

Pharmaceutical Sales Representatives and Patient Safety Preliminary Results



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Study Aims

- Examine the influence of the regulatory environment on pharmaceutical promotion
- Focus on consequences for patient safety
- Aim – identify ‘best practices’ in regulation



Three regulatory environments

- Canada – self-regulation via Rx&D Code
 - *Montreal and Vancouver – differ in per capita drug costs, reimbursement, culture*
- US FDA – government regulation
 - *Additional ‘fair balance’ requirement*
 - *Reprints on unapproved uses*
- France – government + sales visit charter



“Charte de la Visite Médicale” 2005

- Approved product information
- Comparative therapeutic value (ASMR)
- No free samples, gifts or food
- No invitations to participate in studies
- Sales representative certification



Methods

- 'Real life' observational study
- Random sample of family physicians
- Rolling enrolment May 2009 - June 2010
- Unit of analysis = each promoted drug
- Presence/absence of information
- Consistency with approved information – assessed post hoc
- Sample size based on estimated ~20% 'minimal safety information'; $\geq 10\%$ difference

Primary outcome measure

- "Minimally adequate" information for safe prescribing:
 - ≥ 1 indication ("approved use")
 - ≥ 1 serious adverse event (leading to death, hospitalization)
 - ≥ 1 common adverse event ("side effects")
 - ≥ 1 contra-indication ("who should not use this medicine")
 - No unqualified safety claims (i.e. "this medicine is safe")
 - No unapproved indications ("unapproved uses")
2. Primary Hypotheses:
- More often in Toulouse than Vancouver or Montreal
 - Sacramento, more harm, but more unapproved indications
 - Vancouver = Montreal

Physician inclusion criteria

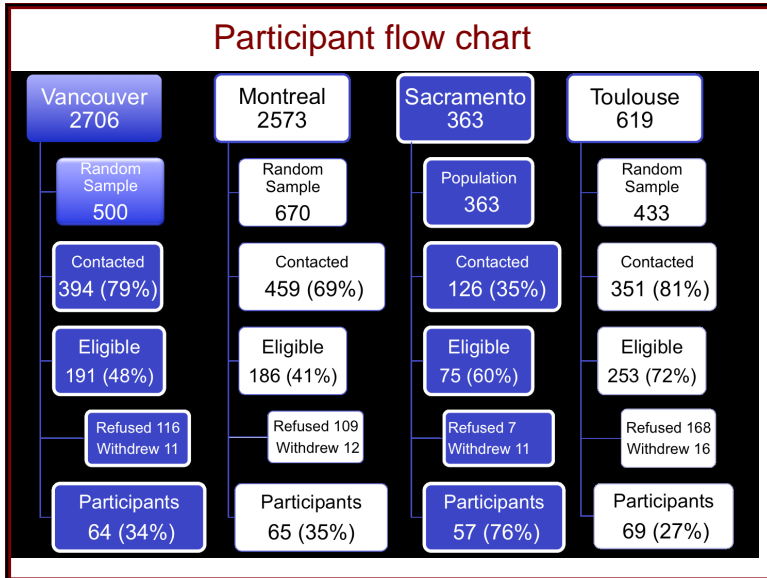
- Sees sales representatives as part of normal practice
- ≥ 20 hours per week in clinical care
- Primary care non-referral population ($>50\%$)

Exclusion criteria

- Member of a group with a focus on drug promotion (e.g. No Free Lunch, Healthy Skepticism)
- Employee of a drug company (salaried or on contract)

Preliminary Results

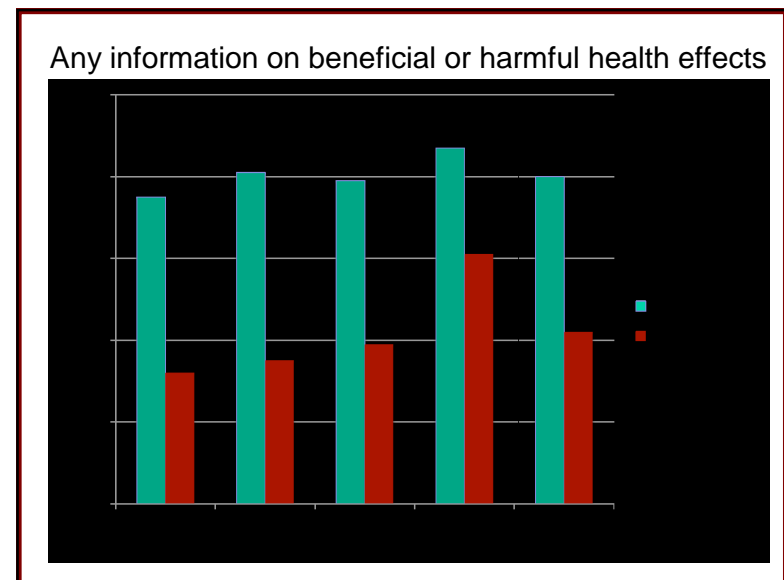




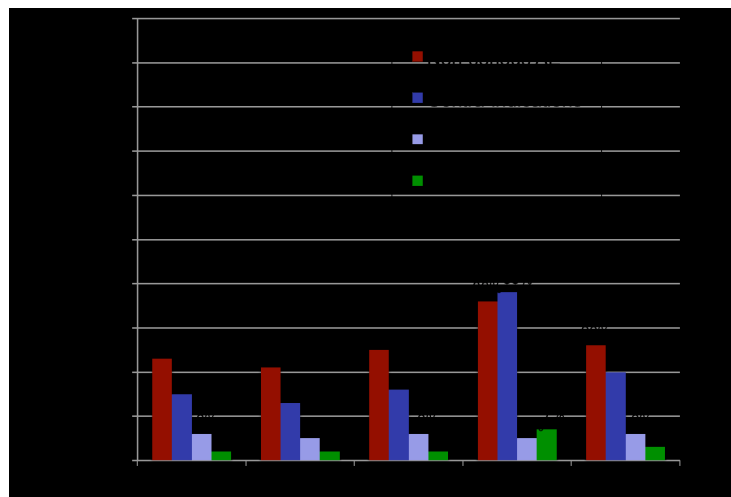
- ### In total
- 255 physicians enrolled
 - 1785 questionnaires (web & paper)
 - 93 (5%) ineligible
 - 83 not Rx drugs
 - 10 protocol violations
 - 1692 drug-specific questionnaires

The sales visit

	Van N=418	Mont N=423	Sac N=445	Toul N=406	Total (n=1692)
First promotion of drug	26%	23%	19%	18%	22%
Session ≤ 5 minutes	49%	39%	56%	36%	45%
One-to-one session	76%	80%	78%	96%	82%
Free samples	75%	57%	57%	4%	49%
Lunch or other food	23%	9%	24%	0.2%	14%
Invited – sponsored event	10%	19%	9%	8%	12%
Invited – study	1%	2%	0	5%	2%



Specific types of harm mentioned (n=1693)



Top 10 drugs – all four sites combined

Brand name	generic	condition
Crestor	rosuvastatin	lipid lowering
Cipralex	escitalopram	depression
Advair	fluticasone/salmeterol	Asthma, COPD
Onglyza	saxagliptin	diabetes
Cymbalta	duloxetine	depression
Rasilez	aliskiren	hypertension
Spiriva	tiotropium	COPD
Actonel	risedronate	osteoporosis
Januvia	sitagliptin	diabetes
Micardis	telmisartan	hypertension

Overall, what was the sales representative's key message about the drug?*

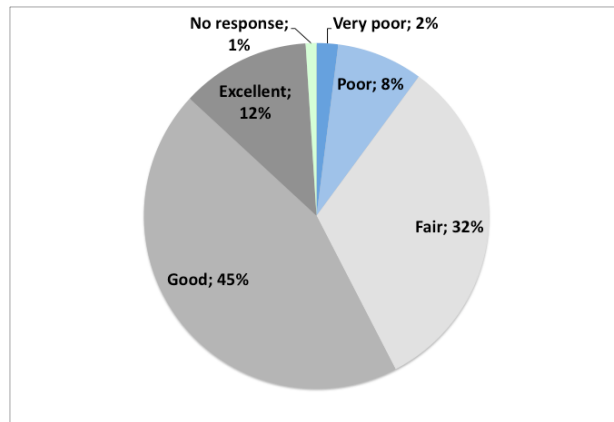
- “Avandia is safe even in patients with heart disease, as long as they don’t have heart failure.”
- “New studies indicate safety”
- “Safe in patients not in congestive heart failure”
- “Avandia is safe.”
- “cardiovascular safety.”
- “Avandia is not as dangerous as the public makes it out to be.”
- “Now recommended by AACE as safe to use, same as Actos.”

*Vancouver, Montreal, Sacramento: 07/2009 – 03/2010

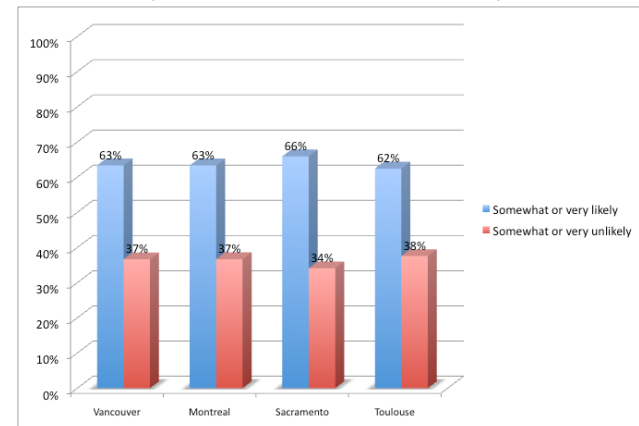
Minimally adequate information for safe prescribing

- Vancouver: 5 (1.2%)
- Montreal: 7 (1.7%)
- Sacramento: 4 (0.9%)
- Toulouse: 12 (3.0%)
- **Total: 28/1692 (1.7%)**

Physician's judgment - quality of scientific information provided (n=1693 promotions)



Stated likelihood to prescribe (n=1662; > 98% of interactions)



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