



THERAPEUTICS INITIATIVE

Evidence Based Drug Therapy

Is prescribing information from sales representatives balanced?

Many Canadian physicians see pharmaceutical sales representatives (“drug detailers”) as a way to obtain free samples, keep up-to-date about new treatments, or as a friendly break from patient care. A common attitude to the promotional information provided is that “I take it with a grain of salt.”

But are sales visits innocuous? A recent study examined the information provided to family doctors during sales visits in Vancouver, Montreal, Sacramento, California, and Toulouse, France.¹ The main aim was to measure how often information was provided on potential harmful effects of promoted drugs. Canada, the US and France differ in how they regulate drug promotion; the researchers asked whether this leads to differences in information quality. This Letter reviews the study results and what they mean for patient care.

Study Methods

A random sample of primary care physicians was drawn in each city and those who see sales representatives as part of their normal practice were invited to participate. Physicians belonging to groups critical of drug promotion (No Free Lunch or Healthy Skepticism) and drug company employees were excluded. Each physician filled in a questionnaire on each promoted drug immediately after the sales visit. Physicians were asked to treat visits as they usually would and to report on the information provided, whether spontaneous or in response to questions.

255 physicians participated. The main aim was to examine how often sales representatives provided “minimally adequate safety information”. This measure was based on a Canadian physician survey on needed prescribing information in sales visits.² If a sales representative mentioned at least one approved indication, common adverse event, serious adverse event and contra-indication (and no unqualified safety claims or unapproved uses), they were considered to have provided “minimally adequate safety information”.

How often was “minimally adequate safety information” provided?

Fewer than 2% of the 1692 drug promotions included “minimally adequate safety information”. This did not differ by country. Serious adverse events were mentioned only 5-6% of the time, despite the fact that over half of the drugs promoted carried US FDA ‘black box’



warnings or Health Canada boxed warnings of serious risks.

Sales representatives provided no oral or written information on harm, including no mention of contraindications, in 40% of promotions in Vancouver and Montreal. If only oral information is considered, no harm was mentioned 59% of the time in the four sites. In Toulouse, sales representatives were more likely to mention harm (in 61% of promotions) compared to the North American sites (35%). This study involved over 300 brand-name drugs in total, and 25% of promotions were for drugs the physician had not previously prescribed; no harm was mentioned in over half of promotions for these drugs.

Despite the lack of safety information, the physicians judged information quality to be ‘good’ or ‘excellent’ in 57% of promotions and ‘poor’ or ‘very poor’ in only 10%. Nearly two-thirds of the time they indicated their readiness to start or increase prescribing.

In Vancouver, physicians received free samples for 75% of promoted drugs versus 57% in Montreal and Sacramento and 4% in Toulouse. Physicians received lunch or other food around one quarter of the time in Vancouver and almost never in Toulouse (0.2%).

Was promotion consistent with national regulatory standards?

In all three countries, regulations governing prescription drug promotion require harm as well as benefit to be mentioned.³⁻⁵ The study results indicate that these regulations are contravened more often than they are respected. There is no active monitoring of the one-to-one discussions between sales representatives and physicians. Regulatory standards are stricter in France than in Canada and the US⁵ and this may explain the more fre-

quent mention of harmful effects or contraindications in France. However, information on serious adverse events remained rare in France, and the sales representatives made more unqualified safety claims.

Do sales representatives affect prescribing?

Despite the lack of information on harm, physicians judged the information quality positively and stated their readiness to prescribe. This raises serious concerns about the basis for such prescribing decisions. However, this study did not measure prescribing decisions, only intent.

Two systematic reviews have examined the effects of promotion on prescribing.^{6,7} More contact with sales representatives is associated with higher prescribing volumes and costs, and lower quality of prescribing.⁷ Free samples also influence prescribing. For example, a US dermatology study found that national prescribing trends closely reflect which brands are provided as samples. A large academic medical centre that prohibits samples prescribed generics for 83% of initial acne treatments, compared with 21% nationally, and had costs for acne treatments that were less than half of the US average.⁸ The main reasons that physicians say they like free samples are for treatment of low income uninsured patients, convenience, and because patients appreciate them. Ironically, free samples often lead to higher longer-term treatment costs.⁹

What is the solution?

Better regulation of promotion during one-to-one visits by sales representatives requires active monitoring and effective regulatory enforcement, with sanctions that prevent repeat violations, and corrective information when physicians or the public have been misinformed. *La Revue Prescrire* has developed an inexpensive model for monitoring, through an anonymous 'sentinel network' of physicians¹⁰, that regulators

could adopt. Institutional policies that prevent one-to-one visits to physicians are another solution. For example, physicians working with the US health insurer Kaiser Permanente decided 10 years ago to ban sales visits from their workplaces, and instead rely on independent information.¹¹ A new alliance of Australian doctors has pledged to ban sales representatives from their practices.¹² **Around 8% of Canadian and 17% of US physicians make a similar personal choice, and avoid sales visits.**¹³ Independent, accessible medicines' information for both professionals and the public is another much-needed solution (see Table).

Clinical implications

Prescribing quality depends on physicians having ready access to unbiased, comprehensive information about prescription drugs that includes both benefit and harm, and provides a fair assessment of the drug's contribution to care, based on outcomes of importance to patient health. Promotion focuses on new drugs, for which understanding of clinical effects, especially infrequent serious harm, remains incomplete;¹⁴ cautious prescribing is warranted. Sales representatives aim to sell a product and cannot be expected to provide unbiased information. Physicians must remember the "myth of unique invulnerability". Everyone thinks (s)he is unaffected, yet promotion flourishes because it increases prescribing.

Conclusions

- Sales representatives increase sales of the drugs they promote.
- A recent study in Canada, the US and France showed that sales representatives seldom provide the information on harm that is needed for rational, evidence-based prescribing decisions.
- Greater regulation of sales visits in France is associated with a higher likelihood that information about harm is provided, although serious harm remains underreported.
- Prescribing decisions require balanced understanding of potential harm as well as benefit, especially for newer, less familiar drugs. Promotional information is unlikely to meet that need.

References

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For a complete list of references go to: www.ti.ubc.ca/letter91

The next TI Best Evidence course is at Surrey Memorial Hospital on Nov. 1, 2014. See: ti.ubc.ca/BestEvidence

Table: A few sources of independent information

Information source	Country	URL	Cost
Prescrire International	France	english.prescrire.org/en	\$200
Drugs & Therapeutics Bulletin of Navarre	Spain	http://goo.gl/V8RPCT	Free
Drugs & Therapeutics Bulletin	UK	dtb.bmj.com	\$130
NICE	UK	www.nice.org.uk	Free
Worst Pills Best Pills	US	www.worstpills.org	\$22
The NNT (numbers needed to treat)	US	www.thennt.com	Free
Cochrane Database of Systematic Reviews	Global	www.thecochranelibrary.com or via libraries	Free
BC Provincial Academic Detailers	Canada	www.bcpad.ca	Free
CADTH – Common Drug Review	Canada	www.cadth.ca/en/products/cdr	Free
Independent information with a focus on harm			
RxIsk: Making Medicines safer	Global	www.rxisk.org	Free
Institute for Safe Medication Practices Newsletter	US	www.ismp.org	Free

See also *Therapeutics Letter* 35, May - June 2000

References

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