The sustainability of Medicare – are doctors part of the solution or part of the problem?

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Divisions of Cardiology and Clinical Epidemiology,
McGill University Health Center,
Medical Grand Rounds June 11 2013

Conflicts of Interest

I have been a paid consultant for Canadian Agency for Drugs and Technologies in Health (CADTH) and patent law firms representing generic drug companies, am also on the board of INESSS (pro bono)

Otherwise no known conflicts associated with this presentation and to, the best of my knowledge, am equally disliked by all pharmaceutical and device companies

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Genesis of this presentation

- Dec 2012, gave rounds at the Resp. Clin Epi
- In the week before that talk I looked at 4 drugs and this is a rough estimate of quasi-wasteful spending, i.e. extra spending with no or little health benefits

Drug	$
• Non generic Statins	500 – 1000MM
• Ipilimumab	50MM
• Dronedarone	50MM
• Apixaban	500 -1000 MM

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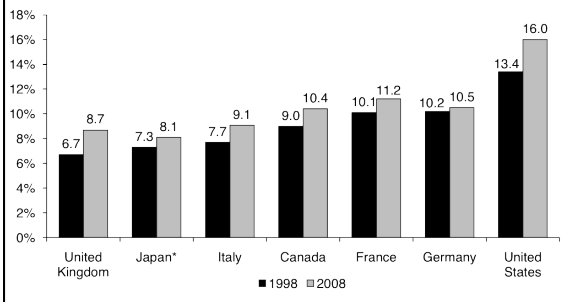
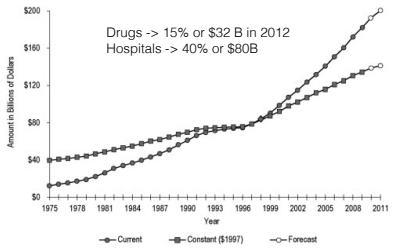
Perspective

- "A billion here, a billion there—pretty soon you're talking about real money." - Everett Dirksen US senator

Total Health Spending (%GDP)in G7 Countries

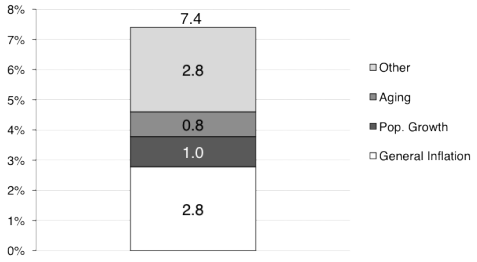


Total Health Expenditure,



Population Growth and Aging Account for Less Than 2% of Growth in Public-Sector Health Spending

Average Annual Growth Rate, 1998 to 2008



Technology: Important Supply-Side Factor for hospital costs

- New pharmaceuticals
- Imaging equipment (CT and MRI scanners)
- Other medical / surgical devices (Robotic) devices
- IT, Electronic health records
- Innovative procedures, applications and techniques and changes in clinical practices
- Do we get good value for these choices?

Types of Economic Analyses

Cost-Minimization Analysis (CMA)

- when the consequences of the intervention are the same, then only inputs are taken into consideration. The aim is to decide the cheapest way of achieving the same outcome.

Cost-Benefit Analysis (CBA)

- when both the inputs and consequences of different interventions are expressed in monetary units so that they compare directly and across programmes even outside healthcare.

Cost-Effectiveness Analysis (CEA)

- when the consequences of different interventions may vary but can be measured in identical natural units, then inputs are costed. Competing interventions are compared in terms of cost per unit of consequence.

Cost-Utility Analysis (CUA)

- when interventions which we compare produce different consequences in terms of both quantity and quality of life, we express them in utilities.

Economic Analysis – a Simple Starting Point

		Effectiveness: Less	Effectiveness: More
Incremental cost	More	Dominant Reject	Non-dominant Is added effect worth $?
	Less	Non-dominant Is reduced effect worth $ saving	Dominant Accept

Cost-utility Analysis

- Purpose: Consider both the effectiveness and cost of an intervention
- $$CE_{2\text{-}1} = \frac{Cost_2 - Cost_1}{QALY_2 - QALY_1}$$

Cost = Cost of medical intervention + cost of illness

Effectiveness = quality-adjusted life year saved

CE = Cost-effectiveness ratio

Standard benchmark has been dialysis ≈ 50,000 $/QALY

Some difficulties

- RCTs more difficult (product modifications, "moving targets", "learning curves')
- Effectiveness = f (device + MD skill)
- New devices can have wider economic implications (training, health care delivery)
- Prices evolve over time
- Can QALYS be reliably measured?
- Requires constant addition of new money
- No consideration of opportunity cost

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Not quite so easy

20 June 2000 Volume 132 Number 12
Annals of Internal Medicine

The Cost-Effectiveness of Sildenafil

- Sildenafil (Viagra) ≈ 11,000 $/QALY cost-effectiveness compares favorably with that of accepted therapies for other medical conditions. (*Ann Intern Med.* 2000;132:933-937)

Not quite so easy

20 June 2000 Volume 132 Number 12
Annals of Internal Medicine

The Cost-Effectiveness of Sildenafil

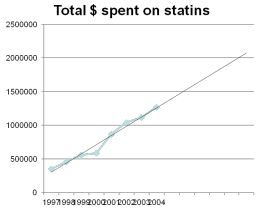
- Assume disutility of 0.74 based on interview of 20 men
- When their wives were interviewed disutility was 0.98 or $200,000/QALY

Volk R. Arch Fam Med. 1997;6:72.-6

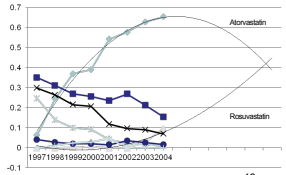
Statins

- Atorvastatin RCTs now >160,000 pt years
- Rosuvastatin 69,000 (35,000 pt yrs no benefit in secondary prevention compared to placebo!)
- No studies showing superiority, 3-5X more + evidence with atorvastatin

Total $ spent on statins



% of market share



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Economics

- Rosuvastatin $1.70 vs generic atorvastatin $0.56
- Sales of rosuvastatin $800MM could save > $500MM with no adverse outcomes
- Why is this drug on the MUHC drug formulary? Hospital cost is probably small (15K?) but influence on out of hospital Rx prescriptions are potentially large
- Given thin evidence base, could we not spend this money better elsewhere?
- Not only cardiologists!

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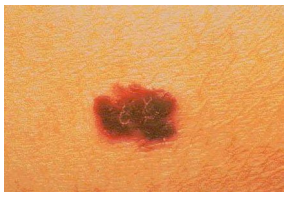
Cancer de la peau: des Québécois devront être traités à Toronto! Le Soleil Oct 4 2012



- à la suite de la recommandation contenue dans un rapport gouvernemental de reporter la décision de couvrir deux nouveaux médicaments prometteurs.
- C'est l'une des possibilités qu'a évoquées, mercredi, au cours d'un entretien avec *Le Soleil*, le Dr Joël Claveau, dermatologue renommé de la Clinique du mélanome de L'Hôtel-Dieu de Québec.

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Quote from lay press

- "Les deux nouveaux médicaments - l'Ipilimumab et le Zelboraf - qui sont testés depuis près de trois ans, sont la seule avancée majeure pour traiter les cancers avancés de la peau. Le taux d'efficacité des médicaments est de 80 % comparativement à 10 % avec la chimiothérapie."

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Another medical journal

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 AUGUST 19, 2010 VOL. 363 NO. 8

Improved Survival with Ipilimumab in Patients with Metastatic Melanoma

- phase 3 study, to evaluate if ipilimumab +/- gp100 improves overall survival

CONCLUSIONS

Ipilimumab, with or without a gp100 peptide vaccine, as compared with gp100 alone, improved overall survival in patients with previously treated metastatic melanoma.

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Some interesting quotes - ? Academic integrity

- "Draft prepared by six of the academic authors in collaboration with the sponsor and a professional medical writer paid by the sponsor. "
- "All the authors signed a confidentiality disclosure agreement with the sponsor."
- "Data were collected by the sponsors and analyzed in collaboration with the senior academic authors“

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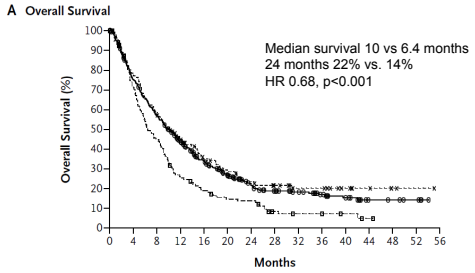
Survival



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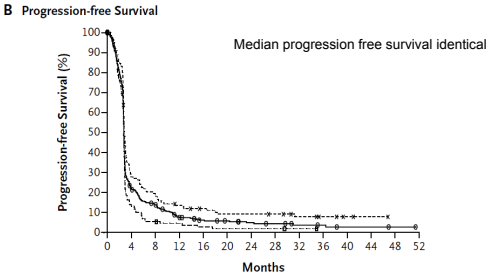
Disease free progression



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What was the primary outcome?

- The original primary end point was the best overall response rate at 24 months (i.e., the proportion of patients with a partial or complete response).
- Primary end point amended to overall survival January 15, 2009) on the basis of “data from phase 2 studies suggest that there is a long-term survival effect”
- But and the referenced phase 2 study actually had no comparator group to suggest better survival

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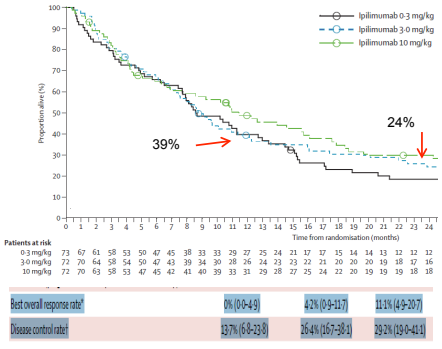
Phase 2 Data



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Clinical doubts

- Randomization from Sept 2004 and completed on July 25, 2008, with 676 pts but planned sample size 750 so why stopped early and why was the primary outcomes changed?
- Was the data looked at prematurely?
- Grade 3 or 4 immune-related adverse events was 10 -15% vs. 3.0%, resolution about 6 weeks or 50% of median extra survival time
- Le Soleil news report inaccurate but successful in pressuring government

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The elephant in the room

- The drug costs $92 800 (10% of population would receive it twice, $184K)
- Sponsor assumes 1 yr extra survival and gets ICER of $98K, using 10 year horizon
- Is this reasonable ?

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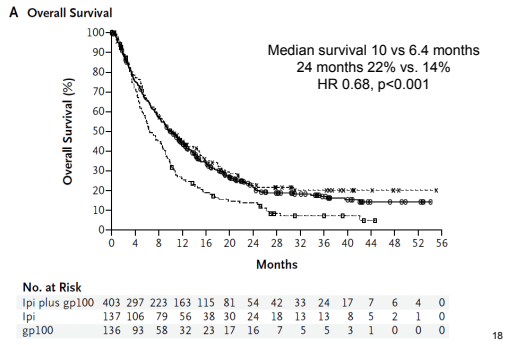
Survival



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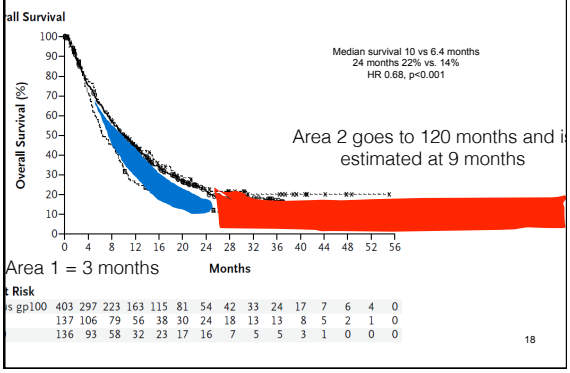
Survival



18

The elephant in the room

- The drug costs $92 800 (10% of population would receive it twice, $184K)
- Sponsor assumes 1 yr extra survival and gets ICER of $98K, using 10 year horizon
- Is this reasonable?
- Reality mean additional survival < 3-4 months
- No good estimates QoL
- ICER $300K, 0% prob < 100K
- Quebec budget impact likely 21MM over 3 years
- Are there not better buys?

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The elephant in the room

- The drug costs $92 800 (10% of population would receive it twice, $184K)
- Sponsor assumes 1 yr extra survival and gets ICER of $98K, using 10 year horizon
- Is this reasonable?
- Reality mean additional survival only 3 months, with no good estimates of QoL
- ICER $300K, 0% probability < 100K
- Budget impact likely 21MM over 3 years
- Other places were we could get better value?

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Back to cardiology - ATHENA 2009

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Effect of Dronedarone on Cardiovascular Events in Atrial Fibrillation

CONCLUSION

Dronedarone reduced the incidence of hospitalization due to cardiovascular events or death in patients with atrial fibrillation. (ClinicalTrials.gov number, NCT00174785.)

N Engl J Med 2009;360:668-78.

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Results

Outcome	Dronedarone (N=2301)	Placebo (N=2327)	Hazard Ratio for Dronedarone (95% CI)
Primary outcome — no. (%)	734 (31.9)	917 (39.4)	0.76 (0.69–0.84)
First hospitalization due to cardiovascular events — no. (%)	675 (29.3)	859 (36.9)	0.74 (0.67–0.82)
First hospitalization — no. (%)			
For atrial fibrillation	335 (14.6)	510 (21.9)	0.63 (0.55–0.72)
Death from any cause — no. (%)	116 (5.0)	139 (6.0)	0.84 (0.66–1.08)

- Approved FDA July 2009 based on 24% reduction of primary endpoint
- Secondary outcome CV mortality reduction RR 0.71 (0.51–0.98) p= 0.03
- Was this compelling evidence (risk benefits analysis) for approval?

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Was placebo an appropriate comparator?

- While other drugs have not been shown to reduce recurrent AF hospitalizations, an outcome not been previously measured, they have been shown to reduce recurrent AF
- ATHENA primary benefit uniquely driven by fewer AF hospitalizations (7.3%)
- Is it not reasonable to think that if other drugs reduce recurrent AF episodes, it is likely they will reduce hospitalizations due to recurrent AF?

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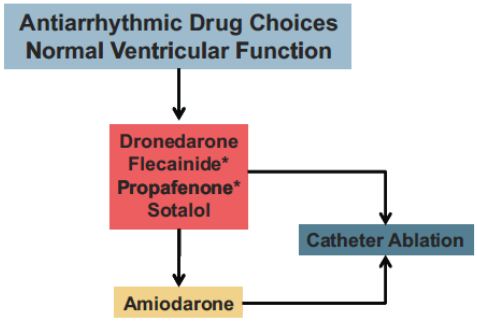
Canadian 2010 guidelines

(published 2011)



Better than active amiodarone?

- DIONYSIS (published June 2010) compared both the efficacy and safety of amiodarone and dronedarone in 504 persistent AF patients.
- Premature study drug discontinuation due to drug intolerance occurred more frequently with dronedarone (75.1% versus 58.8%, HR 1.59 95% CI 1.28–1.98; P < 0.0001).
- Deaths occurred in 2 of 249 dronedarone patients and 5 of 255 amiodarone patients.

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PALLAS 2011

The NEW ENGLAND JOURNAL of MEDICINE

ORIGINAL ARTICLE

Dronedarone in High-Risk Permanent Atrial Fibrillation

CONCLUSIONS

Dronedarone increased rates of heart failure, stroke, and death from cardiovascular causes in patients with permanent atrial fibrillation who were at risk for major vascular events. Our data show that this drug should not be used in such patients. (Funded by Sanofi-Aventis; PALLAS ClinicalTrials.gov number, NCT01151137.)

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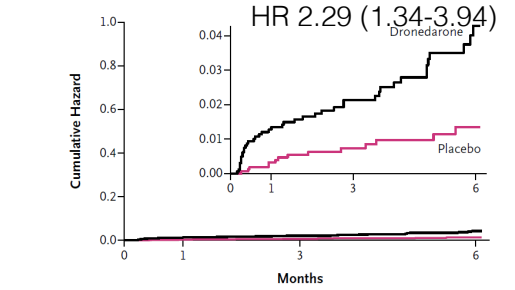
Primary - Stroke, Embolism, or CV Death



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Is the drug really safe?

- Previously ANDROMEDA showed increased mortality in CHF patients (25 (8.1%) vs 12 (3.8%), HR 2.13; 95% CI 1.07 to 4.25)
- Other small trials (ERATO, EURIDIS and ADONIS) also showed increased deaths (9 in the 913 dronedarone patients vs.3 in 498 placebo patients.)

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How to combine studies?

- Spectrum from assuming complete independence (don't combine) to homogeneity (assuming identical studies with no between study variation)
- Choice of homogeneity or independence too limited for practical decisions (cf need to make informative inferences with absent or limited data).

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Hierarchical modeling

- Possible compromise between these 2 extremes involves hierarchical modeling (may follow Bayesian or frequentist paradigm)
- This involves a more flexible assumption termed *exchangeability,* which may be regarded as a compromise between assuming independence and assuming identicality of the treatment effects from different sources

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Hierarchical modeling

- With a hierarchical model, information from all of the exchangeable groups is shared to some extent (borrowed);
- The amount of borrowing is flexible and results in the partial pooling of data.
- The effect of borrowing is shrinkage as estimates are pulled toward one another with a narrowing of their intervals
- Shrinkage may introduce bias, more than offset by a reduction in variance, and total accuracy increases.

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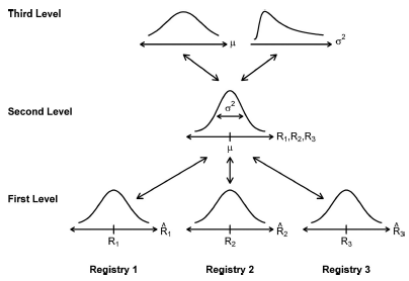
Hierarchical modeling



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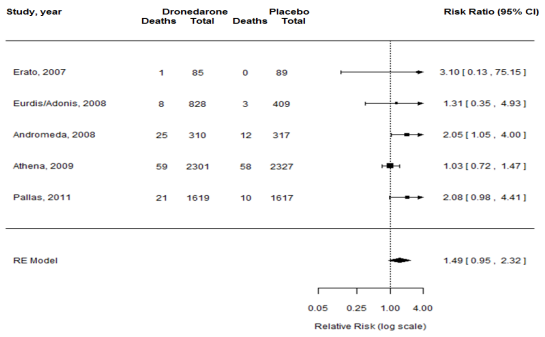
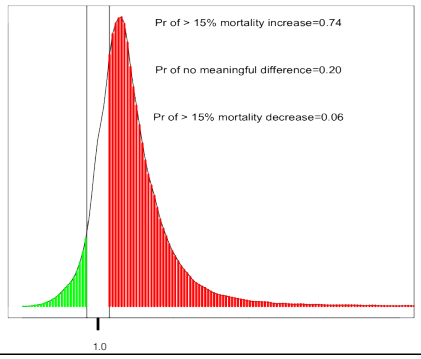
The totality of the evidence



Bayesian approach – The totality of the evidence



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Even if it kills, it is still cost effective!

Clinical Therapeutics/Volume 34, Number 8, 2012

Cost-Effectiveness of Dronedarone in Atrial Fibrillation: Results for Canada, Italy, Sweden, and Switzerland

[1]OptumInsight, Stockholm, Sweden; [2]Sanofi Aventis, Paris, France; [3]Institute of Environmental Medicine, Karolinska Institute, Stockholm, Sweden; and [4]Division of Cardiology, Beth Israel Deaconess Medical Center, Harvard Clinical Research Institute, Boston, Massachusetts

Conclusions: Dronedarone on top of SOC appears to be a cost-effective treatment for atrial fibrillation compared with SOC alone. Despite the differences in the local settings considered, the results were consistent among all the countries included in the study.

The study was funded by sanofi-aventis, Paris, France.

Even if it kills, it is still cost effective!

Canadian Journal of Cardiology ■ (2013) 1–7

Clinical Research

Cost-Effectiveness of Dronedarone in Patients With Atrial Fibrillation in the ATHENA Trial

Conclusions: Compared with generally accepted thresholds, our results indicate that treatment with dronedarone as in ATHENA is cost-effective. $ / QALY CAD$7560

a Optum Insight, Stockholm, Sweden
b Division of Cardiovascular Epidemiology, Institute of Environmental Medicine, Karolinska Institute, Solna, Sweden
c Sanofi-aventis, Laval, Quebec, Canada
d Population Health Research Institute, McMaster University, Hamilton, Ontario, Canada

The study was funded by sanofi-aventis, Paris, France.

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CDN 2012 guidelines

RECOMMENDATION

We recommend that dronedarone not be used in patients with permanent AF nor for the sole purpose of rate control (Strong Recommendation, High-Quality Evidence).

We recommend dronedarone not be used in patients with a history of heart failure or a left ventricular ejection fraction ≤ 0.40 (Strong Recommendation, Moderate-Quality Evidence).

Practical tip. Dronedarone is a reasonable choice for rhythm control in selected patients with AF. Typically, these would be patients with nonpermanent (predominantly paroxysmal) AF with minimal structural heart disease. Consideration should be given to monitoring for liver enzyme elevations within 6 months of initiating therapy with dronedarone.

Reasonable conclusion?

- Implies that no sharing of information between studies is possible, even though same drug, and all with cardiac history
- OK for paroxysmal AF or persistent less than 6 months duration but dangerous if AF lasts longer – can we accurately measure this?
- OK if EF is >41% but may kill you if <40%
- Bottom line therapeutic window very narrow and other safer choices exists
- So, why are we still recommending this drug which is also 5-8 times more expensive than other agents?

CDN Guidelines New Anticoagulants

RECOMMENDATION (Fig. 1)

We recommend that all patients with AF or AFL (paroxysmal, persistent, or permanent), should be stratified using a predictive index for stroke risk (eg, $CHADS_2$) and for the risk of bleeding (eg, HAS-BLED), and that most patients should receive either an OAC or ASA (Strong Recommendation, High-Quality Evidence).

We suggest, that when OAC therapy is indicated, most patients should receive dabigatran, rivaroxaban, or apixaban (once approved by Health Canada), in preference to warfarin (Conditional Recommendation, High-Quality Evidence).

Apixaban – the best?

The NEW ENGLAND JOURNAL of MEDICINE

ESTABLISHED IN 1812 SEPTEMBER 15, 2011 VOL. 365 NO. 11

Apixaban versus Warfarin in Patients with Atrial Fibrillation

CONCLUSIONS

In patients with atrial fibrillation, apixaban was superior to warfarin in preventing stroke or systemic embolism, caused less bleeding, and resulted in lower mortality. (Funded by Bristol-Myers Squibb and Pfizer; ARISTOTLE ClinicalTrials.gov number, NCT00412984.)

Results

Outcome	ARISTOTLE	
	Apixaban N=9120	Warfarin N=9081
SSE (Primary outcome)		
n, N (%)	212 (2.3)*	265 (2.9)
RR (CI)	**0.80 [0.67, 0.95]**	
Ischemic or unspecified stroke	162 (1.78)	175 (1.93)
RR (CI)	0.92 (0.74, 1.13)	
Hemorrhagic stroke	40 (0.44)	78 (0.86)
RR (CI)	0.51 (0.35, 0.75)	
Systemic embolism	15 (0.16)	17 (0.19)
RR (CI)	0.87 (0.44, 1.75)	
All-cause deaths		
n, N (%)	603 (6.6)*	669 (7.4)
RR (CI)	**0.89 [0.81, 0.99]**	
Cardiovascular deaths		
N (%)	308 (3.4)	344 (3.8)
RR (CI)	**0.89 (0.76, 1.04)**	
SAEs		
n, N (%)	3182 (35.0)*	3302 (36.5)
RR (CI)	**0.96 [0.92, 1.00]**	
Major bleeding		
n, N (%)	327 (3.6)*	462 (5.1)
RR (CI)	**0.70 [0.61, 0.81]**	

Different view of results

Outcome	ARISTOTLE	
	Apixaban N=9120	Warfarin N=9081
SSE (Primary outcome)		
n, N (%)	212 (2.3)*	265 (2.9)
RR (CI)	0.79 [0.67, 0.95]	
Annual rate	1.27%	1.60%
Difference	3.3 / 1000 treated	
NNT (95%CI)	**333 (185-1250)**	
All-cause deaths		
n, N (%)	603 (6.6)*	669 (7.4)
RR (CI)	0.89 [0.81, 0.99]	
Difference	4.2/ 1000 treated	
NNT (95%CI)	**238 (127-2500)**	

Results

Outcome	ARISTOTLE	
	Apixaban N=9120	Warfarin N=9081
SSE (Primary outcome)		
Difference $CHADS_2$ < 3	1.3 / 1000 treated	
Difference $CHADS_2$ ≥ 3	8.5 / 1000 treated	
NNT (95%CI) $CHADS_2$ < 3	769 (200 to 1:450 harmed)	
NNT (95%CI) $CHADS_2$ ≥ 3	117 (78- 400)	

www.thelancet.com **Published online October 2, 2012**

Other points to consider

- Real world compliance for BID vs. daily Rx
- New agents, no means of measuring compliance, no means of reversing effect
- Cost is $3/day vs. $0.16 / day
- Given >1 MM with AF, additional budget impact for general use is $ 1 B annually
- Full economic analysis is req'd but would a target approach not make more sense?

Conflict of interest

Consulting fees/ Honoraria	Officer, director, or in any other fiduciary role	Clinical Trials
Boehringer Ingelheim, Johnson & Johnson, Medtronic	None	Boehringer Ingelheim
Bayer, Boehringer Ingelheim	None	AstraZeneca, Boehringer Ingelheim, Boston Scientific, St Jude Medical
Boehringer Ingelheim, Bristol-Myers Squibb, sanofi-aventis	None	None
Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Portola, sanofi-Aventis	None	Bayer, Boehringer Ingelheim, Boston Scientific, Bristol-Myers Squibb, Johnson & Johnson, Portola, sanofi-Aventis, St Jude Medical
None	None	None
Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Pfizer, sanofi-aventis	None	Boehringer Ingelheim, Bristol-Myers Squibb, Pfizer, sanofi-aventis
None	President Elect of the Heart Rhythm Society	Medtronic Inc
To be updated	To be updated	To be updated
Boehringer Ingelheim, Johnson & Johnson, St Jude Medical	None	None
None	None	Pfizer

Only 1 of 10 authors had no COI

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COI ? Which affiliations count more?

Consulting fees/ Honoraria	Clinical Trials
Boehringer Ingelheim, Johnson & Johnson, Medtronic	Boehringer Ingelheim
Bayer, Boehringer Ingelheim	AstraZeneca, Boehringer Ingelheim, Boston Scientific, St Jude Medical
Boehringer Ingelheim, Bristol-Myers Squibb, sanofi-aventis	None
Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Portola, sanofi-Aventis	Bayer, Boehringer Ingelheim, Boston Scientific, Bristol-Myers Squibb, Johnson & Johnson, Portola, sanofi-Aventis, St Jude Medical
None	None
Bayer, Boehringer Ingelheim, Bristol-Myers Squibb, Pfizer, sanofi-aventis	Boehringer Ingelheim, Bristol-Myers Squibb, Pfizer, sanofi-aventis
None	Medtronic Inc
To be updated	To be updated
Boehringer Ingelheim, Johnson & Johnson, St Jude Medical	None
None	Pfizer

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[b] Population Health Research Institute, McMaster University, Hamilton, Ontario, Canada
[c] University of British Columbia, Vancouver, British Columbia, Canada
[d] St Michael's Hospital, University of Toronto, Toronto, Ontario, Canada
[e] Libin Cardiovascular Institute of Alberta, University of Calgary, Calgary, Alberta, Canada
[f] University of Alberta, Edmonton, Alberta, Canada
[g] Southlake Regional Health Centre, Newmarket, Ontario, Canada
[h] Montreal Heart Institute, Université de Montréal, Montreal, Québec, Canada

CDN Guidelines

Canadian Journal of Cardiology 28 (2012) 125–136

Society Guidelines

Focused 2012 Update of the Canadian Cardiovascular Society Atrial Fibrillation Guidelines: Recommendations for Stroke Prevention and Rate/Rhythm Control

[a] Arrhythmia Service, University Hospital, University of Western Ontario, London, Ontario, Canada
[b] Population Health Research Institute, McMaster University, Hamilton, Ontario, Canada
[c] University of British Columbia, Vancouver, British Columbia, Canada
[d] St Michael's Hospital, University of Toronto, Toronto, Ontario, Canada
[e] Libin Cardiovascular Institute of Alberta, University of Calgary, Calgary, Alberta, Canada
[f] University of Alberta, Edmonton, Alberta, Canada
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More or less believable guidelines?

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Society Guidelines

Focused 2012 Update of the Canadian Cardiovascular Society Atrial Fibrillation Guidelines: Recommendations for Stroke Prevention and Rate/Rhythm Control

[a]Boehringer Ingelhiem,
[b]Bayer,
[c]Johnson & Johnson,
[d]Sanofi-Aventis,
[e]Medtronic,
[f]Bristol Myers Squibb,
[g]Pfizer,
[h]Boston Scienitifc,
[i]St. Jude

Off label promotion fines

Overpromoted pills

US fines for big drug companies, for promoting drugs as treatments for conditions for which they were not approved by the Food and Drug Administration

Company	Date	Fine, $bn	Drugs	Promoted as a treatment for:
GlaxoSmithKline	Jul 2012	3.0	Paxil Wellbutrin	Depression in under-18s Sexual dysfunction, weight gain, ADHD*
Abbott Laboratories	May 2012	1.5	Depakote	Aggression in dementia patients and schizophrenia
Merck	Nov 2011	1.0	Vioxx	Arthritis (also fined for alleged misleading statements)
AstraZeneca	Apr 2010	0.5	Seroquel	Anxiety, fatigue, depression, aggression (charges denied)
Pfizer	Sep 2009	2.3	Bextra	Acute pain at high doses
Eli Lilly	Jan 2009	1.4	Zyprexa	Dementia in elderly

Sources: US Department of Justice; ProPublica; *The Economist*

*Attention Deficit Hyperactivity Disorder

The Economist, July 13 2012

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Astro-turfing

- **Astroturfing** refers to political, advertising or public relations campaigns that are designed to mask the sponsors of the message to give the appearance of coming from a disinterested, grassroots participant
- In our context, academic MDs, or even patient groups providing the work for industry whose goals of profit are not necessarily aligned with those of the medical system (value)

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What to do?

- Be aware of the problem
- Easy steps – no free lunch, no gifts, no to CME drug sponsorship
- Moderate – full declaration, local full disclosure of research interests, guidelines without COI
- Difficult – Canadian Sunshine Act (covers speakers' bureau, consulting, etc),change our culture, improve our critical evaluative skills

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My biggest concerns today

- Lunches, dinners, and conferences sponsored (and organized) by industry
- Academics who downplay or hide their conflict of interests (including $ and ghost writing)
- Impact of COI on guidelines and editorial decisions
- Pressure groups (patient advocacy groups) that follow an industry agenda
- All lead to inappropriate spending and lack of value for our limited resources

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Thank you