

The Black Box

It's not just for doctors anymore

Jim McNulty, NAMI Board President Emeritus
ISCTM Meeting February 25, 2008

- Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (suicidality) in children, adolescents and young adults in short term studies of major depressive disorder (MDD) and other psychiatric disorders. Anyone considering the use of [insert established name] or any other antidepressant in a child, adolescent, or young adult must balance this risk with clinical need. Short-term studies did not show a risk of suicidality with antidepressants compared with placebo in adults 65 and older. Depression and certain other psychiatric disorders are themselves associated in the increased risk of suicide. Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior. Families and caregivers should be advised of the need for close observation and communication with the prescriber...¹

¹ US Food and Drug Administration. Revisions to product labeling. <http://www.fda.gov/cder/drug/antidepressants/default.htm>

- Antidepressants increased the risk compared to placebo of suicidal thinking and behavior (~~suicidality~~) in children, adolescents and young adults in short term studies of major depressive disorder (~~MDD~~) and other psychiatric disorders.

**IF THE BLACK BOX IS FOR
PRESCRIBERS, DON'T THEY
ALREADY KNOW THIS
WORD?**

~~(suicidality)~~

**LOTS OF PROBLEMS:
WHO USES THIS?
INSIDERS/OUTSIDERS
ETC.**

~~(MDD)~~

- Anyone considering the use of [insert established name] or any other antidepressant in a child, adolescent, or young adult must balance this risk with ~~clinical need~~.

**MISSED OPPORTUNITY:
RISK/BENEFIT
RISK MANAGEMENT
WHOSE NEED?
PATIENTS MUST BE
PARTNERS IN DECISIONS!**

~~(clinical need)~~

- Short-term studies did not show a risk of suicidality with antidepressants compared with placebo in ~~adults 65 and older~~.

SO, IS THIS HOW LONG WE
WAIT FOR RISK TO PASS?
(AND WHEN WE GET TO
STOP WORRYING??)

~~(adults 65 and older)~~

- Depression and certain other psychiatric disorders are themselves associated in the increased risk of suicide. ~~Patients of all ages who are started on antidepressant therapy should be monitored appropriately and observed closely for clinical worsening, suicidality, or unusual changes in behavior.~~

**COMMON SENSE WOULD
DICTATE THIS IF** *“Depression
and certain other psychiatric
disorders are themselves
associated in the increased risk
of suicide.”*

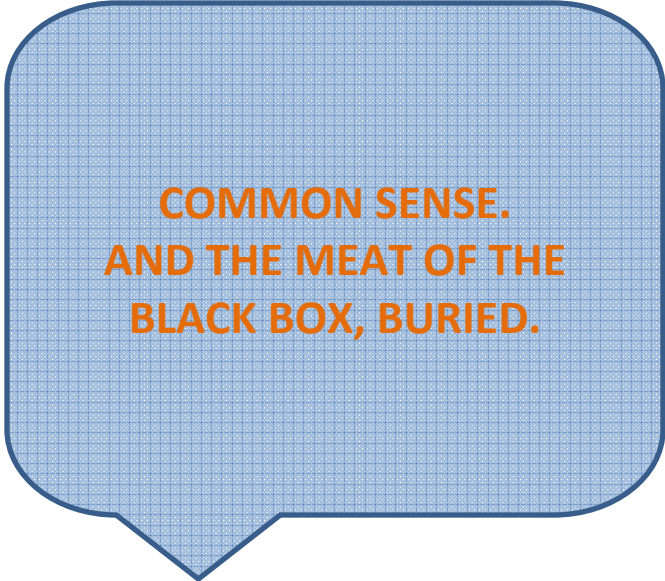
**MOST DOCTORS ARE SMART!
PATIENTS ARE: _____?**

~~(Patients of all ages
who are started on antidepressant
therapy should be monitored)~~

OUCH.
VALUE-LADEN

EFFECTIVE MONITORING IS
WHAT WE NEED.

~~(appropriately)~~



**COMMON SENSE.
AND THE MEAT OF THE
BLACK BOX, BURIED.**

{and observed closely for
~~clinical worsening, suicidality,~~ or unusual changes in
behavior.}

- ~~Families and caregivers~~ should be advised of the need for close observation and communication ~~with the prescriber...~~¹

UM.
WHERE'S THE PATIENT?

~~(Families and caregivers)~~



**NO OFFENSE, BUT HOW
ABOUT A MORE HOLISTIC
APPROACH?**

~~(with the prescriber...¹)~~

- New warning proposal – stress risk/benefit discussion, recognize that shared decision-making (consumer/provider) is a model which should promote the “therapeutic alliance”, and perhaps lead to more consumer satisfaction.