Canadian Consensus Development Conference: **SURVEILLANCE and SCREENING of AROs (Antimicrobial-Resistant Organisms) - Consensus Statement of the Jury**

Calgary, Alberta, Canada – June 20th, 2014

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IHE INSTITUTE OF HEALTH ECONOMICS ALBERTA CANADA

Acknowledgments

As Jury Chair, Dr. Tom Marrie, Dean of Medicine, Dalhousie University, led a distinguished panel tasked with summarizing the evidence and developing recommendations to improve policy and practice in surveillance and screening for AROs.

The conference program was developed with advice from a Scientific Committee Chaired by Dr. John Conly, Professor and Co-Director, Snyder Institute, University of Calgary, and Co-Chaired by Dr. Mark Joffe, Professor, University of Alberta and Senior Medical Director, Infection Prevention & Control, Alberta Health Services, and Dr. Geoff Taylor, Professor and Director, Infectious Diseases, University of Alberta.

This event was the 6th Consensus Development Conference organized by the Institute of Health Economics (IHE) since 2006 when the IHE introduced the conference format to Canada.

The conference was funded by the Government of Alberta.

Disclosure Statement

All of the jury members who participated in this conference and contributed to the writing of this statement were identified as having no financial or scientific conflict of interest.

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About this Consensus Statement

This Consensus Statement was prepared by an independent 11-member jury of health professionals, academics, and public representatives based on: 1) relevant published studies assembled by the Scientific Committee for the conference; 2) presentations by experts in areas relevant to the conference questions; 3) questions and comments from conference attendees during open discussion periods; and 5) the private deliberations of the jury.

The conference was held in Calgary, Alberta, Canada. The Consensus Statement therefore refers to circumstances in Alberta, although data were not only drawn from Alberta but also from other parts of Canada, the U.S. and other countries.

This statement is an independent report of the jury and is not a policy statement of the conference partners, conference sponsors or the Government of Alberta.

The recommendations were read aloud by the Jury Chair and discussed with delegates at the conference in an open session on the closing day of the conference, June 20, 2014, together with the Jury Chair's Introduction which is included here.

IHE Consensus Development Conferences

IHE delivers a branded program of Consensus Development Conferences, the only events of their kind in the health care field in Canada. Our conference model is a deliberative process bringing together experts and policy-makers to provide clear findings and recommendations aimed at promoting the integration of scientific evidence into policy and practice.

IHE introduced the Consensus Development Conference format to Canada in Edmonton in 2006. To date, IHE has organized 6 Consensus Development Conferences:

Conference title	Date	Jury Chair	Scientific Chair
Self-Monitoring in Diabetes	2006	Michael Decter	(no single Chair)
Healthy Mothers–Healthy Babies: How to Prevent Low Birthweight	2007	Dr. Shoo Lee	Dr. Anthony Armson
Depression in Adults	2008	Hon. Michael Kirby	Dr. Scott Patten
Fetal Alcohol Spectrum Disorder – Across the Lifespan	2009	Hon. Anne McLellan	Dr. Gail Andrew
Legal Issues of FASD	2013	Hon. Ian Binnie	(no single Chair)
Surveillance & Screening for AROs	2014	Dr. Tom Marrie	Dr. John Conly

The conference model

The Consensus Development Conference has a unique format based on a jury trial, which provides an independent and critical review of issues by an unbiased panel. The conference is a survey of the best available evidence and the views of leading experts, which informs a Consensus Statement that is relevant for policy and practice. The conference involves 20-25 experts who deliver the scientific evidence around 5-8 questions in a given field over two days of hearings, to a jury or panel of about 12 members and an audience of delegates.

The conference model is flexible; for example, it can include a "Town hall" session with the entire faculty (expert presenters), a Q & A session following each presentation, and/or a session with the faculty for each main question following the presentations on that question. Q & A periods provide opportunity for testimonial input from the audience, which can include laymen and members of the public. The Consensus Statement is essential; but the conference can also produce other outputs, eg Proceedings, Charter, etc. The conference sessions are for paid delegates only, but are normally open to the media; a conference can also include a separate public-education session or program.

The Jury takes all the conference input into consideration in "sequestered" deliberations following each day of presentations. The Jury then renders its summary of the evidence and its recommendations in a Consensus Statement. The Statement is read aloud by the Jury Chair at the start of the third and final day of the conference, and then widely disseminated to targeted policy-makers, professionals, and other relevant stakeholders across Canada and beyond.
The transparent format of the conference maximizes its impact. The Consensus Statement is written in plain language and designed as a booklet, and published in printed and electronic form.

Jury Chair's Introduction

Antibiotic-Resistant Organisms (AROs) are a serious health problem, though they are more prevalent in some settings than others. We were asked to make findings and develop recommendations on how to address surveillance of and screening for AROs in acute care hospitals. This consensus statement addresses these requests. However, confining the discussion and recommendations to hospitals overlooks some root causes of the problem and potential strategies for improvement at the level of the population. Hospitals are part of a continuum of care and AROs do not respect institutional or community boundaries. While it is critical to prevent the transmission of AROs in hospital, there is also considerable potential to address some problems upstream through more prudent prescribing and consumption in the general population and in the agricultural and aquaculture sectors.

We are at a critical moment in health-care history, and especially in infection prevention and control. The golden age of antibiotic development has long since ended. Few new significant antibiotics are in the pipeline and the economics discourage R&D investment by the private sector pharmaceutical industry. For the first time, the overuse of health services has become a major topic of discussion of debate. The Choosing Wisely campaign has documented a wide variety of overused procedures. Antibiotics have been recognized for decades as a particularly worrisome example of overuse. The overuse of CT scanning does not make CT scans less effective, but overuse of antibiotics renders them less efficacious over time and promotes development of virtually untreatable microorganisms.

Making progress on AROs is contingent on broader system developments, and there is reason for cautious optimism on other fronts. There is increasing investment in patient safety and quality improvement across the country and greater interest in adopting evidence-informed guidelines and care pathways. Primary care is gradually become more organized, with stronger attachment to the rest of the health-care system. Governments have recognized that they cannot spend their way to excellence.

Yet there remains a considerable gap between policy and practice. Policy unsupported by change management strategies is unlikely to be effective. Weakly enforced regulation and tolerance of wide and unjustified variations in practice guarantee indifferent performance. What we permit, we promote. The recent Commonwealth Fund survey once again gave Canada's health-care system low grades – 10th of 11 peer countries, and last in timeliness and efficiency. Neither intrinsic motivation nor voluntary and incremental improvement are sufficient to close the gap. This is not a culture that produces quantum leaps in achievement.

The success of even the most comprehensive and ambitious ARO strategy will inevitably be affected by developments in the system of which it is a part.

Finally, it was a challenge to craft a statement to guide the world as it should be versus the world that exists. Recommendations that can transform a system with a strong culture of improvement, advanced information system, and effective regulation may be premature in some settings. Our recommendations attempt to balance the here-and-now with an ambitious vision for the future. Some strategies that may be unnecessary in high-performing systems may be essential fall-backs in environments where safety gaps persist. While some of our recommendations apply universally, some will be contingent on local circumstances.

Taking these factors into account, the following principles and logic underlie the recommendations.

1. The problem should be conceived as multi-factorial – there is no single cause or explanation for infection rates and variations among facilities and communities.

2. A holistic approach that extends across sectors and includes primary prevention is more likely to yield better and more durable results than treating AROs in isolation in hospitals.

3. Simpler and less costly strategies should be pursued before more complex and expensive strategies.

4. A higher standard of evidence should be required to support the more costly and time-consuming interventions.

5. Policies and practices should be considered provisional and subject to ongoing research and evaluation. AROs and their consequences are a constantly moving target requiring ongoing surveillance.

6. It is essential to conduct real-world trials of all interventions to assess their effectiveness.

Question 1: Overview

a) What are AROs? What is their incidence and prevalence (in health care facilities and in the community)? (Global, US, Canadian, and Alberta perspectives) Why are they a problem, globally and in Canada what burden do they impose on patients and the health system?

AROs are microorganisms that are resistant to one or more antibiotics. For the purposes of this conference we are focusing on MRSA, VRE, CRE and multi-resistant gram negative organisms. It is the jury's belief that *C difficile* should be considered as there is significant evidence of mortality in vulnerable populations and it is a proxy measure for the effectiveness of multiple aspects of Infection Prevention and Control (IPAC) measures.

AROs are a problem because we risk returning to the pre-antibiotic era and there is a real and current human cost. They are also a problem because they render treatment much more difficult as the current, safer, lower-cost antibiotics are no longer effective, causing increased cost and limiting treatment options. If unrecognized and uncontrolled, they have the potential to spread in the health-care environment, causing preventable morbidity, mortality and costs.

CNISP data for 2012 provide national and regional infection rates for MRSA, VRE, and CPO per 10,000 patient days, with MRSA being dominant.

b) Where do AROs come from (genetics and evolution)? How big a factor is the use of antimicrobials, and what is the contribution from various settings (healthcare, home, agriculture)?

In order to survive over the millennia, bacteria have had to develop defense mechanisms against lethal compounds in the soil and other environments that resemble current antibiotics. These genetically controlled defense mechanisms can be transferred between different bacterial families as they reproduce in the environment, in the food chain, or in infected animals and humans. One such means of transfer is mediated by a plasmid – a DNA molecule that is physically separate from the bacteria of origin, and that can infect other bacteria in the ecosystem, thus transferring genetic material from one type of bacteria to another.

Human and animal bacterial infections are caused by a mixture of bacteria from the same family with varying levels of defense. When they reproduce in the presence of antibiotics, those bacteria with the strongest antibiotic defense mechanisms are not killed and become

AROs. As AROs reproduce in infected humans and animals, they replace the non-resistant bacteria that have been killed by the antibiotic.

AROs can develop wherever antibiotics are used, but when antibiotics are misused, resistance develops more rapidly than when they are used correctly. Antibiotic misuse is high in both developing and industrialized countries, and the majority of known bacteria have developed resistance to one or more antibiotic. Through our current modern treatment patterns we thus create reservoirs of AROs in patients who travel between hospitals and the community, to long term care facilities, and to other destinations in today's globalized world.

AROs also develop in animals and fish that are given antibiotics either specifically for treatment or as prophylaxis against infection; and non-specifically in feed. Human and animal waste disposal systems contribute AROs from both animals and humans to the shared ecosystem in which they can easily spread among and between species, providing possibilities for cross-species infection with AROs.

c) What is surveillance; what is screening? How are they related?

Surveillance is defined as "the systematic, ongoing collection, collation and analysis of health-related information that is communicated in a timely manner to all who need to know which health problems require action in their community."[1]In other words, surveillance is the management of information for the purpose of taking action on important health issues.

Screening is defined as a strategy (in this setting obtaining swabs from potential carriage sites of AROs) used in a population to identify an unrecognized disease (in this instance colonization) in individuals without signs or symptoms.

There is no standardized set of protocols to guide surveillance in place in Canada. There is no audit or evaluation of either the application of the protocols or the accuracy of the results.

d) What can we learn from the experience of other jurisdictions? (International, US, Canadian, and Alberta perspectives) Why does control of AROs vary so much? – e.g., is mandatory public reporting of data on AROs helpful?

A number of countries have extensive, often country-wide surveillance systems for AROs. Currently the U.S. has 4,000 hospitals reporting such data.

[1] Last, J.M., A Dictionary of Public Health, Oxford University Press, 2007

Illinois hospitals have mandatory reporting of MRSA but the evaluation of this has demonstrated no change in rates due to the fact that almost all patients are already on isolation and MRSA is spread by mechanisms other than person to person.

In the last decade there have been very marked declines in morbidity and mortality related to MRSA infection in the U.K. Annual MRSA bacteraemia rates fell from 17.7 to 3.2 cases per 100,000 bed days between 2005-2006 and 2011-2012. Significant declines have also been observed in surgical site infections where MRSA was reported as the causative microorganism. The number of death certificates in England and Wales mentioning MRSA infection has decreased each year since 2006, when the figure peaked at 1,652. In 2012, MRSA accounted for 292 mentions on death certificates.

Scientific uncertainty and debate about the effectiveness of screening-based strategies relative to other approaches is one of the contributing factors to the variability in this practice from country to country and among sites within a country. A further reason for this wide variability is the complexity of the issue and the context in which it exists.

"There is currently little high-quality evidence that screening of patients [whether universal or targeted and primarily relating to MRSA] is associated with reduction in hospital-acquired ARO infection, mortality or morbidity in endemic settings. Results from a single large RCT suggest that universal approaches to infection control may be more effective than approaches that target single pathogens. Future research should focus on conducting well-designed, prospective studies that can disentangle relative contributions of the measures used in the various approaches to hospital-acquired ARO infection prevention and control."

The rest of this report is organized as follows: Key findings are reported in point form and linked to recommendations.

Recommendations:

1. Develop, implement and evaluate an integrated One Health strategy to minimize the misuse of antibiotics in animals and humans.

Question 2: Surveillance

The jury noted that the best ARO surveillance systems, despite different structures, all have in common an integrated collaborative approach to national and regional/local data collection and analysis across public health and food production agencies. The complex ecology of antimicrobial resistance development calls for a robust cross-sectorial and trans-disciplinary approach so that surveillance information can inform control efforts. The jury also heard that for the Canadian context, the European ARO surveillance system EARS-Net may be the most appropriate model to emulate. Key features would include:

- Laboratory-based reporting underpins the system, but should be supplemented as required with additional data.
- Sufficient capacity for data capture, storage and analysis at the local/regional, provincial/territorial and federal levels.
- Timely, mandatory electronic reporting of AROs to public health and all other stakeholders.

Although constrained by a number of shortcomings – including lack of standardization, incomplete coverage and narrow focus – the current Canadian ARO surveillance programs (principally CIPARS and CNISP) form a good basic infrastructure that can be built upon, in partnership with laboratory networks and clinician groups.

Recommendations:

2. Establish comprehensive and standardized information systems for documenting antibiotic use and resistance in humans and animals. Adapt EARS-Net as Canada's surveillance platform, building on and integrating CNISP, CPARS and other existing surveillance systems to produce timely, relevant and robust surveillance data.
3. Maintain robust standardized surveillance in all health-care facilities for AROs and related infections. Make this information publicly available.

Question 3: Screening

Major Infection Prevention Strategies

High quality reviews such as RCTs and quasi-experimental studies showed little or no effect of screening on ARO-related outcomes. In addition currently published clinical practice guidelines do not recommend universal ARO or ESBL admission screening. Many of the studies were confounded as they did not examine screening alone. Identification of colonized patients through admission screening of high risk patients and those on high-risk units allows for initiation of contact precautions.

A strong set of IPAC processes including hand hygiene, environmental cleaning, antimicrobial stewardship and routine practices must be pursued. Along with targeted screening this can mitigate the risk of transmission from colonized asymptomatic patients. This is especially important for vulnerable patients in areas such as the ICU, burn units, cardiac care units, NICUs and bone marrow transplant units.

The jury also heard that horizontal and/or vertical approaches can be taken.

The jury heard about several recent studies demonstrating the efficacy of targeted decolonization in select high-risk settings. There is a need for further research on this approach. It is possible that universal decolonization may lead to resistance to the decolonizing agents.

Recommendations:

4. Do not conduct universal screening for AROs.
5. Pursue relentlessly and fully resource hand hygiene, environmental cleaning, antimicrobial stewardship and routine practices in hospitals.
6. Include a strong evaluation program with process and outcome measures.
7. Ensure consistent application of infection prevention and control practices province-wide.
8. Continue and/or implement targeted screening programs of high-risk populations at admission and at intervals during their hospital stay, based on local epidemiology.
9. Decolonize for AROs on a case by case basis only, after considering current evidence and with infectious disease/medical expert consultation.

Question 4: What factors can facilitate or hinder effective ARO control in practice?

Organizational and Environmental Factors

ARO control measures are often poorly communicated and not appropriately reinforced. There are few consequences for non-compliance, for instance low rates of hand hygiene. Organizations often rely on individual behaviours and are thus severely compromised if their strategies are not underpinned by an adequately resourced culture of safety and committed governance and leadership.

The aging infrastructure of many of our acute-care facilities does not meet the requirements for adequate infection control. There is a compelling argument for all hospital clinical inpatient beds to be located in single rooms.

Focusing solely on individual factors will not bring about the needed change. Instead, a strong emphasis on environmental and organizational factors is more effective.

Human factor engineering is essential to building modern and comprehensive infection control programs. The Center for Healthcare Design has developed over 100 evidence-based design principles that should be incorporated in any new health-care facility build or renovation in Canada. In addition there is a need to ensure that all patient information is available to care providers in an integrated way and in a timely manner.

Laboratory Capacity

The jury heard that there is a growing body of evidence and opportunity to more effectively manage increasing workload arising from ARO screening and other clinical specimens through system automation and physical consolidation. Automation can provide significantly improved turn-around time, more rapid diagnostics, higher quality and appropriate antibiotic stewardship at a lower cost than at present. Such improvements have reduced lengths of in-patient stay, reduced risk of sepsis and resulted in more timely reporting of laboratory results.

Laboratory capacity can be optimized by carefully considering the appropriateness of the design of screening programs and control systems.

Recommendations:

Organizational and environmental strategies

10. Incorporate evidence based design principles in all new build and significant renovations of hospitals. The majority of beds should be located in single rooms.
11. Optimize health systems by using human factor engineers.
12. Improve and integrate information technology systems that transfer information from point of admission through to the community care providers.
13. Create and embrace a culture of safety starting with senior leadership and governors.
14. Embed accountability for specific goals and targets at all levels of the organization.
15. Remove unnecessary barriers that prevent the local implementation of infection prevention and control practices.

Laboratory Capacity

16. Involve microbiology laboratory leaders in shaping and designing ARO control programs.
17. Ensure the optimum use of resources by harnessing new automated diagnostic and reporting microbiology laboratory platforms.
18. Enhance antibiotic stewardship by utilizing point of care diagnostics.

Question 5: Ethical and policy implications

The impact of screening on patients and families appears to be variable and nuanced. In the best-case scenario, screening will identify colonized and infected patients at personal risk of an adverse health event or of transmitting infections to others. Benefits for individuals include reduced risk of infections through transmission and faster and more effective treatment should screening allow earlier diagnosis and intervention. Drawbacks include the minor inconvenience of testing, the possibility of false positives and false negatives, and – although the evidence is mixed – the consequences of reduced contact with providers when a positive test leads to being placed on contact precautions. Consequences of a positive test may be increased time to diagnosis, delayed discharge or transfer to long-term care. Other adverse events such as depression and anxiety have been suggested, however the strength of the evidence is questionable.

Whether or not patients have the legal right to refuse screening is ultimately a matter of law and jurisprudence. It is an accepted ethical principle that patients have an absolute right to refuse treatment where the consequences accrue exclusively to them. Where the consequences may affect others, the principle of proportionality would normally govern both law and policy: the higher the risk of adversely affecting others, the reduced latitude for patient autonomy. Public health regulations allow for mandatory quarantine for certain defined conditions.

The evidence for public education as a strategy for reducing inappropriate antibiotic utilization is modestly positive but well short of conclusive. That said, there are benefits to patient and public engagement and transparency that may not necessarily translate into concrete impact in a specific area. Patients are becoming partners in their health-care decisions, they must be fully informed about the risks and benefits of testing and treatment options and alerted to the potential consequences of both under- and over-utilization of services. The philosophy “nothing about me, without me” should be embraced. These efforts are more likely to succeed if providers are fully committed to such partnerships and if patients, the public, and professionals work from a common evidence base. Patient stories can be an extremely powerful mechanism to explain the effects of AROs.

An effective strategy for ARO education would need to be comprehensive. The general public could be educated on hand hygiene and antibiotic stewardship through mass media campaigns and various modes of communication. Discharge protocols are yet another opportunity to educate patients and could include a request to report post-discharge infections for improved hospital surveillance.

Recommendations:

19. Develop plain language materials about AROs and infection prevention and control practices in partnership with patients and families.
20. Minimize the potential adverse effects of patient isolation.

Question 6: Research/Evidence

The jury heard that significant research is needed to close current gaps and provide the information needed to answer basic questions about the effectiveness of approaches to control of AROs, such as horizontal and vertical intervention strategies. We heard that current funding for research in this area is limited and might be improved by developing international collaborations since AROs are a global problem.

Two speakers identified specific gaps where more research is needed but emphasized the importance of education to create the capacity for research in the field and infrastructure development to provide a comprehensive and integrated surveillance system that would be required to generate the data to measure the outcomes of various intervention strategies.

Specific gaps identified by the speakers included: training/education/infrastructure, surveillance, infection control, antimicrobial stewardship, diagnostics, biomedical/genomics/proteomics, pharmacological/ development of new antibiotics, health services and policy research, links to agriculture and alternative approaches.

The jury feels the most important area of research is evaluating the effectiveness of ARO detection and control strategies.

Recommendations:

21. Create an Alberta-based and funded ARO infection prevention and control research agenda.
22. Focus the research agenda on determining what works.

Recommendations

Overview

1. Develop, implement and evaluate an integrated One Health strategy to minimize the misuse of antibiotics in animals and humans.

Surveillance

2. Establish comprehensive and standardized information systems for documenting antibiotic use and resistance in humans and animals. Adapt EARS-Net as Canada's surveillance platform, building on and integrating CNISP, CPARS and other existing surveillance systems to produce timely, relevant and robust surveillance data.
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Ethics and patient engagement

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20. Minimize the potential adverse effects of patient isolation.

Research

21. Create an Alberta-based and funded ARO infection prevention and control research agenda.
22. Focus the research agenda on determining what works.

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