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Using population-based routine data for evidence-based health policy decisions: lessons from three examples of setting and evaluating national health policy in Australia, the UK and the USA

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ABSTRACT

Background The desire for evidence-based health policy and practice is well established. Routine population-based health information systems play a fundamental role to inform policy decisions and to evaluate their effectiveness.

Methods This paper presents three case studies of using population-based data in national health policy from three countries—USA (prescription drug safety), Australia (childhood immunization) and UK (hospital waiting times)—which were chosen to represent a diversity of health policy issues. The utilization of population-based databases and the social and political context in which the data were used are examined. Our goal was to summarize general lessons learned for policy decision-makers and other users and developers of population-based databases.

Results Key lessons presented include: the importance of political will in initiating and sustaining data collection and analysis at a national level; the types of decision-making factors databases can address; and how the data were integrated into the decision-making process.

Conclusion Population-based routine data provide an important piece of the mosaic of evidence for health policy decision makers. They can be used to assess the magnitude of the health problem, including which populations are most vulnerable; to develop policy goals; and to track and evaluate the effectiveness of health policy interventions.

Keywords decision-making, evaluation, health policy, retrospective databases, routine databases

Introduction

The desire for evidence-based healthcare and public policy, and its goal of rational decision-making, is well established. Perhaps, the movement is no where more developed than in the practice of evidence-based medicine, for which there are several national and international forums for evaluating the body of evidence supporting healthcare interventions.[1–4] Interest in, and application of, evidence-based health policy and practice has also grown.[5–7] For example, a major component of the US Agency for Healthcare Research and Quality's mission is increasing the visibility and usability of scientific findings for policy making in a format that is 'actionable and solution oriented'.[5] In the UK, policy makers have taken the pragmatic political stance of measuring 'what works?' to ensure better policy development and delivery.[7]

However, evidence-based policy differs from evidence-based medicine in one important aspect, that is, the 'decision-making context' may be as, or more, important as the level of 'evidence'.[8] In evidence-based medicine, systems for determining the level of evidence favor randomized clinical trial data over observational study data.[9,10] However, the most policy-relevant data for decision-making may never come from randomized trials. Policy makers are as interested in the 'distributional consequences' of their policies—that is, who has to pay, how much, and who benefits—which cannot be obtained from controlled clinical trials.[1,8,11]

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Likewise, randomized trials are conducted in non-representative patients carried out by non-representative doctors, which severely limits their usefulness for informing large-scale policy decisions. This is reflected by the sometimes wide discrepancy between efficacy results from randomized trials and effectiveness in routine care, the latter often being substantially lower. Moreover, in many circumstances policy makers do not have the luxury of time nor ethical acceptability to conduct randomized controlled trials testing different health policy options to guide their decision-making. Instead, routine population-based health information systems play a fundamental role for evidence-based health policy,[12,13] which is largely underutilized. They provide both the quantitative information needed for setting priorities and establishing rational health policy and the real-world context for understanding how the policy affects the public.

The purpose of this paper is to analyse three case studies of how population-based data have been used in evidence-based health policy and practice in different settings and countries. The examples come from the USA (prescription drug safety), Australia (childhood immunization) and the UK (hospital waiting times). They demonstrate the use of retrospective and prospective routinely collected health information in setting and evaluating national health policy. Each case example examines the utilization of population-based evidence and the social and political context in which the data were used. Our goal was to summarize lessons learned for health policy makers and other users and developers of population-based routine databases.

Childhood immunization in Australia

In 1993, the National Health and Medical Research Council (NHMRC) made recommendations to the Federal Ministry of Health and Ageing for a National Immunization Strategy to increase immunization rates in Australia. This led to wide ranging reforms in funding, provision, storage, surveillance and reporting of vaccine preventable diseases.[14] However, immunization rates did not increase sufficiently, and reform measures were expanded in 1997 through the Immunize Australia 'Seven Point Plan'.[14] The Immunize Australia Program is a joint Federal, State and Territory Government initiative in partnership with local governments, immunization providers and community-based organizations. Reforms included immunization requirements for family benefits and school entry, education campaigns and infrastructure development.

Australian childhood immunization register

The Australian Childhood Immunization Register (ACIR) is a national registry established in 1996 that monitors vaccinations given to children under 7 years of age who live in Australia. Its goal is to measure and promote age-appropriate childhood immunization throughout Australia.[15] As part of the Seven Point Plan, quarterly reporting on national immunization rates was instituted to provide immunization coverage data for governments, immunization providers, parents and key stakeholders.[16] The database is maintained by Medicare Australia and data are added by health care providers on a local community and individual level. Indicators include the percentage of children fully immunized at 12, 18 and 36 months.[17] ACIR data are published quarterly in Communicable Diseases Intelligence and in other on-line publications.[18]

Other population-based data sources reporting on health outcomes are used to supplement ACIR vaccination rate data and to facilitate the implementation of evidence-based immunization policy and program development in Australia. For example, outbreaks of vaccine preventable diseases are monitored using the National Notifiable Diseases Surveillance System (NNDSS).[19] The Australian Institute of Health and Welfare (AIHW) National Hospital Morbidity Database provides information on hospitalizations due to vaccine preventable diseases or adverse events associated with vaccination,[20] and data from the AIHW Mortality Database can identify deaths attributable to vaccine preventable diseases.[20]

How population-based data were used for vaccine policy

Data obtained from the ACIR, combined with the other national databases on hospitalization, mortality and disease notification, are used to guide Australia's national immunization policy. For example, in 2001, a pneumococcal vaccine was funded as part of a targeted national immunization program for Indigenous children and children with underlying medical conditions. On the basis of results obtained from the ACIR, the National Centre for Immunization Research and Surveillance of Vaccine Preventable Diseases found that the incidence of invasive pneumococcal disease in Indigenous children under 2 years of age was lower than the levels in non-Indigenous children; whereas prior to the implementation of the targeted pneumococcal vaccination program, there was a disparity in the reverse direction.[21] On the basis of these findings, it was decided that the vaccination program would be extended to provide free pneumococcal conjugate vaccine for all children at 2, 4 and 6 months and a catch-up for children under 2.[22]

ACIR data are also routinely reviewed by the Australian Technical Advisory Group on Immunization (ATAGI), an advisory committee to the Minister for Health and Ageing,

as part of the policy review process. For example, ACIR data on overall vaccination rates were presented and reviewed at the 2004 national immunization conference.[23] At the final session of the conference, which is traditionally when resolutions are developed, the ATAGI and the NHMRC recommended to establish universal vaccination coverage for all children at 2, 4 and 6 months and a catch-up vaccination for children under 2.

Lessons learned

Table 1 summarizes application of ACIR and the other morbidity and mortality databases for childhood immunization policy. Experience in Australia shows that strong political support accompanied with funding for a national vaccination delivery program and immunization registry to monitor progress and set goals has led to significantly improved immunization rates for children in a short timeframe. In 2004, 12 month immunization rates increased to over 90% from 75% in 1997.[24]

Routine analysis of gaps in vaccination coverage and operational efficiency is an institutionalized component of Australia's evidence-based vaccination policy. For instance, the cost of extending the pneumococcal vaccination for universal coverage was estimated to increase in cost from $6 million per year (coverage for high-risk children alone) to $50–$60 million.[25] Population-based surveillance data play an important role in determining the incremental gain of expanded policy such as this.

Lessons from Australia also suggest the importance of continually engaging and incentivizing national and local stakeholders at the national and local level. Within the Australian government structure, there are defined roles and responsibilities for the different layers of government, advisory committees, research centers and the Department of Health and Ageing, which allows these groups to collaborate better and support each other in decision-making activities. The General Practitioner (GP) Immunization Incentive provides financial reimbursement for GPs who achieve immunization goals within their clinical practice and has been an important factor for increasing awareness and knowledge of immunization and in gaining GP support for carrying out immunization services.[26]

Table 1 Case example of the use of population-based data for evidence-based health policy decision-making in Australia

Health policy	*Childhood immunization*
Population-based databases	Australian Childhood Immunization Register (ACIR) National Notifiable Diseases Surveillance System (NNDSS) National Hospital Morbidity Database
Application for specific policy questions[a]	Size of the problem—How many children have not met immunization goals? Equitability—Have immunization resources been distributed fairly? Policy effectiveness—Did immunization rates increase? Were there outbreaks of vaccine preventable diseases? Incremental gain—What is the additional cost of expanding immunization coverage and potential health benefits compared to what is already being done?
Advantages	Clear delineation of roles and responsibilities across government policy makers, advisory committees, and researchers analysing these data Population-based analysis of vaccination delivery and operational efficiency is now a standard part of the national immunization decision-making process Ability to relate immunization rates with outbreaks of vaccine-preventable diseases
Limitations	Challenges in adequately measuring vaccination rates and outcomes in remote populations, such as the Indigenous peoples

[a]Applications adapted from factors in health policy and practice decision making [1].

Hospital waiting times in the UK

Reducing hospital care waiting times in the UK has remained a government priority since the introduction of the National Health Service (NHS) system in 1948. Despite political and social will for improvement, waiting times had remained suboptimal. In 1989, one-third of people on the waiting list had waited more than 1 year, and by 1997 there were 1.3 million people on waiting lists, an all-time high for the NHS.[27] Reducing the number of people on waiting lists was one of the Labour party's main priorities when they took office in 1997. In 2000, the government introduced reform measures to progressively reduce the number of people waiting and the maximum waiting time.[27] In order to meet national health policy goals, the government created the NHS Modernization Agency and introduced treatment

centers with targeted initiatives to reduce waiting times, such as, the introduction of patient choice, tighter management of hospital care and the hospital 'star-rating' system. In 2005, new policy initiatives were undertaken with the goal that by 2008 no patient should wait longer than 18 weeks from receiving a GP referral to hospital admission.[28]

NHS Trusts and other data sources

Population-based data have been vital in establishing policy goals and tracking the effectiveness of government initiatives aimed at reducing hospital-waiting times. Up-to-date information on waiting times is published monthly by NHS Hospital Trusts and by Primary Care Trusts for the population at large. Information on national waiting times for outpatient appointments, hospital admissions and elective procedures are publicly available by provider and by commissioner on the Department of Health website (www.performance.doh.gov.uk/waitingtimes/). Individual NHS Trusts also collate information for their use on a monthly basis. For example, the Queen's Medical Centre University Hospital NHS Trust has a monthly internal publication with a breakdown of waiting times by specialty and consultant at their center. This monthly internal publication is used to produce a monthly 'Waiting Times Report', which is regularly released to GPs.[29]

How population-based data were used for the waiting list policy

The government's investment in population-based data tracking created the infrastructure for evaluating the effectiveness of waiting time interventions. For example, data from the Department of Health showed that the number of people treated who were on waiting lists declined, during 2000–2004; however, the number of people with long waits did not decrease.[27] Research by the Audit Commission found significant variation in waiting times for certain procedures at different Trusts and even within Trusts.[30] The Queen's Medical Centre found an inverse relationship between high waiting list densities and low patient referrals, suggesting that there was some form of informal demand management by GPs.[29]

Waiting list data have also been routinely used to establish and justify the government's national waiting list goals. For example, the move toward 'no patient should wait longer than 18 weeks from receiving a GP referral for hospital treatment' was a direct result of the on-going data tracking and findings on the variation of waiting times at different Trusts. Expert advice, using cumulative waiting time data along the care pathway, was used to set this numerical target.

Waiting list data have also been used to reframe the policy discussion. For instance, the Audit Commission report highlighted national differences in the management of waiting lists and suggested system-based improvements to increase hospital capacity and more efficiently manage waiting lists.[30] The King's Fund highlighted the need for a new framework to look at waiting lists and elective procedures and the need to understand the interplay between GP referrals, hospital capacity and supply of physician specialists.[31] Given the variability in waiting times between Trusts, the Modernization Agency has taken a similar systems approach and has recommended each Trust analyse its own patient care pathway from GP referral to hospital admission in order to identify opportunities for improving the total patient referral process.[32]

Lessons learned

Application of the NHS Hospital and Primary Care Trust data is summarized in Table 2. The UK experience represents a successful model of using population-based data to monitor the impact of national health care policy and to guide rational policy decision-making. Strong political will and support for the collection of credible, population-based data contributed to comprehensive waiting list reforms in the UK. Because the NHS is a national health system, data on hospital waiting times could be feasibly collected from a single source and analysed both nationally and locally to aid political decision-making. Efforts of non-governmental organizations to improve data collection and measurement allowed Trusts to ensure the data used for making decisions were valid, reliable and current.

Data transparency was another factor contributing to the success of the UK's hospital waiting lists policy reform. Research using hospital waiting list data is regularly reported in the media and in leading medical journals (e.g. the BMJ) raising public and health professional awareness of the issues and the progress being made.

Policy implementation challenges have centred on the 3-year political election cycle in the UK and the ability to sustain long-term reform. Although the government understands the importance of collecting data and measuring the effectiveness of policies, the NHS Trusts must re-compete for government priority and funding to sustain on-going measurement of hospital waiting times. Another barrier for long-term reform may be its sustainability. It may also be difficult for the government to continually decrease waiting times as eventually costs may exceed incremental gains. Maintaining waiting list data collection over time will be important for evaluating temporal trends and for determining whether a shift in policy focus will be required.

Table 2 Case example of the use of population-based data for evidence-based health policy decision-making in the UK

Health policy	*Hospital waiting lists*
Population-based databases:	NHS Hospital Trusts NHS Primary Care Trusts
Application for specific policy questions[a]	Size of the problem—What is the public health burden of long waiting lists? What should the reform goals be? Equitability—Are long waiting times distributed fairly? Problem preventability—What is known about the health care system components contributing to long waiting lists? Are they modifiable? Incremental gain—What are the additional costs associated with reducing waiting times further? Intervention effectiveness—How much were waiting lists and waiting times reduced? How did this vary by Trust?
Advantages	Single national data collection system ensures consistency in data quality and reporting Ability to produce national and local Trust reports to meet the needs of both national policy makers and local hospital administrators and GPs Monthly reports available for timely decision making
Limitations	Sustainability over time as political parties and priorities change

[a]Applications adapted from factors in health policy and practice decision making [1].

Prescription drug safety in the USA

In the USA, there is public and political interest in strengthening the drug safety system. Several highly publicized market withdrawals of popular drugs have compromised the public's perception of the Food and Drug Administration (FDA) and the pharmaceutical industry.[33] As the Institute of Medicine's report on *The Future of Drug Safety* notes, most stakeholders in the USA, including the FDA, the pharmaceutical industry, consumer groups, Congress and medical societies, agree that drug safety reform is needed.[34]

Pre-marketing data are inherently limited in their ability to fully dimension a drug's safety profile. At the time of drug approval, there is typically too few subjects, too short of follow-up and too homogeneous of a patient population to adequately identify all drug risks, particularly after its use broadens in clinical practice.[35] In the past, the FDA's Adverse Event Reporting System (AERS) has been the primary surveillance tool for identifying emerging post-marketing drug safety issues; however, it relies on passive reporting.[36,37] AERS has been a useful data source for identifying new safety signals.[36] Today, health policy experts have called for more active surveillance of drug safety,[34,38] including recommendations for routine 'data mining of existing health-record databases . . . to pick up early warnings of adverse side effects'.[38]

Retrospective health record databases

Automated health-record databases in the USA have generally been administrative, that is, the data are derived from requests to insurers for health care payments, or claims, for clinical services and therapies. These retrospective databases have several important advantages, including a large, population-based sample of clinical care, data already collected and relatively inexpensive to use and information on all medical care provided, regardless of who the provider was, without the risk of recall and interviewer bias.[39] Health care databases are ideal for evaluating health service utilization and prescribing patterns. The major weakness of administrative claims data is the uncertain validity of medical diagnosis, and information on some potentially important confounding factors, such as smoking status and alcohol use, may be lacking.[39] Medical records data have the added advantage of greater validity of a patient's medical history because the physician-made diagnoses are directly recorded.

Several medical record databases have been used for drug safety research in the USA (Group Health Cooperative, Kaiser Permanente Medical Care Program, HMO Research Network/Harvard Pilgrim, UnitedHealth Group, and state Medicaid programs); Canada (Saskatchewan Health Services Databases); and Europe (Automated Pharmacy Record Linkage in The Netherlands, Tayside Medicines Monitoring Unit in Scotland (MEMO), and the UK General Practice Research Database (GPRD)).[40] The FDA directly contracts with four database groups to monitor adverse effects of marketed drugs.[41] The International Society for Pharmacoeconomics and Outcomes Research (ISPOR) maintains an online digest of retrospective databases (http://www.ispor.org/Intl_Databases/index.asp).[42]

How population-based data have been used for drug safety regulation

Retrospective health record databases are a valuable resource for drug regulatory decision makers. They have been used for post-marketing safety surveillance[43–45] and for

evaluating the effectiveness of risk management interventions, including their impact on physician prescribing and patient monitoring.[46–48] Medical record data provide a context for interpreting spontaneous adverse event reporting data and a means to conduct epidemiological studies for testing specific hypotheses on drug-adverse event associations,[49] particularly in assessing rare adverse events.[50] In fact, the FDA and other health agencies formally support the conduct of population-based studies for assessing drug risk[51–54] and evaluating risk minimization interventions.[52,55]

Cardiovascular risk with COX2-selective non-steroidal drugs (NSAIDS) is one example in which retrospective data have been used to estimate the magnitude of safety risk associated with these drugs and to inform policy decision makers. FDA researchers found increased risk of heart attacks among users of rofecoxib (Vioxx®) compared to celecoxib (Celebrex®).[43] Although the manufacturer of rofecoxib withdrew the drug from the market primarily based on results from a large randomized, placebo-controlled trial,[56] the observational data contributed to the FDA's decision to add warnings for all prescription NSAIDS and to revise labeling for over-the-counter NSAIDS.

Administrative health record data have also been used to determine whether interventions to minimize drug risk were successful. In the case of propulsid (Cisapride®), a popular heartburn drug associated with a rare, but potentially fatal heart arrhythmia, FDA's warning and the 'Dear Doctor' letter notifying physicians which patients should not receive cisapride, had no effect on prescribing behavior.[46] In the situation of troglitazone (Rezulin®), an anti-diabetic medication with the risk of acute liver failure, three successive waves of risk communication from the manufacturer were ineffective in changing adherence to recommended liver enzyme monitoring.[47] Both drugs were withdrawn from the market as a result of these studies. Importantly, they were also landmark studies demonstrating the ineffectiveness of traditional risk management interventions and the need for post-marketing drug safety reform in the USA.

Table 3 Case example of the use of population-based data for evidence-based health policy decision-making in the USA

Health policy	*Prescription drug safety*
Population-based databases	Administrative health record databases Medical record databases
Application for specific policy questions[a]	Size of the problem—What is the actual safety risk? How many patients are affected by the risk? Problem preventability—Can the safety risk by minimized by preventing use in some patients or adding monitoring in others? Intervention effectiveness—Did the risk minimization program work in changing behavior or improving health outcomes? Benefits and harms—What are all the consequences of the risk minimization intervention? Are some patients being harmed by the policy because access is restricted? What is the trade-off?
Advantages	Large sample, particularly beneficial for investigating rare adverse events Readily available and relatively inexpensive data that can be analysed quickly for time-sensitive drug safety questions Electronic data that can be analysed by multiple stakeholders to increase transparency and credibility of the results
Limitations	Insufficient analytic capacity and capability to meet the policy demand for routine data mining of these databases, but this is a focus for future growth Retrospective data may not include information on some relevant confounders in health risk

[a]Applications adapted from factors in health policy and practice decision making [1].

Lessons learned

The use of population-based data has an important role in drug regulatory policy in the USA. Application of electronic health record databases for drug risk assessment and management is summarized in Table 3. Retrospective medical record databases not only provide readily available data for timely decision making, but the fact that the same data are analysed by policy decision makers, academic researchers and the pharmaceutical industry enhances the credibility and transparency of the findings. Unfortunately, funding for this research falls short of the demand.[34] Instead, more researchers trained in pharmacoepidemiology, drug safety and risk management are needed in the USA to increase research capacity for this important policy-relevant work.[57]

Discussion

Main findings

This paper presented three case studies of how population-based routine health data have been used successfully for

setting and evaluating national health policies in Australia, the UK and the USA. In the US example, retrospective health record databases were used to assess post-marketing drug risk and to evaluate the effectiveness of risk minimization interventions in clinical practice. In Australia, a national immunization register was established by policy makers to monitor progress of their national immunization program and to identify vulnerable groups requiring additional interventions. In the UK, NHS Hospital and Primary Care Trusts used data on hospital waiting list times to establish reforms and evaluate their effectiveness. In each case, real-world data sources provided timely results, which were important pieces of evidence decision makers used in formulating evidence-based health policy.

What were some of the factors that contributed to the successful utilization of population-based data in national health policy? First, in all three examples there was strong political will supporting the value of population-based evidence in public health decision-making. This political will translated into financial support to either create new databases, as in the UK and Australia, or to purchase access to existing databases for retrospective analysis, as in the USA. Second, evidence-based health policy formulation requires regular updates of information.[6] In each example, routine reporting became institutionalized as the value of the data for public health decision makers was established. In each case, the findings were also shared at scientific forums and with the public, which improved transparency of the evidence including how it contributed to health policy decisions.

What is known already

Population-based databases provide many advantages for health policy makers. For example, 'decision makers often confront the pressing need to act' and routine data sources inform policy makers with timely and current information needed for decision-making.[1] Evidence-based policy must also address the needs and values of the population because policy decisions are made in the context of competing social, financial and political goals.[58,59] Population-based data reflect real-world experience, which facilitates the generalizability of the findings and allows better comparison with other public programs. Population-based data also help to answer questions on the size of the public health problem and intervention effectiveness and equity.

What this study adds

This study provides tangible examples of how population-based routine data have been applied in real-world public health settings. So how transferable are the lessons from these three policy examples to other health policy issues or to other decision-making forums? We found the lessons from these USA, Australian and UK examples were similar to other cross-sector policy lessons reported by Nutley and colleagues.[60] Namely, evidence based policy and practice works best when there is agreement on priority, a strategic and systematic approach to the selection or creation of the evidence, broad dissemination of the evidence, and initiatives to institutionalize and facilitate integration into the policy decision-making process. However, other national settings may not have the financial resources, capability, or political will to replicate and sustain data collection on such a frequent or national scale. Although learning from the World Health Organization's Global Burden of Disease project suggests data collection every three or 5 years may be sufficient for some health policy questions.[6]

Limitation of this study

The primary concerns of case study evaluations center around generalizability and validity and reliability.[61,62] Clearly, each example is not representative of all health policy decision-making in its respective country. Rather, the goal of these case studies was to explore the contextual factors associated with health policy and practice decision-making when applying population-based routine data so that it might stimulate discussion among public health decision makers endeavouring to achieve evidence-based policy. To address concerns about validity and reliability, we employed the process of triangulation, i.e. the use of a variety of data sources as opposed to relying solely upon one observation. We also consulted with key public health informants experienced with the case examples we explored for additional policy background.

In summary, routine population-based data provide an important piece of the mosaic of evidence for health policy decision makers. They can be used to assess the magnitude of the health problem, including which populations are most vulnerable; to develop policy goals; and to track and evaluate the effectiveness of health policy interventions. The three case examples from Australia, the UK and the USA demonstrate the utility of using routine database evidence for different health policy issues in different political and health care settings.

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