Medwatcher Japan (MWJ) Conference

Tokyo, Japan
23 November 2004

Patient perspectives on informed drug prescribing

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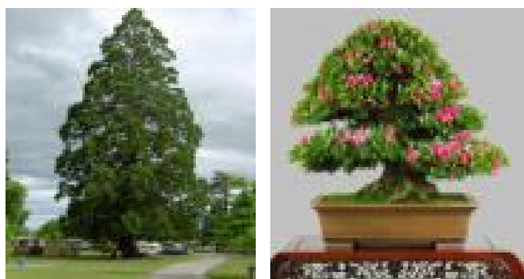
More about Social Audit …

- part of the consumer movement since 1971
- a charitable company, with six directors
- independent: mainly funded by grants
- no membership, not a 'representative' body
- focus on corporate behaviour, social impact
- emphasis on research and (catalytic) action
- focus on asking questions to generate ideas
- networking, collaboration, publication
- operating budget – under 10m Yen/year

Is Social Audit an 'organisation' ? It's a matter of scale…



One man band … (2)

Patient perspectives ???

on informed drug prescribing

- Different patients have different perspectives, interests, understandings and competencies
- Many people who use prescribed drugs (or are affected by them) are not "patients" at all.
- Individual health greatly depends on public health. 'Health for one and all' is increasingly a global concern

… *informed drug prescribing* ???

- In the 'traditional' model, the patient is hopelessly ill-informed, highly dependent and deeply grateful - and 'doctor knows best'
- The reality is that most doctors know much more than most patients – but also that most doctors know much less than they need to know to be truly 'informed prescribers'
- Informed prescribing is very hard: much depends on who informs prescribers and how
- Informed prescribing depends on feedback from drug users – if only to contain their unrealistic expectations (3)

Focus on relationships …
and on the main actors

the public – as users, consumers, purchasers, patients, relatives, dependents …

professionals - academics, research scientists, doctors, pharmacists, nurses etc

business – generating economic wealth, producing drugs and drug information

government – simultaneously promoting trade and health objectives

From benzodiazepine tranquillisers …
… to antidepressants

- Media reports, legal action (1985 – 1991)
- *Book: Power & Dependence* (1992)
- Review of *Listening to Prozac* (*Nature* 1994)
- The Antidepressant Web (*IJRSM*,1997)
- ADWEB (socialaudit.org.uk), 1998 – 2004
- Book: *Medicines out of Control?* (2004)

ADWEB – www.socialaudit.org.uk

Launched in February 1998, the purpose of ADWEB was to find out what the authorities thought about the risks of antidepressant drugs – and what they were doing about it.

There seemed to be two main problems: [a] severe drug withdrawal symptoms, linked to drug dependence; and [b] some risk of drug-induced suicidal and violent behaviour. But other adverse drug reactions (ADRs) could cause serious problems too.

ADWEB was open and interactive: it now contains hundreds of letters to and from the authorities, and thousands of user reports

Key questions about antidepressants

1. Who needs antidepressants?
2. Are newer ones better than old ones?
3. How do antidepressants work?
4. Are antidepressants "effective"?
5. How safe is 'safe'?
6. Is the drug dosage right for you?
7. Can you trust drug warnings?

What is an 'effective' antidepressant?

A drug is *officially* considered 'effective' if it proves more effective than a 'sugar pill' – a placebo. The authorities usually require evidence from two such clinical trials … but the manufacturers of antidepressants have found they need to do *eight* such trials to get positive results in two.

The drug licensing authorities accept this – and ignore trials with negative results. The antidepressant drug, reboxetine, is used in Europe, even though seven out of eight trials produced negative results (4)

What is an 'effective' drug?

Allen Roses, worldwide vice-president of genetics at GlaxoSmithKline (GSK), said fewer than half of the patients prescribed some of the most expensive drugs actually derived any benefit from them. *"The vast majority of drugs - more than 90 per cent - only work in 30 or 50 per cent of the people,"* Dr Roses said. "I wouldn't say that most drugs don't work. I would say that most drugs work in 30 to 50 per cent of people. Drugs out there on the market work, but they don't work in everybody." *(5)*

Therapeutic area: drug efficacy rate in per cent
(after Roses A; *Independent*, 9 December 2003)

- Alzheimer's: 30 — Analgesics (Cox-2): 80
- Asthma: 60 — Cardiac Arrythmias: 60
- Depression (SSRI): 62 — Diabetes: 57
- Hepatitis C (HCV): 47 — Incontinence: 40
- Migraine (acute): 52 — Migraine (prophylaxis) 50
- Oncology: 25 — Rheumatoid arthritis 50
- Schizophrenia: 60

How safe is 'safe'? It can depend on point of view …

Contrast the *"official"* descriptions of adverse drug reactions with patients' descriptions of the same thing.

"Official" descriptions used "approved terminology" and rely much more on numbers than on words

Numbers may tell you no more than the final score in a football match – they don't tell you what happened in the game …

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Different descriptions of suicidal behaviour

***Official* terminology:**
"Agitation"; "abnormal thinking"; "restlessness" "suicidal ideation"; "emotional lability"

Report from patient's wife:
After 3 days on drug, "he sat up all night forcing himself to keep still because he wanted to kill everyone in the house"

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Reports from patients and relatives add colour and meaning

"My son committed suicide after being on Seroxat only 7 weeks---. He became a lot of worse whilst on this medication."

"One weekend we went away. I forgot my tablets. I became irrational, violent, and asked my husband to commit suicide with me …"

"My husband shot himself after 4 days on Seroxat never having been suicidal in his life"

"In the space of one week, he underwent a complete personality change, going from someone who was kind, gentle, caring and strong, to a suicidal wreck who couldn't think straight, became aggressive, insulting to his friends and totally believed he was someone else."

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Withdrawal symptoms – '*officially*' described

"paraesthesia" (181/1370);
"electric shock" (6)
"Abnormal eye movements" (5/1370 reports);
"abnormal eye sensations" (3);
"abnormal vision" (3);
"accommodation abnormal" (12);
"Flashing vision" (8);
"vision blurred" (24);
"visual acuity reduced" (3);
"visual disturbance, not specified" (25).

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Withdrawal symptoms – described by *patients*

"the electric explosions in my head were triggered off by the movements from left to right of my eyes";

"An "electrical zapping" in my head when I move my eyes quickly or move my head from side to side";

"my eyes felt jumpy when I looked from side to side";

"eye movement was out of the question if I wanted to remain standing and if I move my head or my eyes quickly I get a strange feeling in my head as if there's an electric current being discharged into my brain."

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withdrawal Symptom -difficult to be recognized by doctor

"I too am experiencing the electric head'.
What an appropriate name.

My Dr. told me that it was simply my anxiety returning. I explained that my eyes felt jumpy when I looked from side to side, but he still attributed it to returning anxiety.

It's good to see others having the same symptoms, so I know I'm not imagining things!"

(Int J Risk & Safety Med 15(2002) : 161)

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Antidepressants: how safe is 'safe'?

Not much is known about the safety of new drugs. *After* licensing, serious risks are revealed with about half of all new drugs (6)

It took more than ten years to establish the risks of antidepressant-induced suicidal behaviour.

For ten years, the authorities insisted that paroxetine withdrawal symptoms were rare (0.2%) and generally mild. In June 2003, the authorities reported that 25% of users could expect withdrawal reactions – a 125-fold increase on the original estimate. (7)

Limitations of (sponsored) clinical trials

Finding the right drug dosage …

About one in six drugs are first marketed at a dosage that later proves too high …

Many users are exposed to needless risks when the drug dosage is recommended on the basis that 'one size fits all'.

Probably about half of all users of fluoxetine (Prozac) are prescribed about four-times the dosage they need. (8)

Can you trust the drug warnings?

Drug regulatory agencies focus on measuring harm, and have generally failed to communicate the uncertainties of risk:

'Science' looks to *certainties*, while 'common sense' is about *probabilities*. Would you want to be warned of the possibility that a drug caused harm:

1. only if the risk was certain (p =< 0.05)?
2. if it was probable this was so (p => 0.51); or
3. something in between?

Antidepressants: matters arising …

- Most new drugs no better than older ones (9)
- Too many new 'diseases', new diagnoses (10)
- Intense promotion, not enough innovation (11)
- Trade imperatives obscure health priorities
- Conflicts of interest - from the top down (12)
- Clinical drug trials: poor quality is the norm (13)
- Secrecy: an affront to democracy and science
- Lack of feedback, oversight, accountability
- We systematically over-estimate drug benefits, and under-estimate drug risks

Continuing, underlying problems …

- Under-investigation of clinical outcomes
- Lack of comparative drug testing
- Lack of productivity in drug innovation (10)
- Company mergers > ‘institutional obesity’
- Direct to Consumer drug promotions (14)
- High prices and problems of access to drugs
- Heath inequalities and ‘health illiteracy’
- “How tainted has medicine become?” … ”*Heavily and damagingly so*” (15)

Relationships: the “Conspiracy of Goodwill”

- An alliance fuelled by optimism and hope - reinforced by lack of information and feedback. Promotion helps us to over-estimate drug benefits, and secrecy leads to under-recognition of drug risks.
- Expressinons of the ‘Conspiracy of Goodwill’: cohesion cooperation and confidence – but also denial, bias, resistance to critical ideas; not learning from mistakes
- The essence of the ‘Conspiracy of Goodwill’ is that it seems to exist for the mutual advantage and benefit of the parties involved. In practice, it may have the opposite effect.

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… and future opportunities

- Much to learn from the history of medicine
- Better understanding of placebo effects (16)
- Make much better use of feedback from users
- A public register of all clinical drug trials?
- Learn to learn how not to repeat mistakes – *public* enquiries can teach us much we need to know, but they are very rare. The present UK enquiry into the “Influence of Pharma-ceutical Industry” is due in mid-2005 (17) (18).

Key factors: balance and transparency

Complexities of ‘informed prescribing”

- Informed prescribing demands rigorous, if not impossible, requirements to be informed
- Prescribers greatly depend on other actors – notably pharmaceutical companies and regulators – to be well-informed
- Informed prescribing depends on a clear understanding of how much more we need to know …
- Safe and effective drug use greatly depends on human (including institutional) behaviour and on the balance of power in relationships.

Medicines out of Control?

www.socialaudit.org.uk

“… beautifully written, painstakingly researched, thoroughly referenced, powerfully and persuasively argued, and eerily up to date.”

Lancet, 26 June 2004

References

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