



April 2015

HAI AP News

Penang, Malaysia

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HAI AP Est. 1981

Health Action International Asia-Pacific (HAIAP) is part of an independent global network, working to increase access to essential medicines and improve their rational use through research excellence and evidence-based advocacy. HAIAP is an informal network of non-governmental organisations and individuals in the Asia-Pacific Region committed to strive for health for all now. HAI AP News is the organ of Health Action International – Asia Pacific and presents the happenings in the regional campaigns for more rational and fairer health policies and carries material in support of participants' work.

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Message from the Coordinator

From 6-7 April 2015, together with several HAIAP partners: Dr Zafrullah Chowdhury, Dr Krisantha Weerasuriya, Dr Manuj Weerasinghe, Dr Mira Shiva, Dr Delen de la Paz and Ms Evelyne Hong, I participated in a two day workshop on Universal Health Care, Anti-microbial Resistance and Access to Medicines organized by TWN and the Commonwealth Foundation, in Kuala Lumpur, Malaysia. We met over lunch on 7 April to update and share HAIAP matters.

We discussed HAIAP's status as a virtual entity and agreed that this continue in view of the funding situation. We agreed that HAIAP provided a platform

for members to share information, views, opinions, news and research and that members should try and utilize this platform more frequently. I expressed appreciation of the contributions of Beverley Snell who oversees the functioning of the HAIAP website and is producer and principal editor of HAIAP News.

We agreed that members should try to identify, mentor and inculcate younger health activists and interest them in HAIAP matters.

In addition we agreed that we should continue to use opportunities such as the TWN-organised workshop, to meet and update each other as well as renew familial (HAIAP) ties, whenever possible. We shall try to explore project possibilities for funding in the future, following up on leads given by members.

On 14 April 2015, I met with Prof Niyada Angsulee Kiatying, Chairperson of HAIAP's Governing Council, in Penang, to share information on HAIAP matters including the HAIAP satellite meeting in KL. Niyada will explore funding possibilities for a small 3-4 country project on drug pricing and IPRs.

Niyada and I will be part of the HAI team participating at this year's 68th WHA 2015 in Geneva from 19 - 26 May 2015. Niyada will be self-funded while my travel and accommodations costs will be covered by the Commonwealth Foundation and TWN.

Shila Kaur, Coordinator, April 2015

TPPA negotiations as at April 2015

Beverley Snell

As we know, the Trans Pacific Partnership (TPP) <<http://www.citizen.org/TPP>> is a massive, controversial 'free trade' agreement currently being pushed by big corporations and negotiated behind closed doors by officials from the United States and 11 other countries – Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam.

Leaders from the 12 countries negotiating the controversial TPP indicate that the next meeting will lead to a signing of the agreement. However each time there has been a 'final' meeting so far, the Agreement has not been concluded because there are still areas of serious disagreement. HAIAP News has been following the developments. Our last issue gave a comprehensive picture of what is at stake. [HAIAPNews10December2014](#)

It is not easy to even find out when the next meeting will be and where, because of the secrecy surrounding the whole venture.

Dr Deborah Gleeson, a member of the People's Health Movement, is a lecturer in the School of Public Health and Human Biosciences at La Trobe University. Her research focuses on the impact of trade agreements on health care and public health policy. Deborah has followed the negotiations associated with the development of the TPPA as closely as possible, given the secrecy, since its beginning. Thanks to Deborah, HAIAP has been able to keep in touch with developments.

Some major Concerns

Elements of the US Congress are concerned about the impact on agricultural products among other things.

http://www.nytimes.com/2015/03/26/business/trans-pacific-partnership-seen-as-door-for-foreign-suits-against-us.html?_r=1

Australian Minister for Health Andrew Robb assures Australians that he will not permit the Pharmaceutical Benefits Scheme to be compromised and a negative impact on access to medicines will not be allowed. Without transparency and access to the complete text we are not convinced. Secrecy still surrounds all

aspects of negotiations. An impact assessment published by Dr Gleeson *et al* in February 2015 focussed on the cost of medicines, tobacco control policies, alcohol control policies, and food labelling; and showed a negative impact on all those areas.

In New Zealand March 7 was a National Day of Action against the TPPA and rallies took place in major cities through the country.

'The TPPA poses an enormous threat to NZ's ability to regulate for itself, and gives foreign investors and multinationals new rights to control our laws. This could mean losing the ability to regulate our workplaces, our environment, our health and education systems and much more.'

www.itsourfuture.org.nz

Vietnam is the poorest country and the TPPA could have an enormous impact on availability of affordable essential medicines in Vietnam. Access to treatment for HIV infection could be halved.

In *Assessing the impact of alternative patent systems on the cost of health care: the TPPA and HIV treatment in Vietnam*, presented by Moir, Tenni, Gleeson and Lopert in November 2014, the authors summarise

'In the Trans Pacific partnership Agreement (TPPA) negotiations, the United States has proposed expanded patent protections that will likely impact the affordability of medicines in TPPA partners. This includes antiretroviral (ARV) medicines used in the treatment of HIV and AIDS. Vietnam has the lowest GDP per capita (US\$1,911 in 2013) of the 12 countries participating in the TPPA negotiations. Official estimates suggest that in 2014 Vietnam had around 256,000 people living with HIV. By the end of 2013 antiretroviral (ARV) therapy was provided to 82,687 people – 68% of those meeting the clinical criteria for such medicines.' Read more [here](#)

We have been informed that the next 'Ministerial meeting is expected to be held in May 2015. It has been agreed that there are 'lots of loopholes' still to be fixed and there are some indications that if negotiations are not concluded by mid year, the TPPA could go 'on to the back burner'.

Important current references:

Hirono K, Haigh F, Gleeson D, Harris P, Thow AM. *Negotiating healthy trade in Australia: Health Impact*



Assessment of the proposed Trans Pacific Partnership Agreement. February 2015. Centre for Health Equity Training Research and Evaluation, part of the Centre for Primary Health Care and Equity, Faculty of Medicine, UNSW Australia. Click [Here](#)

Neuwelt P , Gleeson D and Mannering B. Patently obvious: a public health analysis of pharmaceutical industry statements on the Trans-Pacific Partnership international trade agreement. *Critical Public Health*, 2015

<http://www.tandfonline.com/doi/abs/10.1080/09581596.2015.1022510#> or Click [here](#)

Thow AM, Gleeson D, Friel S. What doctors should know about the Trans-Pacific Partnership Agreement *MJA* 202 (4) · 2 March 2015 165 Click [here](#)

<http://cutyourteeth.co/2015/03/27/sovereignty-at-stake-wikileaks-releases-draft-tpa-chapter-on-investment/>

<http://www.smh.com.au/federal-politics/political-news/wikileaks-reveals-local-health-and-environment-rules-under-threat-20150326-1m7y8d.html>



Drugs to Avoid

Prescrire International March 2015
Vol 24, #158

<http://english.prescrire.org/en/81/168/49881/0/NewsDetails.aspx>

To help healthcare professionals and patients choose high-quality treatments that minimise the risk of adverse effects, we have updated our list of drugs to avoid in early 2015.

Prescrire's assessments of the harm-benefit balance of new drugs and indications are based on a rigorous procedure that includes a systematic and reproducible literature search; identification of patient-relevant outcomes; prioritisation of the supporting data based on the strength of evidence; comparison with standard treatments; and an analysis of both known and potential adverse effects.

This 2015 review of medications examined in these pages over a five-year period, from 2010 to 2014, identified 71 drugs that are more harmful than beneficial in all their authorized indications.

Drugs are considered within therapeutics categories.

Prescrire considers it is necessary but not sufficient for healthcare professionals to remove these drugs from their list of useful treatments: health authorities must also take concrete steps to protect patients and promote the use of treatments that have an acceptable harm-benefit balance.

Literature Links

The Cynical Connectedness of Gilead's Pricing and Anti-Diversion Policies

Professor Brook K. Baker, Senior Policy Analyst Health GAP, Northeastern U. School of Law January 16, 2015

<http://www.thebodypro.com/content/75407/the-cynical-connectedness-of-gileads-hepatitis-c-p.html>

Gilead has both announced the highest recorded prices ever for its direct acting hepatitis C antivirals, sofosbuvir/ledipasvir, and one of the most stringent anti-diversion programs ever devised. The price, highest in the US, comes in at a whopping \$94,000 for a 12-week course of treatment, with slightly lower prices in Europe. Before this combo was approved, Gilead charged \$84,000 – a \$1000 a pill – for stand-alone sofosbuvir, earning \$8-10 billion in the first year of sales. This is for a course of treatment that experts have estimated can be manufactured for approximately \$100.

International Women's Day 2015

[http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(15\)60469-X.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60469-X.pdf)

The 2015 UN theme for International Women's Day (March 8) - Empowering Women, Empowering Humanity: Picture it! - envisions a world in which women can exercise their choices, whether that be participating in politics or living in a society free from violence and discrimination. This year marks the 20th anniversary of the adoption of the Beijing Declaration and Platform for Action, a globally endorsed framework towards advancing gender equality, human rights, and women's empowerment.

Universal health coverage: reaching a consensus

David Nicholson www.thelancet.com Vol 385 March 7, 2015
[http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(15\)60129-5.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60129-5.pdf)

After World War 2, the UK was on its knees. Many soldiers and civilians had died in the fighting, major cities had been ravaged by bombings, and the economy was on the brink of bankruptcy. The situation could not have been less auspicious. And yet the UK invested in health, launching the National Health Service on July 5, 1948, available to everyone, paid for by general taxation, and free at the point of delivery. The following decades have seen various waves of international debate about the value of universal health coverage (UHC) and the best way to achieve it.

Experts and international organisations flirted with the potential of user fees and of voluntary insurance. A global consensus is now emerging on the best ways to pursue UHC, as documented in the report of the

Universal Health Coverage Forum, of the World Innovation Summit for Health. Delivering Universal Health Coverage: a Guide for Policymakers.

Delivering UHC: a guide for policy makers

Report of the WISH Universal Health Coverage Forum 2015.
David Nicholson, Robert Yates, Will Warburton, Gianluca Fontana

<http://wish-qatar.org/summit/2015-summit/reports-en/universal-health-coverage-en>

This review summarizes the evidence around some of the critical policy choices and issues related to UHC and addresses:

What to cover: The choices and trade-offs policymakers need to make between the dimensions of population coverage, service coverage and financial protection.

How to pay for UHC: Raising the necessary resources, then allocating and managing these resources efficiently and equitably.

How to implement UHC: The issues that need to be addressed to implement UHC reforms successfully.

The Fukushima Daiichi disaster: 4 years on

Justin McCurry
www.thelancet.com Vol 385 March 21, 2015
[http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736\(15\)60302-6.pdf](http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736(15)60302-6.pdf)

4 years after a tsunami caused devastation and a nuclear disaster in Japan's Fukushima prefecture, life is far from restored for the local residents evacuated from the area.

Immunisation: graphic reminder

Clem Broughton
<https://www.mja.com.au/insight/2015/4/clem-broughton-graphic-reminder>

In the 1950s, if a person developed acute flaccid paralysis it created fear and apprehension in the neighbourhood, as everyone knew that this condition could be permanent and occasionally life-threatening. It also meant that the infectious polio virus was active, possibly in the local neighbourhood. Communities faced similar apprehension when there were cases of diphtheria and acute meningitis, as both were recognised as being infectious, dangerous and sometimes fatal. Other infectious diseases such as mumps were considered painful and unpleasant, and measles, chickenpox, and rubella were a part of growing up and virtually unavoidable. Today parents do not see polio, diphtheria or most of these infectious diseases as a result of effective immunisation programs.

The complacency that doctors predicted many years ago is now happening. An added problem is that doctors today are graduating without the ability to recognise some of these diseases, such as measles.

While most parents do respond positively to objective data on the protective efficacy of available vaccines, small groups of chronic sceptics opposed to immunisation persist and they seem quite impervious to such information, however eloquently it may be presented.

The only approach likely to be effective is an emotional one — show them what these diseases actually look like in living breathing colour and sound, and what they can do to young children.

A video is now available online — [click here](#) to watch it. I know of no more convincing argument for the importance of immunisation.

Industry: code breaches

Ken Harvey
<https://www.mja.com.au/insight/2015/7/ken-harvey-code-breaches>

Self-regulation does not ensure drug companies comply with ethical standards. An analysis of the prevalence and severity of breaches of codes of conduct in the pharmaceutical industry in the UK and Sweden prompted me to review data in Australia. The *PLOS Medicine* analysis of complaints, complainants and rulings regarding drug promotion in the UK and Sweden between 2004 and 2012 revealed the discrepancy between the ethical standards codified in industry codes of conduct and the actual conduct of the industry.

For comparison, I reviewed data from annual reports of the [Medicines Australia](#) Code of Conduct.



Krill oil marketing: a case study of Australia's broken regulations

6 February 2015, *The Conversation*.
<https://theconversation.com/krill-oil-marketing-a-case-study-of-australias-broken-regulations-36770>

Ken Harvey, Aaron Kovacs, Grace Jackel
[In Australia, complementary medicines are not traditional medicines that are available affordably to the population. They are manufactured and marketed commercially and vogueously at prices often far exceeding the cost of essential allopathic medicines. BS Ed.]

Complementary medicines such as krill oil don't always have the science to back up their claims.

Two out of three Australians regularly use complementary medicines, which constitute a A\$3.5 billion (US\$2.6 billion) domestic market. But the

industry's marketing strategies are a source of ongoing controversy and pose a significant challenge for regulators.

Products containing krill oil provide a good example of the kinds of extravagant claims made by supplement manufacturers. The oil is derived from a tiny, shrimp-like crustacean and, like fish oil, contains omega-3 fatty acids.

Company claims include krill oil's capacity to 'relieve arthritic symptoms [of osteoarthritis and rheumatoid arthritis] within a short period of 7 to 14 days', as well as its 'superior absorption' and the curiously ambiguous '9x [strength]' of the less expensive fish oil. Such claims are found on product packs and manufacturers' websites, as well as the websites of third-party stockists.

Few companies provide links to research supporting such claims. What research does exist is not easily accessible to most consumers, who, at any rate, can rarely assess its validity.

Claims and science

The widely used claim that krill oil relieves the symptoms of arthritis within seven to 14 days appears to be based on a small 2007 study. The research focused on one specific formulation of krill oil, produced by a Canadian company. Possible conflicts of interest, including the source of funding for the study, are notably absent from the paper.

The study recruited 90 people with a confirmed diagnosis of one or more of cardiovascular disease, rheumatoid arthritis (ten people) and osteoarthritis (30 people). They were compared to placebo groups of 12 and 26. Three patients pulled out of the trial before completion, and 12 did not have a diagnosis of either osteoarthritis or rheumatoid arthritis. While some results at seven and 14 days were deemed statistically significant, the meagre number of people involved raises questions about the clinical significance of its conclusions.

Regardless of this and other details of the report that suggest only people with very severe cases of illness were included, the findings of this early and isolated study can, at best, be considered preliminary. And a search of a comprehensive research database found no evidence that the results had been replicated independently.

The claim of krill oil having 'superior absorption' is also dubious and not supported by research evidence. A 2014 review of krill oil absorption actually concluded

there was no evidence for krill oil being more easily absorbed by the human body.

Regulatory challenges

Companies that market complementary medicines in Australia are legally required to comply with standards set by the Therapeutic Goods Administration (TGA) relating to both the quality of the product and advertising claims.

But manufacturers self-certify their compliance with TGA requirements. Limited, as well as poorly targeted, post-market surveillance of complementary products means they can contravene standards without fear of reprisal. Then there's the lack of effective penalties to deter companies from breaching TGA regulations.

In May 2013, the Therapeutic Products Advertising Complaint Resolution Panel determined claims such as '9x stronger' and 'reduce[s] pain, stiffness and inflammation caused by arthritis, within a short period of 7 to 14 days' breached a number of sections of the Therapeutic Goods Advertising Code 2007.

It said such statements: *ought to be supported by a wide body of scientific evidence involving a number of independent studies.*

But the claims continue, even by companies asked to withdraw them. Numerous reports over the last decade have recommended that the lack of effective penalties for offending companies be redressed. But it seems unlikely any changes will be implemented any time soon as

both industry and government support a deregulation agenda. Meanwhile, consumers continue to be ripped off by products that cannot deliver on their promises.

Notice

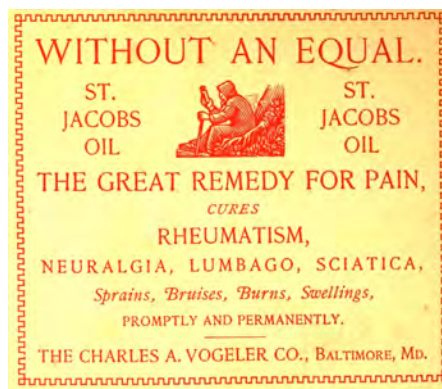
Several HAIAP members attended the Asia Pacific Conference on National Medicines Policies in Sydney 2012. The whole report is now available as a supplement to Australian Prescriber:

Asia Pacific Conference on National Medicines Policies; Conference Report, Aust Prescr 2013;36 Suppl 1:S1-56

<http://www.australianprescriber.com/supplement/36/1/1/1>

Another supplement, Independent therapeutic advice: How achievable is it? is also available. Independence Forum, Aust Prescr 2013;36 Suppl 2:S1-48

<http://www.australianprescriber.com/supplement/36/2/1/>



Feature: Health Care Systems - Antibiotics and Antimicrobial Resistance

Krisantha Weerasuriya

Presented at the Workshop on Universal Health Care, Anti-microbial Resistance & Access to Medicines
Kuala Lumpur, Malaysia, 6-7 April 2015

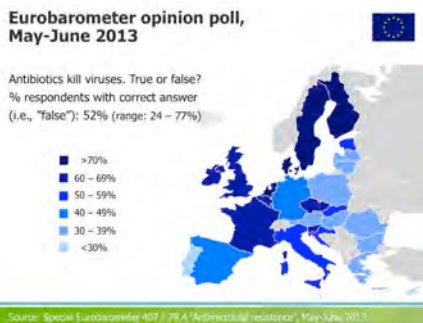
Some principles and questions concerning access to medicines with a focus on antibiotics

- Health care systems should regulate all medicines
- Are antibiotics special in regulation or the same as other medicines?
- Other medicines (antihypertensives) do not have effects in the community
- Antibiotics do have effects in the community and are special areas in medicines regulation
- Antibiotics have uses outside human medicines use (animal farming)
- The effects of antibiotics (and Antimicrobial Resistance) have a large economic impact on society

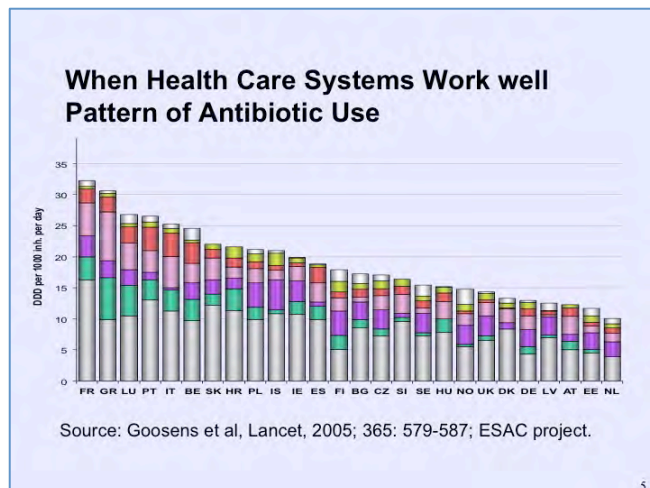
Regulation of Medicines by Health Care System:

- Regulatory control of manufacturing needs to be in place to ensure the quality of products - availability of poor quality products has an impact on individuals and communities.
- Prescribing of antibiotics needs to be controlled and focused on treatment with narrow spectrum and not broad spectrum drugs to avoid negative consequences for communities
- Antibiotic treatment guidelines should be adhered to, to avoid the consequences of misuse of antibiotics
- Regulation should control advertising so Prescription Only Medicines may not be advertised to the public
- Dispensing – full courses, particularly of antibiotics, need to be dispensed
- Affordability is an issue – if drugs are cheap enough they can be subject to misuse, if they are expensive there can be problems of access
- How are Pharmacists reimbursed? What incentives are in place? Fee for service or percentage of the cost of the drug?

The Eurobarometer opinion poll, May-June 2013 asked what is responsible for the 'success' in the use of Antibiotics in HICs?

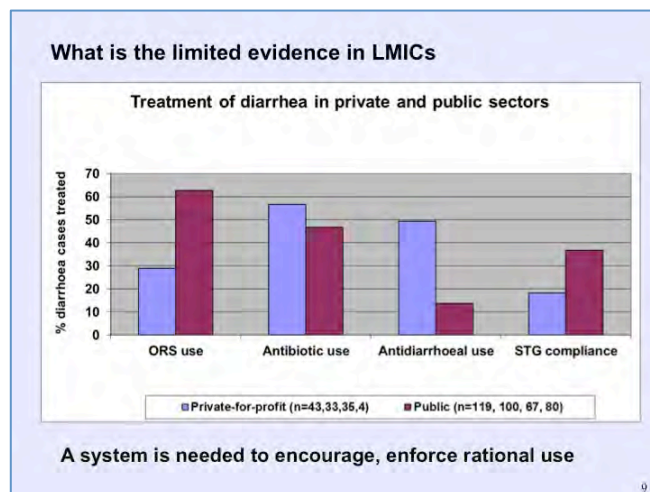


Universal Health Coverage was seen as effective - through a comprehensive health care system (mainly in High Income Countries – HIC) Bhutan was given as an Example from LMICs and Oman from a HIC. However where UHC exists, it still may not be totally satisfactory.



Note the health care system is able to provide the data on antibiotic consumption – health system working well. However note France (extreme left) Belgium (middle) and Netherlands (extreme right); neighbouring countries but extremes in antibiotic use.

Effects of poor control and regulation of antibiotics can still be seen and the availability of poor quality antibiotics results in increase in resistance.



Resistance also results from common inadequate treatment courses that result in partial cure and recurrence. We know irrational use is common but it is difficult to detect failures and consequences of irrational use. Diarrhea, coughs and colds get cured anyway as the natural history of illness.

Major questions arise

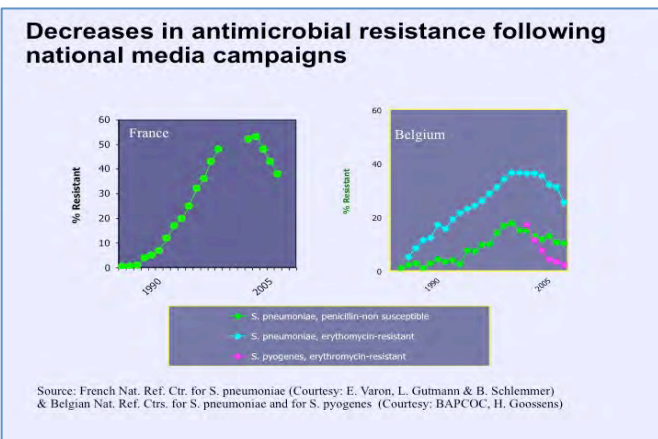
- Powerful antibiotics are needed for serious infections but there is increased mortality due to resistance – how can it be detected?
- Can we achieve rational use of antibiotics in private for profit (out of pocket payment) health care systems?

WHA 68.20 Draft global action plan on antimicrobial resistance could be helpful:

Initiatives suggested for activities under the global action plan

Objective 1: Improve awareness and understanding of antimicrobial resistance through effective communication, education and training

- Antibiotics awareness days [Note – National Media campaign to decrease demand from patients/consumers and to persuade doctors not to prescribe antibiotics.]



- Educating the consumer (or helping him to save money in LMICs?)
(Don't waste money on antibiotics for coughs, colds and simple diarrhea – these conditions will become better naturally)
- Antibiotic resistance in professional education (medical, pharmacy, veterinary, nursing)
- Every ill does not require a pill
- Common sense about the common cold

Objective 2: Strengthen the knowledge and evidence base through surveillance and research

- What is the extent of antibiotic resistance? Provide information to reach the prescribers
- Standardised measurement of Antibiotic resistance to compare data within and across countries
- Surveillance will be a routine part of health care system activities
- Demonstrate the economic impact of antibiotic resistance

Objective 3: Reduce the incidence of infection through effective sanitation, hygiene and infection prevention measures

- Use simple measures – alcohol hand rub in between examining patients
- Keep pre-school children with cough and cold at home to prevent them spreading infection
- Decrease antibiotic use in animal production (Mc Donalds initiative on antibiotic free meat but not completely there yet)

Objective 4: Optimize the use of antimicrobial medicines in human and animal health

- Use simple low-cost diagnostics at point of care
- Separate lists of antibiotics for human health, animal health and agriculture
- Prevent/Regulate promotion of antibiotics in animal health
- Antibiotic Guidelines – Practical and Enforceable
- Use medicines reimbursement systems to monitor antibiotic use according to guidelines
- Control promotional practices of the pharmaceutical industry

Objective 5: Develop the economic case for sustainable investment that takes account of the needs of all countries, and increase investment in new medicines, diagnostic tools, vaccines and other interventions.

It is recognised that the 'Market' will not provide new antibiotics

- New public sector driven agenda for antibiotic research – discovery, development, diagnostics
- Collaboration among various national and international partners
- Research - Vaccines to prevent infection

What implications for AMR are seen in this consumer advertisement?

1. Are antiseptic soaps necessary for these daily occurrences?
2. What effect on the usual antimicrobial flora?
3. What regulation maybe needed if at all?

These issues demonstrate the complexity of the whole AMR issue

Advertisement from a supermarket in Sri Lanka: Antibioticing daily life?

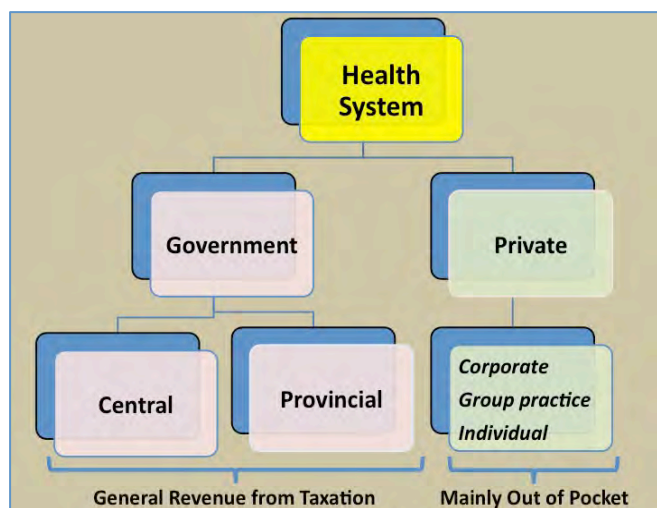
Feature: Universal Health Coverage: Sri Lanka

Manuj Christantha Weerasinghe

Presented at the Workshop on Universal Health Care, Anti-microbial Resistance & Access to Medicines
Kuala Lumpur, Malaysia, 6- 7 April 2015

Experience from Sri Lanka

Sri Lanka has a health system that encompasses state funded 'free of charge at the point of delivery' service and a fee levying private sector. The government sector has a centrally controlled and a provincial setup. Both are funded by revenue from general taxation. The private sector is mainly funded by out of pocket expenditure of patients. Only few corporate employees get Insurance schemes for health.



Government has a good network of both curative and preventive facilities throughout the country and usually a government health facility is within 5 km from a household. Major private facilities are clustered in the capital Colombo and regional main cities. However, individual practice is seen even in rural areas.

Health Financing: The percentage of GDP for health has been reducing during the last five years. The private sector expenditure for health has been rising despite free health service in the government sector, and most of private expenditure is out-of-pocket (OOP).

Further, the recurrent expenditure on health is rising compared to the capital expenditure. It is also seen that expenditure for preventive and promotive healthcare is stagnating while curative expenditure takes the lion's share.

Strengths in the system

The welfare policies in the health and social sectors in the country have continued for the last eight decades despite changes in political and world orders. High literacy gained through free education and the public conscience on the value of free healthcare has

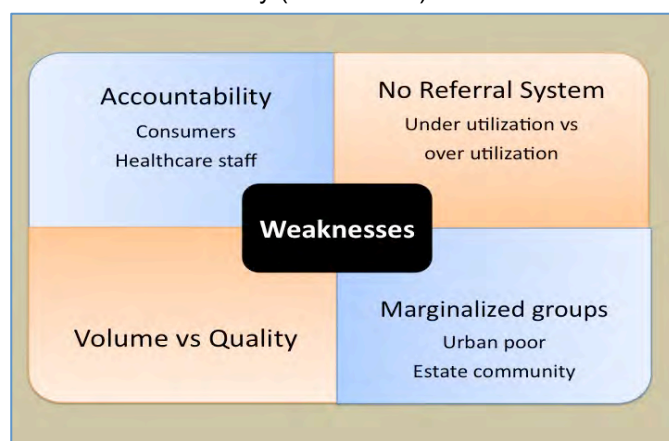
prevented any government from making radical changes in the financing of health. In particular, pushing for privatization of health is resisted by the consumers as well as the employees of the public system - certainly for two different reasons. Availability of a good network of infrastructure and skilled human resources in the state sector have supported the present UHC model to continue. However, unlike the public system there is no guaranteed employment in private sector for the healthcare workers so the majority of the trained Health HCWs are still in the government system. They do work in the private sector afterhours for additional income.

Weaknesses

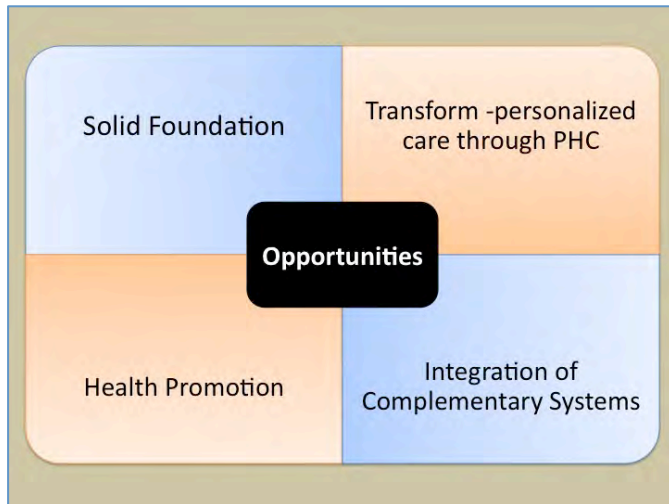
One of the key issues is accountability of consumers and HCW in the free health system. Because they do not directly pay for services and have a guaranteed employment, both parties are not conscious of the cost to maintain the system. This situation has created opportunities to abuse the system and there is ignorance of the very concept of sustainability. Accountability mechanisms are very weak in the system and wasteful spending is unaccounted for.

Lack of a strict referral system creates a situation where PHC centres are grossly underutilized and major facilities are over burdened. These circumstances result in waste of resources in both facilities; and further increase of patient volume at major facilities reduces the quality of care - both technical and service quality. It has been difficult to implement a referral system due to high expectation of consumers and also attitudes of Health Centre staff.

Within this system, certain groups do not get the optimal benefits of the free system, particularly the urban poor and estate community (tea estates).



Opportunities



The present infrastructure, skilled human resources and the social welfare policy could be the basis of further strengthening UHC in Sri Lanka. It is a solid foundation to work on. There is the opportunity to convert the episodic care delivery model to a continued care for the consumers making it a personalized care system through PHC - particularly for the non-communicable diseases. This approach would reduce the complications and disease burden in the long run.

Further, health promotion can be further strengthened to reduce the disease burden and improve wellbeing, using the existing solid foundation.

Sri Lanka still retains a plural system with other complementary healing modalities. There is a huge opportunity for harmonizing the health system to make use of those complementary resources.

Challenges

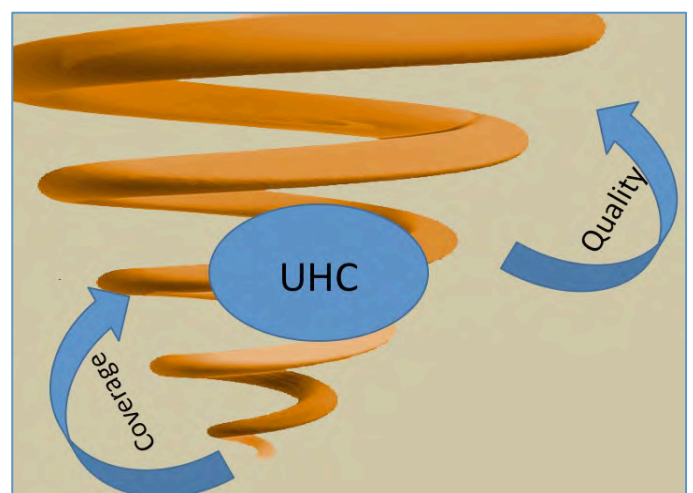
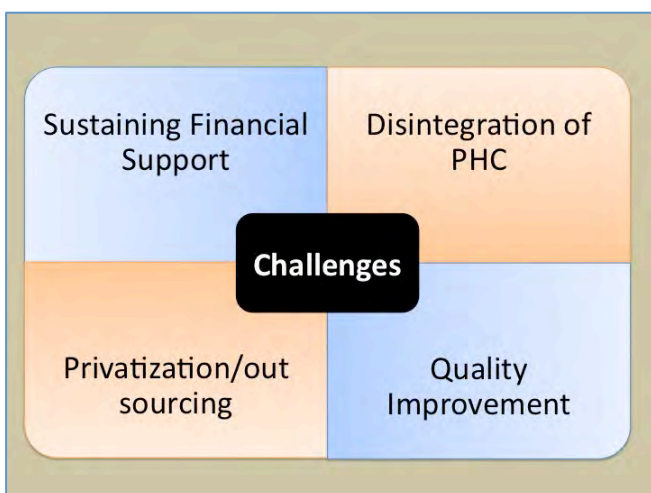
With the financial crisis world wide and in the country, it is a huge challenge to sustain the resource allocation to maintain a free health system - particularly at a time when consumer expectations are high – for both service and technical quality. Quality improvements need

higher spending on capital works. In addition, Human Resources need development and increasingly trade union demands must be accommodated. All those add to the cost factor.

Although poor urban communities and estate populations are covered by free health care, access remains a challenge. The urban poor live in an environment that is not conducive to keeping health as a priority. Lives are dedicated to making enough money to survive. In the estate sector, literacy of the population is lower than the rest of the country and their work norms are different to many other manual workers. In addition they tend to feel culturally isolated from mainstream services.

At the same time, the international fiscal influences are moving towards curtailing welfare measures and converting to private enterprise. There is a tendency for the government to slowly out-source services to the private sector and finally privatise government establishments.

Some disintegration of preventive and promotive agencies within the government sector is also seen. This tendency is due to a multitude of reasons, from wrong policy decisions to personal attributes of HCWs. In the PHC system many agencies that were functioning as pillars of Public Health have been eroded during the last two decades. Unnecessary expansion of the directorate resulted in further compartmentalization of decision making and service provision. For example, maternal health services have been divided into several units looking at morbidity, mortality, family planning, ante natal, post natal, special services and so on. There Those sub-sections are being managed by different program officers working more or less independently without the much needed integration. Added personal differences of those decision makers make it further difficult to implement integrated programs. New efforts are needed to integrate policy making process and service delivery to sustain a healthy public health system.



Homeopathic Drugs: approaches to assessment in Canada and Australia

[Larry Sasich in Canada and Ken Harvey in Australia. with thanks to E-drug]

1. Canada: Regulation of Homeopathic Drugs and Natural Health Products

Larry D. Sasich, Canada

Dear Colleagues,

The March 13th episode of the Canadian Broadcasting Corporation's Market Place program focused on Health Canada's regulation of homeopathic products and by implication Natural Health Products. To say the least, it was eye opening. The producers of Market Place were able to license a fictitious homeopathic product for children with Health Canada and the only evidence required for safety and efficacy being photocopies of two homeopathic drug monographs from old textbooks. This is the link to a 22-minute program:

<http://www.cbc.ca/marketplace/episodes/2014-2015/drugstore-remedies-licence-to-deceive> [not available all countries]

The reputation of a country as having an advanced regulatory authority is not sufficient to license products and should be viewed with skepticism.

2. Australia: National Health and Medical Research Council (NHMRC) releases final statement and advice on homeopathy March 11.

<http://tinyurl.com/lfj3coo>

Ken Harvey, Australia

The National Health and Medical Research Council released a statement concluding that there is no good quality evidence to support the claim that homeopathy is effective in treating health conditions. Its release follows a thorough review of the evidence, conducted as part of NHMRC's responsibility to provide advice and support informed health care decisions by the Australian community.

The conclusion is based on the findings of a rigorous assessment of more than 1800 papers. Of these, 225 studies met the criteria to be included in NHMRC's examination of the effectiveness of homeopathy. The review found no good quality, well-designed studies with enough participants to support the idea that homeopathy works better than a placebo, or causes health improvements equal to those of another treatment.

Although some studies did report that homeopathy was effective, the quality of those studies was assessed as being small and/or of poor quality. These studies had either too few participants, poor design, poor conduct and or reporting to allow reliable conclusions to be drawn on the effectiveness of homeopathy.

According to CEO Professor Warwick Anderson, 'All medical treatments and interventions should be underpinned by reliable evidence. NHMRC's review shows that there is no good quality evidence to support the claim that homeopathy works better than a placebo.' He drew particular attention to the NHMRC Statement on Homeopathy's advice that homeopathy should not be

used to treat conditions that are chronic, serious, or could become serious: 'People who choose homeopathy may put their health at risk if they reject or delay treatments for which there is good evidence for safety and effectiveness. People who are considering whether to use homeopathy should first get advice from a

registered health practitioner and in the meanwhile keep taking any prescribed treatments.'

'From this review, the main recommendation for Australians is that they should not rely on homeopathy as a substitute for proven, effective treatments.' 'This statement was the result of a rigorous examination of the evidence and used internationally accepted methods for assessing the quality and reliability of evidence for determining whether or not a therapy is effective for treating health conditions.' 'NHMRC is also aware of strongly held views on this topic so it is important to note that the process was thoroughly consultative and that the public was invited to submit information and evidence, all of which was considered by our expert working committee.'

The findings of the homeopathy working group's review are summarised in the final NHMRC Information Paper: Evidence on the effectiveness of homeopathy for treating a clinical condition was also released.

See: <http://www.nhmrc.gov.au/guidelines-publications/cam02>

The release follows public consultation on the draft information paper in 2014. The Statement, Information Paper and Frequently Asked Questions are available on the above NHMRC website.



Ketamine secured for medical and veterinary use!

Willem Scholten

[With thanks to E-drug March 13, 2015]

[Proposals brought before the UN to restrict global access to ketamine would leave the two billion people living in most rural areas of developing countries with no alternative anaesthetic for vital surgeries. Ketamine is an essential medicine used for anaesthesia. In developing countries it is commonly used in caesarean sections and without it many women enduring difficult labours would die, as they would be deprived of life-saving surgery. Like many important medicines, ketamine is misused by some populations including those in China. We could not allow that to stop people living in poorest countries from accessing life-saving medicines. BS Ed]

This morning, the Commission on Narcotic Drugs discussed the possible bringing of ketamine under international drug control. Initially, China proposed to add the substance under Schedule I of the UN Convention on Psychotropic Substances. Such a scheduling means that the substance can be used for medical purposes only under direct governmental supervision, and in very limited situations. The proposal was very inappropriate for an essential medicine. However, thanks to the efforts of many, China amended its proposal to the less strict Schedule IV of the same convention. Again we opposed this and thanks to our opposition, China withdrew this morning its entire proposal. The CND then decided to postpone its decision on scheduling ketamine to a future date to allow more information to be gathered. A transcript of the debate is available here:

<http://www.cndblog.org/2015/03/agenda-item-6b-change-in-scope-of.html#more>

This is a very good result and I want to thank everyone who was involved in the lobbying to keep access to ketamine as a human and veterinary medicine for his or her efforts. In the end we had 87 endorsements on the fact sheet and several organizations came to Vienna to convince the delegates personally. Many went to their governments to convince the ministries of health and the drug controllers that any scheduling of ketamine was not a good idea.

Over the past few weeks it became more and more clear that we were successful, and many countries declared that they would oppose the scheduling. Initially, we were able to find over 19 CND members opposing schedule IV, and once we had these, we continued to convince more CND Member countries to oppose all scheduling. This became clear only gradually toward last weekend.

Finally China withdraw its proposal while saving face by saying that this allows for more data collection. It may be that we never hear back about ketamine scheduling, but some vigilance is needed in the coming years.

What further to do? There are over 50 countries who have scheduled ketamine in their national legislation (i.e. independent from the international drug control conventions). In several of these countries, veterinarians and physicians may have experienced reduced availability of ketamine already. They and their organizations may want to discuss the issue now with their governments in order to re-increase availability. Because of this CND and China's proposal, the climate may have changed now. After some of the preparatory meetings, someone mentioned that this was the first time ever that the countries at the CND discussed medicines availability for over three hours. Never before was there such a focus at the international level on the relationship between drug control and medicines availability. Therefore, this is the moment that most drug controllers around the world are seeing there can be a negative impact of drug control on public health and medicines unavailability. Medical and veterinary organizations may also want to use the opportunity for general discussion on controlled drugs and medicines availability, for example the availability of opioid analgesics, long-acting opioids for the treatment of opioid dependence, phenobarbital and other controlled medicines.

For those who want to take action in this regard, I also refer to the WHO Guidelines on this issue, available in multiple languages, including English, French and Spanish:

http://www.who.int/entity/medicines/areas/quality_safety/guide_nocp_sanend/en/index.html

I thank you once more, and I dare to do so also on behalf of the others who were involved in a core team of campaigners.

[The e-drug forum proved very useful for sharing information on the ketamine issue and for promoting awareness raising among CND delegates We believe these activities contributed greatly to the ultimate favourable decision. BS Ed.]

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What will it take to create a tobacco-free world?

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Last month, British American Tobacco released their preliminary results for 2014. 'I am delighted with the excellent progress we have made', said chief executive, Nicandro Durante. It has been 'another strong performance in 2014', he added. The Group's revenue continued to grow by 2.8% and its adjusted profit from operations increased by 4.4%. Of the 667 billion cigarettes sold in 2014, 197 billion were sold in the Asia-Pacific and 227 billion were sold in Europe, the Middle East, and Africa—regions known as 'high-growth markets'. An increase in market share driven by continued growth of leading brands meant the Group's cigarette volume decline of 1.4% was less than the overall industry decline, estimated at 2.5%.



Contrast this glowing picture with a public health view. The WHO Framework Convention on Tobacco Control (FCTC) is often referred to as a landmark treaty in global health, ushering in optimism and hope of turning back the tobacco tide with its raft of tobacco control

measures. However, despite considerable, although uneven, progress in reducing the global prevalence of daily smoking in the decade since the FCTC came into being, around 50 million people, mostly men and largely in the poorer countries of the world, have died from using tobacco.

So what is needed to turn the tide on tobacco?

In March 2015, *The Lancet* launched a campaign for a tobacco-free world by 2040. A three-paper Series marks the 10-year anniversary of the coming into force of the FCTC, and was published to coincide with the 16th World Conference on Tobacco or Health which took place in Abu Dhabi, United Arab Emirates (March 17–21).

Current global anti-tobacco strategies are failing. We endorse the Series' call for a UN high-level Summit on tobacco use to reinvigorate global and national efforts to achieve a tobacco-free world by 2040. The time has come for not only greater WHO leadership, but also leadership from the UN Secretary-General, because tobacco is not just a threat to health, it is also a threat to sustainable human development

Also check this video: *Last Week Tonight with John Oliver: Tobacco* <https://www.youtube.com/watch?v=6UsHHOCH4q8>

Strengthening adverse drug reaction reporting in Nepal

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http://pmindexing.com/journals/index.php/AJMS/article/view/635/pdf_309

Pharmacovigilance in Nepal is still in infancy. To date only healthcare professionals are involved and the problem of under-reporting is seen. The national pharmacovigilance centre is located in the national regulatory authority of Nepal, i.e. Department of Drug Administration (DDA). Lack of adequate human resources for managing the pharmacovigilance program in Nepal has limited the growth of pharmacovigilance activities. Currently, there is neither any involvement of community pharmacists in Adverse Drug Reaction (ADR) reporting process nor any involvement of consumers for the same. This paper reviews the current status of pharmacovigilance and mentions possible benefits of involving consumers or patients in the existing pharmacovigilance program. This study also describes the role of healthcare professionals in ADR reporting, possible reasons for underreporting of ADRs, regulatory perspectives and benefits of involving consumers in pharmacovigilance.

Until now, there are no plans for risk alleviation caused due to medicines among consumers in Nepal. Initiating consumer pharmacovigilance can be an important beginning made towards strengthening the existing pharmacovigilance systems as well as providing an opportunity for consumers to be involved in pharmacovigilance. This study also highlights the approaches for strengthening pharmacovigilance in Nepal.
