Feedback on

Strategic Review of Health and Medical Research in Australia

CONSULTATION PAPER SUMMARY

Issues and Proposed Recommendations

Draft for Public Comment

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Foreword *(page 4)*

> **' … The Australian Government is keen to ensure that its investment is used wisely and equitably so that *all* Australians benefit through better health outcomes, and so that it delivers the greatest economic value.**
>
> As we face a trajectory of unsustainably increasing healthcare costs, **Australia needs a comprehensive strategic plan to ensure it optimizes government investment in health and medical research.** In establishing this Review, the Australian Government has taken a vital step in support of this need. … '
>
> **' … In addition, an overarching message that emerged from the plethora of evidence was the lack of a sufficiently strong connection between health and medical research and the delivery of healthcare services.** Thus, the Panel's overarching vision for the future of health and medical research is one where research is fully embedded in all aspects of healthcare to deliver **'Better Health Through Research'.** … '

1. Executive Summary *(page 5)*

> Vision. The Panel's vision for health and medical research (HMR) is 'Better Health Through Research'.
>
> **[(1)]Better health encompasses population health outcomes, such as increased life expectancy, as well as *social goals such as equity, affordability and quality of life.**
>
> **[(2)]HMR is the R&D arm of Australia's $130bn health sector, so investment in research is vital to support innovation, performance improvement, and curtail escalating healthcare costs.**
>
> **[(3 & 4)]The vision is for a high quality and efficient health system, where a defined proportion of the health budget is invested in research in the health system and where all research activity is well managed to deliver health impact.**
>
> Initially, the focus should be on spending current investment more effectively. Within the next ten years, an additional $2–3bn p.a. should be invested in research to deliver a better health system and an additional $0.4–0.6bn p.a. for other initiatives. The strategy to achieve this vision has seven themes:

NB *Quality of life (QOL) is a complex measure of individual health status that includes amongst other measures, the degree of pain and suffering and the degree this impacts upon capacity to achieve social goals.

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Feedback

1. Roadmap to achieve 'better health'

(a) 'Better health' necessitates the question… better than what?

It is not possible to provide reliable evidence of improved health without a baseline measure, and Australia does not routinely or centrally collect high quality, transparent patient health outcomes data to provide a reliable baseline measure. We can't measure and provide evidence of 'better health' if there is nothing to measure against.

In the absence of a central health data collection, 'better health' will remain an 'ideal' that can't be readily translated into achievable, measurable goals, and in the future, absence of a central data collection will hinder efforts to present any reliable evidence of 'better health' outcomes being achieved.

The highest priority, therefore; must be to capture high quality, transparent patient health outcomes data that can be reliably put to meaningful use.

(b) Aiming for high quality, transparent public health outcomes data

High quality data has a high degree of integrity and reliability based on its;

- uniformity (common language, definitions, interpretation and understanding);
- completeness;
- accuracy;
- timeliness;
- transparency, and;
- degree of static assurance (secured against alteration).

A foundational patient dataset that will be utilised by all scientific disciplines must, therefore, as a critical prerequisite; be developed and managed within a structured governance framework to the highest possible degree of uniformity, completeness, accuracy, timeliness, transparency, and a degree of assurance that it has not been, and cannot be altered.

Data Uniformity

Free reign of health and eHealth market forces has resulted in a landscape that lacks uniformity due to the use of various terminologies, technologies, and processes in use, and subsequently; data can be misunderstood, misinterpreted or misrepresented which infers Australians are subjected to an unnecessary degree of higher risk of poor quality health outcomes

For health and medical research to gain the most effective traction from reforms, everyone must start from the same solid, reliable, foundational starting block.

Progress to introduce a common health and medical nomenclature has been made but is not yet complete.

Australia needs to learn how to walk before it can run

Rubbish in, rubbish out. Data without integrity leads to unnecessary (avoidable) higher risk of less optimal outcomes.

Poor quality or gaps in public health data will lead to less reliable clinical guidance, higher risk of adverse health outcomes that could have been avoided, and HMR activities and outcomes that are less productive and reliable where this data is applied across;

- biomedical research;
- statistical analyses;
- short and long term studies;
- clinical trials;
- treatment reviews;
- federal and state policies;
- programs and budgets;
- grant funding, and;
- all other linked activities.

Subsequently, it would also have a degree of negative impact upon Australia's national and international scientific contribution and reputation.

Clearly, critically, public health data completeness, integrity and reliability should be THE starting point from which ALL guns can then be fired.

Australia needs a sounder foundation for future meaningful purpose and use of public health data.

Australia must prioritize development of a comprehensive public health dataset that has integrity and reliability to secure the future prospects of health and medical research and outcomes in this country;

- **so that every outcome generated from that sound foundation can be reliably tested and attributed with the same high degree of integrity at any future point in time (data and outcomes Australia and the rest of the world can take to the bank), and;**

- **so we can all achieve our collective aspirations for a perpetual cycle of improvements/gains in the health outcomes of all Australians.**

Australia must secure, protect and manage this critical investment through developing a robust public health and eHealth data governance and management framework that is completely removed from, and protected against all undue influences or conflicts of interest.

2. Meaningful use to achieve 'Better health' necessitates population health comparative treatment effectiveness

The meaningful purpose of HMR is to contribute value to national public health outcomes through maximising improvements in long term quality of life and increased life expectancy for its citizens, individually and collectively, which in turn will maximize the productivity and sustainability of our subsidized public health system, already under threat.

A dedicated scientific focus on comparative treatment effectiveness has long been overlooked as a pathway to improving health outcomes and/or reducing subsidized healthcare costs.

Comparative treatment effectiveness should begin with an analysis of present outcomes (the degree of short and long term improved or adverse health outcomes), and should then scope/retrace and map the variable factors within patient health profiles that contributed to those outcomes, in order to analyse which individual or collective factors contributed across a scale from best to worst outcomes, and to determine priorities in direction and funding.

Mapping of health outcomes and variable factors would;

- back-fill the gaps in our health and medical knowledge and data;
- create valuable new knowledge that supports cyclic improvement in primary healthcare, clinical decision-making, and health outcomes;
- enable new and/or more detailed population health measures and statistics;
- inform and justify subsidized public health funding;
- dramatically enhance, inform and justify productivity and economic models and measures;
- inform National Public Health and Medical Research (NPHMR) prioritized direction and funding and justify investment in HMR in the public's best interest, and;
- dramatically improve upon present limited measures of the value of health and medical research and its contribution to Australians and the Australian economy.

For example; rather than a simple count of the number of publication citations in scientific papers, health and medical researchers would have access to a far wider range of 'real-life' measures and statistics of 'real-world' health outcomes from their research; its beneficial impacts on population health and the economy and the degree to which they have contributed to the economic sustainability of our subsidized public health system.

We must question the wisdom of over-representation of HMR resources on futuristic goals with too great an emphasis on 'new treatments' (discoveries that have the greatest potential for new patent applications and development of new products) whilst we are continually overlooking and under-representing present-day potential to comprehensively scope and share what's working right now.

We can economically rationalize the need for more productive outcomes in the current healthcare environment. If we map and share all the factors of successful or beneficial outcomes, then we dramatically improve our capacity to perpetually increase the number of successful or beneficial outcomes, and through working smarter, we also improve productivity.

Australia needs to capture, measure and analyse outcomes and variables in a structured and routine way so we can gain new knowledge of how and why some patients experience 'better health' outcomes than others (sometimes dramatically so), and all the variable factors involved in those most desirable of outcomes:

I. What data presently exists and what is the degree of its reliability as justifying evidence for individual and/or collective health outcomes? Are there gaps in that evidence, and what measures must be taken to fill those gaps to improve data integrity and reliability?

II. Which health protocols, treatments, or interventions contribute to short and/or long term improvement in health outcomes, to what degree, and which do not?

III. Which contribute to short and/or long term adverse health outcomes, and to what degree?

IV. Which health protocols, treatments, or interventions represent the highest quality and least invasive options or pathways to the best short and/or long term health outcomes? What were all the variable factors involved and are they mappable and reproducible?

V. Which health protocols, treatments, or interventions represent the most invasive options or pathways with the worst short and/or long term health outcomes? What were all the variable factors involved and how can that risk best be avoided or minimized?

VI. How can we best share all that information to maximize opportunities to improve short and/or long term health outcomes, minimize adverse health outcomes, stop or alleviate avoidable, unnecessary suffering and maximize health workforce and HMR productivity?

VII. How can we comprehensively capture reliable evidence that justifies improvements and achievements across better health, social, and economic outcomes so we can report on the value of this dedicated investment in the best interest of all Australians?

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VIII. How can we best measure the present and future economic contribution of reforms to the sustainability of our subsidized public health system and HMR?

IX. Is there a suitable, proven economic model available today that we can employ to reliably model economic return, quality of life, and social value of HMR? No. Could Australia lead the world in initiating and developing such a model after if it had optimized foundations for quality assured, reliable public health dataset, secured and protected within a governance framework? Yes.

It is often said of data collection and analysis… 'rubbish in, rubbish out'.

We pose good questions but when we pose them to incomplete or bad (corrupt) data, we get incomplete or wrong answers.

The outcome of every historical or proposed reform or solution, policy, project or program is dependent upon that, as is its funding/investment.

If we want reliable, testable, justifiable outcomes, they must be based on reliable evidence (data).

If we want reliable, testable reforms, solutions, policies, projects or programs that adequately justify public or private funding/investment, then we must first prioritize routine, structured collection of the highest quality data by ensuring its completeness, integrity, reliability and eminent testability from any angle.

Commendably, the Strategic Review recommendations included the development of a 'patient database'.

The final recommendation should provide clear guidance that optimizes the potential of Australia's new ehealth system to fulfil that recommendation, as it will underpin and support all other Strategic Review recommendations:

Australia's new eHealth System and Personally Controlled Electronic Health Records (PCEHRs)

Australia's new eHealth system will utilise information technologies (IT) to facilitate and streamline team-based healthcare networking and co-ordination.

It will also facilitate consolidation of a patient's healthcare history into a single patient health profile (PCEHR) that can be shared across care dimensions.

PCEHRs can also be de-identified and merged with others to create a single patient population health database or other health-related sub-groupings for the purpose of individual or collective mapping, analysis and measurement.

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Unfortunately a key aspect of potential evidence in a patient's health profile will be missing due to the PCEHR not being purposefully designed as a comprehensive patient health profile to facilitate meaningful purpose and use in clinical decision-making or HMR.

The PCHER was designed to meet the everyday needs of healthcare practitioners and patients but not for secondary health and medical use, such as comparative treatment effectiveness which would support clinical decision-making, priority-driven or curiosity-driven HMR.

Patients have been given capacity to contribute some information to their PCEHRs but that contribution has been limited to allergies, living wills, organ donation status, and unstructured, freehand diary notations of little use to physicians and health and medical researchers.

The PCEHR has not been designed to fill gaps that already exist in Australia's health data collections through facilitating valuable structured, self-reported feedback from patients on treatment effectiveness, eg;

- drop down lists to capture treatment side effects;
- quality of life surveys and measures;
- symptom lists to aid health outcome tracking, measures and graphing, and;
- reasons for patient treatment variations, compliance or non-compliance with recommendations, etc.

The PCEHR has not been designed to collect new and valuable aspects of health outcome evidence through enabling patients to self-report their experiences and outcomes in structured ways, and so it will not have capacity to enhance the completeness of patient health profiles, nor generate new knowledge, nor improve the testability or reliability of clinical and research data on health outcomes.

Subsequently, clinical and research data and outcomes will to be considered less reliable, and; data collections based on those outcomes will have to be devalued and considered to have less integrity; as will all HMR activities and outcomes based on the same incomplete data.

The Strategic Review should clearly state that the degree of completeness, integrity and reliability of every aspect of Australia's 10-year Strategic Plan for Health and Medical Research (every policy, resource, funding, justification, or measure of achievement or economic return across all people, process and technologies) will be fully reliant on the degree of completeness, integrity and reliability of the underpinning health and medical population health data upon which it is all based.

3. The difference between Visions and Missions

Vision statements are blue sky statements with non-defined goals and plans, and where often, desired outcomes are also non-defined with little prospect of being achieved, evidenced or measured.

Visions result in disjointed activities, inefficient use of resources, and loss of productivity. Alternatively, mission statements are unifying statements that promote alignment of all activities under a meaningful purpose and enhance the prospect of efficient and meaningful use of resources (enhance productivity).

Mission statements define and clarify meaningful purpose, which in turn guides associated strategic and operational planning frameworks, goal-setting, resource allocation, activities and outcome measures, so all are united, aligned and can work collaboratively and productively toward one or more aligned primary and secondary goals.

This was and remains the reasoning behind my earlier proposal for a **new National Public Health and Medical Research (NPHMR) mission statement** in order to guide all Health and Medical Research activities and investment across Australia's $130bn health sector, related agencies and activities:

National Public Health & Medical Research
Mission Statement

HMR should foster a continuous cycle of measurable improvement in public health, medical, and research outcomes through prioritizing and directing national public health and medical research funding to where it can contribute the greatest value to;

- improving long term quality and sustainability of life, to;
- minimize unnecessary suffering, and;
- fulfil unmet public health and medical research needs;

to enhance national productivity and economic sustainability of government subsidized health and medical research, treatment and care.

The Strategic Review should recommend a unifying mission that will guide the priorities of all related agencies' planning, resource allocation, funding, and activities.

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4. Measuring return on investment

We don't presently have the capacity to reliably measure the effectiveness of, or return on investment in HMR, so if we are to improve upon that capacity it should also be given consideration within this review.

The Strategic Review committee should specify that Australia's new eHealth system and PCEHRs should be purposefully re-designed to enhance data completeness, integrity and reliability, and with enhanced capacity to achieve meaningful, justifiable purpose and use across comparative treatment effectiveness, clinical decision-making, and all HMR planning and activity to take advantage of this unique opportunity to develop a robust framework for cyclic improvements in health outcomes and compound potential achievement for economic return.

Sampling of Related Media

(1) Support scarce when cancer returns
Tachel Browne, Sydney Morning Herald, September 30, 2012

When Kirsty Smith was first diagnosed with breast cancer four years ago at the age of 28, she never felt she was alone. She was invited to join support groups for young women with breast cancer and built up a network of fellow patients while undergoing treatment.

The Mount Colah teacher had been in remission for three years and was planning on starting a family when she underwent a scan before trying to conceive. It showed that she had secondary breast cancer in the bone.

While the diagnosis came as a blow, Mrs Smith was also frustrated to discover the same level of support she had enjoyed earlier just did not exist for women with secondary breast cancer.

Breast cancer overall has a high survival rate - about 88 per cent of people beat the disease.

"When you have early breast cancer there are support groups, there is lots of information and you have a goal to annihilate this thing," she said. "With secondary breast cancer, it's quite different."

She has been unable to find a support group for young women with secondary breast cancer in Sydney and groups for women with early stage breast cancer are not suited to her needs.

"I know I'm not the only young woman going through this," she said. "I know there are others out there. The lack of support can make you feel very isolated."

About 8000 Australian women are living with secondary breast cancer, according to figures from Breast Cancer Network Australia. Those women have vastly different needs to patients diagnosed with early breast cancer.

"When I was first diagnosed my goal was to hit remission," Mrs Smith said.

"Now my goal is to live as well as I can for as long as my body will let me."

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Tomorrow, Breast Cancer Network Australia will launch a reworked resource for women with secondary breast cancer. The information pack, called Hopes & Hurdles, aims to help women to come to terms with the illness and learn what to expect at their own pace.

The chief executive of Breast Cancer Network Australia, Maxine Morand, said women with secondary breast cancer required a different level of support than those with early breast cancer.
"With an initial diagnosis of breast cancer you're looking for a cure and a long, healthy life after that," she said.

"For the vast majority of women, that's exactly what happens. But secondary breast cancer is a much more challenging diagnosis. When you move from early breast cancer to being told it has spread somewhere else in the body, it becomes an incurable disease."

Associate Professor of medical oncology at the University of Sydney, Frances Boyle, said while there are no accurate statistics on how long women can live with secondary breast cancer, she is aware of patients who have survived up to a decade after diagnosis.

"We know on average they survive for years rather than months and we know from our clinical experience that they are living with the illness for longer and often living quite well," she said.

http://www.smh.com.au/national/health/support-scarce-when-cancer-returns-20120929-26s1b.html

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(2) Implementation science links research with real-world practice to improve health

Medical Express, October 3, 2012 by Steve Tokar

Why do medical research findings often fail to reach the people who could benefit from them most? And why are health programs proven to work in one setting frequently unable to achieve success in other places?

These and other questions are the focus of "implementation science," a field of study that addresses the wide-ranging challenges of translating research knowledge into real-life practice.

"Implementation science is a relatively new way of describing efforts to improve health by taking advantage of proven - though often underutilized - health interventions and thoughtfully and creatively applying them for general use," said Ralph Gonzales, MD, a professor in the UCSF School of Medicine and director of the Implementation Science (ImS) program at the University's Clinical and Translational Science Institute (CTSI).

In practice, implementation science covers diverse activities, including working to change behaviors such as ensuring that clinicians wash their hands regularly, improving care in hospital delivery rooms, and collaborating with community groups to promote disease prevention through youth-focused activities, said Margaret Handley, PhD, MPH, co-director of the ImS program.

It also may focus on research in environments defined by complex variables, such as tracking and treating tuberculosis in developing countries, helping women make informed decisions about reproductive health, or linking with community-engaged research.

According to Gonzales, as more researchers learn about implementation science, it's not uncommon to hear comments like, "Haven't researchers been doing this all along in areas such as applied science and public health?"

Implementation Science is Inherently Multidisciplinary

There's more to implementation science, he said. ImS applies theories and principles from diverse fields-economics, behavioral and social sciences, public health, marketing, public policy-and is inherently multidisciplinary. For researchers with years of training in a medical specialty, collaborating with diverse colleagues is not as common, nor as simple, as people might think.

Recognizing that ImS is a key component of translational research, which is ultimately focused on improving health, Gonzales and his team at CTSI are leveraging training and community-building to bridge the gap.

"Training offers researchers the tools, skills and strategies needed to address important contextual factors-including human practices, not all of which are rational or easily predictable-that may be limiting the widespread use of a proven intervention or preventing

a project from being sustainable," said Sara Ackerman, PhD, MPH, a medical anthropologist and the ImS program coordinator.

The goal is to train researchers to ask the right questions and design interventions that are relevant and acceptable to their audience - whether at the level of individuals, communities, institutions, or policies, she added.

Implementation science training and support opportunities include a one-year, part-time certificate program and a master's degree program in clinical research with an ImS track. Both are offered through the Training in Clinical Research (TICR) program. In addition, the CTSI Consultation Services program offers expert advice in implementation science methods and principles from UCSF faculty.

Building an Implementation Science Community at UCSF

"Implementation science is a growing discipline, and it's exciting to be pulling together a diverse community of researchers," said Handley, who also is a public health-trained epidemiologist and associate adjunct professor in the UCSF School of Medicine. "There are great lessons to be learned from those with a wide range of experience, including thinking about touch points and opportunities for collaboration earlier in the research process. At UCSF, we're helping investigators develop a skill set early in their careers so that they can come to good ideas more quickly."

However, she said, there are researchers and clinicians engaged in implementation science-type projects at UCSF who aren't even aware of it, or they have misconceptions such as the belief that the National Institutes of Health (NIH) doesn't fund this type of research. With that in mind, an effort is underway to build a community of like-minded scientists to dispel myths, promote and support interdisciplinary collaborations, and help direct investigators to funding opportunities.

Researchers interested in learning more or joining a growing community of ImS researchers at UCSF can contact Ralph Gonzales or Margaret Handley. Also follow the ImS program on Twitter.

UCSF's CTSI is a member of the Clinical and Translational Science Awards network funded through the National Center for Advancing Translational Sciences at the NIH (Grant Number UL1 TR000004).

Under the banner of "Accelerating Research to Improve Health," CTSI provides a wide range of services for researchers, and promotes online collaboration and networking tools such as UCSF Profiles.

http://medicalxpress.com/news/2012-10-science-links-real-world-health.html
http://www.ncats.nih.gov/

(3) Mexiletine improves patient-reported stiffness in nondystrophic myotonia
Jeffrey Statland, M.D, Robert Griggs, M.D., et al; October 4, 2012

> ' ... "This study shows that by bringing together experts and patients around the world and building a common infrastructure, we can tackle rare conditions that have eluded rigorous clinical study up to now." ... "There isn't much financial incentive for a pharmaceutical firm to sink money into a study of a disease that affects a small number of people, especially if the medication is generic. ... Pulling off this study is quite an accomplishment when you consider not only the relatively small number of people who have this disease, but also the challenge of getting enough of them together to do a study that is statistically significant," said Griggs. ... '

An older medication originally approved to treat heart problems eases the symptoms of a very rare muscle disease that often leaves its sufferers stiff and in a good deal of pain, physicians and researchers report in the Oct. 3 issue of the Journal of the American Medical Association.

The findings are good news not only for the relatively small number of people around the world estimated to have nondystrophic myotonia, but also for many other patients who have one of the thousands of diseases that are very rare, according to neurologists at the University of Rochester Medical Center who took part in the study.

"This study can serve as a blueprint for future rare disease research," said neurologist Jeffrey Statland, M.D., senior instructor in Neurology and the first author of the paper. "This study shows that by bringing together experts and patients around the world and building a common infrastructure, we can tackle rare conditions that have eluded rigorous clinical study up to now."

Rochester neurologist Robert "Berch" Griggs, M.D., another author of the paper and the leader of a Rochester center devoted to studying rare neurological disorders, notes that, ironically, many people suffer from rare diseases.

"Each rare disease might affect only a few thousand people, but there are thousands of rare diseases. Current estimates are that perhaps 30 million people are affected by some form of rare disease," said Griggs.

The corresponding author of the study is Statland's former adviser, Richard Barohn, M.D., the overall principal investigator of the study and chair of the Department of Neurology at the University of Kansas Medical Center.

The study is the brainchild of Griggs and several other investigators who are part of a consortium known as CINCH - the Consortium for Clinical Investigation of Neurologic Channelopathies. Griggs heads the group, which studies neurologic
disorders caused by irregularities in the cell gates or channels that regulate levels of crucial substances like potassium, sodium and calcium in our cells. Nondystrophic myotonic is one such condition.

People with nondystrophic myotonia generally have very stiff and painful muscles. Sometimes when they sneeze, for instance, they have trouble opening their eyes afterward, or they might have trouble loosening their hand once they've gripped a doorknob or shaken someone's hand. Usually, sports are very difficult, and sometimes, holding a regular job is impossible.

Since so few people have the disease - neurologists think the incidence is roughly 1 in 100,000 - the disease hasn't captured the attention of the public or researchers in the same way as Parkinson's or Alzheimer's diseases. Without any thorough, reliable studies to go on, physicians have treated patients based on experience or anecdotal evidence.

Statland and Griggs expect that approach to change with the new study, which pulled together doctors and patients from four nations to study whether the generic drug mexiletine alleviates symptoms. The 59 participants received either 200 mg of mexiletine three times daily, or placebo, for four weeks, and then after one week, they received the other treatment for four weeks.

The results show that mexiletine, an anti-arrhythmic medication rarely used for its original indication, significantly improved patient-reported stiffness in nondystrophic myotonia. Participants reported that their stiffness improved by at least 40 percent; pain reported by patients was slashed in half; and patients reported improvements in their everyday quality of life. Testing also showed that mexiletine reduced the abnormal electrical activity in the muscles, and patients were able to relax their grip and open their eyes much faster.

Griggs said the Rare Disease Network begun by the National Institutes of Health, which supported CINCH for 10 years, exists to tackle problems just like this one. There isn't much financial incentive for a pharmaceutical firm to sink money into a study of a disease that affects a small number of people, especially if the medication is generic.

"Pulling off this study is quite an accomplishment when you consider not only the relatively small number of people who have this disease, but also the challenge of getting enough of them together to do a study that is statistically significant," said Griggs.

http://www.news-medical.net/news/20121004/Mexiletine-improves-patient-reported-stiffness-in-nondystrophic-myotonia.aspx

(4) Bad medicine takes toll on Australians

by: Lisa Cornish and Sue Dunlevy, News.com, September 15, 2012

THE top ten drugs used by Australians were linked to 2925 adverse events and 67 deaths in the last five years, an exclusive analysis of the adverse events data base of the national drug watchdog has found.

Information provided by the Therapeutic Goods Administration, collected from patients, consumers, health professionals and sponsors of medicines, reveal the risks Australians are exposed to on a daily basis.

Women are slightly more prone than men to adverse effects, and the elderly are involved in more than 60 per cent of recorded cases.

Since 2007, the most commonly used drugs have been linked to 950 cases of musculoskeletal and connective tissue disorders, 633 nervous system disorders, 331 cases of respiratory, thoracic and mediastinal disorders and 286 cases of psychiatric disorders.

The cholesterol lowering medicine Atorvastatin produced the highest number of adverse events between 2007 and 2011, and was linked to 815 reports of side effects including 13 deaths.

Paracetamol, found in common over-the-counter products such and Panadol, was being taken in more than one third of deaths linked the ten most commonly used drugs.

Twenty-four deaths were reported as being linked to Paracetamol between 2007 and 2011 but the TGA says this does not mean the drug directly caused these deaths.

"An adverse event report does not mean that the medicine is the cause of the adverse event and should not influence a person's decision to stop taking a medicine," the TGA says.

A spokeswoman for the National Prescribing Service, which aims to improve quality use of medicines, says around 190,000 people are admitted to hospital each year as a result of problems with medicines.

Karen Kaye said people should consult their doctor if they are worried about a medicine side effect and should ask their pharmacist for the consumer medicine information sheet on their medicine which lists possible side effects, this information can also be downloaded from the National Prescribing Service's website www.nps.org.au.

The TGA data base shows there are slightly more adverse reactions reported for women (51 per cent) while elderly patients, aged 60 and over, accounted for 63 per cent of reports. And parents are warned to be aware of the impact

common drugs with 2% of adverse events associated with children aged 17 and under.The winter months are the highest risk period for Australians.

Thirty per cent of adverse reactions are reported during this period as Australians turn to medicines to help them flight the cold and flu season.

The news is not all bad with the number of reports associated with commonly used drugs on the decline. Between 2007 and 2011, the number of reports of adverse events decreased from 731 to 533, a drop of 27%.

http://www.news.com.au/national/bad-medicine-takes-toll-on-australians/story-fndo4eg9-1226474568593

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(5) Patient-led advocacy has changed how US government funds medical research

Rachel Kahn Best, ScienceBlog, October 2012

Patient-led advocacy has created a shift in the way the U.S. government has prioritized funding for medical research, and significantly changed the way policymakers think about who benefits the most from these dollars, a University of Michigan School of Public Health fellow in the Robert Wood Johnson Foundation Scholars in Health Policy Research Program found.

In "Disease Politics and Medical Research Funding: Three Ways Advocacy Shapes Policy," a paper published in the October issue of the American Sociological Review, Rachel Kahn Best analyzed data on 53 diseases over a 19-year period from 1989-2007.

She found that those diseases tied to strong advocacy organizations received millions of dollars more in research funding over the period than others whose advocates were not as strong. She also found an increasing number of these organizations, from about 400 large nonprofits working on disease advocacy in the early 1990s to more than 1,000 by 2003.

In addition, Best noted another fundamental shift in policy brought about by advocacy. Where policymakers once focused on providing dollars to the scientists who made the best case for funding-with the general population thought of as the beneficiaries of their research-the government began to think of patients with particular diseases as the recipients of the research funds. This resulted in funding based on "perceived moral worthiness."

"The downside is not every disease has this potential for strong advocacy," Best said. "In addition to things like lung cancer and liver disease, which lose out because of the social stigma tied to those diagnoses, there are diseases like pancreatic cancer, whose patients often don't live very long after diagnosis and, therefore, don't have time to tell their stories.

"In the years I studied, the National Institutes of Health budget was expanding rapidly. But in more recent years, we've seen a leveling off of what funding is available. It will be interesting to see if, after the time period I studied, disease advocates have become more competitive in their efforts to secure a share of the dollars."

Best also found that advocacy groups created political pressure to have funding allocated in line with mortality rates. After activists mobilized against an initially weak response to AIDS, it eventually received more research funding than any other disease.

Subsequently, advocates for other diseases protested that they were receiving fewer "dollars per death." Policymakers then pressured the NIH to bring the funding distribution more in line with mortality, even though NIH officials preferred to set priorities based on scientific criteria.

To reach her conclusions, Best collected data from the NIH and the Department of Defense-Congressionally Directed Medical Research Programs to determine dollars spent on various diseases. She gathered tax data on disease-related nonprofits and collected data on congressional hearings at which disease advocates gave testimony. She also reviewed mortality data for the 53 diseases that ranged from various cancers and influenza to hypertension and diabetes.

http://scienceblog.com/56900/patient-led-advocacy-has-changed-how-us-government-funds-medical-research/

(6) The 50-year global cover-up

Nick McKenzie and Richard Baker, The Age, July 26, 2012

Philippa Bradbourne was one of about 10,000 babies born with deformities as a result of their mothers taking thalidomide for morning sickness.

SECRET files reveal the German maker of thalidomide ignored and covered up repeated warnings that its drug could damage unborn babies.

The Age has obtained excerpts of never-before-published files from the archives of pharmaceutical giant Grunenthal which detail explicit warnings the company received about its drug's potential to harm foetuses well before it was withdrawn from sale in late 1961.

An estimated 10,000 babies worldwide - including hundreds in Australia - were born in the late 1950s and 1960s with severe physical deformities because their mothers had taken thalidomide drugs, which were marketed as a safe sedative and remedy for morning sickness.

The Grunenthal files expose a 50-year global cover-up and demolish the company's long-held position that the scandal was unforeseeable tragedy and that its "actions were consistent with the state of scientific knowledge and prevailing standards of the 1950s".

The files reveal that for at least two years before the drug was banned in late 1961, German medical professionals had told Grunenthal staff of concerns that children's deformities were caused by women taking thalidomide during pregnancy.

Between 1959 and 1961 - while the drug was still being marketed as safe - Grunenthal employees and their families began having deformed babies.

In one company file, it is noted that "eight families, which, as dependants of the Chemie Grunenthal Company, during the years between 1959 until 1961, had had deformed children".

Rather than act on the internal warnings, Grunenthal simply told concerned doctors there was no information to suggest the drug was unsafe.

The Grunenthal documents have come to light after they were lodged in the Victorian Supreme Court by Slater & Gordon lawyer Michael Magazanik in support of a compensation claim by Melbourne thalidomide victim Lynette Rowe.

Ms Rowe, in a case led by prominent plaintiff lawyer Peter Gordon, last week secured a multimillion-dollar payout from UK company Diageo, which bought thalidomide distributor Distillers in 1997. Diageo is considering settlements with up to 130 other thalidomide victims in Australia and New Zealand. But Grunenthal continues to deny any culpability and is aggressively defending lawsuits.

The Grunenthal files include a statement by German pharmacist Friedrich Koch revealing that he wrote to the firm in late 1960, having spoken to a mother who took Contergan - a brand name for thalidomide - during pregnancy and whose child was born with internal injuries.

"After my discussions with (a patient), I felt compelled to write a letter to the company Grunenthal on 24 November 1960. In this letter . I inquired whether a child could develop injuries if the mother had taken Contergan regularly during pregnancy.

''The thought that medication might possibly affect a foetus . did not seem absurd to me, but rather worth investigating,'' Mr Koch wrote.

Grunenthal wrote back to Mr Koch enthusiastically giving the drug the all clear. ''Based on the contents of the letter, I was then able to tell the parents that according to the company, their babies injuries were not caused by the mother taking Contergan during pregnancy,'' Mr Koch's statement says.

''Naturally I presumed that the scientists in Stolberg [Germany] had already looked into the problem of their Contergan breaking through the foetus or that they would at least look into it after receiving my letter.''

A year before Grunenthal assured Mr Koch the drug was safe, the firm was contacted by a German medical practitioner, Dr K, with similar concerns.

Dr K's statement reads: ''I can recall with certainty that I made a possible connection between Contergan and my son's deformities as early as 1959.

''In the same year, my wife and I had discussed this problem with [Grunenthal employee] Dr Mannheim at various times. He always explained that he just could not imagine thalidomide causing these types of injuries. I established at least a further two malformations during 1959 which I also connected to Contergan.''

Several files reveal Grunenthal was receiving an increasing number of queries about the drug's potential to harm babies at the same time it was telling the public it was safe.

An internal document dated February 1961 - almost a year before thalidomide was banned - poses a question about its potential to effect the foetus. Another document includes a reference to Grunenthal being told that thalidomide was ''known as an abortive drug''.

A March 1961 document says animal testing might shed light on the effect of thalidomide on a foetus while also acknowledging that the company had no idea what this impact could be. ''[We have] no experiences ourselves regarding [thalidomide] and pregnancy,'' the March 1961 memo states.

Around this time, Grunenthal sales representatives wrote confidential memos to the firm about what doctors had told them about possible impacts of the drug. A February 1961 letter from a doctor working in sales for Grunenthal states that his ''main objective'' in responding to such concerns was ''once again . to generate general interest and cause confusion''.

An April 1961 memo from another Grunenthal sales representative deals with the drug's potential to cause nerve injury, finding that in one medical ward there were ''20 clear Contergan [thalidomide] allergies and 2 cases of polyneuritis''.

''On the psychiatric wards with huge use of 271 [thalidomide] no side effects at all (maybe the idiots are happy when they are tingling!),'' the sales representative noted.

Another file reveals that in the months before July 1961, a German doctor quizzed Grunenthal about the potentially harmful effects of the drug during his wife's second pregnancy, given she had previously miscarried after taking Contergan.

The doctor's wife gave birth to a severely deformed child in July 1961 and he immediately suspected "the potentially harmful effect of Contergan on the child".

In mid-1961, a Grunenthal doctor told a fellow employee "that in regard to Contergan, significantly more severe injuries than those already known were to be anticipated in his opinion".

Yet another company doctor also confidentially flagged concerns, telling a Grunenthal meeting that the firm "needed to investigate the diaplacental transfer of [thalidomide] by way of animal test to determine the possibility of damage to the foetus."

According to one of Mr Magazanik's affidavits, "by May 1961, Grunenthal knew that its own medically trained staff had 'a very real fear of [thalidomide] side effects' and were refusing to use thalidomide drugs within their own families."

By late 1961, when United States regulators had refused to licence thalidomide due to safety concerns, Grunenthal's internal files reveal a growing acknowledgment inside the company that there may be a serious problem with its drug.

In September 1961, the company wrote to a medical expert querying if it could draw on his expertise on the "effects of medication on the foetus".

But no tests were done in the last six months of 1961, despite further concern expressed to Grunenthal that their drug might be harming or killing babies.

It wasn't until November 1961 that the company finally moved to ban the drug after getting now well-known reports by Dr Widikund Lenz and Australian obstetrician William McBride about the links between the epidemic of birth defects and thalidomide.

The company at this time began formulating its position that it was not to blame.

But privately, Grunenthal's own lawyers had their doubts about aspects of the company's behaviour, including its response to hundreds of reports of nerve damage caused by thalidomide which prompted them to warn it was facing "a dangerous and uncomfortable situation so injurious to the reputation of the organisation".

http://www.brisbanetimes.com.au/national/the-50year-global-coverup-20120725-22r5c.html

Read the affidavit material containing confidential Grunenthal files - Part 1 (http://images.theage.com.au/file/2012/07/25/3486637/thalid1.pdf?rand=1343218296209) Part 2 (http://images.theage.com.au/file/2012/07/25/3486947/thalid2.pdf?rand=1343218286415)

(7) Chemo 'can backfire, boost cancer'

From: AFP, August 05, 2012

CANCER-BUSTING chemotherapy can cause damage to healthy cells which triggers them to secrete a protein that sustains tumour growth and resistance to further treatment, a study has found.

Researchers in the United States made the "completely unexpected" finding while seeking to explain why cancer cells are so resilient inside the human body when they are easy to kill in the lab.

They tested the effects of a type of chemotherapy on tissue collected from men with prostate cancer, and found "evidence of DNA damage" in healthy cells after treatment, the scientists wrote in Nature Medicine.

Chemotherapy works by inhibiting reproduction of fast-dividing cells such as those found in tumours.

The scientists found that healthy cells damaged by chemotherapy secreted more of a protein called WNT16B which boosts cancer cell survival.

"The increase in WNT16B was completely unexpected," study co-author Peter Nelson of the Fred Hutchinson Cancer Research Centre in Seattle said.

The protein was taken up by tumour cells neighbouring the damaged cells.

"WNT16B, when secreted, would interact with nearby tumour cells and cause them to grow, invade, and importantly, resist subsequent therapy," Dr Nelson said.

In cancer treatment, tumours often respond well initially, followed by rapid regrowth and then resistance to further chemotherapy.

Rates of tumour cell reproduction have been shown to accelerate between treatments.

"Our results indicate that damage responses in benign cells ... may directly contribute to enhanced tumour growth kinetics," wrote the team.

The researchers said they confirmed their findings with breast and ovarian cancer tumours.

The result paves the way for research into new, improved treatment, said Dr Nelson.

"For example, an antibody to WNT16B, given with chemotherapy, may improve responses (kill more tumour cells)," he said in an email exchange.

"Alternatively, it may be possible to use smaller, less toxic doses of therapy."

http://www.google.com/hostednews/afp/article/ALeqM5gFc7yPJHmW-aZnlAT7k6qrAKYt3w?docId=CNG.945b2a3907990e6013ce343d3f70dfe5.101

(8) Families count cost of dementia drugs prescriptions

Australian Broadcasting Corporation, Broadcast: 16/08/2012
Reporter: Margot O'Neill

Up to 6,000 elderly people could be dying prematurely each year because of widespread over-prescription of anti-psychotic drugs to dementia patients in nursing homes.

Transcript

TONY JONES, PRESENTER: Up to 6,000 elderly people could be dying prematurely each year because of widespread over-prescription of powerful drugs to dementia patients in nursing homes. While one expert has put the number in the thousands, another has told Lateline it certainly runs into the hundreds.

Experts say anti-psychotic drugs can leave patients immobilised and unable to speak and are often used unnecessarily to keep dementia sufferers quiet for over-worked staff. But the drugs can increase the risk of death by 50 per cent and family members are often left in the dark about their use.

Margot O'Neill has this exclusive report.

MARGOT O'NEILL, REPORTER: John Burns's family thought they were doing the best thing for their father when they booked him into a nearby nursing home in Adelaide, offering specialist dementia care.

Just 63 years old, he had severe symptoms such as disinhibited sexual behaviour. He never hurt anyone, but his lewd remarks and wandering put him at risk of harm.

What then happened to John Burns, while extreme, is not uncommon, according to experts.

JODY PLAYFORD, DAUGHTER: Don't think in your worst nightmares you could have ever imagined it could have gone so wrong.

MARGOT O'NEILL: John Burns walked into the nursing home able to feed and clean himself, able to converse with his family. Within 24 hours, he was so doped up they could barely wake him. Within a week, he was unable to sit upright or converse at all. Within 12 days, he was dead.

JODY PLAYFORD: I went down to the lounge room and - only to find dad (getting emotional) sitting in the lounge in his own urine and he had jelly in his eyes, his eyes had turned to jelly and the jelly was, like, coming out of his eyes and he was away with the fairies, like, he didn't know me. And of course, you know, we hadn't had that problem with the dementia and so I was rubbing his hand and going, "Dad, it's Jody, it's Jody."

MARGOT O'NEILL: Jody Playford knows now that her father had a stroke. She also knows that during his short time in the nursing home he was massively dosed with dangerous anti-psychotic drugs that can heighten the risk of stroke and death.

But why was he drugged?

Soon after arriving at the nursing home, John Burns tried to leave. He guessed a security code

and wandered outside the locked dementia wing. He also made sexual remarks to staff, raised his fist and touched a female staff member's breast.

None of this is unusual behaviour for dementia patients, who often become agitated when adjusting to new environments. No-one was hurt and each time John Burns became compliant again.

But some staff were worried enough to call a doctor who prescribed the powerful anti-psychotic Haloperidol, which he was given repeatedly in large doses.

JODY PLAYFORD: This is a level four chemical restraint, which means your life's in danger, the client's life's in danger, it drops them to the floor instantly.

MARGOT O'NEILL: One of South Australia's leading geriatric experts testified at a coronial hearing into John Burns' deaths that he believed the overall dose over the next five days was excessive.

CRAIG WHITEHEAD, ADELAIDE REPAT GENERAL HOSPITAL: He did have a very high dose of particularly Haloperidol I think was - which is a very potent anti-psychotic. ... I think he had about 35 milligrams. I would ordinarily give in that circumstance at best five orally.

MARGOT O'NEILL: In fact John Burns was given 45 milligrams in five days as well as other anti-psychotics and sedatives.

The coroner heard that sometimes he was drugged just because he was restless or wanting to go for a quiet walk in the corridor at night.

JODY PLAYFORD: And even the coroner said, "Well, what else is the man meant to do in a facility? You know, what's wrong with going for a walk?"

MARGOT O'NEILL: The coronial inquest heard the doctor believed he'd prescribed an appropriate amount and that he was concerned for the safety of nursing home staff because John Burns had become aggressive and abusive.

The South Australian Coroner, Mark Johns, found last year that John Burns died of a stroke in 2006. He did not link it to anti-psychotic drugs, but he noted that Dr Whitehead's expert concerns that Haloperidol played a role, "... may well be correct".

CRAIG WHITEHEAD: Essentially the man died of a stroke and that had been acquired after what seemed to my mind significant prescription or over-prescription of anti-psychotics to treat his behaviour. ... I thought it was a really important example of how these medications that we give to people with dementia - a very common problem and behavioural disturbance is a very common problem - have serious and high-risk side effects, and it was clear to me that the family had never been engaged in a discussion about that.

MARGOT O'NEILL: Dr Whitehead says while there are many excellent nursing homes, he's concerned about a lack of properly trained staff to care for the 140,000 dementia patients who now dominate residential care and whose numbers are set to explode.

CRAIG WHITEHEAD: I think there is a sense that the aged care industry is less tolerant to

patients with behavioural disturbance. ... There is a tendency to gravitate towards blaming the person for their behaviour.

MARGOT O'NEILL: Jodie Playford was at her father's bedside when the doctor who'd prescribed the anti-psychotics arrived.

JODY PLAYFORD: Mum and I couldn't quite believe it really because he looked at dad and he said, "You know what you did, Mr Burns. We're not gonna tolerate that sort of behaviour in here and you know what's gonna happen if you continue to do this."

MARGOT O'NEILL: Many of the same issues were faced by Beverly Harvey and her family when their mother went into a Gold Coast nursing home late last year suffering dementia. Even though she was 93 years old, Annetta Mackay was mobile and could converse with her family, but within two months she'd lost 16 kilograms and was hard to wake.

BEVERLEY HARVEY, DAUGHTER: We walked in and our mother looked dead. Naturally while I was there I suspected she was heavily drugged so that's why I spoke to the doctor. He said, "Your mother has been - is on massive amounts of drugs."

MARGOT O'NEILL: Beverly and her family were told their mother was calling out at night and using vulgar language that upset other residents. Once her sedation began, it didn't seem to stop.

BEVERLEY HARVEY: They were still drugging her even though she was well and truly comatose, not eating, not drinking, just sleeping.

MARGOT O'NEILL: Experts have told Lateline the science is clear. Anti-psychotics are not beneficial for the vast majority of dementia patients whose behaviour can often be managed by better trained staff.

DAVID LECOUTEUR, CONCORD REPAT. GENERAL HOSPITAL: We also have some limited evidence that's stopping those medications improves their outcomes, improves their behaviour and improves their cognition. So from my perspective, the correct management of behavioural problems in dementia is nearly always reducing medications, not starting them.

MARGOT O'NEILL: The anti-psychotic drugs were stopped when Beverly's mother went to hospital. Suddenly, Annette Mackay was able to chat to her family again, but when she went back to the nursing home ...

BEVERLEY HARVEY: Well, she was like a zombie. The last day, I put my arm around her (getting emotional) and said, "We're going now." And she didn't open her eyes, she just made sure I kept there. She was sort of holding me in and said, "Beverley, don't leave me here."

MARGOT O'NEILL: Her family managed to have the anti-psychotics stopped in January after four months. Annetta Mackay died in April.

Up to 60 per cent of nursing home residents are on psychiatric drugs. Up to 30 per cent are on powerful anti-psychotics.

DAVID LECOUTEUR: So in many cases, yes, we are treating people with dementia in order to make life easier for the carers and health care workers.

MARGOT O'NEILL: But it comes at a high price. Professor Lecouteur calculated how many patients were dying six to 12 months prematurely each year because of the over-prescription of anti-psychotics. His figures range from 500 to 6,000.

What is the most likely number?

DAVID LECOUTEUR: I think the answer is thousands. I think there are probably thousands of deaths where you could attribute the deaths to the use of these medications.

MARGOT O'NEILL: Were you aware that the figure would be so high before you did these numbers?

DAVID LECOUTEUR: No, I wasn't. I feel shocked, very sad for the elderly people.

MARGOT O'NEILL: While not commenting on specific cases, Queensland specialist geriatric psychiatrist Professor Gerard Byrne says there are likely to be hundreds of premature deaths each year with thousands more adversely affected.

GERARD BYRNE, ROYAL BRISBANE AND WOMEN'S HOSPITAL: Yeah, I think there are likely to be hundreds if not thousands of people severely adversely affected each year in this country. I have certainly seen on a fairly regular basis older people with dementia who have been prescribed anti-psychotic medication either inappropriately or in excessive dose or for too long a period. The problem is that they seem to be used indiscriminately and significantly over-used, really.

DAVID LECOUTEUR: People with dementia are human beings and they're needed to be treated with respect and sedating them because of their behaviours just feels wrong as a human being.

MARGOT O'NEILL: Margot O'Neill, Lateline.

http://www.abc.net.au/lateline/content/2012/s3569736.htm