August 2017

HAI AP News

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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.

In this issue

HAIAP Meeting at Gonoshasthaya Kendra, Bangladesh November 10-12, 2017

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The meeting will concentrate on Ensuring Access to Affordable, Safe, Quality Essential Medicines and their Rational Use, there will be a focus on antibiotic resistance, the failure of a profit-orientated pharmaceutical system to meet the challenge of providing new antibiotics, the role of antibiotic guidelines and other educational initiatives, meeting the challenge of pharmaceutical promotion and a multi-country study on drug pricing.

Relevant country stories will be solicited and presented: action-orientated initiatives that have made a difference. The aim is to stimulate HAIAP members to further action, nurture younger health activists by promoting intergenerational exchange and identify underlying problems for placing on the agenda of the 2018 *Revive Health for All* meeting.

In the preliminary program for the HAIAP November 10-12 meeting at GK, The following sessions have been suggested:

S1. Key note address, possible speaker to be contacted:

S2. National Medicine Policy:

S3. Promotion:

S4. Antibiotic resistance:

S5. Multi-country drug pricing study: Niyada

S6. Country sharing:

S7. Trade and Medicines:

S8. Key issues for 2018 meeting:

S9. HAIP Internal matters:

People who wish to share ideas, contribute to the sessions proposed and /or attend the meeting please contact Shila

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WHO updates Essential Medicines List 20th Essential Medicines List (2017)

http://www.who.int/medicines/news/2017/20th_essential_med-list/en/

The 20th Essential Medicines List, published on 6 June 2017, marks the ***40th anniversary*** of this flagship WHO tool to expand access to medicines. The updated list adds 30 medicines for adults and 25 for children, and specifies new uses for nine already-listed products; bringing the total to 433 drugs deemed essential for addressing the most important public health needs globally.

The 20th List also provides new advice on which antibiotics to use for common infections and which to preserve for the most serious syndromes, based on a thorough review of all essential antibiotics. Intended to optimise antibiotic use and reduce antibiotic resistance without restricting access, the List categorises antibiotics into three groups: ACCESS, WATCH, RESERVE.

Important additions include medicines for HIV, hepatitis C, tuberculosis and cancer. The updated EML also includes several new drugs, such as two oral leukemia treatments, a new pill for hepatitis C that combines two medicines, a new treatment for HIV as well as an older drug that can be taken to prevent HIV infection in people at high risk, new paediatric formulations of medicines for tuberculosis, and two cancer pain relievers.

The 6th list for Children is also available.

- EML 20th edition (March 2017) pdf, 1.50Mb <http://www.who.int/entity/medicines/publications/essentialmedicines/20th_EML2017.pdf?ua=1>

- EML Children 6th edition (March 2017) pdf, 1.19Mb <http://www.who.int/entity/medicines/publications/essentialmedicines/6th_EMLc2017.pdf?ua=1>

- Executive Summary pdf, 723kb <http://www.who.int/entity/medicines/publications/essentialmedicines/EML_2017_ExecutiveSummary.pdf?ua=1>

- Unedited Full Report pdf, 8.91Mb <http://www.who.int/entity/medicines/publications/essentialmedicines/EML_2017_EC21_Unedited_Full_Report.pdf?ua=1>

HAI Commends WHO Decision Not To Include Long-Acting Analogue Insulins On The Essential Medicines List

Health Action International (Europe) commended the decision by the WHO to reject a proposal to include long-acting analogue insulin on the WHO Model List of Essential Medicines (EML).

A decision to include long-acting analogue insulin on the EML would have increased pressure on national governments to purchase these insulins, which are seven to nine times more expensive than human insulin, while providing limited added value to users. The result would have been fewer people being treated and more deaths.

To read the full press release, including comments from Health Action International's Dr Margaret Ewen, co-leader of the Addressing the Challenge and Constraints of Insulin Sources and Supply (ACCISS) Study, please go to: http://haiweb.org/media-centre/

The global war on tobacco is far from over

MJA Issue 28 Insight 24 July 2017

https://www.doctorportal.com.au/mjainsight/2017/28/the-global-war-on-tobacco-is-far-from-over/?utm_source=MJA+InSight&utm_campaign=fd0ee98a5a-EMAIL_CAMPAIGN_2017_07_21&utm_medium=email&utm_term=0_7346f35e23-fd0ee98a5a-42154993

Authored by Alessandro Demaio

Dr Alessandro Demaio is a staff member of the World Health Organization in Geneva. He alone is responsible for the views expressed in this publication and they do not necessarily represent the decisions or policies any third party.

This article is dedicated to the incredible, tireless efforts of the globally renowned Australian public health leaders who have defined and inspired leadership on tobacco control for decades.

Australia now has one of the lowest smoking rates in the world, with 14.7% of adults aged 18 years and over smoking daily, down from 16.1% in 2011-12. Australian federal, state and territory governments have made a commitment to further reduce the smoking rate to 10% by 2018. The residual smokers are concentrated among marginalised people including people with mental health issues and the indigenous population.

At the global level, there is good news too. According to a new report from the WHO this week, 63% of the global population are now covered by policies such as strong tobacco warning labels and smoke-free public places – a quadrupling in coverage since 2007 alone. In the 7 years to 2014, more than 53 million people in 88 countries stopped smoking because of anti-smoking measures driven through the Framework Convention on Tobacco Control (FCTC); this framework itself represents an incredible achievement from the global community.[1]

Industry tactics

The same week in July, sobering new evidence emerged reminding us that a sense of accomplishment, or worse, completion, couldn't be further from the truth, and that risks from public health complacency could be enormous and deadly. Leaked internal documents from

1. http://tobaccocontrol.bmj.com/content/early/2016/12/09/tobaccocontrol-2016-053381http://apps.who.int/iris/bitstream/10665/255874/1/9789241512824-eng.pdf

the tobacco giant, Philip Morris, offered additional insights into the appalling and progressively complex tactics used by industry to protect profits over population health; increasingly focused on the world's poorest nations, coordinated and effective beyond imagination, and ruthlessly deadly in nature.

Never before seen papers showed deliberate and calculated strategies to obstruct progress on health policies worldwide. [2] Efforts included holding simultaneous and secretive industry meetings alongside major global health and WHO-led conventions in Moscow and New Delhi, with the sole purpose of obstructing progress towards further achievement of tobacco control. A 2014 internal company presentation refers to these conventions as 'regulatory runaway trains' driven by 'anti-tobacco extremists'. It details intricate plans to counter plain packaging programs: an evidence-based and WHO-endorsed strategy for reducing tobacco deaths. Industry 'roadblocks' (their term), for example, by challenging such policies as unconstitutional and a breach of trade agreements and copyrights, were cited as 'important solutions' to delay health policies.

Such scare and delay tactics are effective; the Philip Morris litigation against Australia's plain packaging laws saw New Zealand delay the adoption of similar strategies in 2013. This intimidation approach is particularly effective when waged on poorer nations with less economic ability to defend public health efforts. These sorts of legislative challenges to tobacco control measures also work to deter efforts by other nations; this is known to industry and reflected in their business strategies. The 2014 Philip Morris meeting concluded with emails from company executives congratulating their team on efforts to dilute or block measures intended to strengthen tobacco controls and reduce cigarette-related deaths.

Industry targets national health programs

Leaked papers also show that tobacco executives target health programs and policies at a country level. One method described complex efforts aimed at ensuring that tobacco policy decisions remained in the hands of Ministries of Finance and ***not*** Ministries of Health, as the former were perceived as more likely to prioritise revenue from tobacco sales over the resulting disease. Indeed, one written and systematic objective of the tobacco industry was 'avoiding a declaration of health over trade'.

Condemning evidence also emerged of Philip Morris's actions in India [3] with a 2014 internal document explicitly highlighting the targeting of India's youth as an opportunity to increase market share. The company has been linked to direct payments to tobacco shops to display advertising, and distributing free cigarettes at nightclubs and bars, both in direct conflict with national law.

The threat to public health posed by predatory, pernicious and pervasive industry practices such as these cannot be overstated: it is a matter of life and death. In India alone, tobacco accounts for almost 1 million deaths per year and health expenditure on tobacco-related disease is estimated at $16 billion annually.[4]

These newly leaked documents describe cold, calculated obstructions of public health efforts by strategic, powerful and unscrupulous industry executives. These are not desperate acts of a dying industry, in fact Philip Morris International's share price has doubled since 2008 and no fewer people smoked daily in 2016 worldwide than they did 10 years earlier.[5]

The tobacco industry is not alone

These behaviours are not limited to the tobacco industry alone, with many of the same approaches now adopted by food, alcohol and soft drink producers alike. In 2016, the Global Energy Balance Network[6] encouraged policy

[2] http://www.reuters.com/article/pmi-india-idUSL3N1KA1VE

[3] http://www.reuters.com/article/pmi-india-idUSL3N1KA1VE

[4] http://www.reuters.com/article/pmi-india-idUSL3N1KA1VE

[5] https://www.forbes.com/sites/danielfisher/2014/05/28/philip-morris-international-bets-big-on-the-future-of-smoking/3/#6f4bc49f1c56

[6] https://well.blogs.nytimes.com/2015/12/01/research-group-funded-by-coca-cola-to-disband/

to emphasise exercise in the mitigation of obesity. As it turns out, the primary goal of this network was to shift health policy focus away from effective, nutrition-based interventions by using distraction tactics and dubious science. Later, it was revealed that this very platform was funded by Coca-Cola, with even its website registered to the soft-drink multinational.

While cigarettes are the only product that when used exactly as designed will kill one in two of its users, the continuing power and influence of the global tobacco industry cannot be underestimated. Nor should the public health or medical communities expect the tactics to be any different as we strive to protect populations from other highly profitable health threats. If anything, as further progress is made, we should expect such tactics to become more desperate, depraved and deadly. And while we should be proud of the progress made to date, not for a moment should we think that the battle is even close to ending.

E-cigarettes in Australia and regulatory options

https://theconversation.com/twelve-myths-about-e-cigarettes-that-failed-to-impress-the-tga-72408

February 6, 2017

Author Simon Chapman, Emeritus Professor in Public Health, University of Sydney
Simon Chapmans Public Health Advocacy and Tobacco Control: ***Making Smoking History*** *was published by Blackwell (Oxford) in 2007.* ***Removing the emperor's clothes: tobacco plain packaging in Australia*** *(free as e-book) was publiished by Sydney University Press in 2014.*

Before retiring he contributed to an options paper on the regulation of Electronic Nicotine Delivery Systems commissioned by the Department of Health, Canberra.

Australia's Therapeutic Goods Administration (TGA) rejected an application to liberalise the scheduling of nicotine. This prompted the predictable round of protests from proponents of e-cigarettes who have long touted them as the next public health wonder of the world, even as important as antibiotics.

But unlike antibiotics, which are heavily regulated, require a prescription, and must demonstrate both safety and efficacy to regulatory bodies, e-cigarettes and the liquids used in them are virtually unregulated.

Tobacco harm reduction has had a history of monumental failures. It started with the global multi-million dollar promotion of filters. One of these was the infamous asbestos-filtered 'micronite filters' in Kent cigarettes. More recently, we saw the now outlawed consumer deceptions of the light and mild cigarette fiasco. And on the way we even had 'reduced carcinogen' brands.

These were designed to keep people smoking and slow the mass exodus that began in the early 1960s. Millions did just that. Only quitting and the decreasing incidence of smoking (ie. never starting) have dramatically decreased the tobacco disease epidemic.

Professor Chapman looked at 12 mantras about e-cigarettes that seem to have failed to impress the TGA. You can read his full analysis here:

https://theconversation.com/twelve-myths-about-e-cigarettes-that-failed-to-impress-the-tga-72408

Here is the list with some comments:

1. Vaping is '95% less harmful than smoking'

This specific point estimate (synonymous with '5% as bad for you as smoking') has rapidly evolved into 'fact' (in the political sense of that term). It seems to have emerged from nowhere when the Public Health England report asserted the figure. That was traced to what was actually a huge misinterpretation of what was only a made-up number, from one junk-science journal article.

2. Vaping is orders of magnitude less harmful than smoking

3. Nicotine in vaping is benign

4. Vaping has caused 6.1 million European smokers to quit

How many of those who claim that they have stopped with the aid of e-cigarettes would have stopped anyway, and how many of those who used an e-cigarette but failed to stop would have stopped had they used another method.

This raises important questions about whether e-cigarettes may be keeping many smokers smoking, while helping others to quit.

5. Just cutting back smoking (rather than quitting) significantly reduces risk

6. Vape is just like water vapour and (often) nicotine

And there's the liquid propylene glycol in which the nicotine and flavour chemicals are vapourised.

7. Nicotine-free cigarettes contain no nicotine

Advertisement: 'Nicotine-Free' E-Cigs Still Deliver the Juice'.

8. Second-hand vape is harmless, so it should not be restricted

9. There's no good evidence for e-cigarettes being a gateway to smoking in young people

10. E-cigarette explosions are overrated

11. Big Tobacco really wants its smoking customers to switch to e-cigarettes

Companies continue to do all they can to wreck effective tobacco control policies like plain packaging, graphic health warnings and significant tobacco tax hikes.

Philip Morris has been running targeted advertising campaigns with major youth appeal. And new evidence collated from its own documents demonstrates its interest in e-cigarettes, as long ago as 1990, was only ever for them to be used as a complement to cigarettes.

In June 2017 Philip Morris advertised for a 'Manager-scientific – explaining that

> 'Philip Morris International has made a dramatic decision to build our future on smoke-free products that are a much better choice than cigarette smoking. Indeed Our Vision is that these Reduced Risk Products (RRPs) will one day replace cigarettes.'

Big Tobacco has heavily invested in e-cigarettes, with all major tobacco companies now having them in their portfolios. The big picture here is that Big Tobacco wants people to smoke *and* vape, not vape *instead of* smoking.

And 12. Leading public health agencies encourage 'light touch' regulation

Eighteen countries ban e-cigarettes outright, with more having various degrees of restrictions. Among leading agencies with strong concerns about e-cigarettes are the US Surgeon General, the World Health Organization, the FDA, 31 mostly major health agencies that petitioned the FDA to regulate e-cigarettes, Australia's National Health and Medical Research Council and now the TGA.

Australia: *New complementary medicine health claims lack evidence, so why are they even on the table?*

Ken Harvey and Beverley Snell

See also https://theconversation.com/new-complementary-medicine-health-claims-lack-evidence-so-why-are-they-even-on-the-table-80896 July 21, 2017

Australia's Drug Regulator, the Therapeutic Goods Administration, (TGA) is responsible for registering medicines that have passed the quality safety and efficacy criteria to be available in Australia.

Complementary and 'Traditional' medicines are not registered but can become available as ***Listed*** Medicines. ***Listed medicine***s are all unscheduled medicines with supposed well-known low-risk ingredients, often with a long history of use, and also include such items as vitamin and mineral products or sunscreens. These products are assessed by the TGA for quality and safety but not for efficacy. It is a requirement under the Therapeutic Goods Act 1989 [7] that sponsors hold information to substantiate all of their product's claims. But the sponsors do not have to ***produce*** that information to achieve Listing of products.

The Therapeutic Goods Administration (TGA) is proposing changes to their permitted indications. An example of a 'low level' permitted indication might be 'may relieve the pain of mild osteoarthritis'.

If approved, the suppliers can use this permitted indication to market its Listed product, one of ***about 11,000*** Listed complementary medicines on the Australian Register of Therapeutic Goods (indicated by 'Aust L' on packaging).[8]

The spread-sheet of 1,345 draft permitted indications published by the TGA for review, includes many that seem to lack evidence to back them.

For instance, despite the Therapeutic Goods Advertising Complaints Resolution Panel upholding complaints of a lack of evidence that magnesium (and homeopathy) 'relieve muscle cramps (and restless legs)', this permitted indication is still on its draft list.

Other examples include 'supports transport of oxygen in the body', 'regulates healthy male testosterone levels'.

The list contains around 140 traditional Chinese medicine indications, such as 'Harmonise middle burner (Spleen and Stomach)', 'Unblock/open/relax meridians', 'Balance Yin and Yang'.

There are also around 900 additional indications for unspecified 'traditions'. These include, 'Renal tonic', 'Helps healthy liver regeneration', 'Emmenagogue', 'Vermifuge' and 'Vulnerary'.

Endorsing traditional medicines without evidence that they work

Scientific investigation has not substantiated many aspects of so-called traditions, such as the homeopathic principles of 'like cures like' and traditional Chinese medicine concepts of meridians through which the life-energy known as 'qi' flows.

Safety?

We also cannot assume traditional medicines are safe. Emerging data highlight how common adverse reactions and drug interactions really are.

[7] https://www.tga.gov.au/legislation-legislative-instruments

[8] https://www.tga.gov.au/australian-register-therapeutic-goods

For example, Hyland's homeopathic baby teething products were recalled by the US Food and Drug Administration and then the TGA. This was because lack of quality control over potentially toxic ingredients – belladonna alkaloids – associated with adverse events in hundreds of babies.

In China, out of the 1.33 million case reports of adverse drug event reports received by the National Adverse Drug Reaction Monitoring Center in 2014, traditional Chinese medicine represented around 17.3% (equivalent to around 230,000 cases). [9]

What we propose

Listed medicines, like those mentioned, are meant to contain pre-approved, relatively low-risk ingredients. They should be produced with good manufacturing practice and be safe and only make 'low-level' health claims for which evidence is held. Given the lack of pre-market evaluation of listed products, and the high levels of non-compliance with the requirement that sponsors must hold evidence to support their claims, we believe that to safeguard shoppers the proposed draft list of permitted indications should be drastically shortened and only contain modest indications stating, 'may be helpful for..', 'may assist..', etc. If sponsors have evidence that would justify a higher-level claim than they should use the proposed new pathway whereby the TGA would assess the evidence before approving the claim.

We submit that it is essential that all such medicines contain a prominent disclaimer along the following lines:

> *'This product's traditional claims are based on alternative health practices that are not validated by modern medical science. There is no scientific evidence that this product works. Also, a tradition of use does not guarantee product safety.'*

We welcome moves to better regulate complementary medicines in Australia, but the current list of permitted indications, without disclaimers, represents a government endorsement of pseudoscience. Worse, it will encourage consumers to purchase often ineffective and sometimes dangerous products.

Industry position

Industry representatives argued they needed a long list of permitted indications to allow consumers to tell the difference between one product and another. They also argued that disclaimers for traditional medicines were unnecessary. Their wishes made it to the draft list, rather than ours.

Summary

Recommendation 44 of the Medicines and Medical Devices Review advocated that a prominent disclaimer should apply to all promotional materials relating to Listed complementary medicines, including product information on websites, to the effect that the efficacy claims for the product have not been independently assessed and/or are based on presumed traditional use. This approach was opposed by industry and rejected by the current government, presumably because of industry lobbying and a compliant regulator.

Australia is a multicultural society, and it's appropriate we respect and have some knowledge of other medical traditions. However, traditional use does not mean that that the medicine is effective; this requires scientific study. In addition, medicines are not necessarily safe just because they are said to be 'traditional'. Studies by TGA and others have found that many so called traditional medicines have contained heavy metal contaminants, rat poisons, illegal substances like prescription medicines and obsolete prescription medicines as well as endangered animal parts.[10]

'Traditional' and other 'ethnic' products can contain endangered animal parts which are prohibited under the CITES Convention which bans the import and export of endangered animals and plants and their parts. In addition to animals being endangered, some components such as bear bile and bear paws are from living bears held in conditions of extreme cruelty. Other components such as rhino horn and tiger penis are from endangered animals killed by poachers; and have been scientifically proven to have absolutely no therapeutic value. But they are sold at enormous cost to 'believers' who think they have aphrodisiac properties.

Malaysia

Urgent action needed on Hepatitis C

By Martin Khor

This article was first published in The Star (Malaysia, 31 July).
http://www.thestar.com.my/opinion/columnists/global-trends/2017/07/31/urgent-action-needed-on-hepatitis-c-its-not-acceptable-that-500000-msians-are-infected-with-the-dise/

It's not acceptable that 500,000 Malaysians are infected with the disease but cannot afford treatment, when a total cure is available.

WORLD Hepatitis Day fell on July 28. So it was timely that the alarming situation of Hepatitis C in Malaysia has been highlighted.

The Star revealed last Friday that over 500,000 Malaysians aged 15 to 60 are infected with Hepatitis C, but most are unaware because there are no early symptoms. Hepatitis C can seriously damage the liver,

[9] http://www.sda.gov.cn/WS01/CL0078/124407.html

[10] http://www.abc.net.au/news/2015-12-10/traditional-chinese-medicines-dangerous-chemical-contaminants/7015534

especially when it leads to cirrhosis (serious scarring) and cancer.

What is more alarming is the high incidence and its recent rate of increase. In 2009, the Hepatitis C incidence rate was 3.71%, and this shot up to 8.57% in 2016, said Health Minister Datuk Seri Dr S. Subramaniam on July 20.

That indicates one in 12 adult Malaysians has Hepatitis C. The incidence rate for Hepatitis B also rose from 2.13% to 12.6% in the same period. Combined, that's a very high rate of hepatitis.

The good news is that a new cure for Hepatitis C is now available. The bad news is that it is very expensive for Malaysians, though much cheaper in other countries. And the hopeful news is that we might get good treatment at a cheap rate by next year, if all goes well.

The year 2013 saw a breakthrough in Hepatitis C treatment with new direct-acting antivirals which may cure up to 95% of cases.

In the new regime, the main drug is sofosbuvir (produced by Gilead) which is often combined with another drug to make it more effective.

The big problem is that the original price of sofosbuvir was fixed at US$84,000 (RM 359,436) for a 12-week treatment course in the United States.

Currency conversion: approximately RM 4 = US$ 1.

In Malaysia, the cost may be up to RM 300,000 for the full treatment, according to *The Star* report.

Last November, the Consumers Association of Penang reported that a patient in a private hospital had been charged RM 385,000 for a 24-week course a few years ago.

Even though prices may have fallen since, 'life-saving Hepatitis C treatment is beyond the reach of most Malaysians', said CAP president S.M. Mohamed Idris.

Gilead has entered agreements allowing some Indian drug companies to produce and sell sofosbuvir in about 100 low- and middle-income countries, and the cost has gone down to about US$200 to US$300 (RM 855 to RM 1,283) for them. But Malaysia is one of the 41 middle-income countries excluded.

In countries which have not patented the drug, generic versions of sofosbuvir are available for a 28-day course at prices ranging from US$15 (RM 64) in Pakistan to US$197 (RM 842) in Bangladesh in 2016, according to World Health Organization (WHO) data.

In countries where Gilead holds the patent, the originator branded product (Sovaldi) was selling for prices ranging from US$2,292 (RM 9,807) in Brazil to the launching price of US$28,000 (RM 119,812) in 2013 in the US for a 28-day supply.

The company has been criticised for making super profits through charging as much as the market can bear and excluding the majority who need treatment.

Worldwide, Hepatitis C causes 700,000 deaths each year.

'It can be completely cured with direct acting antivirals (DAAs) within three months. However, as of 2015, only 7% of the 71 million people with chronic Hepatitis C had access to treatment,' said WHO.

In Malaysia, the situation is bad, as very few of the infected are able to get treatment. The Health Minister said on July 21 that 'it currently costs RM 30,000 to RM 40,000 per person for 12 weeks of treatment'. But he also indicated that 'we hope to bring it down to RM 1,000; if we do that it will be a major success'.

The Health Ministry is cooperating with the Drugs for Neglected Diseases initiative (DNDi), a Geneva-based non-profit research and development organisation, to do clinical trials for a combination of sofosbuvir and ravidasvir drugs. According to DNDi executive director Dr Bernard Pecoul, DNDi had agreed with Pharco, an Egyptian drug company, to provide treatment for Malaysians for around US$300 (RM 1,283).

One issue is that sofocbuvir is patented in Malaysia, unlike Egypt which rejected the patent application. If a product is patented, rival brands are not allowed to be sold.

However, the WHO and national patent laws allow governments to issue 'compulsory licences' or 'government use orders' on various grounds.

Malaysia is no stranger to this. In 2003, the Government issued a government use order to enable import of two combination HIV and AIDS drugs from an Indian generic company, which resulted in great savings as the cost fell by 68% to 83%, and three times more patients could be treated.

Malaysia earned praise for this action, with other countries following suit, including Thailand and Indonesia. Today it is quite common for countries to issue compulsory licences.

If the price can be brought down from the original RM 400,000 and the present RM 40,000 to only RM 1,000, imagine the massive savings to the Government and country, and the joy of the patients.

Feature: Antimicrobial Stewardship

Analysis of AMR/AMS Plans in the Western Pacific and South East Asia Regions

Prepared by Beverley Snell and colleagues

Introduction

The United Nations General Assembly and the World Health Organisation have identified antimicrobial resistance (AMR) as a fundamental threat to human health and global health security.[11] In 2014, the WHO's Global Surveillance Analysis recognised alarming rates of resistance to essential antibacterial drugs among bacteria commonly associated with hospital and community acquired infections in each of the six WHO global regions. Rates of multi-drug resistance among previously treated Tuberculosis (MDR-TB) cases have risen to 20.2% in Eastern Europe and Central Asia, while the prevalence of artermisinin-resistant malaria infections is increasing globally.[12]

A draft of the WHO's Global Action Plan on AMR was put forward at the Sixty-eighth World Health Assembly in 2015, with the aim of ensuring continuity, accessibility and responsible use of existing treatments for infectious diseases. [13] These resolutions were supported by joint commitments from the World Organization for Animal Health and the Food and Agriculture Organization of the United Nations (FAO) in May and June of 2015, respectively. [14]

The WHO's Global Action Plan calls for all WHO member nations to construct their own national plans by May, 2017. The WHO Global Action Plan provides a template as a guide for developing all components of the National Action Plans (NAPs) as well as a guide for the implementation plans that would be developed following the development of the NAPs.

Several national action plans in the WHO's Western Pacific Region and South East Asia region were available on the WHO websites by early 2017. [15]

The format and content of the identified national action plans were examined against the WHO's Global Action Plan template.

Western Pacific Countries

Seven of the 37 Countries in the Western Pacific region with Plans available in English were Australia, Cambodia, People's Republic of China, Fiji, Japan, Philippines and Vietnam. Cambodia's National Policy to Combat Antimicrobial Resistance is supported by a partner document, the National Strategy to Combat Antimicrobial Resistance; for our purposes, the latter document has been viewed.

South East Asia countries

The WHO South East Asia Region has 11 Member States: Bangladesh, Bhutan, Democratic People's Republic of Korea, India, Indonesia, Maldives, Myanmar, Nepal, Sri Lanka, Thailand, Timor-Leste.

Countries with Plans available on the website are Bangladesh, Democratic Republic of Timor-Leste, India, Indonesia, Maldives, Nepal, Sri Lanka, Thailand.

The WHO Global template:

The WHO guidance manual is here

http://www.who.int/antimicrobial-resistance/national-action-plans/manual/en/

WHO provided a 22 page sample template for a National Action Plan on Antimicrobial Resistance to assist countries in the development of their own Plans.

http://www.who.int/antimicrobial-resistance/national-action-plans/sample-template.pdf?ua=1

The template provides guidance for development of

- Executive summary
- Background
- Introduction
- Situation analyses and assessment
- Country response
- Governance

Country responses could be developed under the following strategic objectives.

Strategic objective 1: Improve awareness and understanding of antimicrobial resistance through effective communication, education and training.

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[11] WHO. At UN, global leaders commit to act on antimicrobial resistance New York: WHO; 2016 [cited 2017. Available from: http://www.who.int/mediacentre/news/releases/2016/commitment-antimicrobial-resistance/en/

[12] WHO. Antimicrobial Resistance Global Report on Surveillance. Geneva, Switzerland: WHO; 2014.

[13] WHO. Global Action Plan on Antimicrobial Resistance. Geneva: WHO; 2015. p. 28.

[14] Resolution 26: Combating Antimicrobial Resistance and Promoting the Prudent Use of Antimicrobial Agents in Animals. Paris: OIE; 2015; Status Report on Antimicrobial Resistance. Rome: FAO; 2015.

[15] Library of national action plans Geneva: WHO; 2017 [Available from: http://www.who.int/drugresistance/action-plans/library/en/.

Strategic objective 2: Strengthen the knowledge and evidence base through surveillance and research.

Strategic objective 3: Reduce the incidence of infection through effective sanitation, hygiene and prevention measures.

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

Strategic objective 5: Prepare the economic case for sustainable investment, ... and increase investment in new medicines, diagnostic tools, vaccines and other interventions.

Operational Plan of Activities Template

Following the guidance for the development of a strategic plan, the template included guidance for development of an operational plan of activities.

The National Plans

Most countries had followed the template format to a major extent but there is significant variation in the interpretation of the template. The Plans showed that countries addressed issues perceived to be most relevant for them. Australia, Fiji and Cambodia in the WPR and Bangladesh and Maldives in the SEAR were guided by the template to develop strategic plans that would be followed by detailed Operational Plans of Activities that would satisfy the Strategic Plans. The others incorporated action plans into their documents.

One Health Approach

Commitment to the *One Health* model, which recognizes the interconnectedness of animals, humans and the ecosystem as contributing factors to AMR, and therefore promotes a multi-sectoral response, was demonstrated in all the national plans. Genuine involvement in the planning across all relevant sectors was demonstrated in most plans.

Ownership of the Plans

Ownership of the Plans among all 'stakeholders' would be important for successful implementation. A few countries had involved a group of Plan Developers from a fairly narrow range of health sector representatives while naming a wide range of representatives on their steering and implementing committees. Involving as many 'stakeholders' as possible in the development of the plan might result in stronger ownership.

The format of the plans

Those countries whose Plans were presented as *Strategic* plans, to be followed by operational *plans of activities* are difficult to compare with those that included activities for implementation.

Most of the plans that included activities could perhaps have been better conceived had activities been developed later by a dedicated body - to satisfy the needs of *strategic* plans. That would have enabled activities to be planned more precisely with identification of who is responsible and how the activity would be implemented, together with better outcome indicators.

Many, but not all, countries have undertaken studies that identify targets that need to be addressed by an AMR Plan but most countries have not completed a comprehensive situation analysis across all areas.

It is suggested that it could be a sound approach to develop the Plan as a Strategic Plan before developing an operational plan of activities. The *strategic* plan could identify areas needing more study and studies of identified areas could be built into the implementation plan along with other activities.

AMS Guidelines

All plans committed to establishing and maintaining standardised antimicrobial stewardship (AMS) guidelines, programs and materials in hospitals. Australia extended this commitment to aged care and general practice settings, while China, Cambodia and Vietnam committed to AMS programmes in pharmacies.

All countries expressed a commitment to establishing, monitoring and improving surveillance and testing of AMR in human and animal healthcare settings, along with a universal commitment to ensuring adequate laboratory and research facilities. The less developed and smaller countries may not have the capacity to conduct testing to support surveillance and may need to establish links with reference laboratories in more developed countries.

in Thailand before the development of the plan, ineffective coordination meant that antimicrobial resistance profiles produced at sentinel hospitals were not used effectively for clinical decision-making. There was no integrated system for the surveillance of antimicrobial resistance, no system for monitoring consumption of antimicrobial drugs by humans, livestock and pets and little public awareness of antimicrobial resistance.

In August 2016, a national steering committee was formed to guide the plan's implementation with a module to assess the prevalence of household antibiotic use and antimicrobial resistance awareness. A national system for the surveillance of antimicrobial consumption has also been initiated.

Animal Sectors

The countries from Western Pacific and South East Asia that had developed National AMR Plans had very diverse animal sectors. Japan, China and Australia have significant commercial livestock industries. Cambodia has increasing buffalo, pig and chicken industries; Vietnam has increasing dairy industry and extensive poultry farms with a history of bird flu infection.

Thailand has identified in animals, resistant MRC-1 genes that can be traced to China. In December 2015 bacteria with the MRC-1 gene were also found in humans and in meat in England.

Indonesia has a significant commercial meat production industry. Poultry and goat farming exist in Maldives and Philippines has poultry, pig and cattle industries; while in Fiji and several other countries livestock farming is insignificant with most animals kept as 'family' animals. It is clear that plans need to be developed to address the specific needs in the sector. Plans indicate that most countries have identified their needs.

In the Philippines animal sector, excellent targets are identified against which to measure changes while in India there are large livestock industries with no regulatory control at all on the use of antibiotics and they have identified very poor documentation of antibiotic use and AMR in animals that must be addressed.

In May, ReAct Asia Pacific organized a one-day consultation entitled 'Workshop on Anti-Microbial Resistance and use of Antibiotics in non-human sectors' at Thiruvananthapuram, the capital city of the State of Kerala, India. The context for the workshop was set by Dr. B. Ekbal, HAIAP member and member of the State Planning Board.

The workshop attracted delegates from the government Departments of Animal Husbandry, Fisheries, Agriculture, Dairy Development and Environment as well as from large farms, government institutions, and two state universities. The following issues were discussed:

- Surveillance of antibiotic use and resistance in the fisheries sector
- Rational antibiotic use in fisheries sector
- Surveillance of antibiotic use and resistance in production of food animals
- Rational antibiotic use in production of food animals
- Surveillance in environment and agriculture.

The Directors of the Departments of Animal Husbandry and Fisheries gave assurances that the issue of antimicrobial resistance will definitely find a prominent place in the policies of their respective departments. Also, Dr Ekbal stated that he will include the issue of antibiotic resistance in the upcoming five year plan for the state. This is a significant step for a state with population of over 35 million

General approach

While factors needing attention were identified among health care providers, community members and industry, in some cases more detailed studies were needed to identify exact targets and provide a baseline. Several countries, for example Timor Leste, had undertaken significant situation analyses that guided their planned activities.

It is important to be able to identify where additional information gathering or audits are needed. It is equally important that recommendations from studies and audits are implemented promptly and the outcomes evaluated.

Although monitoring is built into most plans, addressing targets identified by monitoring is not always mentioned. It is expected that addressing targets as needed will be covered in further operational plans of activities. Several countries gave no attention to vaccination coverage against vaccine preventable infectious diseases in animals or humans.

Incentives and Morale

Incentives for health staff might encourage adherence to the plans and interest in achieving the goals. Including AMS components in mandatory continuing professional development to maintain their registration, would facilitate greater knowledge of the program and achievement of its goals.

Morale needs to be high so it is important that staff receive adequate support and recognition including adequate salaries.

Lines of Authority

Clear lines of authority need to be in place at all levels of the system so there is no doubt about who can make decisions or provide direction or support concerning activities to support AMS.

Conclusion

Almost all countries in the SEA region have plans. In the WP region many countries still have to develop plans. All countries with plans have demonstrated significant commitment to controlling AMR. Strong political commitment, national ownership and adequate multi-sectoral institutional capacities will be essential for the effective implementation of the national plans. A robust monitoring and evaluation platform must contribute to evidence-based interventions. An integrated system for the surveillance of antimicrobial resistance needs to be established.

You can find the available plans and their titles - to look at in detail - at the following links

Plans from countries

http://www.who.int/antimicrobial-resistance/national-action-plans/library/en/

On the above page, the WHO web library includes, so far, the following:

Western Pacific Region

Australia 36 pages

Responding to the threat of antimicrobial resistance.pdf

Cambodia 19 pages Cambodia Strategy to Combat AMR-3 years 22 July 2014(FINAL).pdf

Cambodia National Policy to Combat AMR 22 July 2014(FINAL).pdf

China 4 pages (link to Chinese language document)

Fiji 17 pages Fiji National AMR Action Plan.pdf

Japan 69 pages JAPAN_National Action Plan on Antimicrobial Resistance.pdf

Philippines 40 pages THE PHILIPPINE ACTION PLAN TO COMBAT ANTIMICROBIAL RESISTANCE.pdf

Republic of Korea National Action Plan on Antimicrobial Resistance (2016-2020).zip in Korean language

Vietnam 27 pages NATIONAL ACTION PLAN ON COMBATTING DRUG RESISTANCE in the period from 2013 - 2020.pdf

Aide Memoire.pdf

South East Asian Region

Bangladesh 12 pages

Antimicrobial Resistance Containment in Bangladesh 2017-2022.pdf
Road map of National Action Plan of ARC.pdf

Democratic Republic of Timor-Leste 53 pages

National Action Plan on Antimicrobial Resistance Timor-Leste 2017-2020.pdf

India 53 pages

National Action Plan on AMR (India).pdf

Indonesia 56 pages

National Action Plan on Antimicrobial Resistance Indonesia 2017-2019.pdf

Maldives 63 pages

National Action Plan for Containment of Antimicrobial Resistance 2017-2022.pdf

Nepal 24 pages

National Antimicrobial Resistance Containment Action Plan_Nepal.pdf

Sri Lanka 38 pages

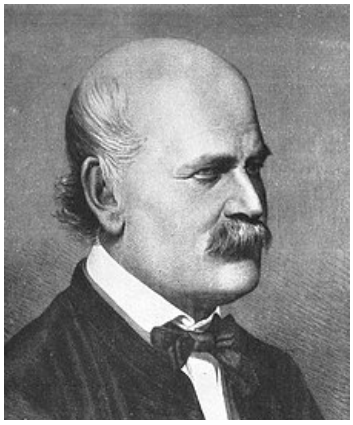
National Strategic Plan for Combating Antimicrobial Resistance in Sri Lanka 2017–2022.pdf

Thailand 43 pages

Thailand's National Strategic Plan on AMR 2017-2021.pdf

Hand Hygiene saves lives

https://www.reactgroup.org/news-and-views/news-and-opinions/year-2017/hand-hygiene-saves-lifes/



The most influential measure to prevent infections in all of recorded history has been hand hygiene. When Hungarian Dr Ignaz Semmelweis, working in Vienna, ordered all physicians and medical students to thoroughly wash their hands in chlorinated lime in 1847, the rate of infections plummeted. Hand hygiene is not only about preventing infections, but also controlling antibiotic resistance. It is the single most important – and most cost-effective – measure to control spread of pathogens whether resistant to antibiotics or not.

As with other 'innovative' ideas about the germ theory of disease, the ideas of Dr Semmelweis were widely rejected at the time. The so-called Semmelweis reflex – to describe a certain type of human behaviour characterized by reflex-like rejection of new knowledge because it contradicts entrenched beliefs - is named after him; his ideas were ridiculed and rejected by his contemporaries.

The most influential measure to prevent infections in all of recorded history has been hand hygiene. Before the time of Ignaz Semmelweis (1818-1865), physicians could move between wards without washing their hands. As an example, a physician could go directly from an autopsy to a delivery. Childbed fever killed 5-10% of all women in obstetric wards run by physicians, which was 10-20 times more than in wards run by midwives. When Dr Semmelweis ordered all physicians and medical students to thoroughly wash their hands in chlorinated lime in 1847, the rate of infections plummeted. Interestingly, this highly effective intervention was done before it was understood that bacteria cause disease.

How does hand hygiene work?

In general, hand sanitation routines rely on two components: washing with soap and running water, and disinfection with alcohol hand sanitizer. The components act differently and are not wholly interchangeable.

Soap acts by making oily substances soluble in water. Infectious agents, bacteria and virus, stick to the oily substances and dirt on our hands. When soap, water and rubbing is added, the oils and dirt are lifted off from the skin and are rinsed away with the water. In the same process, most of the bacteria and viruses are flushed away.

While soap does kill bacteria to some extent, it is not the main effector in hand washing. Notable downsides with soap and water are that water sinks are not possible to set up everywhere, and that washing with soap also removes the protective oils from the skin, causing dryness and skin lesions.

While alcohol hand sanitizers can be placed virtually anywhere or be carried around and do not dry out the hands as soap and water, they too have drawbacks. They do not do a good job on dirty or greasy hands, and have limited effect on some microorganisms. As hand sanitizers do not flush away dirt or contaminants, they also do not remove residues of e.g. body fluids.

Hand hygiene interventions

The WHO and others have developed several resources and tools. Measures include technical improvements such as hand washing stations near all points of care, access to hand sanitizers and good sanitary solutions, such as piped water supply, clean toilets/latrines and proper handling of latrine waste. Staff need to be trained to understand the importance of hand hygiene and to make use of the technical solutions and guidelines for hand hygiene. It is also necessary to understand that healthcare staff set an example of good hygiene routines for the patients they meet.

In the community, the sanitary solutions needed are similar to the ones in health-care. Educational measures include understanding the importance of hand hygiene in daily life: to wash hands before handling food, after toilet visits and when caring for sick family members. In these settings, it is also important to remember that not all bacteria are harmful. Many of the bacteria are shared within the family. These bacteria are not only good for us, but are necessary for our health. Thus some of the rigorous hygiene measures used in healthcare may not be necessary in the community. But it is equally important to remember that pathogens are spread within the family, especially via food.

Article about Dr. Semmelweis.

http://www.pbs.org/newshour/updates/ignaz-semmelweis-doctor-prescribed-hand-washing/

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