic minorities or those living in poverty or areas of social deprivation also experience inequality. Some needs may be relevant across groups, such as improving accessibility of services. However, the extent of inequality is greater for people with intellectual disabilities than for other excluded groups, as shown by their standardised mortality ratio. This combined with the markedly different pattern and spectrum of health need (rather than just the excess of unmet health need) indicates a requirement for specific action. This may entail redistribution of finite healthcare resources and difficult decisions regarding competing interests.

Developing guidelines can improve health by influencing policy, commissioning of services, and practice. However, guidelines can also unintentionally increase health inequalities.¹³ The amount of evidence relating to people with intellectual disabilities is less than for other groups, hence relevant issues are unlikely to be selected for development of guidelines. Assumptions are made that reports or guidelines apply to all members of the population, but panels are unlikely to have included expertise on the differing health needs of people with intellectual disabilities. Hence everyone benefits except people with intellectual disabilities. Similar unintentional discrimination can be found throughout the NHS in the United Kingdom.¹² Further discrimination in Scotland is caused by the Adults with Incapacity (Scotland) Act 2000. This prohibits research with adults who do not have capacity to consent unless their nearest relative or welfare guardian consents, but almost no one has a welfare guardian, and many adults with intellectual disabilities have no contact with a relative.

These inequalities and discrimination exist despite legislation explicitly outlawing discrimination—for example, the Australian Disability Discrimination Act 1992, the Americans with Disabilities Act 1990, the UK Disability Discrimination Act 1995, and the Human Rights Act 1998. These laws require services to make reasonable adjustments and accommodations. How-

ever, the reality is that legislation does not yet seem to have translated into improved health status for people with intellectual disabilities.

We need to change these inequalities. High quality research needs to be supported to develop the evidence base. We need to ask obligatory questions during the development of every piece of work. “How might this affect specifically people with intellectual disabilities?” “Could it possibly disadvantage some people with intellectual disabilities?” “What additional supports or reasonable adjustments are required so that it equally benefits people with intellectual disabilities?” Additionally, the population with intellectual disabilities requires specifically targeted public health interventions.

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Access to high cost drugs in Australia

Risk sharing scheme may set a new paradigm

The Australian pharmaceutical benefits scheme provides universal subsidised access to a wide range of medicines (www.health.gov.au/pbs/). Consumers make a co-payment of \$A23.70 (£8.90; €13.50) per prescription (\$A3.80 for patients who get concessions) for medicines that cost the government more than this amount (and pay in full for medicines

that cost less than \$A23.70). Prescription medicines are assessed by the Pharmaceutical Benefits Advisory Committee, which evaluates incremental cost effectiveness (including quality adjusted life years) of the prod-

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uct compared with other treatments that the new treatment could replace.¹ Expenditure of the pharmaceutical benefits scheme has been rising at some 10% per year, a rate greater than any other federal health programme, and this situation is considered by many to be economically and politically unsustainable.²⁻³ Recent listings of costly medicines used for relatively common conditions, underestimates of prescribing rates for drugs such as celecoxib and omeprazole, and prescribing beyond the approved restrictions have contributed to the increased expenditure.^{4 5}

Payers in the public and private health systems face the challenge of increasing demands for effective but expensive medicines. One approach has been to target a subset of individuals in whom acceptable cost effectiveness has been shown. The recent listing of etanercept for the treatment of rheumatoid arthritis illustrates an attempt to balance competing health, economic, societal, and ethical demands.

The listing of etanercept in the pharmaceutical benefits scheme costs government \$A1888 per month per patient.⁶ It emerged from a unique collaboration between the key stakeholders—the Pharmaceutical Benefits Advisory Committee, the sponsor (Wyeth), rheumatologists, and consumers (Arthritis Foundation of Australia and Arthritis Research TaskForce). These stakeholders addressed issues of efficacy, cost effectiveness, and possible arrangements for access. They agreed on eligibility criteria for the initial prescription and for continuation of treatment beyond three months.^{6 7} Prescribing rights were limited to rheumatologists and evidence was required that patients agreed to abide by a decision to stop treatment at three months if response criteria were not met. The Pharmaceutical Benefits Advisory Committee felt that etanercept would achieve acceptable cost effectiveness if listed under these restrictions.

The annual expenditure for the pharmaceutical benefits scheme from this endeavour was predicted to be up to \$A140m by the government. Wyeth believed that outlays would “not exceed \$A100m” and agreed to pay for expenditure above this figure.⁸ This risk sharing agreement provided incentives to the sponsor to promote the drug in accordance with the restrictions and to prescribers and consumer organisations, to avoid leakage to individuals outside the restrictions. Other risk sharing arrangements have been adopted elsewhere—for example, in the United Kingdom for access to interferon beta and glatiramer acetate for multiple sclerosis.⁹

Several questions emerge as this novel programme of access evolves. Will the collaboration of stakeholders remain intact as the programme is implemented? Will the agreement process for patients be acceptable and effective? How concordant was the prediction with actual usage of the drug and the number of eligible patients according to the criteria? How effective will be the risk sharing agreement in containing costs but achieving desired patient health outcomes? How does the system manage patients who received the drug as part of a clinical trial or an early access programme and who have shown a benefit but do not meet the eligibility criteria for subsidy?

The key to evaluation will be accurate and timely data. National datasets will provide information on prescription rates, but these are not linked currently to information on health outcomes in individual patients.

The Australian Rheumatology Association has recently established a national database to track patient outcomes over the long term. These data will allow the stakeholders to determine whether the restrictions are achieving the desired clinical responses.

Arrangements for access will need revision as new data emerge and other drugs in the group are listed. The importance of the rheumatoid factor status as a modifier of the treatment effect and the decision to exclude patients who are negative for rheumatoid factor has been contentious. Broadening access criteria will depend on the government's confidence that predictions of usage are accurate, and that all stakeholders, including those at the grass roots, embrace criteria for starting and stopping etanercept. The unique consultation process that achieved a consensus on access to etanercept in Australia may set a new paradigm for ensuring equitable distribution of limited resources based on evidence and ethical practice. It may thus allow sustainability of publicly subsidised access to effective but expensive treatments. Whether the collaboration is durable as the programme unfolds and the lessons learned used to improve the system will have far reaching consequences for publicly funded formularies such as the pharmaceutical benefits scheme.

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