Outline
Communicating Findings from Active Medical Product Surveillance
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Introduction: Our mission is to empower consumers.

1. At what point will the public want information derived from Sentinel?

Take off your professional hat, and ask this question of your own life and your own family.

> Understanding the downsides, we would err on the side of early disclosure.

The issue of (lack of) Trust

> Early disclosure can help build trust [see Handout #2].

What type of information?

> We assume that the 'information' will be as described in FDA publications:
>
> > "Mini-Sentinel Coordinating Center [when it gets the data in from the various partners] will conduct additional analyses of the results to assess their validity and provide FDA with both the aggregated results and the summary results from each data partner."
>
> We assume FDA will coordinate these warning signals: AERS, NME monitoring, Sentinel, CDC, etc., need to deliver a coordinated message.

More justification for early disclosure

> Patients assume drug/device/surgery is good
>
> Pervasive advertising of medical products
>
> Benefits are so overwhelmingly promoted, the FDA and Sentinel should be an aggressive counter-balance to warn of risks (and report new benefits).

2. **How can the residual uncertainty associated with active surveillance findings be best communicated?**

   Need to have in place a strategy, staff, and templates to convey various discovered risks

   For example, FDA needs to have a system like the VA uses for large-scale adverse events [See Denise M. Dudzinski et al., "The Disclosure Dilemma…" NEJM, Sept. 2, 2010]

   Base decisions on best available science: FDA has research under way on risk communication.

   Include confidence interval ranges, and explain what that means.

Incredibly rough and raw draft of a 'system' to communicate

For illustrative purposes only: expert panels obviously needed to refine such a system

	Minor Drug/Device**		Important Drug/Device		Life-Essential Drug/ Device***	
	Safe Alternative available	No-Alternative	Safe Alt. Av.	No-Alt	Safe Alt. Av.	No-Alt.
Strong signal* of serious risk, many patients	Withdraw drug	REMS Suspend or amend DTC	Withdraw	REMS	Withdraw, or REMS (e.g., Avandia)	Tell, Black Box (BB), or REMS
Strong signal of serious risk, few patients	Withdraw	REMS, or withdraw?	Withdraw	REMS	REMS Suspend DTC	Tell, BB, or REMS
Strong signal of moderate or minor risk	BB or REMS Suspend DTC	BB or REMS Suspend DTC	REMS Suspend DTC	BB	BB	BB
Significant signal, many patients	REMS Suspend DTC	BB, or REMS Suspend DTC	BB, or REMS Suspend DTC	BB, or REMS	BB, or REMS Suspend DTC	BB, or REMS
Significant signal, few	REMS Suspend	"	"	"	"	"

patients	DTC					
Signal of concern justifying study, many patients	Press release, maybe BB Amend DTC	Press release Amend DTC	Press release, maybe BB Amend DTC	Press release Amend DTC	Press release, maybe BB Amend DTC	PR or Wait on study results?
Signal of concern, justifying study, few patients	"	"	"	"	"	"

* Consider a Homeland Security, Red, Orange, Yellow type system?
**Allergy, minor pains, lifestyle type drugs
***If a patient stops taking this medicine, it may result in shorter life, serious event (stroke), etc.

3. What are the unique concerns about communicating findings?

Getting the word out: Current systems don't work. In written communications, use simple quantitative drug fact box type format [See Handout #4].

Use new methods of outreach: Explore developing a system of using e-mail, smartphones, new- device-methods of "pinging" patients with important risk update information.

Speed the Journal publication process?

Timeliness of resolving the fears that have been raised: Once a fear has been raised, it is urgent it be resolved ASAP.

> Dr. Woodcock testified last week to an IOM Committee that there were *resource constraints* on Sentinel. Use PDUFA V to get the necessary resources, including manpower programs to train and recruit biostatisticians and epidemiologists.

How can we educate the public about relative v. absolute risk? Relative risk grossly exaggerates—but compensates for years of relative benefit promotion.

Consider using absolute risk in the important and life-essential categories in the illustrative table, in cases where there are no alternatives, so as to minimize fears, minimize drop-off in prescription use.

Fear of fear may be overstated: AERS and the increased data available in recent years do not seem to have caused disruption.

But monitor impact of warnings: Sentinel is expected to determine impact of warnings. It can help detect the truth of controversies such as that on antipsychotic warnings v. increased suicides, and will permit adjustments.

4. Other recommendations

Clearer public input.

DTC: Use/amend FDCA authorities to suspend DTC on the basis of safety, when there is a strong or significant risk report.

Better pre-approval systems: There would be less concern about post-approval risk, if the pre-approval process was better and all relevant data were public.

Give more attention to outcomes, not just risk