

Submission

Strategic Review

National Public Health & Medical Research (NPH&MR)

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## Executive Summary

The following submission contains;

- ❖ a proposed new mission statement for the National Public Health and Medical Research Council;
- ❖ examples of system and process failures, their inferred collective cost to our nation, and why we need to think differently about national public health and medical research funding;
- ❖ a fully justified proposed solution for national public health and medical research system and process reform;

that if implemented will;

- ❖ enhance the completeness, transparency, and reliability of our health, medical and research data;
- ❖ build greater capacity to achieve measurable improvement in health outcomes, and subsequently will;
- ❖ improve the long-term productivity and economic sustainability of our public healthcare system and its funding.

### National Public Health & Medical Research Mission Statement

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 above statement defines an honourable public health and medical research mission and primary objectives that most Australians would support. But there's a problem...

## System and Process Failures:

### Why we need to think differently about national public health and medical research funding

We don't have all the data we need to effectively and efficiently analyse the comparative effectiveness of treatments, or the degree to which variables impact upon those outcomes; so we don't know which treatments are the most effective and which are the least effective.

Australia does not have a single, comprehensive collection of detailed health outcomes data.

Without a reliable health outcomes dataset to analyse, we can't reliably identify and justify exactly where public health and medical care is most in need of improvement - to more effectively prioritize the direction of health and medical research funding to where it can contribute the greatest value to improving long term quality and sustainability of life.

Further, in the absence of this resource we don't have a reliable baseline dataset upon which to measure achievements; such as improvements in long term health outcomes resulting from improvements in health and medical treatments – and we can't reliably calculate the economic value of the return on our investment in health and medical research funding.

The absence of this resource means we have not been asking the right questions to get the right answers, and so have not been maximising the potential of Australia's public health and medical research investment, which is substantial in the order of around a billion dollars annually... which raises the probability we've been directing funding to areas of less need at the expense of areas in most need.

No commercial organisation would invest around a billion dollars a year without a reliable means to accurately measure the value of the return on their investment.

Australia has been measuring research outcome achievement through publication acceptance in prestigious scientific, medical and health journals.

Research outcomes worthy of publication in a prestigious journal have been published, but other research outcomes also worthy of publication have not. Clearly, this is a hit and miss affair, and is evidence that publication in a prestigious journal is not a reliable measure of research outcome value.

There is also much evidence that worthy health and medical research outcomes are not being analysed for their potential to immediately, effectively and safely, contribute to improvements in long term quality and sustainability of life:

‘ ... Professor Levi says Tenecteplase must be administered immediately after the stroke so the clot can be broken down. He says the team is now applying for additional funding to make it the largest clinical trial co-ordinated in the Hunter. ... This drug looks to be, possibly, twice as effective so the proportion of patients that showed dramatic clinical improvements was substantially higher. It could well be that if this translates through this drug could cure one in every three or one in every four patients.’<sup>(11)</sup>

Hence an outcome that promised immediate improvement in stroke treatment for all Australians was not immediately analysed to identify its inherent potential to;

- ❖ effectively and safely (benefit/risk ratio) minimize unnecessary suffering;
- ❖ effect reductions in long term disability;
- ❖ minimize the health and care cost burden for families;
- ❖ minimize the health and care cost burden on our healthcare system;
- ❖ enhance national productivity, and;
- ❖ contribute measurable improvement to long term quality and sustainability of life.

This outcome was not analysed for its potential for ‘public good’, its public health outcome value. If it had been, it might have been fast-tracked to the healthcare coalface. Instead, Professor Levi’s team will have to apply for additional funding to conduct another area limited trial in the Hunter region.

This will not only limit the number of Australians who might benefit, but could also sentence a percentage of stroke sufferers to unnecessary suffering through lifelong disability, in contravention of human and health rights.<sup>(14) (15) (16)</sup>

Yet this research outcome, as impressive and promising as it is, may be one of many other promising treatments with similar potential. Some of them may already be in use. Others may have been overlooked, ignored, or forgotten, gathering dust on someone’s bookshelf in promising, but unpublished pages.

The above is representative of the status quo... and we can extrapolate what that infers across all other major life-threatening health events, and all chronic and critical diseases.

How many other promising outcomes has Australia overlooked, ignored, or forgotten, and what has the total cost of that been to this nation and its people?

We need to capture the right data, in the right way, at the right time, from the right person, and we need to protect the integrity of that data in the right way, so we can ask the right questions of that data and reliably get the right answers; answers that will be in the best interests of all Australians’ health futures.

## Proposed Solution for National Public Health and Medical Research System and Process Reform

Advances in technology have delivered that opportunity, and Australia has spent a considerable sum of money in order to take advantage of that opportunity.

Australia is developing an eHealth Network to facilitate the transfer of patients' health and medical information (referral letters, prescriptions, test results, etc) between healthcare providers, and is also developing a Personally Controlled Electronic Health Record (PCEHR) to facilitate the merging/collation of that information into a single patient health and medical care summary and historical record.

It is envisaged that with time, a patient's nominated primary healthcare provider will create a PCEHR for those patients who request one, and will subsequently manage updates to each patient's PCEHR - with a view to a patient's PCEHR one day representing a comprehensive historical patient health and medical care record.

This advancement holds promise for the research community due to the potential to merge de-identified PCEHRs into a single health and medical care database that can be analysed or questioned in multiple ways.

Unfortunately PCEHRs will not represent a complete patient profile as there will be gaps in the information this record holds.

For example;

- ❖ a referral letter is not sufficient evidence that a patient followed through with a referral;
- ❖ a prescription, whether filled or not, is not sufficient evidence that a patient took a medication,
- ❖ a prescription is not sufficient evidence that a patient took the prescribed dose, at the prescribed time, in the prescribed way, and;
- ❖ a record of a patient undergoing treatment is not evidence that a patient benefited from that treatment;

and so the PCEHR, in its present design, will not represent a comprehensive health and medical care record, and so it will not represent a reliable source of evidence of health outcomes, and researchers' only options will be to make unreliable assumptions about health outcomes.

This means we haven't planned to capture the right data, in the right way, at the right time, from all the right persons, for all the right reasons, to give it all the right meaning, which means we won't be able to effectively perform comparative treatment effectiveness research.

(10) ‘ ... Comparative effectiveness research generates evidence that helps consumers, clinicians, purchasers, and policy makers make better decisions about health care. ... Capturing the patient's perspective is central to this research because it provides a complete picture of treatment impact. ... ’

Even if we ask the right questions, if those questions are posed to the wrong data, we'll get the wrong answers.

We need to back-fill those information gaps, and the only way to do that is to provide opportunity for patients to self-report their health journey and outcomes in structured ways within their own PCEHR.

Patients will be able to enter some health information, such as allergies. They will also be able to record diary notations, but; they will not be given an opportunity to contribute structured information, such as rating the effectiveness or side effects of a treatment through self-reporting their health outcomes.

If the PCEHR were to facilitate a higher degree of structured patient contribution within a dedicated section of their PCEHR record, it would provide an opportunity for patients to back-fill their own health information gaps.

It would be a simple process to expand upon the dedicated patient section of the PCEHR to populate the section with the same prescription/treatment list that appears in the healthcare provider section. This would then provide opportunity for the patient to rate a treatment's short and long-term effectiveness through, for example, a Quality of Life scale and drop down lists of symptom benefits and side effects.

If this data was also de-identified and merged, it would provide another source of data that could be analysed or questioned in multiple ways, such as;

- ❖ detecting unmet health and medical care needs;
- ❖ comparative treatment effectiveness;
- ❖ mapping of variables in treatment effectiveness;
- ❖ detecting unknown side effects or safety issues;
- ❖ inspiring researchers through enhanced opportunities for discovery, or;
- ❖ could be merged or matched with other health and medical datasets to add a greater depth of meaning to individual or combined data, or;
- ❖ could be compared against other data to enhance transparency, with subsequent enhanced potential to increase the value of other health and medical datasets, and;
- ❖ would provide an additional, valuable tool in the management of data integrity, through facilitating detection of inconsistencies or incorrect assumptions.

I have long advocated the potential value of patient testimony to health and eHealth systems, beginning in 2001 with the creation of Case Health, a community health service website (casehealth.com.au) created to capture and freely share health success stories through an online keyword searchable database.

In 2003, through that website, I learned of an obscure low-cost treatment that had been benefiting sufferers of Multiple Sclerosis since the 1980s. Further research into that treatment revealed it was also benefiting sufferers of many other diseases – HIV, Crohn's Disease, Hepatitis B & C, Fibromyalgia, Cancer, Rheumatoid Arthritis, Primary Lateral Sclerosis (a motor neurone disease), Parkinson's Disease, and many more... all seemingly unrelated on the surface, yet intricately linked below the surface by immune system dysfunction.

Patient testimony of symptom benefits include among others; reduced pain, less frequent urination, enhanced cognition and memory (MS brain fog), reduction in frequency and severity of spasms (MS hug), enhanced mobility, reduction in tumour size, improved sleep, and even a reduction in severity and duration of colds and allergies; with the most common side effects reported being initial sleep disturbance (that usually settles quickly), and symptoms of withdrawal relative to cessation of opioid-based pain medication (medication that employs the same receptor pathways).

Patient testimony revealed some of the variable factors in health outcomes included; the quality and accuracy of compounding, time of administration, the degree and range of involvement of other active chemicals used in combination (both mainstream and alternative), complementary factors such as diet and exercise, and the degree of health professional knowledge of and experience in treating with LDN.

As there are some 200+ diseases related by immune system dysfunction, it was clear this non-mainstream treatment provided me the best available example of the value of patient testimony, and hence; the best opportunity to focus on this treatment and build the evidence to prove the value of patient testimony.

This resulted in a final 'proof of concept' research publication entitled 'Those Who Suffer Much, Know Much' 5<sup>th</sup> 2010 edition<sup>(1)</sup>; the content of which has since been further supported by additional research and trials that strengthen the evidence for its efficacy in HIV<sup>(3) (4)</sup>, and cancer<sup>(6)</sup> - 'Low-dose naltrexone targets the opioid growth factor-opioid growth factor receptor pathway to inhibit cell proliferation'<sup>(5)</sup>.

“Opioid growth factor is otherwise known as met-enkephalin. Low dose naltrexone (LDN) has been shown to double or triple one’s daily output of met-enkephalin.”

Dr David Gluck, October 2010

In the ensuing years my best endeavours failed to find any government department chartered with responsibility to act on the potential of this low dose naltrexone (LDN) treatment to improve health outcomes.

It was during the same period that I first discovered Australia favours a market-based health system – a system that relies heavily on the market to respond to and fulfil 'health need' opportunities.

That's when I also discovered Australia has no system in place to fill the gap when the market does not respond to or fulfil 'health need' opportunities, particularly when those opportunities have much potential to improve health outcomes but little potential for patent and profit.

And so it was that because we have a market-based health system... when I first approached our Therapeutic Goods Association (TGA) about LDN, they directed me to the drug sponsor of Revia, a 50mg naltrexone product, and in doing so; inferred that a commercial enterprise would perceive opportunity in fulfilling this unmet need.

But naltrexone is a very old out-of-patent drug. It was first approved in the 1980s for the treatment of drug addiction (blocks opioid receptor pathways) and has a good safety profile at the approved 50mg dose.

Why would a commercial enterprise be interested in investing hundreds of thousands of dollars (clinical trials are costly) to trial the clinical effectiveness of a single nightly low dose of 3mg-4.5mg for a different indication, without any potential to patent, to secure market share and set their own profitable selling price?

Even if they proceeded and were able to prove an effective new purpose for this old drug, they would most certainly have argued for market-protective conditions beforehand; conditions that guaranteed a healthy return on investment, such that would afford the same degree of exclusivity in market share and the same degree of independence to determine price setting and hence; profitability.

Some quarters have suggested just that, but the drawbacks are many. At last check, low doses of naltrexone were being compounded for around \$60.00 per script. Clearly, to obtain a profitable return on investment, a commercial enterprise would set a much higher price, a substantial increase on the present cost to the patient.

In addition, with some 200+ documented immune system disorders, would the commercial enterprise want to invest in trialling LDN for each and every one, and if not, which diseases would they choose to trial?

Also of critical consideration are other drawbacks associated with a market-based healthcare system. Market-based economies can benefit consumers with the development of new products and where healthy competition for consumer purchases results in lower costs to the consumer, but market-based competitive behaviour does not translate well to healthcare where there is much more at stake.

For example; if a clinical trial of low dose naltrexone (LDN) proved efficacy and safety in its treatment of a particular immune system disorder, and also that health outcome measures compared favourably to other patented, highly profitable treatments approved to treat the same disorder... in the present environment... what is the likelihood or otherwise trial data would be transparently recorded and candidly presented for publication in a prestigious journal?

And what incentive or onus would there be for the commercial enterprise to develop the LDN product in direct market competition to their current, patented, highly profitable product? Would they be free to legally ignore the results of the trial, throw the trial data on a bookshelf somewhere or burn it? Or could they tweak a single molecule, patent it, and sell it as a new drug at today's market prices, which can reach around \$120,000 per annum per patient.

Importantly, is this present system serving the best interests of all Australians – their present unmet healthcare needs, their health futures, their health economy, or the sustainability of their publicly funded public healthcare system?

Is it in anyone's best interest to favour market-based health system responses when opportunities to improve health outcomes can be so easily ignored or discarded based on their potential commercial profitability?

During the past 9 years I have made over a thousand approaches to various government departments (including NHMRC), prime ministers, health ministers and other politicians state and federal, specialist disease organisations, specialist healthcare professionals, specialist researchers, specialist societies, CHIC, media organisations, journalists, and many others without response. Whenever possible I also attended free events and took advantage of formal and informal opportunities to speak in-person directly with federal politicians Mal Brough, Arch Bevis, and state politician Stirling Hinchliffe amongst them.

In the absence of a double-blinded placebo-controlled clinical trial, I have not been able to generate any interest in investigating the potential of this treatment from speciality areas such as Neurology, Endocrinology, Immunology and others. An Alzheimer's physician was not interested in LDN's reported symptom benefits of enhanced cognition and memory, yet I later learned the same physician was looking forward to a trial of a newly developed drug.

I have contributed various formal feedback and submissions, including among them to; Australia 2020, the National Health and Hospital Reform Commission; Draft Concept of Operations for the PCEHR, Inquiry into the Personally Controlled Electronic Health Records (PCEHR) Bill 2011; and most recently responded to a request for feedback on the 'PCEHR Rules and Regulations' My response to the Draft Concept of Operations represented the equivalent of 3 weeks full time work, yet to-date there remains no evidence anyone even read it.

I have taken unpaid days off work to attend free events such as the '7<sup>th</sup> Annual E-Health Research Colloquium on Scalable Research-based Solutions for E-Health's Perfect Storm', and have done the same to attend several PCEHR forums held by the National eHealth Transition Authority (NEHTA).

Throughout, I have highlighted the potential return value to patients, their carers, healthcare providers, researchers, and our health economy if we valued patient testimony of health outcomes, and filled the gaps left behind by our market-based healthcare system.

Throughout I have held firm to the belief that collecting and presenting the evidence of the failures of our present healthcare system along with opportunities to correct them, all neatly stitched together by a reasoned, logical solution, would be sufficient to garner interest and action in the best interests of all those who might benefit through a shortened path to improved health via the most effective and least invasive treatments that minimize unnecessary suffering.

But my belief system was flawed in one and one only respect - there must be an imperative to act – and sadly, these days the imperative of the ‘common good’ appears to come second to Facebook armies, media campaigns, and legal threats – none of which I have at my disposal. No imperative = no due consideration = no change.

In the interim and for the foreseeable future; this nation’s direct public health and medical research funding, presently over \$818 million annually, remains guided by data on ‘burden of disease’, whilst various federal and state government departments, non-government and non-profit organisations collectively also allocate substantial research funding.

Commercial enterprises also fund research, but as mentioned earlier, prioritize opportunities of scale and opportunities to patent and profit, over opportunities to improve individual or public health outcomes and public health sustainability - as evidenced in research and product development trends that target the largest disease markets, eg; immunization, asthma, heart disease/cholesterol, and diabetes; because it is those larger disease markets that offer the greatest opportunity for profitable return on investment.

The same larger disease markets are also well represented by specialist disease organisations, eg; Diabetes Australia; and those organisations are usually well-supported by charitable donations. It would come as no surprise to anyone that those organisations also direct any research funding to researching treatments for the diseases they represent.

So, if the NHMRC directs the greatest proportion of Australia’s public health and medical research funding to ‘burden of disease’, and private enterprise prioritizes investment in the ‘largest disease markets’, and specialist disease organisations are also prioritizing investment in the ‘largest disease markets’, what is the likelihood of a large overlap or perhaps even over-servicing of research funding to that sector?

Is it possible the larger disease markets are receiving a disproportionate percentage of health and medical research funding?

Our public health and medical research funding could be utilised far more effectively, with scarce but much-needed funding being directed to other worthy areas where there is unmet or urgent need.

But if Australia doesn’t first improve the way we collect, analyse and utilize health outcomes data - through providing the best structure and means, the best guidance and safeguards to ensure the integrity of data recorded, its quality management and analysis (garbage in, garbage out) and meaningful use; we’ll never know.

Australia can’t foster a continuous cycle of measurable improvement in public health outcomes if we’re not collecting quality data on health outcomes from the first person, the person at the centre of all healthcare activity, the only person with first-hand experience of their own health journey and health outcomes... and that person is the patient. And Australia can’t measure research achievements that lead to improved health outcomes if no baseline measure exists.

**NO BASELINE MEASURE = NO MEASURE OF IMPROVEMENT.**

## REFERENCES – PART 1 – VALUE OF PATIENT TESTIMONY

This group of references presents;

(A) evidence of the value of patient testimony through a single compelling example of an obscure but effective, economical treatment that has been long overlooked <sup>(1) (2)</sup>;

(B) additional Studies, trials, associated research and articles <sup>(3) (4) (5) (6) (7) (8)</sup> released since publication of the 2010 edition of ‘Those Who Suffer Much, Know Much’, and which add further weight to the evidence for Low Dose Naltrexone (LDN) efficacy and safety;

(C) a response to the promise of LDN by politician, Nia Griffiths in the UK;

(D) research that supports the case for capturing the patient's perspective as being central to comparative effectiveness research <sup>(10)</sup>, and;

(E) provides an additional example in ‘Breakthrough in Stroke treatment’ <sup>(11)</sup> as evidence that LDN is not the only treatment or unmet need being overlooked.

### **(1) ‘Those Who Suffer Much, Know Much’ 2010 5<sup>th</sup> edition**

Cris Kerr, Case Health

This ‘proof of concept’ ebook has previously been submitted to the NHMRC.

The ebook represents a comprehensive and compelling example of the potential value of patient testimony, with more than sufficient evidence to prove the case for (justify) an urgent and comprehensive study into an obscure treatment known as low dose naltrexone (LDN) that has been benefiting sufferers of Multiple Sclerosis, HIV, Crohn's Disease, Hepatitis B & C, Fibromyalgia, Cancer, Rheumatoid Arthritis, Primary Lateral Sclerosis (a motor neurone disease), Parkinson's Disease, and many more diseases... all related by immune system dysfunction.

The publication contains 51 patient testimonies presented as time-lined patient profile case studies, an explanatory article, interviews with 19 health professionals familiar with this treatment, and lists patient advocates and their activities. The content is supported by a comprehensive list of scientific references.

This treatment has the potential to not just improve health outcomes but also minimize unnecessary suffering for other patients at a lower cost to public health expenditure... yet in the past 9 years I have not been able to find a single department or person chartered with responsibility to act on its content or the public health imperative it conveys.

<http://www.ldnresearchtrustfiles.co.uk/docs/2010.pdf>

## **(2) '201 Reasons Why... You Should Know about LDN'**

LDN Research Trust, Linda Elsegood, edited by Cris Kerr

A collection of 201 patient testimonies attributing improved health outcomes and quality of life to low dose naltrexone (LDN).

<http://www.ldnresearchtrustfiles.co.uk/docs/ebook.pdf>

## **(3) 'Single cohort study of the effect of low dose naltrexone on the evolution of immunological, virological and clinical state of HIV+ adults in Mali'**

Abdel K. TRAORE, Oumar THIERO, Sounkalo DAO, Fadia F. C. KOUNDE, Ousmane FAYE, Mamadou CISSE, Jaquelyn B. McCANDLESS, Jack M. ZIMMERMAN, Karim COULIBALY, Ayouba DIARRA, Mamadou S. KEITA, Souleymane DIALLO, Ibrahima G. Traore and Ousmane KOITA.

accepted 29 August, 2011, Journal of AIDS and HIV Research Vol. 3(10), pp. 180-188, October 2011, ISSN 2141-2359 ©2011 Academic Journals

Abstract:

[http://www.academicjournals.org/JAHR/abstracts/abstracts/abstracts2011/October/Traore%20et%20al%20\(1\).htm](http://www.academicjournals.org/JAHR/abstracts/abstracts/abstracts2011/October/Traore%20et%20al%20(1).htm)

Full Article:

[http://www.academicjournals.org/JAHR/PDF/Pdf2011/October/Traore%20et%20al%20\(1\).pdf](http://www.academicjournals.org/JAHR/PDF/Pdf2011/October/Traore%20et%20al%20(1).pdf)

## **(4) 'Impact of low dose naltrexone (LDN) on antiretroviral therapy (ART) treated HIV+ adults in Mali: A single blind randomized clinical trial'**

Abdel K. TRAORE, Oumar THIERO, Sounkalo DAO, Fadia F. C. KOUNDE, Ousmane FAYE, Mamadou CISSE, Jaquelyn B. McCANDLESS, Jack M. ZIMMERMAN, Karim COULIBALY, Ayouba DIARRA, Mamadou S. KEITA, Souleymane DIALLO, Ibrahima G. Traore and Ousmane KOITA.

accepted 29 August, 2011, Journal of AIDS and HIV Research Vol. 3(10), pp. 189-198, October 2011, ISSN 2141-2359 ©2011 Academic Journals

Abstract:

[http://www.academicjournals.org/JAHR/abstracts/abstracts/abstracts2011/October/Traore%20et%20al%20\(2\).htm](http://www.academicjournals.org/JAHR/abstracts/abstracts/abstracts2011/October/Traore%20et%20al%20(2).htm)

Full Article:

[http://www.academicjournals.org/JAHR/PDF/Pdf2011/October/Traore%20et%20al%20\(2\).pdf](http://www.academicjournals.org/JAHR/PDF/Pdf2011/October/Traore%20et%20al%20(2).pdf)

**(5) ‘Low-dose naltrexone targets the opioid growth factor-opioid growth factor receptor pathway to inhibit cell proliferation: mechanistic evidence from a tissue culture model’**

Renee N Donahue, Patricia J McLaughlin and Ian S Zagon.  
Journal of Experimental Biology and Medicine, August 2011.

<http://ebm.rsmjournals.com/content/236/9/1036>

**(6) ‘Opioid growth factor improves clinical benefit and survival in patients with advanced pancreatic cancer’**

PMCID: PMC2947031, NIHMSID: NIHMS202202

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2947031>

(NOTE: Dr Ian Zagon, discoverer of the benefits of low dose naltrexone in the 1980s, has focussed his research in recent years on a single factor... Opioid growth factor, otherwise known as met-enkephalin. Low Dose Naltrexone (LDN) has been shown to double or triple one's daily output of met-enkephalin." Dr David Gluck, Idninfo.org editor, Oct 2010

**(7) ‘Low Dose Naltrexone: Harnessing the Body’s Own Chemistry to Treat Human Ovarian Cancer’**

<http://www.sciencedaily.com/releases/2011/07/110712143012.htm>

**(8) ‘Low-Dose Naltrexone (LDN): Tricking the Body to Heal Itself’**

<http://www.sciencedaily.com/releases/2011/09/110902133047.htm>

**(9) ‘Extending the approved use of low-dose naltrexone’: UK Parliament Adjournment debate**

(Nia Griffith): Labour MP for Llanelli Nia Griffith led a debate on extending the approved use of low-dose Naltrexone, on 8 December 2011 based on the premise that ‘Low Dose Naltrexone or LDN is a drug which can help regulate a dysfunctional immune system in autoimmune diseases including cancers, HIV/Aids, Multiple Sclerosis, Crohn's disease’.

<http://news.bbc.co.uk/1/hi/health/10190213.stm>

**(10) Adding The Patient Perspective To Comparative Effectiveness Research**

Albert W. Wu\*, Claire Snyder, Carolyn M. Clancy and Donald M. Steinwachs, Health Affairs, October 2010, Vol. 29, No. 10, 1863-1871

Comparative effectiveness research generates evidence that helps consumers, clinicians, purchasers, and policy makers make better decisions about health care. Capturing the patient's perspective is central to this research because it provides a complete picture of treatment impact. This can be done with standardized questionnaires that ask patients to

report on their functioning, well-being, symptoms, and satisfaction with care. These data, however, are not collected routinely in either clinical research or practice. Strategies and incentives to link patient-reported outcomes to data from conventional sources-including clinical research, electronic health records, and administrative data-will accelerate the development of useful evidence.

<http://content.healthaffairs.org/content/29/10/1863.abstract?sid=18618fe7-d37f-45f7-be1b-77306039f54f>

## **(11) Breakthrough in stroke treatment**

Updated March 22, 2012

Newcastle researchers say they have had a significant breakthrough in their three-year study on treatment options for people suffering from acute strokes.

The findings published today show two-thirds of patients treated with a new drug, Tenecteplase, demonstrated major improvements within 24-hours.

Newcastle University's, Professor Chris Levi says in some cases patients severely affected by stroke returned to normal function within days.

He says it is a huge improvement on previous treatments.

"This is the first major breakthrough in clot-busting treatment in stroke really over the past decade and the team here in Newcastle are incredibly proud of the work," he said.

"This new drug which has been around for some time and used in heart attack has not been properly tested in stroke until now.

"Lo and behold we've shown that it is much more effective than the standard treatment."

Professor Levi says Tenecteplase must be administered immediately after the stroke so the clot can be broken down.

He says the team is now applying for additional funding to make it the largest clinical trial coordinated in the Hunter.

"The older drug is a good drug - it can effectively cure one in about every 10 patients," he said.

"This drug looks to be, possibly, twice as effective so the proportion of patients that showed dramatic clinical improvements was substantially higher. It could well be that if this translates through this drug could cure one in every three or one in every four patients."

<http://www.abc.net.au/news/2012-03-22/breakthrough-in-stroke-treatment/3905284>

## REFERENCES – PART 2 – PREVIOUS EHEALTH SUBMISSIONS

**(12) Feedback Submission on the Draft Concept of Operations Relating to the introduction of a Personally Controlled Electronic Health Record (PCEHR) System**, submitted 31 May 2011

[http://yourhealth.gov.au/internet/yourhealth/blog.nsf/247FAB32617E207FCA2578DA00084E37/\\$FILE/Case%20Health%20submission.doc](http://yourhealth.gov.au/internet/yourhealth/blog.nsf/247FAB32617E207FCA2578DA00084E37/$FILE/Case%20Health%20submission.doc)

**(13) Submission in response to Community Affairs Committee Inquiry into Australia's Personally Controlled Electronic Health Record (PCEHR) Bill**, submitted 8 January 2012

[http://www.aph.gov.au/Parliamentary\\_Business/Committees/Senate\\_Committees?url=clac\\_ctte/pers\\_cont\\_elect\\_health\\_rec\\_11/submissions.htm](http://www.aph.gov.au/Parliamentary_Business/Committees/Senate_Committees?url=clac_ctte/pers_cont_elect_health_rec_11/submissions.htm)

## REFERENCES – PART 3 – HUMAN & HEALTH RIGHTS REFERENCES

**(14) 'Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights'**

United Nations Economic & Social Council on 'The right to the highest attainable standard of health' (article 12 of the International Covenant on Economic, Social and Cultural Rights) 11 August 2000; E/C.12/2000/4. (General Comment No. 14 (2000))

[http://www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En)

**(15) 'Global Crisis – Global Action: Declaration of Commitment on HIV/AIDS' Adopted by General Assembly resolution S-26/2 of 27 June 2001**

<http://www2.ohchr.org/english/law/hiv.htm>

**(16) 'International Covenant on Civil and Political Rights (ICCPR)'**

PART II: Article 2.2.

‘ ... Where not already provided for by existing legislative or other measures, each State Party to the present Covenant undertakes to take the necessary steps, in accordance with its constitutional processes and with the provisions of the present Covenant, to adopt such legislative or other measures as may be necessary to give effect to the rights recognized in the present Covenant. ... ‘

PART II: Article 2.3.

‘ ... Each State Party to the present Covenant undertakes:

- (a) To ensure that any person whose rights or freedoms as herein recognized are violated shall have an effective remedy, notwithstanding that the violation has been committed by persons acting in an official capacity;
- (b) To ensure that any person claiming such a remedy shall have his right thereto determined by competent judicial, administrative or legislative authorities, or by any other competent authority provided for by the legal system of the State, and to develop the possibilities of judicial remedy;
- (c) To ensure that the competent authorities shall enforce such remedies when granted.

<http://www.austlii.edu.au/au/other/dfat/treaties/1980/23.html>