

Public Health Association of Australia submission on JETACAR recommendations

Australian Senate

Finance and Public Administration References Committee

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15 February 2013

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1. Introduction

The Public Health Association of Australia Incorporated (PHAA) is recognised as the principal non-government organisation for public health in Australia and works to promote the health and well-being of all Australians. The Association seeks better population health outcomes based on prevention, the social determinants of health and equity principles.

Public Health

Public health includes, but goes beyond the treatment of individuals to encompass health promotion, prevention of disease and disability, recovery and rehabilitation, and disability support. This framework, together with attention to the social, economic and environmental determinants of health, provides particular relevance to, and expertly informs the Association's role.

The Public Health Association of Australia

PHAA is a national organisation comprising around 1900 individual members and representing over 40 professional groups concerned with the promotion of health at a population level.

Key roles of the organisation include capacity building, advocacy and the development of policy. Core to our work is an evidence base drawn from a wide range of members working in public health practice, research, administration and related fields who volunteer their time to inform policy, support advocacy and assist in capacity building within the sector. PHAA has been a key proponent of a preventive approach for better population health outcomes championing such policies and providing strong support for the Australian Government and for the Preventative Health Taskforce and National Health and Medical Research Council (NHMRC) in their efforts to develop and strengthen research and actions in this area across Australia.

PHAA has Branches in every State and Territory and a wide range of Special Interest Groups. The Branches work with the National Office in providing policy advice, in organising seminars and public events and in mentoring public health professionals. This work is based on the agreed policies of the PHAA. Our Special Interest Groups provide specific expertise, peer review and professionalism in assisting the National Organisation to respond to issues and challenges as well as a close involvement in the development of policies. In addition to these groups the Australian and New Zealand Journal of Public Health (ANZJPH) draws on individuals from within PHAA who provide editorial advice, and review and edit the Journal.

Advocacy and capacity building

In recent years PHAA has further developed its role in advocacy to achieve the best possible health outcomes for the community, both through working with all levels of Government and agencies, and promoting key policies and advocacy goals through the media, public events and other means.

This submission on JETACAR

The PHAA thanks the Committee for following up on this important issue by assessing the extent to which the JETACAR recommendations have been followed. As an introduction, the PHAA believes that the skills and expertise required to control antimicrobial resistance in Australia are those of good communicable disease control.

However, the current communicable disease control system lacks national expertise and leadership, is already at maximum capacity, and is artificially divided between communicable disease control in acute healthcare facilities and community disease control in the community, with a significant gap in non-acute health care facilities such as aged care facilities. There is also a need for strengthened collaboration across human, animal and environmental health systems to address both existing and potential health threats. Such an approach (sometimes referred to as "One Health") will help to address this threat in a more systematic and sustainable way.

Rather than concentrating solely on antimicrobial resistance, the current skills and expertise in community disease control should be harnessed and grown as a whole-of-system approach. Such skills and expertise could be better coordinated by the creation of an Australian Centre for Disease Control (ACDC) which should have antimicrobial resistance as one of the key national priorities.

2. Recommendations

The PHAA makes the following recommendations that are drawn from the body of our response:

Creation of an Australian Centre for Disease Control (ACDC)

- The creation of an Australian Centre for Disease Control loosely based on the Canadian and (to a lesser extent) the USA models.
 - The ACDC should be an adequately-resourced national centre for excellence in antimicrobial resistance to co-ordinate surveillance, collate evidence and develop public policy with respect to both animals and humans
 - The ACDC should have a broader remit in prevention and disease research, surveillance and policy
- With respect to antibiotic resistance, the ACDC should:
 - Oversee standardisation of testing methods to allow comparisons to be made between laboratories.
 - Facilitate networking of laboratories to enable information sharing for surveillance
 - O Design and implement a comprehensive surveillance system for antimicrobial resistant organisms and antimicrobial use that bridges the gaps between:
 - Hospital and community acquired infections;
 - Human and animal pathogens; and
 - Organisms acquired overseas and in Australia.
 - Be adequately resourced to examine and define the underlying epidemiology of antibiotic resistant organisms
 - Be adequately resourced to examine and define best-practice control and prevention interventions in hospitals and other healthcare settings and the community.

3. The Committee Terms of Reference

Introduction

According to the National Prescribing Service:

"Today, some strains of bacteria that cause infections have become resistant to many antibiotics, so people are again dying of infections caused by them. In Australia, antibiotic-resistant bacteria are thought to cause more than 7000 deaths each year".

http://www.nps.org.au/publications/consumer/medicines-talk/pre-2006/mt7/why-all-the-fuss-about-antibiotic-overuse2

The PHAA sees this issue of antibiotic resistance as an important challenge that needs to be tackled as quickly as possible before the community resistance reaches a level where prevention of the spread of infection moves back to a point prior to the discovery of antibiotics in the 1930s. The JETACAR report provided a strong foundation for action on antibiotic resistance. Unfortunately, this foundation was not effectively used as a springboard to protect key antibiotics.

(a) Examination of steps taken, their timeliness and effectiveness

The Australian Commission on Safety and Quality in Health Care (ACSQHC) and the newly formed National Health Performance Authority are both commencing programs to gather national surveillance data that cover a subset of the required data (specifically on infections involving antibiotic resistant organisms in hospitals).

However, there are still significant gaps in surveillance regarding antimicrobial resistance outside of hospitals including surveillance of antimicrobial resistance in food-producing animals. More importantly, there is limited surveillance of the use of antibiotic in humans and animals. The recently formed Antimicrobial Resistance Subcommittee of the Australian Health Protection Committee provides one step in developing a co-ordinated approach to address antimicrobial resistance in humans and animals.

However, such a step is ad hoc. The government should be establishing an oversight system to deal with research, surveillance, implementation and independent advice for government. This forms part of the reason that the PHAA has been a long-term advocate for an Australian Centre for Disease Control.

The Commonwealth Interdepartmental JETACAR Implementation Group (CIJIG) was established in November 2000 and was tasked with co-ordinating the Commonwealth Government's response to the JETACAR report, incorporating advice from the Expert Advisory Group on Antimicrobial Resistance (EAGAR). However, the implementation group dropped out of existence in 2003. While its final report included the comment that the use of avoparcin, virginiamycin, and tylosin had been reviewed or reviews commenced, Avoparcin was withdrawn from the market worldwide by the sponsor, and the JETACAR Committee was not in a position to monitor the implementation of the suggestion.

In a poorly coordinated manner the Australian Pesticides and Veterinary Medicines Authority (APVMA) (formerly National Registration Authority for Agricultural and Veterinary Chemicals (NRA))

had implemented a policy requiring resistance to be considered as part of risk assessment. As an example, Virginiamycin was reviewed and changes to registration recommended by APVMA, but the case ended up in the Administrative Appeals Tribunal and was ultimately not licenced for veterinary use.

Attempts were clearly made to respond to the JETACAR report by committed people. However, without a strong government commitment to a coordinated surveillance, research, implementation and advisory body the chances of an effective response were limited – if not doomed.

(b) Where and why failures have occurred

There were certainly genuine attempts made but there were also failures. The underlying issue is the piecemeal approach to antimicrobial resistance Australia which accounts (at the very least in part) for the failures. A national oversight body such as an ACDC would help to rectify this situation. For example, measures that were NOT implemented included:

- A co-ordinated approach to develop policies to minimise the use of antibiotics in humans and animals
- A review of the use of antibiotic growth promoters, including tylosin (a macrolide), avilamycin (an orthosomycin with homology to everninomicin), momensin (an ionophore) and bacitracin.
- Licensing and monitoring of antibiotic importers
- Defining threshold rates of resistance in animals that trigger action/intervention
- Development of a harmonised approach to the control of veterinary chemicals including antibiotics
- Introducing legislation to make it an offence to prescribe and/or use a veterinary chemical product contrary to a label constraint
- Requiring the TGA to
 - o define thresholds of resistance for intervention, and
 - include of resistance prevalence data in the product information of on a 5-yearly basis

(c) Implications of antimicrobial resistance on public health and the environment

At a joint summit held by the Australasian Society for Infectious Diseases and the Australian Society for Antimicrobials, the impact of antimicrobial resistance was highlighted. In a summary of the summit published in the Medical Journal of Australia (Gottlieb MJA 2011), it was reported that

"For many bacterial pathogens, resistance to last-line antibiotics, such as carbapenems, fluoroquinolones, glycopeptides and third-generation cephalosporins, is now commonly found in Australian hospitals and, to an increasing extent, in the community. Examples include methicillin-resistant *Staphylococcus aureus*, multiresistant *Streptococcus pneumoniae*, vancomycin-resistant enterococci and multiresistant *Escherichia coli*. This growing ineffectiveness of once-reliable drugs has seen health care professionals increasingly turning to alternatives that are more toxic, more expensive and less likely to be orally available, putting increased pressure on a strained hospital system. In addition,

compared with susceptible bacteria, antibiotic-resistant strains are associated with increased patient morbidity and mortality and increased costs of health care."

Pharmaceutical companies do not have the financial incentives to commit to research in the area of development of new antibiotics. As companies work on a risk assessment of investment against profit it seems that such motivation is unlikely to come until such time as the resistance problem gets out of control. Even then it is unlikely that the problem will be solved as even their new drugs may only have a useful life of a few years. Furthermore, new antibiotics will be more expensive as companies build these factors into their costs. Since 1970 there have been only three new chemical classes of antibiotics developed for use for serious infections in humans - linezolid (2000) and daptomycin (2003) for systemic infections, and fidaxomicin (2012) for the treatment of gut infections caused by *Clostridium difficile*.

According to Carlet (ARIC 2012) only 15 antibiotics that are under development (mostly in the early phases) present a new mechanism of action with the potential to meet the challenge of multidrug resistance. Of these, only two, both in the early development phase, may be active against multidrug- resistant Gram-negative bacteria, a group of bacteria causing serious therapeutic concerns due to their increasingly high resistance to antibiotics.

(d) Implications for ensuring transparency, accountability and effectiveness in future management of antimicrobial resistance

The development of effective public policies regarding antimicrobial resistance requires a process that includes evidence based research, surveillance, evaluation and recommendations on action. A key element of an effective process will be the establishment of either a single independent entity or an independent Centre of Excellence for Research and Surveillance supported by a national organisation providing policy and implementation advice – which should also remain at arms-length from the political process. This does not exist at present.

There are limited and disparate approaches. For example, surveillance for antimicrobial resistance in Australia is currently restricted to planned surveillance studies of a narrow range of organisms conducted by disparate groups (e.g. Australian Group on Antimicrobial Resistance, National Gonococcal Surveillance Programme) and often driven by individual research interests.

Rather than a nationally coordinated approach, the collection of data is by the state/territory authorities on hospital acquired infection for accreditation or quality control purposes, coordinated at a state or regional level. Where such data does exist they are from a sample of large hospitals in the National Antibiotic Utilisation Surveillance Project (operated by SA Health and funded short-term by the Australian Government).

There is no overarching body that is responsible for antimicrobial resistance in Australia. Other countries have successfully implemented such policies. The WHO provides a framework for recommended steps that need to be taken, and two examples of successful implementation are provided by Sweden and the United States, although many more exist.

The 2001 World Health Organization's Global Strategy for Containment of Antimicrobial Resistance recommended:

- The creation of an intersectoral task force to raise awareness about antimicrobial resistance, organize data collection and oversee local task forces.
- Allocation of resources to promote the implementation of measures to contain resistance
- Development of indicators to monitor and evaluate the impact of a resistance containment strategy
- The introduction of legal requirements for manufacturers to collect and report data on antimicrobial distribution
- The creation of economic incentives for the appropriate use of antimicrobials.
- Establishing surveillance for resistance, antimicrobial use in hospitals and the community, and linking these to infectious diseases surveillance

The Swedish Strategic Programme against Antibiotic Resistance (STRAMA) is an example of a whole-of-system approach to the problem of antimicrobial resistance. This body advises the Swedish Institute for Infectious Diseases Control in

- 1. matters regarding antibiotic use and containment of antibiotic resistance
- 2. facilitating an interdisciplinary and locally approved working model, ensuring involvement by concerned authorities, counties, municipalities and non-profit organizations.

STRAMA compiles and publishes reports on resistance and antibiotic use in humans and animals, undertakes studies to better understand antibiotic resistance and interventions that decrease use, and collaborates with other organisations in producing clinical practice guidelines.

In this area we can learn some lessons from the USA. The elements of the 2001 *Public Health Action Plan to Combat Antimicrobial Resistance* (http://www.cdc.gov/drugresistance/actionplan/aractionplan-archived.pdf)

included surveillance, prevention and control, research and product development. The Plan was revised. This task force has established systems for monitoring resistance in food-borne bacteria, published prudent use guidelines for the use of antimicrobials in veterinary medicine, and provided guidance to industry on regulatory requirements for antimicrobials. The Plan was reviewed in 2011 A Public Health Action Plan to Combat Antimicrobial Resistance

(http://www.cdc.gov/drugresistance/pdf/public-health-action-plan-combat-antimicrobial-resistance.pdf) and stated the seriousness with which the matter is viewed:

"The Task Force remains committed to continuing communication with the public and health professionals, since <u>antimicrobial resistance so profoundly affects public health</u> <u>and clinical medicine</u>. Given the public health consequences of AR and its ever changing nature, the Task Force will continue to address the issue of antimicrobial resistance in this and future versions of the Action Plan". (PHAA emphasis).

The 2011 report emphasised the goals required to establish effective management of antibiotic resistance as follows:

I. Surveillance

<u>Goal 1:</u> Improve the detection, monitoring, and characterization of drug-resistant infections in humans and animals.

<u>Goal 2:</u> Better define, characterize, and measure the impact of antimicrobial drug use in humans and animals in the United States.

II. Prevention and Control

<u>Goal 3:</u> Develop, implement, and evaluate strategies to prevent the emergence, transmission, and persistence of drug-resistant microorganisms.

<u>Goal 4:</u> Develop, implement, and evaluate strategies to improve appropriate antimicrobial use.

III. Research

<u>Goal 5:</u> Facilitate basic research on antimicrobial resistance.

<u>Goal 6:</u> Facilitate the translation of basic research findings into practical applications for the prevention, diagnosis and treatment of resistant infections.

<u>Goal 7:</u> Facilitate clinical research to improve the treatment and prevention of antimicrobial drug resistant infections.

<u>Goal 8:</u> Conduct and support epidemiological studies to identify key drivers of the emergence and spread of AR in various populations.

IV. Product Development

<u>Goal 9:</u> Provide information on the status of antibacterial drug product development and clarify recommended clinical trial designs for antibacterial products.

<u>Goal 10:</u> Consider opportunities for international harmonization and means to update susceptibility testing information for human and animal use.

Goal 11: Encourage development of rapid diagnostic tests and vaccines.

(In this document, the term "antimicrobial" is used inclusively to refer to any agent (including an antibiotic) used to kill or inhibit the growth of microorganisms (bacteria, viruses, fungi, or parasites). This term generally applies to agents intended for healthcare, veterinary, and agricultural applications).

(e) any other related matter

Co-ordinated public policy has been shown to work in Australia (Cheng EID 2012). The PHAA has been a long-term advocate of coordinated public policy consistent with the WHO Ottawa Charter. The application of these health promotion principles is appropriate in this context.

We have had a long history of policies to preserve the use of quinolone antibiotics, an important class of antibiotics useful for treatment. These antibiotics have never been licenced for use in animals in Australia. In humans, national therapeutic guidelines and regulatory controls have ensured that its use is restricted where other alternatives are not available. As a result, Australia has one of the lowest rates of fluoroquinolone use and resistance in the world, comparing favourably with most European countries. This has successfully preserved this valuable class of antibiotics for continued use for serious infections. It is a message that should not be lost with regard to our other antibiotics.

4. Action to be taken to restrict inappropriate practices

The 2011 US Report, *A Public Health Action Plan to Combat Antimicrobial Resistance*, explained the urgency of the issue in the following words.

"Antimicrobial resistance (AR) is not a new phenomenon; however, the current magnitude of the problem and the speed with which new resistance phenotypes have emerged elevates the public health significance of this issue. In addition, the scarcity of new antimicrobial agents limits treatment options, particularly for patients with infections caused by multidrug-resistant organisms. For example, surveillance data for *S. pneumoniae*, a common cause of bacterial respiratory tract infections, showed that 24 percent of isolates were not susceptible to penicillin".

The PHAA considers that the following policy decisions should be urgently examined by an independent centre for excellence and action taken.

- Tackle the unnecessary prescribing of antibiotics to humans
 - Modify the regulatory system to reduce inappropriate usage of antibiotics
 - Better education programs for health professionals and the broader community to prevent the unnecessary use of antibiotics to treat colds and flu.
 - Australians are amongst the highest users of antibiotics in the world, with over 22 million prescriptions issued every year – more than one for each man, woman and child.
- Promote strengthened collaboration across human, animal and environmental health systems to address existing and potential disease threats.
- Limit the widespread use of antibiotics in agriculture
 - Tighter monitoring and enforcement of use of antibiotics in agriculture, with a view to banning non-therapeutic use of antibiotics if industry compliance is poor
 - Many farmers are still using antibiotics to improve meat production with limited monitoring, other than end point (meat for human consumption) testing. Excessive use of antibiotics in the agricultural sector can breed superbugs which can reduce the effectiveness of antibiotics for treatment of both animal and human infections.
- Further restrict the unnecessary use of antimicrobials in consumer goods to clinical goods
 - There is evidence that the growing use of consumer goods containing antimicrobials such as triclosan and nano-silver may breed superbugs in our homes.

5. An Australian Centre for Disease Control (ACDC)

The first plenary session at the Public Health Association of Australia Communicable Disease Control Conference in Canberra (4-6 April 2011) considered 'Does Australia need a CDC?'. In the discussion paper for the session, The Australasian Faculty of Public Health Medicine of the Royal Australasian College of Physicians and the Public Health Association of Australia discussed the concept of an Australian Centre for Disease Control (ACDC) with the role of national scientific leadership of surveillance and control of current and emerging infectious diseases across the country and, as appropriate, in the neighbouring region.

The views expressed in the paper do not represent the formal policies of either the RACP or the PHAA. They were presented at the time in order to help stimulate the discussion at the conference. However, they do present key elements pertinent to the discussion of antimicrobial resistance.

Summary of key concepts

The aim of establishing an ACDC would be to provide strong central, expert driven leadership and coordination of national communicable disease control.

An ACDC could operate as the central leading organisation (the hub), in partnership with existing government and non-government agencies: a "Hub and Spoke" model. Key functions could include:

- National coordination of disease surveillance with strengthened collaboration across human, animal and environmental health systems to address existing and potential disease health threats. Experts in communicable disease surveillance should lead the analysis and interpretation of notifiable disease information and the coordination of scientific effort;
- National leadership in communicable disease prevention programs e.g. National Immunisation Program, HIV and antibiotic resistance
- Specialist expertise in the investigation, coordination and management of nationally significant outbreaks of communicable disease or other significant related issues (e.g. adverse events following vaccination);
- Oversight and coordination of training and development of the disease control workforce; and
- Strategic contribution to the control of communicable diseases in the Australian Area of Interest (Western Pacific and Near North) in partnership with World Health Organization regional agencies (SEARO and WPRO).

Such an agency would best be established through legislation to function as a national source of technical capacity separate to the existing Department of Health and Ageing (and jurisdictional equivalents). This 'Agency' should report through a CEO to a Board of eminent leaders in disease control and prevention and ultimately through the Board to the Federal Minister of Health. Appointments to the Board should be made by agreement between the Federal, State and Territory Ministers of Health, through the Australian Health Ministers' Conference (AHMC) and/or Council of Australian Governments (COAG) and in consultation with recognised leaders in disease control.

A framework for implementation and evaluation of this model should be established which takes into account the costs involved, measures of functional improvement in disease control initiatives and particularly improvements in disease control outcomes at jurisdictional levels. This would include measures based around priority targets for disease control and would also involve consideration of current arrangements under the legislative framework of the National Health Security Act 2007.

A copy of the full paper, Does Australia need a national Centre for Disease Control? is available at: http://www.phaa.net.au/documents/110329NationalCentreforDiseaseControldiscussionpaper.pdf

6. Conclusion

PHAA is particularly keen that the following points are highlighted:

- The creation of an Australian Centre for Disease Control loosely based on the Canadian and (to a lesser extent) the USA models.
 - The ACDC should be an adequately-resourced national centre for excellence in, among other things, antimicrobial resistance, to co-ordinate surveillance, collate evidence and develop public policy with respect to both animals and humans
 - The ACDC should have a broader remit in prevention and disease research, surveillance and policy
- With respect to antibiotic resistance, the ACDC should:
 - Oversee standardisation of testing methods to allow comparisons to be made between laboratories.
 - Facilitate networking of laboratories to enable information sharing for surveillance
 - Design and implement a comprehensive surveillance system for antimicrobial resistant organisms and antimicrobial use that bridges the gaps between:
 - Hospital and community acquired infections;
 - Human and animal pathogens; and
 - Organisms acquired overseas and in Australia.
 - Be adequately resourced to examine and define the underlying epidemiology of antibiotic resistant organisms
 - Be adequately resourced to examine and define best-practice control and prevention interventions in hospitals and other healthcare settings and the community.

The PHAA appreciates the opportunity to make this submission and the opportunity provided by the Senate Committee in taking on this most important inquiry.

Please do not hesitate to contact me should you require additional information or have any queries in relation to this submission.

Michael Moore BA, Dip Ed, MPH Chief Executive Officer Public Health Association of Australia