E-Health, patients and ethics

Dr. Ken Harvey MB BS, FRCPA

http://www.medreach.com.au
Disclosure of interests

- Health Action International Asia Pacific (HAI AP).
- Australian Consumers’ Association.
- Public Health Association of Australia.
- Australian National Prescribing Service.
E-Health, patients and ethics
Parallels of medicines policy and E-Health

- Quality products.
- Equitable access.
- Rational use.
- Viable industry.
Case history

- A 23-year-old man presented with fever to a rural hospital in eastern Burma (Myanmar).
- He was diagnosed by microscopy as having falciparum malaria (4.2% infected red blood cells).
Case history

- He was treated with oral artesunate, labelled as made by Guilin Pharmaceutical (Guangxi, People's Republic of China), 4 mg/kg once a day, the treatment of choice in this area.
- Since artemisinin derivatives have been used in this area, not one of 600 patients prospectively studied with 4% parasitaemia has died.
• However, on the third day the young man was found to be in a coma, with renal failure and increased parasitaemia (5.5% infected red blood cells).

• He was perfused with intravenous fluids and given intravenous artesunate but he died 12 hours later from cerebral malaria.
Case history

• However, on the third night the young man was found to be in a coma, with renal failure and increased parasitaemia (5.5% infected red blood cells).

• He was perfused with intravenous fluids and despite treatment with intravenous artesunate he died 12 hours later from cerebral malaria.

Tests showed that the artesunate used was counterfeit and contained no active ingredient.
Counterfeit artesunate in Asia

- The World Health Organization notes that between 38% and 52% of "artesunate" blister packs sampled in Asia contain no active ingredient.
Philippines Bureau of Food & Drugs
High quality products

- Australian Therapeutic Goods Administration (TGA)
  - Appropriate legislative framework.
  - Licensing of manufacturers (GMP inspection, product sampling, testing).
  - Product registration (drug evaluation for quality, safety and efficacy).
  - Post-marketing surveillance (monitoring adverse drug reactions, pharmaceutical promotion).
Relevance to E-Health

• If industry is to play a responsible role:
  – government policy,
  – standards, and
  – tests of product compliance
• are all required.
Report of suspected adverse reaction to medicines or vaccines

(See statement about the collection and use of personal information overleaf)

Please attach any additional data to this sheet.

<table>
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<th>Patient initials or medical record number:</th>
<th>Sex: M □ F □</th>
<th>Date of birth or age:</th>
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<tr>
<th>Suspected medicine(s)/vaccine(s)</th>
<th>Weight (kg):</th>
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<tr>
<td>(please use trade names; include AUST R or AUST L number for non-prescription)</td>
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<tr>
<th>Medicine/vaccine</th>
<th>Dosage (Dose number for vaccines e.g. 1st DTP)</th>
<th>Date begun</th>
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<tr>
<th>Medicine(s)/vaccine(s) taken at the time of the reaction</th>
<th>Dosage</th>
<th>Date begun</th>
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Office use only
Adverse drug reaction reporting

Registered Reporters
You will be prompted to enter a username and password. After logging in you will then be able to create, save and edit ADRS Notifications prior to lodging them with TGA. Logging in also allows you to view previously lodged notifications and request specific ADRS reports.

Unregistered Reporters
This option allows you to lodge a notification without having to register with ADRS. After the ADRS notification is completed and lodged, an acknowledgement receipt will be sent via email as confirmation.

This option is recommended if you only lodge Adverse Drug Reaction System notifications infrequently.

Alternatively you can register with the Adverse Drug Reaction System. Registering provides you with the benefits of registered users.
Adverse drug reaction reporting

AUSTRALIAN DRUG EVALUATION COMMITTEE
ADVERSE DRUG REACTIONS ADVISORY COMMITTEE

PO Box 100
WODEN ACT 2606
Enquiries: 1800 044 114
Email: adrac@health.gov.au
Fax (02) 6232 8392

Successfully tested in 2003
Yet to be implemented!

Dear Doctor

I write to request your assistance with the testing of a new feature
number of desktop prescribing software packages (Locum, Medlink 32). The Adverse Drug Reaction Advisory Committee (ADRAC)
Collaborating Centre for eHealth at the University of Ballarat in electronic transmission of the “Report of Suspected Adverse Reac-
tions to Vaccines” (blue card). ADRAC has been collecting information
reactions from prescribers, pharmacists and other healthcare pro-
for over 30 years. The current process requires a reporter to complete

Acknowledgments to Andrew Magennis, Medical Director
Goals of medicinal drug policy

1. Medicines of high quality, safety and efficacy
2. Equitable access to necessary medicines
3. Quality use of medicines
4. A viable & responsible local pharmaceutical industry
Equitable access

• Two billion people (one third of the world’s population) still lack regular access to essential medicines.
• Six million people in developing countries lack anti-retroviral drugs.
• Medicines are the largest health expense for poorer households and the second largest public health cost.
• The price of drugs in a free market bears no relation to the ability of people to pay.
Equitable access

- Limited list of cost-effective, necessary drugs.
- Cost subsidised by national or private insurance schemes.
- Prices negotiated using:
  - Pharmacoeconomic analysis (pay only what the drug is worth)
  - Monopsony buying power (counters monopoly power of pharmaceutical companies during patent protection)
  - Reference pricing (subsidise only the lowest price product in a generic group and in some therapeutic classes)
  - Generic substitution by pharmacists for drugs of proven therapeutic equivalence.
- Local production (compulsory licensing).
• In January 2003, the Pharmaceutical Research Manufacturers of America (PhRMA) lobbied US trade negotiators to seek Australian government commitment to, “refrain from trade distorting, abusive, or discriminatory price controls found in the Pharmaceutical Benefits Scheme (PBS)”. 

• In October 2003, President George Bush told Prime Minister John Howard that raising drug prices is a key goal for United States negotiators in any FTA deal. Mr Bush said his pharmaceutical industry believes some countries do not pay their share of the cost of research and development to create new medicines, making US consumers pay the bill.
Why doesn't Big Pharma like the PBS?

International drug price differences

2-3 times lower

Productivity Commission Research Report, July 2001 (top 150 PBS drugs)
Are Australian drug prices too low?

- While drug prices in Australia are 2 to 3 times lower than those in similar countries, price differences vary across different categories of pharmaceuticals:
  - Prices for new innovative drugs are much closer to those in other countries.
  - Largest price differences for ‘me-too’ pharmaceuticals (modified versions of older drugs similar in clinical value to drugs already available) and generics.
Are Australian drug prices too low?

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  - Prices for new innovative drugs are much closer to those in other countries.
  - Largest price differences for 'me-too' and modified versions of drugs (similar in clinical value to drugs currently available) and generics.
US drug prices (and profits) are too high!
Hence campaigns for equitable access
Parallels with the digital divide

- Negotiated prices
  - Affordable broadband

- Generic drugs
  - Low cost computers
  - Linux o/s; open office.

- Generic drug substitution
  - Offering a choice of more cost-effective open source software rather than embedding more expensive Microsoft products.
Goals of medicinal drug policy

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My own interest started at the RMH

Hospital acquired infection with antibiotic-resistant microorganisms
Quality Assurance Cycle

- Continually updated standards of practice: treatment guidelines
- Drug audit / utilisation review
- Practitioner reflection / targeted education
- Feedback results to health administrators and guideline authors
Guidelines evolution...
Scaling up nationally

Health Minister, Peter Sharples, with members of the PHARM Committee during the development of the Quality Use of Medicines Policy
Quality Use of Medicines Policy

**Strategies**

- Policy development and implementation.
- National facilitation and co-ordination.
- Independent information.
- Ethical promotion.
- Education and training.
- Services and interventions.
- Evaluation.
Current challenge

To make best-practice Guidelines, medication review and other proven QUM techniques more accessible via physician’s computers.
QUMIT: The vision

Patient problem → Physician decision

Guidelines
- Drug information
- Drug-drug interaction
- Dose calculators

Assisted by decision support software

Prescriptions, Investigations, Consumer information

Alerts

HealthConnect ADRAC

Lab results

e-Patient record

Improve

Outcome analysis

QUMIT: The vision
Challenges: E-conversion
In order to open a guideline topic by selecting a clinical problem the software and guidelines need common (or mapped) terminology &/or code sets.

In order to populate a prescription or drug chart the recommended regimen must be machine readable.
Guideline and formulary information can be atomized into machine readable components using XML tags (but displayed in HTML via XSL)

e.g. *amoxicillin (child 15 mg/kg up to) 500 mg, 8 hourly, orally*

can be represented in machine readable form as:

```xml
<REGIMEN>
  <ATC>J01CA04</ATC>
  <DRUG>amoxicillin</DRUG>
  <DOSE>
    <CHILDREN>15<UNIT>mg/kg</UNIT></CHILDREN>
    <ADULT>500<UNIT>mg</UNIT></ADULT>
  </DOSE>
  <FREQ>8 hourly</FREQ>
  <ROUTE>oral</ROUTE>
</REGIMEN>
```
E-Guidelines: XML technologies

Well styled MS Word manuscript

Parsed by computer

Database application

TGDB

Print

CD-ROM

Intranet

PDA

XML/XSLT

Prescribing system integration...

Acknowledgments: Dr. Bryn Lewis, NPS
The need for standards

Guideline representation
Clinical terminology / Diagnostic coding
Medicines terminology

Drug promotion

Drug company dinners “oiled the wheels” of medical education and $200-a-head meals were appropriate, rather than doctors “slumming somewhere in a budget chain motel”.

AMA President, Dr Mukesh Haikewal

"If doctors don’t learn about new life-saving and health-enhancing drugs through seminars put on by the pharmaceutical companies then patients will not be prescribed the best possible drug for their condition - it’s as simple as that."

AMA President, Dr Mukesh Haikewal

Industry-doctor interaction correlates with:

- Doctors' preferences for new products that hold no demonstrated advantage over existing ones.
- Decreased prescribing of generic drugs.
- A rise in both and irrational and incautious prescribing.
- Rising prescription expenditures.
Hence
Hence

Welcome to the NPS website,

where you will find evidence-based

information about medicines.

NPS is a non-profit, Australian organisation,

independent of both the Government and

pharmaceutical industry.

To speak to someone about medicines, telephone one of our information lines.

Health professionals
please phone:
Therapeutic Advice and Information Service (TAIS)
1300 138 677

Consumers
please phone:
Medicines Line
1300 888 763

http://www.nps.org.au/
NPS: Academic detailing

Also: home medication review by pharmacists (Government-Guild agreement)
NPS: Campaigns

I'VE GOT A SORE THROAT: WILL AN ANTIBIOTIC MAKE ME BETTER?

Some information to help you in the next week or so

What is a "sore throat"?
Sore Throat is a very common infection caused by bacteria or viruses. It is usually part of a simple illness such as the common cold but rarely may be a symptom of more severe illness such as glandular fever. The sore throat may be accompanied by aches, cough and generally feeling unwell and fever. Bacteria and minor irritants like dust at the back of the throat can cause inflammation of the throat. This makes symptoms worse and may cause the glands (lymph nodes) in the neck to swell and become tender.

Most people (80%) are over their infections by one week. Half are better by about 3 days.

Will antibiotics help a sore throat?
Traditionally doctors have prescribed antibiotics to kill any bacteria in the throat. However recent research has suggested that antibiotics do not make much difference to symptoms in fact they only shorten the time you are unwell by 16 hours overall. You have a 65% chance of being better in 36 days without antibiotics and 26 days with them. In other words - with or without antibiotics - you have a 90% chance of being better in 7 days.

There are some rare complications however they are so rare that it is not necessary to use antibiotics routinely to prevent them unless you are in a special risk group such as your doctor can advise you about.

What are the disadvantages of antibiotics?
- Antibiotics can have unpleasant side effects (for example, thrush, nausea, vomiting, upset stomach and diarrhoea).
- Taking antibiotics when you don’t need them isn’t safe.
- Overusing antibiotics produces resistant germs, which means the antibiotic may not work when they are really needed.

Your doctor has examined you during your visit to the surgery and, even though you feel unwell, he or she hasn’t found any serious illness that definitely needs antibiotics today.

So, your sore throat will quite likely get better without antibiotics. However, your doctor may have given you a prescription to have available in case you do need antibiotics in the next few days. Follow your doctor’s advice as to whether to get these, and the prescription should only be used for this episode of illness.

When should I return to my doctor?
If you feel your illness is getting worse.
If you feel your sore throat is getting worse.
If you are not better in 36 days. If you do use antibiotics, do take the FULL course.

Is there anything else I should look out for?
Should you develop any new or worsening symptoms, or you have any persistent problems, telephone the surgery and make an appointment for a further check-up.

Ways to help your sore throat

1. Pain relief may be the most effective thing to do. Take paracetamol or aspirin (for adults). Check the package for dosage instructions.
2. Some people find sucking a lozenge or tea soothing.
Evaluation: antibiotic use is slowly declining
### Project Title

**Establishment of the National Rational Drug Use Policy Implementing System in China**

### Applicant Information

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<tr>
<th>2</th>
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<th>DMA, MoH</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>Address</td>
<td>北京市西城区西直门外南路1号，100044，中国</td>
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### Legal Representative

<table>
<thead>
<tr>
<th>3</th>
<th>Name</th>
<th>Wang Yue</th>
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<tr>
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<td>Phone</td>
<td>010-68792204</td>
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<td><a href="mailto:mohyzyslrc@163.com">mohyzyslrc@163.com</a></td>
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### Project Director

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<tr>
<th>4</th>
<th>Name</th>
<th>Zhang Jun Ouyang Guo</th>
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<td></td>
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### Collaborating Institutions

Australia National Prescribing Service Limited (NPS), share experiences of NPS in promoting quality use of medicines, and implementing National Medicines Policy.

WHO China Office, use the tools developed and advocated by WHO to make changes in the prescriber's environment.

The MoH Hospital Management Institute will take care of the routine part of the project project.

### Project Coverage Area and Time Period

- **Central level and some selected provinces:** Time period: 2008-2009
Relevance to E-Health

• Australian medicinal drug policy is highly regarded.
• We are actively exporting and localising these concepts internationally.
• If only we could get our E-Health act together we could also export and localise relevant software and services.
Goals of medicinal drug policy

1. Medicines of high quality, safety and efficacy
2. Equitable access to necessary medicines
3. Quality use of medicines
4. A viable & responsible local pharmaceutical industry
Viable industry

- Innovation has become more expensive, difficult and time-consuming.
- Drug evaluation and regulation has become more lengthy and more rigorous.
- Companies are merging in order to achieve critical research mass.
Viable industry requirements

• IP protection.
• Stable policy setting.
• Appropriate but not excessive regulation.
• Skilled health labour force.
• Incentives for appropriate research and development (e.g. Medical Innovation Prize Fund)
  - recognising that the profit motive will not produce research into neglected diseases in developing countries.
Conclusions

• Global economic growth is providing greater resources for the purchase of medicinal drugs (and other health services).

• However, market forces do not assure people affordable access to essential drugs of adequate quality nor do they guarantee that drugs are used wisely.

• As a consequence, there is much interest in innovative policy that make markets more responsive to health needs.

• There are many similarities between good medicines policy and E-Health policy.
All counties have the same problem

power, patents and pills
All are interested in solutions
All are interested in solutions.

All can learn from each other!