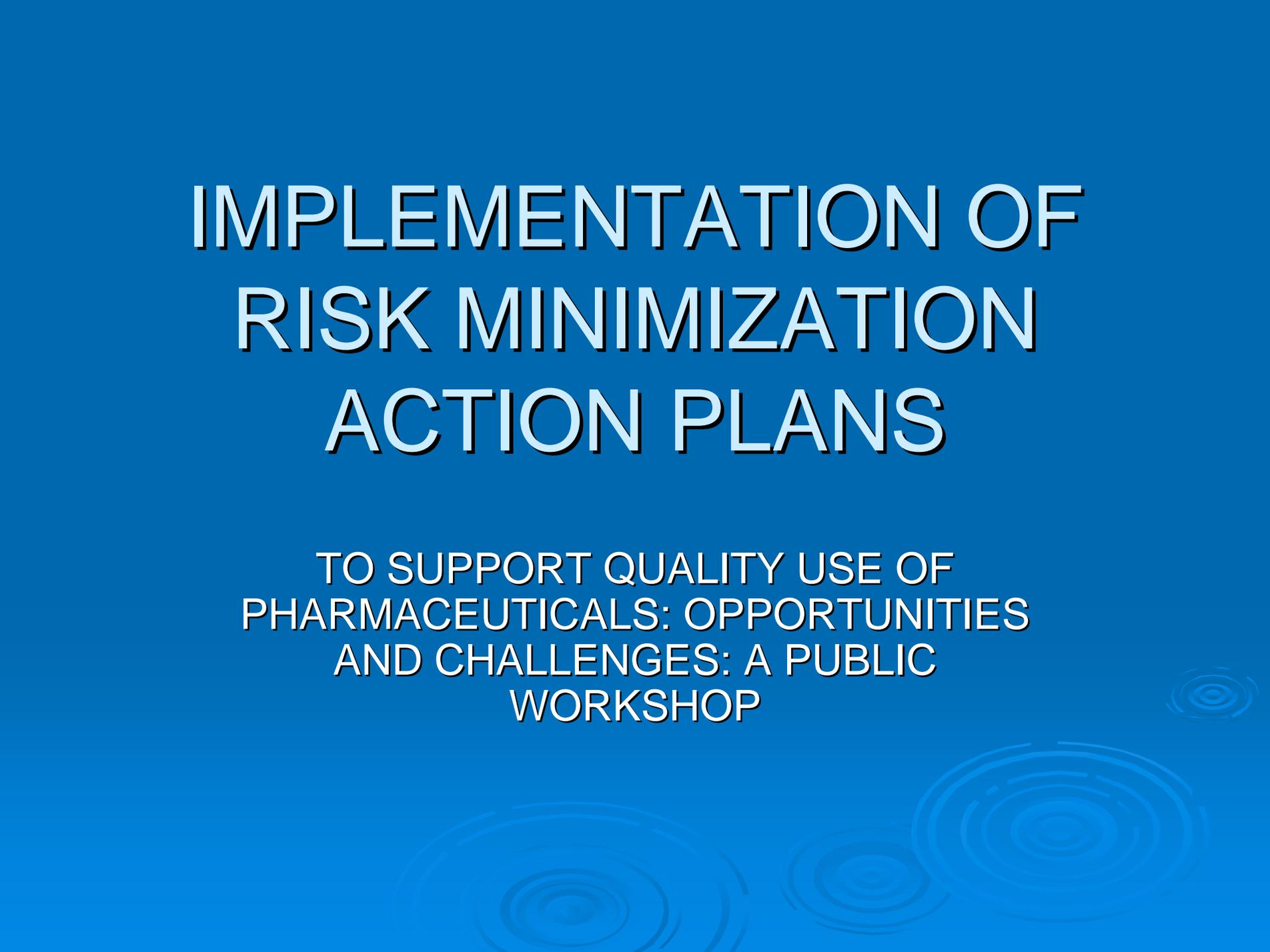


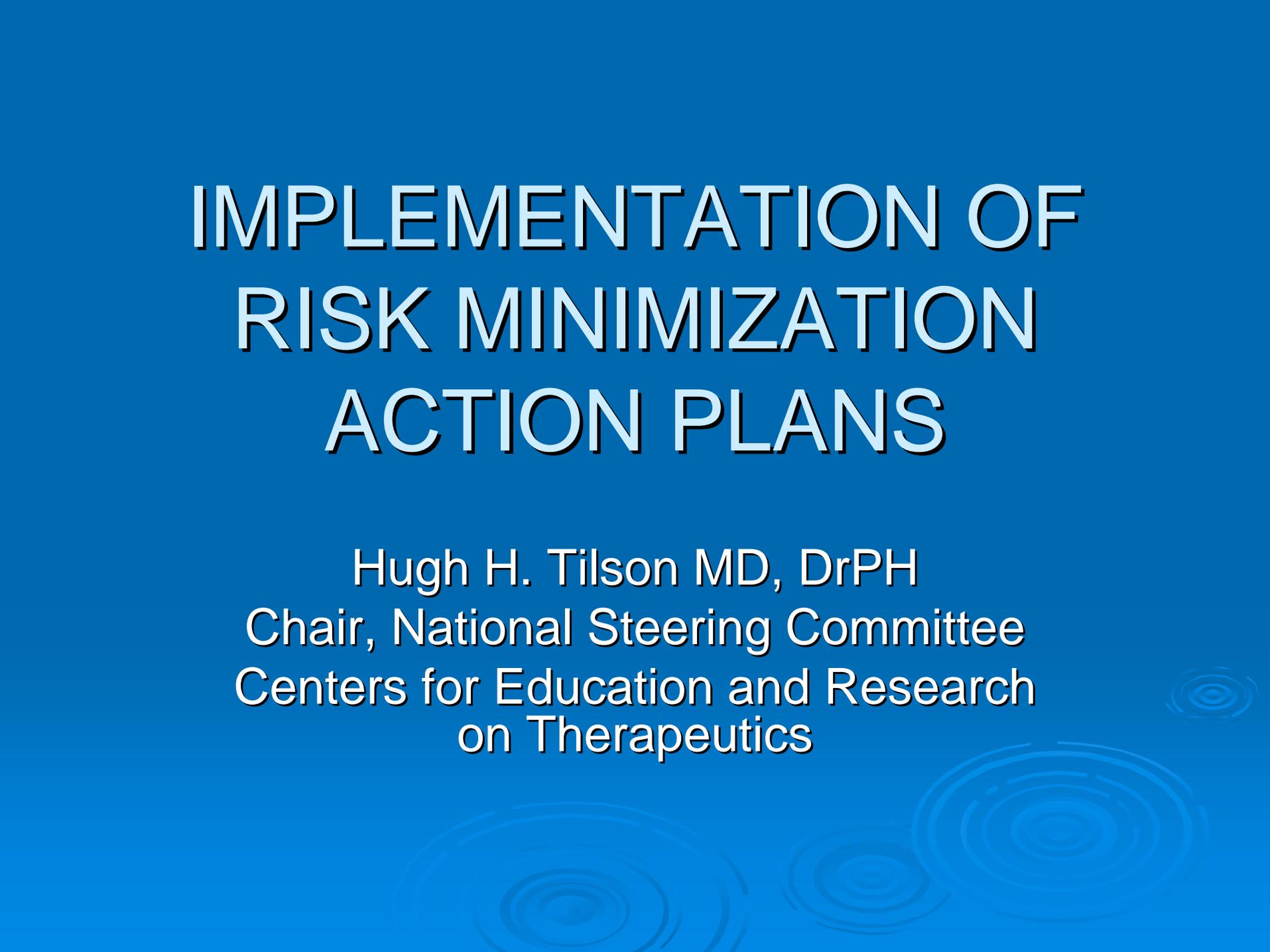
IMPLEMENTATION OF RISK MINIMIZATION ACTION PLANS

TO SUPPORT QUALITY USE OF
PHARMACEUTICALS: OPPORTUNITIES
AND CHALLENGES: A PUBLIC
WORKSHOP

The background of the slide is a solid blue color. In the lower right quadrant, there are several faint, concentric circles that resemble ripples in water, creating a subtle decorative pattern.

IMPLEMENTATION OF RISK MINIMIZATION ACTION PLANS

Hugh H. Tilson MD, DrPH
Chair, National Steering Committee
Centers for Education and Research
on Therapeutics

The background of the slide is a solid blue color. In the lower right quadrant, there are several faint, concentric circular patterns that resemble ripples in water, centered around a point. These patterns are light blue and fade out towards the bottom right corner.

IMPLEMENTATION OF RISK MINIMIZATION ACTION PLANS

Hugh H. Tilson MD, DrPH
Conflict of Interest Statement
(see Strom)

IMPLEMENTATION OF RISK MAPS: SUMMARY OF DAY ONE

- DEFINITIONS
- QUOTABLE MOMENTS
- CROSS-CUTTING ISSUES
- CHALLENGES FOR THIS
AFTERNOON'S PANEL

IMPLEMENTATION OF RISK MAPS: SUMMARY OF DAY ONE

- But first ... the exhortation from Jean Slutsky
- We're here to listen to each other
- Overheard at restaurant last night ...

IMPLEMENTATION OF RISK MAPS: DEFINITIONS

- AHRQ: VERY IMPORTANT ISSUES, VERY MINUTE BUDGETS (js)
- ROCKVILLE/GAITHERSBURG: A HIGHLY VOLATILE AREA REQUIRING TIGHT SECURITY (js)
- FDA: ...A 'PUBLIC HEALTH' INSTITUTION (ps)
- FDA: I WON'T USE THE WORD 'REFORM'
- FDA: AN 'HONEST BROKER' TO BRING THE VARYING INTERESTS TOGETHER
- FDA: MOTIVATED BY THE BEST OF INTENTIONS
- UK: where they pay GPs 150 K
- DISTRIBUTION CENTERS: PART OF THE PROBLEM, ER UM PROGRAM! (ad)
- STROM'S CONFLICT OF INTEREST: ALSO AN EYE TEST (bs)

IMPLEMENTATION OF RISK MAPS: DEFINITIONS

- THE HOLY GRAIL: PERSONALIZED MEDICINE
- RISKMAPS: A STEP TOWARD THE HOLY GRAIL
- RISKMAPS: MOST OF THEM ARE THERE FOR A REASON. THEY'RE ALL DIFFERENT. (sk)
- RISKMAPS: PRESERVE ACCESS TO DRUGS WHICH OTHERWISE WOULD BE LOST
- RISKMAPS: COMPROMISE CONTINUITY OF CARE AND DELAY ACCESS TO MEDS (82% OF HOSPITAL PHARMACISTS)
- RISKMAPS: THE RARE AND HAPPY SITUATION: WHEN WE CAN DO THINGS PROACTIVELY
- THE GOAL OF RISKMAPS: EVERY PATIENT WILL DEMONSTRATE A BASIC UNDERSTANDING OF THE DRUGS THEY'RE ABOUT TO TAKE
- REMS: CONGRESS CATCHING UP ON WHAT FDA WAS ALREADY TRYING TO DO

IMPLEMENTATION OF RISK MAPS: DEFINITIONS

- PHYSICIANS: GRADUATES OF THE JEKYL AND FRANKENSTEIN SCHOOL OF MEDICINE
- PHYSICIANS: RISK AVERSE AND AVERSE TO CUMBERSOME PROCEDURES
- PRIMARY CARE PHYSICIANS: A 'READY-TO-COLLAPSE SYSTEM'
- EVIDENCE BASED MEDICINE: TAKES TIME, WHICH IS PRECISELY WHAT I DON'T HAVE!
- WARNING FATIGUE: HOW MANY ARE TOO MANY; STOP THE SEATBELT DEMOS
- TOUCH: WHAT YOU CAN'T DO WITH THE SLIDES

IMPLEMENTATION OF RISK MAPS: DEFINITIONS

- CONSUMERS: NOT AN EASY CROWD TO KEEP SAFE
- BIKERS WITHOUT HELMETS: KEEP THE ORGAN BANKS IN BUSINESS
- I'M THE PATIENT: THE BOTTOM OF THE FOOD CHAIN (NOT!) (...IN THIS WEEK'S NEJM ...)
- HCDS: FRACTIONATED AND SOMETIMES FRACTIOUS
- DRUGS: AS WITH ANYTHING THERE ARE SOME BENEFITS AND SOME RISKS

RISK MANAGEMENT DILEMMA

- IN THE BALANCE REMEMBER BENEFITS AND NOT JUST HARMS



IMPLEMENTATION OF RISK MAPS: QUOTABLE MOMENTS

- RISKMAP'S ARE NOT NEW: CLOZAPINE "NO BLOOD, NO DRUG" 1990
- RISKMAPS ARE NEW: PDUFA III 2002
- 'THERE IS SOME EVIDENCE THAT THE PROGRAM IS EFFECTIVE ...'
- THE PLURAL OF ANECDOTE IS NOT DATA
- THE QUESTION IS ...

Oh, great guru: What is the
answer?

➤ My son (er, um, daughter): what is the

question???



IMPLEMENTATION OF RISK MAPS: QUOTABLE MOMENTS

- THE QUESTION IS ...WHAT IS THE QUESTION
- THE QUESTION IS: HOW, DESPITE THIS DISARRAY, CAN WE IMPROVE PATIENT CARE?
- THE PROBLEM IS: WE HAVE FOCUSED IN THE PAST ON THE TYRANY OF THE AVERAGE

IMPLEMENTATION OF RISK MAPS: QUOTABLE MOMENTS

- “YOU do WISH TO RESTRICT PHYSICIAN BEHAVIOR THAT IS IRRATIONAL.”
- “RISKMAPS ARE USEFUL IN PROTECTION OF DRUGS, NOT JUST PATIENTS.”
- “THERE IS NO SILVER BULLET HERE.”
- “THE PATIENT, ALREADY COMPROMISED, SHOULD NOT BE BURDENED WITH CONFUSING ENROLLMENT PROCESSES.”
- “THE DOCTORS I ASKED COULD SEE THE NEED FOR CONTROL, BUT FOUND THE SYSTEM ONEROUS.”
- “I’M HERE TO LEARN; I HAVE TO REPORT BACK TO ALL THOSE DOCTORS!”

IMPLEMENTATION OF RISK MAPS: QUOTABLE MOMENTS

- "...NOT ON MY WATCH. I DON'T WANT TO GET SUED."
- "WOULD A PILOT SAY: 'A CHECKLIST IS DEGRADING AND INSULTING TO MY PROFESSIONALISM'? AS A CONSUMER IT MAKES ME GRUMPY."
- "HOW CAN WE MAKE IT EASY FOR PHYSICIANS TO DO THE RIGHT THING? ... AND MAKE IT HARDER TO DO THE WRONG THING?"
- "YOU DON'T JUST DO ONE APPROACH. SOME PHYSICIANS WANT A LITTLE CARD IN THE POCKET OF THEIR WHITE COATS."

IMPLEMENTATION OF RISK MAPS: QUOTABLE MOMENTS

- YOU REALLY HAVE A HARD TIME BELIEVING EVERYTHING THAT POPS UP IN A POP UP WINDOW.
- LET'S USE CARROTS NOT JUST STICKS.
- OUR CURRENT FRAGMENTED APPROACH IS NOT GOING TO SUPPORT THE COMING REALITY.
- PROGRAMMERS NEED TO BE PAID, TOO. (SUBSTITUTE YOUR FAVORITE HERE ...!)
- IT'S NOT JUST WHO IS THE SUBJECT OF A RISKMAP. IT'S WHO IS LEFT OUT.
- IF THE PATIENT DOESN'T GET THE (RISKMAP) PRODUCT AT ALL, YOU'VE STILL GOT A PROBLEM.

IMPLEMENTATION OF RISK MAPS: QUOTABLE MOMENTS

- “WHAT WE REALLY NEED ARE FOOL PROOF SYSTEMS.”
- “WOULDN'T IT BE NICE IF WE ALL HAD E-PRESCRIBING?”
- “HELP ME TO DO WHAT I AM BUILD RISKMAPS INTO THE WORKFLOW. TRYING TO DO ANYWAY.”
- “THERE ARE PROCESSES WE CAN ADAPT AND ADOPT FROM THE DISEASE MANAGEMENT SAFETY MANAGEMENT WORLD.”
- “LET'S TAKE RISKMAP DRUGS AND PUT THEM INTO EXISTING SYSTEMS.”
- Perhaps the RISKMAPS CAN BE THE driving force BEHIND HEALTH SYSTEM REFORM.

IMPLEMENTATION OF RISK MAPS: CROSS-CUTTING ISSUES

- CONSENSUS: WE APPEAR TO AGREE ON THE OBJECTIVES; BUT NOT YET THE METHODS
- STANDARDIZATION: EACH RISKMAP IS UNIQUE; BUT THE SYSTEMS INTO WHICH THEY ARE INSERTED REQUIRE STANDARD APPROACHES
- TRANSPARENCY: ADOPTION REQUIRES ACCEPTANCE; ACCEPTANCE REQUIRES UNDERSTANDING; BUT THE SECTOR REQUIRES INTELLECTUAL PROPERTY PROTECTION AND HAS YET TO DEVELOP EFFECTIVE COMMUNICATION

IMPLEMENTATION OF RISK MAPS: CROSS-CUTTING ISSUES

- EMPOWERMENT: MANAGEMENT REQUIRES CONTROL; PROFESSIONALISM REQUIRES FLEXIBILITY. REGULATION IS CENTRAL; IMPLEMENTATION IS LOCAL.
- RESOURCES: SPECIALIZED PROCESSES INCREASE COSTS; THE SECTOR NEEDS COST-CONTAINMENT
- EVIDENCE: RISK MANAGEMENT IS AN INTERVENTION; INTERVENTIONS ARE THERAPY TOO AND REQUIRE THE SAME ETHICS AND PROOFS.

CHALLENGE TO THE FINAL PANEL: ACTIONABLE STEPS

...



IMPLEMENTATION OF RISK MAPS: CHALLENGES FOR TODAY'S PANELS

- PROMOTE INTERACTION
- PROMOTE INFORMATION SHARING
- ENLIST NEW PARTNERS
- IMPROVE UNDERSTANDING OF THE HCDS PROCESSES
- DEVELOP ACTIONABLE STEPS