Vaccines: The Week in Review
9 May 2011
Center for Vaccine Ethics & Policy
http://centerforvaccineethicsandpolicy.wordpress.com/
A program of
- Center for Bioethics, University of Pennsylvania
http://www.bioethics.upenn.edu/
- The Wistar Institute Vaccine Center
http://www.wistar.org/vaccinecenter/default.html
- Children's Hospital of Philadelphia, Vaccine Education Center
http://www.chop.edu/consumer/jsp/microsite/microsite.jsp

This weekly summary targets news and events in global vaccines ethics and policy gathered from key governmental, NGO and industry sources, key journals and other sources. This summary supports ongoing initiatives of the Center for Vaccine Ethics & Policy, and is not intended to be exhaustive in its coverage. Vaccines: The Week in Review is now also posted in pdf form and as a set of blog posts at http://centerforvaccineethicsandpolicy.wordpress.com/. This blog allows full-texting searching of some 1,200 items.

Comments and suggestions should be directed to
David R. Curry, MS
Editor and
Executive Director
Center for Vaccine Ethics & Policy
david.r.curry@centerforvaccineethicsandpolicy.org

Documentation supporting the Sixty-fourth World Health Assembly, 16–24 May 2011, Geneva, Switzerland was published at http://apps.who.int/gb/e/e_wha64.html including:
A64/1 - Provisional agenda
A64/8 - Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits
A64/10 - Implementation of the International Health Regulations (2005). Report of the Review Committee on the Functioning of the International Health Regulations (2005) in relation to Pandemic (H1N1) 2009
A64/14 - Global immunization vision and strategy
A64/17 - Smallpox eradication: destruction of variola virus stocks

The *Global immunization vision and strategy* document above (A64/14) includes an overview of the Decade of Vaccines Collaboration and its status, reproduced in full text below. The paragraph numeration continues from a more general update on GIVS earlier in the document:

"THE DECADE OF VACCINES, 2011–2020: A COMPREHENSIVE VENTURE TO ADVANCE IMMUNIZATION

19. The Decade of Vaccines envisages a world in which children, families and communities enjoy lives free from the fear of vaccine-preventable diseases. Its goal is to extend the full benefits of immunization to all people, regardless of where they live. This

goal reflects the perspective that access to safe and effective vaccines is a human right that is not currently enjoyed by all people, particularly in low- and middle-income countries.

20. Achieving this goal will require full engagement of the diverse stakeholders needed to facilitate the discovery, development and delivery of vaccines, including donor governments, policy-makers, industry, researchers, the private sector and civil society, philanthropic bodies, and health workers in the countries where most vaccine-preventable diseases currently occur.

21. The planned activities of the decade build on and apply the lessons learnt from the work done so far in implementing the Global Immunization Vision and Strategy, and extend the base and time period of the strategy's framework. WHO, UNICEF, the Bill & Melinda Gates Foundation and other partners are beginning a 12-month collaborative process to draft together a global vaccine action plan for consideration by the Sixty-fifth World Health Assembly. Such a plan should enable greater coordination between all stakeholders, outline the steps necessary to achieve the vision and goals outlined above, and identify gaps that must be filled in order to realize the potential of vaccines by 2020 and beyond. The action plan will comprise four essential components:

(i) establishing and sustaining broad public and political support for the use of vaccines and the financing of immunization services,

(ii) strengthening the equitable delivery of immunization services so as to achieve universal coverage of safe and effective vaccines by 2020 in order to prevent, control, eliminate or eradicate vaccine-preventable diseases,

(iii) cultivating a robust scientific environment for innovation in the discovery and development of new and improved vaccines and associated technologies for high-priority diseases,

(iv) creating the right market incentives to ensure an adequate and reliable supply of affordable vaccines.

Delivering immunization services in the next decade

22. Initial discussions on the strategies and key actions needed to improve delivery of immunization services have been held with stakeholders and country representatives, under the joint coordination of WHO and UNICEF. The ensuing programme of work recognizes the centrality of demand-driven, country-led approaches and action, based on equity, responsibility and accountability and a spirit of national self-reliance and gradual self-sufficiency to achieve commonly-shared global immunization goals.

23. The overall goal is to prevent, eliminate or eradicate diseases by means of achieving high and equitable coverage with effective and safe immunization along with other essential health-care interventions throughout the life course.

24. The proposed delivery strategy comprises five overarching objectives:

Objective 1. To uphold immunization as a human right: creating, increasing and sustaining community trust in immunization and awareness of this right; and focusing on underserved and marginalized communities by shifting the current emphasis on "Reaching Every District" to "Reaching Every Community".

Objective 2. To achieve equity in the use of vaccines: reaching every community with vaccination through complementary delivery methods that engage all appropriate health service providers in the public, private and nongovernmental sectors, thereby ensuring that vaccination covers the poorest and least-served as well as all persons at risk and not just children; building demand for the wider use of new vaccines; and strengthening

the efforts to eradicate poliomyelitis and eliminate measles and maternal and neonatal tetanus.

Objective 3. To seek synergies with other programmes and re-establish immunization as a core component of primary health care: putting increased emphasis on reducing the disease burden; coordinating the multiplicity of interventions needed to achieve this reduction with vaccination as an entry point or a complement to other interventions; and participating in collaborative efforts to renovate and strengthen health systems overall.

Objective 4. To develop immunization systems able to meet the challenges posed by the ambitious new goals: improving systems and tools for generating evidence, the monitoring of programme performance and the use of data for action; training, deploying and supporting adequate human resources for programme management and implementation; and building, maintaining and sustaining systems for regular procurement, delivery and effective supply of vaccines.

Objective 5. To bolster national self reliance and partnerships: strengthening structures and processes for countries to develop immunization policies, strategies and best practices; promoting greater ownership, political commitment, accountability and self-reliance of national immunization programmes; enabling formation of collaborative endeavours and engaging actors with diverse expertise across different sectors; achieving sustainable financing of immunization and sound financial management; and establishing national structures and enforcing processes for accountability.

NEXT STEPS

25. The process for preparing the global vaccine action plan will include extensive consultations with Member States and engage various stakeholders, including civil society organizations, professional societies and the private sector, and will provide an opportunity to estimate the costs of implementing the action plan. The Decade of Vaccines secretariat will ensure the overall oversight and coordination of the collaborative project (see paragraph 21) with working groups corresponding to each of the four proposed components undertaking detailed planning."

The Global Fund announced completion of the selection of the panel that will review its financial safeguards. The panel's co-chairs – Festus Mogae and Michael O. Leavitt – "selected the group of eminent persons and experts who will jointly conduct the assessment" and agreed on the scope and timeline of the review, which is scheduled to be concluded by 15 September 2011. The members selected to complete the high-level panel are:

- Zeinab Bashir El Bakri, Director, Office of His Highness the Prime Minister of Kuwait and former Vice-President Sector Operations of the African Development Bank;
- Norbert Hauser, Germany's Vice-President of the Federal Court of Audit;
- Gabriel Jaramillo, Chairman of the Sovereign Bank Board and Special Advisor at the United Nations Secretary-General Office of the Special Envoy for Malaria;
- The Honourable Barry O'Keefe, Consultant, Clayton UTZ Sydney and former Justice of the Supreme Court of New South Wales (Australia); and
- Claude Rubinowicz, Chief Executive for France's Agence du patrimoine immatériel de l'État (APIE, Agency for Public Intangibles of France) and former Inspecteur Général des Finances.

The panel "is assessing the risk of fraud and misappropriation in the current Global Fund portfolio, and the systems and controls in place which seek to ensure that the resources reach beneficiaries and are used for their intended purposes. To perform the assessment, the members of the panel will examine a representative sample of grants in countries in different risk categories, drawing conclusions and making recommendations, as appropriate."
http://www.theglobalfund.org/en/pressreleases/?pr=pr_110504

The **Weekly Epidemiological Record (WER) for 6 May 2011**, vol. 86, 19 (pp 177–188) includes: Second meeting of the GPEI (Global Polio Eradication Initiative) Independent Monitoring Board; 180 Progress towards meeting the 2012 hepatitis B control milestone: WHO Western Pacific Region, 2011
http://www.who.int/entity/wer/2011/wer8619.pdf

Twitter Watch

A selection of items of interest this week from a variety of twitter feeds. This capture is highly selective and by no means intended to be exhaustive.

AIDSvaccine IAVI
Seth Berkley sat down with John Donnelly from #GlobalHealth Magazine's blog for a Q&A about the #AIDS #vaccine field. http://bit.ly/iUSlpN

EndPolioNow EndPolioNow
In 10 years, 15 million more kids are alive because of vaccines. See the vaccine PSA from ONE. http://www.one.org/us/actnow/vaccines2011/

Journal Watch

[Editor's Note]
Vaccines: The Week in Review continues its weekly scanning of key journals to identify and cite articles, commentary and editorials, books reviews and other content supporting our focus on vaccine ethics and policy. ***Journal Watch* is not intended to be exhaustive, but indicative of themes and issues the Center is actively tracking.** We selectively provide full text of some editorial and comment articles that are specifically relevant to our work. Successful access to some of the links provided may require subscription or other access arrangement unique to the publisher. If you would like to suggest other journal titles to include in this service, please contact David Curry at: david.r.curry@centerforvaccineethicsandpolicy.org

Annals of Internal Medicine
May 3, 2011; 154 (9)
http://www.annals.org/content/current

Original Research

Cholera Epidemic in Haiti, 2010: Using a Transmission Model to Explain Spatial Spread of Disease and Identify Optimal Control Interventions

Ashleigh R. Tuite, Joseph Tien, Marisa Eisenberg, David J.D. Earn, Junling Ma, and David N. Fisman

Ann Intern Med May 3, 2011 154:593-601; published ahead of print March 7, 2011,

Abstract

Background: Haiti is in the midst of a cholera epidemic. Surveillance data for formulating models of the epidemic are limited, but such models can aid understanding of epidemic processes and help define control strategies.

Objective: To predict, by using a mathematical model, the sequence and timing of regional cholera epidemics in Haiti and explore the potential effects of disease-control strategies.

Design: Compartmental mathematical model allowing person-to-person and waterborne transmission of cholera. Within- and between-region epidemic spread was modeled, with the latter dependent on population sizes and distance between regional centroids (a "gravity" model).

Setting: Haiti, 2010 to 2011.

Data Sources: Haitian hospitalization data, 2009 census data, literature-derived parameter values, and model calibration.

Measurements: Dates of epidemic onset and hospitalizations.

Results: The plausible range for cholera's basic reproductive number (R0, defined as the number of secondary cases per primary case in a susceptible population without intervention) was 2.06 to 2.78. The order and timing of regional cholera outbreaks predicted by the gravity model were closely correlated with empirical observations. Analysis of changes in disease dynamics over time suggests that public health interventions have substantially affected this epidemic. A limited vaccine supply provided late in the epidemic was projected to have a modest effect.

Limitations: Assumptions were simplified, which was necessary for modeling. Projections are based on the initial dynamics of the epidemic, which may change.

Conclusion: Despite limited surveillance data from the cholera epidemic in Haiti, a model simulating between-region disease transmission according to population and distance closely reproduces reported disease patterns. This model is a tool that planners, policymakers, and medical personnel seeking to manage the epidemic could use immediately.

Primary Funding Source: None.

Editorials

Cholera in Haiti: Fully Integrating Prevention and Care

David Walton, Arjun Suri, and Paul Farmer

Ann Intern Med May 3, 2011 154:635-637; published ahead of print March 7, 2011,

British Medical Bulletin

Volume 97 Issue 1 March 2011

http://bmb.oxfordjournals.org/content/current

[Reviewed earlier]

British Medical Journal
7 May 2011 Volume 342, Issue 7805
http://www.bmj.com/content/current

Editor's Choice

Cost is an ethical issue

Fiona Godlee, editor, BMJ

Money is tight, so getting value for money has to be a top priority for all of us in healthcare. As Jim Easton, the man in charge of improvement and efficiency for the NHS, says whenever he speaks, cost is an ethical issue. Why, then, do we have so little information on cost effectiveness?

Teppo Järvinen and colleagues find this especially worrying in the case of drug treatments for prevention (doi:10.1136/bmj.d2175). They say that for major preventive drugs, such as statins, antihypertensives, and bisphosphonates, there are "no valid data" on effectiveness or cost effectiveness. This may come as a surprise to some of you. It did to me. They explain that claims for the cost effectiveness of these and other drugs are based on efficacy data from randomised trials in idealised populations. In the real world of clinical care, true cost effectiveness may be much lower. Malcolm Willett's cartoon shows a man standing on the bottom "efficacy" rung of a ladder: "This is fine," he says. "I can see all the evidence I need from here."

What Järvinen and colleagues urge us to recognise is that we can't. To really see whether these drugs represent value for money, we need to take two steps up. We need to understand effectiveness and cost effectiveness in real clinical settings. As an example of how to do this, they refer to a 2001 study by Clare Robertson and colleagues (BMJ 2001;322:701, doi:10.1136/bmj.322.7288.701). But they point out that this assessed a non-drug intervention—exercise for preventing falls in older adults. "We wonder at the virtual absence of empirical cost effectiveness data on preventive drugs when drug companies stand to make millions of profit a week if their drugs are shown to reduce important clinical outcomes in the community setting."

The BMJ has a longstanding policy of publishing cost effectiveness studies alongside or after randomised trials and systematic reviews. This week we apply the policy to the challenge of how best to treat heavy menstrual bleeding. A systematic review and individual patient data meta-analysis published last year found that hysterectomy scores higher (least dissatisfaction among patients) than endometrial ablation or the Mirena coil (BMJ 2010;341:c3929, doi:10.1136/bmj.c3929). Now the same group has done a full cost effectiveness analysis (doi:10.1136/bmj.d2202) and concludes that hysterectomy is likely to be the most cost effective strategy. NICE guidelines currently favour Mirena.

At least we do have NICE. With all its inevitable imperfections, it's still a national treasure. Spare a thought for those charged with creating something similar in the United States, where the C word can't be mentioned. Instead of "cost," the focus is firmly on comparative effectiveness in the form of head to head comparisons. And even then, as Doug Kamerow reports (doi:10.1136/bmj.d2635), the Wall Street Journal snipes "Comparative effectiveness isn't about informing choices, it's about taking away options." But there's no alternative to comparing one treatment with another if we are to make rational decisions; and whatever your health system, cost is an ethical issue.

Analysis

The true cost of pharmacological disease prevention

Teppo L N Järvinen,
Harri Sievänen, Pekka Kannus, Jarkko Jokihaara, Karim M Khan

BMJ 2011;342:doi:10.1136/bmj.d2175 (Published 19 April 2011)

Extract

Despite widespread use of preventive drugs such as statins, antihypertensives, and bisphosphonates, there is no valid evidence that they represent value for money, argue Teppo Järvinen and colleagues

Large randomised clinical trials are considered to represent the strongest form of evidence in assessing whether a particular healthcare intervention works. However, little attention has been paid to the fact that people treated in large multicentre randomised trials may not accurately reflect the population receiving the drug in real world settings.

Recently, van Staa and colleagues assessed the external validity of published cost effectiveness studies of selective cyclo-oxygenase-2 (COX 2) inhibitors by comparing the data used in these studies (typically from randomised trials) with observed clinical data. 2 The trial data suggested that the cost of avoiding one adverse gastrointestinal event by switching patients from conventional non-steroidal anti-inflammatory drugs to COX 2 inhibitors would be about $20 000 (£12 500; €14 000). However, when the same analysis was performed using the UK's General Practice Research Database, comprising anonymised medical records of general practitioners, the cost of preventing one bleed was fivefold greater ($104 000). 2 The authors concluded that the published cost effectiveness analyses of COX 2 inhibitors neither had external validity nor represented the patients treated in clinical practice. They emphasised that external validity should be an explicit requirement for cost effectiveness analyses that are used to guide treatment policies and practices.

Efficacy versus effectiveness

This striking difference between the results from randomised trials and the real world clinical implications was recognised by Archie Cochrane, the pioneering clinical epidemiologist. Almost 40 years ago, Professor Cochrane introduced a specific hierarchy of evidence required from any healthcare intervention before it can be applied to real life situations (table ⇓). Three simple questions summarise Cochrane's scheme: can it work (efficacy)? does it work (effectiveness)? and is it worth it (cost …

Clinical Infectious Diseases
Volume 52 Issue 10 May 15, 2011
http://www.journals.uchicago.edu/toc/cid/current
[Reviewed earlier]

Cost Effectiveness and Resource Allocation
(accessed 8 May 2011)
http://www.resource-allocation.com/
[No relevant content]

Emerging Infectious Diseases
Volume 17, Number 5–May 2011
http://www.cdc.gov/ncidod/EID/index.htm
[Reviewed earlier]

Health Affairs
April 2011; Volume 30, Issue 4
http://content.healthaffairs.org/content/30/2.toc
[Reviewed earlier; No relevant content]

Health Economics, Policy and Law
Volume 6 - Issue 02
http://journals.cambridge.org/action/displayJournal?jid=HEP
[Reviewed earlier; No relevant content]

Human Vaccines
Volume 7, Issue 5 May 2011
http://www.landesbioscience.com/journals/vaccines/toc/volume/7/issue/4/
NEWS, POLICY AND PROFILES
Response to Commentaries
Open Access Article
Donald W. Light
Extract
Human Vaccines has assembled a set of high quality, important commentaries on my policy analysis and concerns about the future of GAVI and its Advanced Market Commitment (AMC). Several affirm the value of GAVI in raising funds and playing a key role in immunizing millions more children than before, and I fully agree. The real worries concern their current and upcoming use of donations….
RESEARCH PAPERS
Projecting the effectiveness of RotaTeq® against rotavirus-related hospitalizations and deaths in 6 Asian countries
Open Access Article
Antoine El Khoury, T. Christopher Mast, Max Ciarlet, Leona Markson and Michelle Goveia
RotaTeq is an oral pentavalent rotavirus vaccine (RV5) that has shown high and consistent efficacy in preventing rotavirus gastroenteritis (RGE) in randomized clinical trials conducted mostly in industrialized countries. We projected the effectiveness of RV5 against RGE-related hospitalizations and deaths in 6 Asian countries by using a simple mathematical model. Model inputs included rotavirus surveillance data collected 2006-2007 in China, 2001-2002 in Hong Kong, 2005-2007 in India, 2005-2007 in South Korea, 2005-2007 in Taiwan, and 2001-2003 in Thailand; the numbers of rotavirus-related deaths in each country; and published rotavirus serotype-specific efficacy of RV5. The model projected an overall effectiveness in the region of 82% to 89% against RGE-related hospitalizations and a substantial reduction in RGE-related deaths, suggesting that RV5 could substantially reduce the burden of rotavirus disease in Asia.
Commentaries
Application of 'Public Health Epidemiological Logic' in devising a vaccination policy: A broad public health criteria-for routine Immunization
Rajan R. Patil
There is a need to develop clear cut public health criteria for consideration of new vaccines for use in public health. Most of the vaccines which have become recently available or will soon be available are mostly recommended for use in clinical/office

practice. A new vaccine that is highly recommended for use in clinical setting may not be effective at all for larger public health use or may even lack rationale to put it in use for public health. It is stressed that a new vaccine which is proven to be good clinical tool for preventing particular disease at individual level need not necessarily be good public health tool in combating the same disease at community level.

The present paper takes a closer look at the logical basis for use of any vaccine in public health. Rabies vaccine is used as a case study to set the background to scrutinize the criteria for eligibility for considering any new vaccine to be included in routine immunization program A rough & ready algorithm is proposed as a check list for a new vaccine as a likely candidate for inclusion in Universal immunization programme. The suggested new algorithm is basically a public health criteria called as Public Health Epidemiological Logic [PHEL] Criteria.. The public health debate and the arguments against inclusion of Rabies vaccine in routine national immunization programme in India is a argued in the frame work of PHEL criteria in this paper Rabies vaccine to drive home the point, that a vaccine which is a good clinical tool need not always be a good public health tool, where as a vaccine which is proven to be a good public health tool will always invariably be a good clinical tool as well.

JAMA
May 4, 2011, Vol 305, No. 17, pp 1733-1824
http://jama.ama-assn.org/current.dtl

Brief Report

Availability of Comparative Efficacy Data at the Time of Drug Approval in the United States

Nikolas H. Goldberg, Sebastian Schneeweiss, Mary K. Kowal, Joshua J. Gagne
JAMA. 2011;305(17):1786-1789.doi:10.1001/jama.2011.539

Abstract

Context Comparative effectiveness is taking on an increasingly important role in US health care, yet little is known about the availability of comparative efficacy data for drugs at the time of their approval in the United States.

Objective To quantify the availability of comparative efficacy data for new molecular entities (NMEs) approved in the United States.

Data Sources Approval packages publicly available through the online database of drug products approved by the US Food and Drug Administration (FDA).

Study Selection Identification of efficacy studies that supported approval of each NME approved by FDA between 2000 and 2010.

Data Extraction We determined whether eligible studies were head-to-head active controlled trials and whether the results of such studies were available in the approval packages. We recorded the approved indication, whether the NME was an orphan product, whether the NME had undergone priority review, and whether the control group was a specific active comparator or standard care.

Results Of 197 NMEs identified that met eligibility criteria, 100 (51% [95% confidence interval {CI}, 44%-58%]) met criteria for having comparative efficacy data available at the time of market authorization. After excluding NMEs designated as orphan products (n = 37) and those approved for indications for which no alternative treatments existed (n = 17), this proportion increased to 70% (95% CI, 62%-77%). The proportions of NMEs with available comparative efficacy data varied widely by therapeutic area, from

33% (95% CI, 9%-67%) for hormones and contraceptives to 89% (95% CI, 56%-99%) for diabetes medications.

Conclusion Publicly available FDA approval packages contain comparative efficacy data for about half of NMEs recently approved in the United States and for more than two-thirds of NMEs for which alternative treatment options exist. We did not investigate the extent to which available comparative efficacy information is useful for clinical guidance.

Commentaries

What Next for QALYs?

Peter J. Neumann

JAMA. 2011;305(17):1806-1807.doi:10.1001/jama.2011.566

Extract

The quality-adjusted life-year (QALY) has come under fire lately. In the United States, health reform legislation prohibited use of cost-per-QALY thresholds. 1 The United Kingdom has proposed that the National Institute for Health and Clinical Excellence (NICE), which has influenced reimbursement through cost-per-QALY ratios, will not in the future use such information to make yes or no recommendations; instead NICE's cost-effectiveness assessments would provide an input into price negotiations for technologies. 2 In Germany, the Institute for Quality and Efficiency in Health Care implemented a new system for evaluating the value of medical technologies but rejected the cost-per-QALY model on ethical and methodological grounds. 3 Many countries (including France, Spain, and Italy) have opted for other approaches. Other articles have criticized use of QALYs. 4, 5

The drawbacks of QALYs are well known. QALYs represent health over time as a series of preference-weighted health states, for which the preference …

Journal of Infectious Diseases

Volume 203 Issue 10 May 15, 2011
http://www.journals.uchicago.edu/toc/jid/current

[Reviewed earlier; No relevant content]

The Lancet

May 07, 2011 Volume 377 Number 9777 Pages 1543 - 1624
http://www.thelancet.com/journals/lancet/issue/current

Editorial

Financing HPV vaccination in developing countries

The Lancet

Preview

5 years have passed since the first vaccines against the human papillomaviruses (HPV) that cause cervical cancer came onto the market. At the end of 2010, 33 countries had national HPV immunisation programmes. However, few of these initiatives were in developing countries and none were in Africa.

The Lancet Infectious Disease

May 2011 Volume 11 Number 5 Pages 333 - 416
http://www.thelancet.com/journals/laninf/issue/current

[Reviewed last week]

Medical Decision Making (MDM)
March/April 2011; 31 (2)
http://mdm.sagepub.com/content/current
[Reviewed earlier]

Nature
Volume 473 Number 7345 pp5-118 5 May 2011
http://www.nature.com/nature/current_issue.html
[No relevant content]

Nature Medicine
May 2011, Volume 17 No 5
http://www.nature.com/nm/index.html
News
Russia pledges $4 billion for Pharma-2020 plan - p517
Gary Peach
doi:10.1038/nm0511-517

Russia's biomedical industry is woefully underdeveloped, accounting for only 0.2% of the world market. But plans are afoot to change that. Speaking at the opening of a new birth center in Ryazan on 11 March, for example, Prime Minister Vladimir Putin stated that the government wants to boost Russia's presence on the world biopharma stage to 3–5% in the next decade. And he emphasized that the country already possesses the necessary academic and research institutions to achieve that. "We need to come up with measures to stimulate demand for Russia-made biotechnological products and remove barriers that often prevent businesses from working," he said.

To that end, Russian leaders announced in March that they have approved 120 billion rubles ($4 billion) for a strategic investment program aimed at developing the country's massively import-dependent pharmaceutical and medical supplies industries.

Dubbed Pharma-2020, the program—which was adopted two years ago although financing was only approved by the government last month—will attempt to boost output of local medicines, in gross sales terms, from nearly 25% last year to 50% by 2020. In addition, the program calls for ensuring that 90% of vital medicines are domestically produced, retooling some 160 companies to good manufacturing practice standards, establishing ten research and development centers that will focus on creating innovative products and boosting exports to $100 million.

Like nearly all of Russia's state-driven initiatives, Pharma-2020 sets seemingly unattainable targets. Still, some insiders believe it is realistic. "Everyone acknowledges that it's an ambitious program, but, considering the amount of construction work going on right now, and the state funds being allocated, then this task is manageable," says Nikolai Bespalov, an analyst at Pharmexpert, a Moscow-based market research center.

Others have reservations. "I perceive the program as a document and not much more. The strategy is written, the concept approved, but there are more acute problems that could be solved today without strategies and concepts, such as the low level of domestic

products in state purchases," says Viktor Dmitriev, director of the Association of Russian Pharmaceutical Manufacturers, based in Moscow.

New England Journal of Medicine
May 5, 2011 Vol. 364 No. 18
http://content.nejm.org/current.shtml
Perspective
Statistics in Medicine: Pragmatic Trials — Guides to Better Patient Care?
J.H. Ware, M.B. Hamel
[no abstract, first 100 words…]
Although randomized clinical trials provide essential, high-quality evidence about the benefits and harms of medical interventions, many such trials have limited relevance to clinical practice. The investigations are often framed in ways that fail to address patients' and clinicians' actual questions about a given treatment. For example, placebo-controlled trials of a new migraine medication help to establish its efficacy, but they may not help clinicians and patients choose between the new medication and other available treatments. Moreover, since most randomized clinical trials are efficacy trials, researchers enroll a homogeneous patient population, define treatment regimens carefully and require that they be . . .
Listening to Provenge — What a Costly Cancer Treatment Says about Future Medicare Policy
J.D. Chambers, P.J. Neumann
Free Full Text

The Pediatric Infectious Disease Journal
May 2011 - Volume 30 - Issue 5 pp: A9-A10,365-450,e75-e87
http://journals.lww.com/pidj/pages/currenttoc.aspx
[Reviewed earlier; No relevant content]

Pediatrics
May 2011 / VOLUME 127 / ISSUE 5
http://pediatrics.aappublications.org/current.shtml
[No relevant content]

Pharmacoeconomics
May 1, 2011 - Volume 29 - Issue 5 pp: 361-454
http://adisonline.com/pharmacoeconomics/pages/currenttoc.aspx
[Reviewed earlier]

PLoS Medicine
(Accessed 8 May 2011)
http://www.plosmedicine.org/article/browse.action?field=date

Meta-analyses of Adverse Effects Data Derived from Randomised Controlled Trials as Compared to Observational Studies: Methodological Overview

Su Golder, Yoon K. Loke, Martin Bland Research Article, published 03 May 2011
doi:10.1371/journal.pmed.1001026

Abstract

Background

There is considerable debate as to the relative merits of using randomised controlled trial (RCT) data as opposed to observational data in systematic reviews of adverse effects. This meta-analysis of meta-analyses aimed to assess the level of agreement or disagreement in the estimates of harm derived from meta-analysis of RCTs as compared to meta-analysis of observational studies.

Methods and Findings

Searches were carried out in ten databases in addition to reference checking, contacting experts, citation searches, and hand-searching key journals, conference proceedings, and Web sites. Studies were included where a pooled relative measure of an adverse effect (odds ratio or risk ratio) from RCTs could be directly compared, using the ratio of odds ratios, with the pooled estimate for the same adverse effect arising from observational studies. Nineteen studies, yielding 58 meta-analyses, were identified for inclusion. The pooled ratio of odds ratios of RCTs compared to observational studies was estimated to be 1.03 (95% confidence interval 0.93–1.15). There was less discrepancy with larger studies. The symmetric funnel plot suggests that there is no consistent difference between risk estimates from meta-analysis of RCT data and those from meta-analysis of observational studies. In almost all instances, the estimates of harm from meta-analyses of the different study designs had 95% confidence intervals that overlapped (54/58, 93%). In terms of statistical significance, in nearly two-thirds (37/58, 64%), the results agreed (both studies showing a significant increase or significant decrease or both showing no significant difference). In only one meta-analysis about one adverse effect was there opposing statistical significance.

Conclusions

Empirical evidence from this overview indicates that there is no difference on average in the risk estimate of adverse effects of an intervention derived from meta-analyses of RCTs and meta-analyses of observational studies. This suggests that systematic reviews of adverse effects should not be restricted to specific study types.

Science
6 May 2011 vol 332, issue 6030, pages 625-752
http://www.sciencemag.org/current.dtl

EDITORIAL

Indigenous Genomics

Vanessa Hayes
Science 6 May 2011: 639

Summary

Studies of indigenous peoples are a crucial part of genomic research, not only to define the extent of human diversity but to provide medical benefit to all people. There are more than 370 million indigenous people living in almost half the countries of the world. Exploding interest in indigenous genomics and global population structure has raised debate about issues of informed consent and community benefit. As was evident in

March 2011 during the African and Southern African Society of Human Genetics Meeting in Cape Town, South Africa, the inclusion of indigenous people in future genomic research is paramount, but ethical guidelines must address local concerns. Scientific practices and values must be integrated with indigenous governance so that such genomic research can continue, with the benefits fully realized by all.

Science Translational Medicine
4 May 2011 vol 3, issue 81
http://stm.sciencemag.org/content/current
[No relevant content

Vaccine
Volume 29, Issue 22 pp. 3827-3930 (17 May 2011)
http://www.sciencedirect.com/science/journal/0264410X
Letters
Cost-effectiveness of Ontario's pandemic vaccine program
Page 3829
Elizabeth Rolland-Harris, Martin Tepper
Regular Papers
Barriers to early uptake of tetanus, diphtheria and acellular pertussis vaccine (Tdap) among adults—United States, 2005–2007 Original Research Article
Pages 3850-3856
Brady L. Miller, Katrina Kretsinger, Gary L. Euler, Peng-Jun Lu, Faruque Ahmed
Abstract
Background
The tetanus, diphtheria and acellular pertussis vaccine (Tdap) was recommended by the Advisory Committee on Immunization Practices (ACIP) for U.S. adults in 2005. Our objective was to identify barriers to early uptake of Tdap among adult populations.
Methods
The 2007 National Immunization Survey (NIS)-Adult was a telephone survey sponsored by the Centers for Disease Control and Prevention (CDC). Immunization information was collected for persons aged ≥18 years on all ACIP-recommended vaccines. A weighted analysis accounted for the complex survey design and non-response.
Results
Overall, 3.6% of adults aged 18–64 years reported receipt of a Tdap vaccination. Of unvaccinated respondents, 18.8% had heard of Tdap, of which 9.4% reported that a healthcare provider had recommended it. A low perceived risk of contracting pertussis was the single most common reason for either not vaccinating with Tdap or being unwilling to do so (44.7%). Most unvaccinated respondents (81.8%) indicated a willingness to receive Tdap if it was recommended by a provider.
Conclusions
During the first two years of availability, Tdap uptake was likely inhibited by a low collective awareness of Tdap and a low perceived risk of contracting pertussis among U.S. adults, as well as a paucity of provider-to-patient vaccination recommendations. Significant potential exists for improved coverage, as many adults were receptive to vaccination.

Mumps outbreaks in four universities in the North West of England: Prevention, detection and response Original Research Article
Pages 3883-3887
D. Kay, M. Roche, J. Atkinson, K. Lamden, R. Vivancos
Abstract
Evidence suggests that primary and secondary vaccine failure have contributed to recent university-based mumps outbreaks. We describe the epidemiology and public health management of two such outbreaks that occurred simultaneously in two areas of the North West of England, affecting four universities, using data from routine surveillance, serology testing, and telephone interviews and electronic questionnaires. Vaccination status was obtained from GP records. Cases were predominantly first year students living in university halls of residence. Public health response involved active surveillance, isolation advice and targeted vaccination clinics. Many students lack natural immunity and mumps vaccination. Factors hindering the public health response include delayed notifications, inability to readily define the 'at risk' population, low vaccine uptake, and lack of an evidence-based, cost effective strategy.

Value in Health
December 2010 Volume 13, Issue 8 Pages 863–1065
http://onlinelibrary.wiley.com/doi/10.1111/vhe.2010.13.issue-8/issuetoc
[Reviewed earlier]