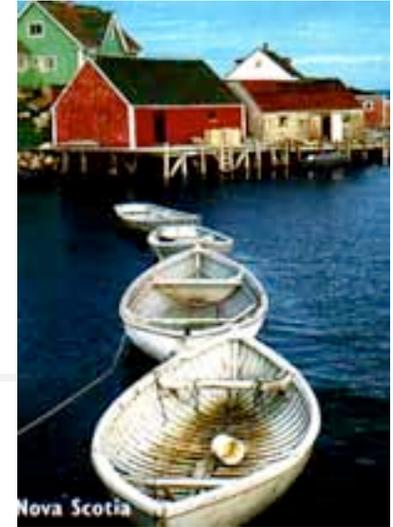


Mt Uniacke Cam Thu Feb 19 14:27:50 2004

Mt Uniacke Cam Sat Feb 21 13:08:22 2004

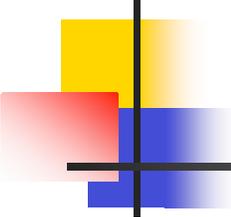


Nova Scotia

Practical clinical trials: ideas & examples

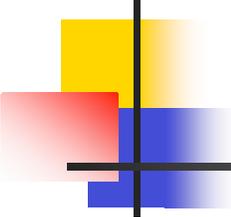
Patrick.McGrath@dal.ca

IWK Health Centre
Dalhousie University



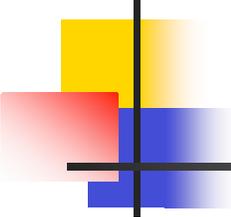
Goals of this presentation

- Think about what your goals are
- Discuss how trials meet different goals
- Determine how to make your trial meet your goals
 - Exemplars
 - Family Help
 - Pain Attack Treatment



What are your goals?

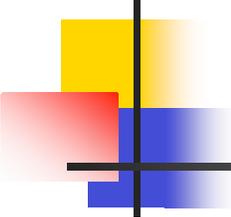
- To get tenure?
- To publish in NEJM?
- To change practice?
 - Where? With whom?
- Multiple goals are OK but get priorities straight
 - If tenure is your primary goal, don't do clinical trials
 - If you want to publish in NEJM, try a drug trial



But

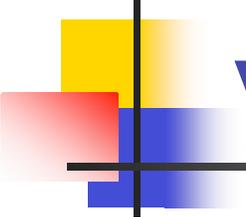
- If you want
 - to have intellectual challenge
 - to make a difference
 - to work in a team
 - to never grow bored
 - to have fun

Do behavioral clinical trials



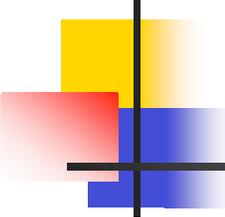
What is the question

- Your goal is to answer a question
- Primary question, most important
 - Secondary questions should not drive trial
- Formulation of question is critical



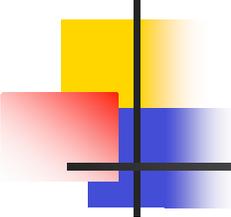
Every decision informed by your goals

- **Your research Question**
- selection of participants,
- the nature of control groups,
- the statistical treatment
- dissemination plan



The Problem I

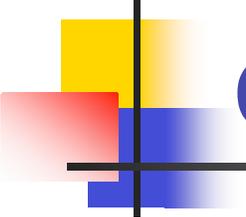
- Psychosocial, mostly behavioral, interventions WORK
 - for mental health problems
 - for physical health problems
- Hundreds of good clinical trials
 - Show treatments effective
 - Effect sizes = \$100 million drugs
 - What % of people with depression, anxiety, migraine, cardiac problems, bedwetting, obesity, behavior disorders, stuttering, tension headache, get behavioral interventions?



The Problem II

- Most investigators say they want to change practice
- Trials are not designed to change practice
 - Narrow range of patients, impossible interventions, narrow measures
- Knowledge transfer is not considered

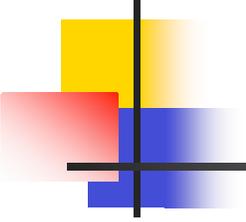
Changing practice is not the only legitimate goal of an RCT



Pharma Clinical trials are designed to sell drugs

- To sell drugs Pharma needs to
 - Get FDA approval
 - Get the right FDA labelling
- Position drug
- Flog it (marketing)

Three types of trials?

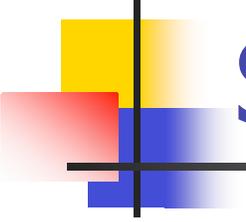


- Efficacy trials

- Tightly controlled,
- Ideal conditions
 - Use highly motivated therapists
 - Excellent supervision
- Excellent internal validity

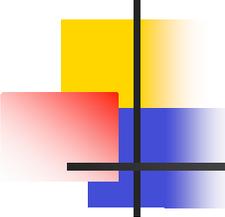
- Effectiveness trials

- Less tightly controlled
- Realistic
- In real world environments
- External, ecological, validity



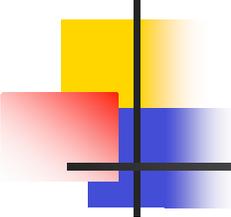
Practical trials (Tunis, Clancy, Stryer, 2003)

- Choose clinically relevant alternative treatments
- Include diverse study participants
- Recruit participants from diverse practice settings
- Collect data on broad range of outcomes



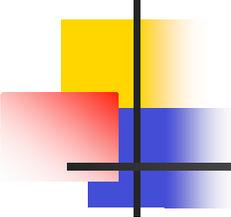
Traditional model of stages

- IN HOTHOUSE
 - Hypothesis generation
 - Testing under controlled conditions
 - Evaluations of defined populations
- IN THE FIELD
 - Dissemination research



Do stages work?

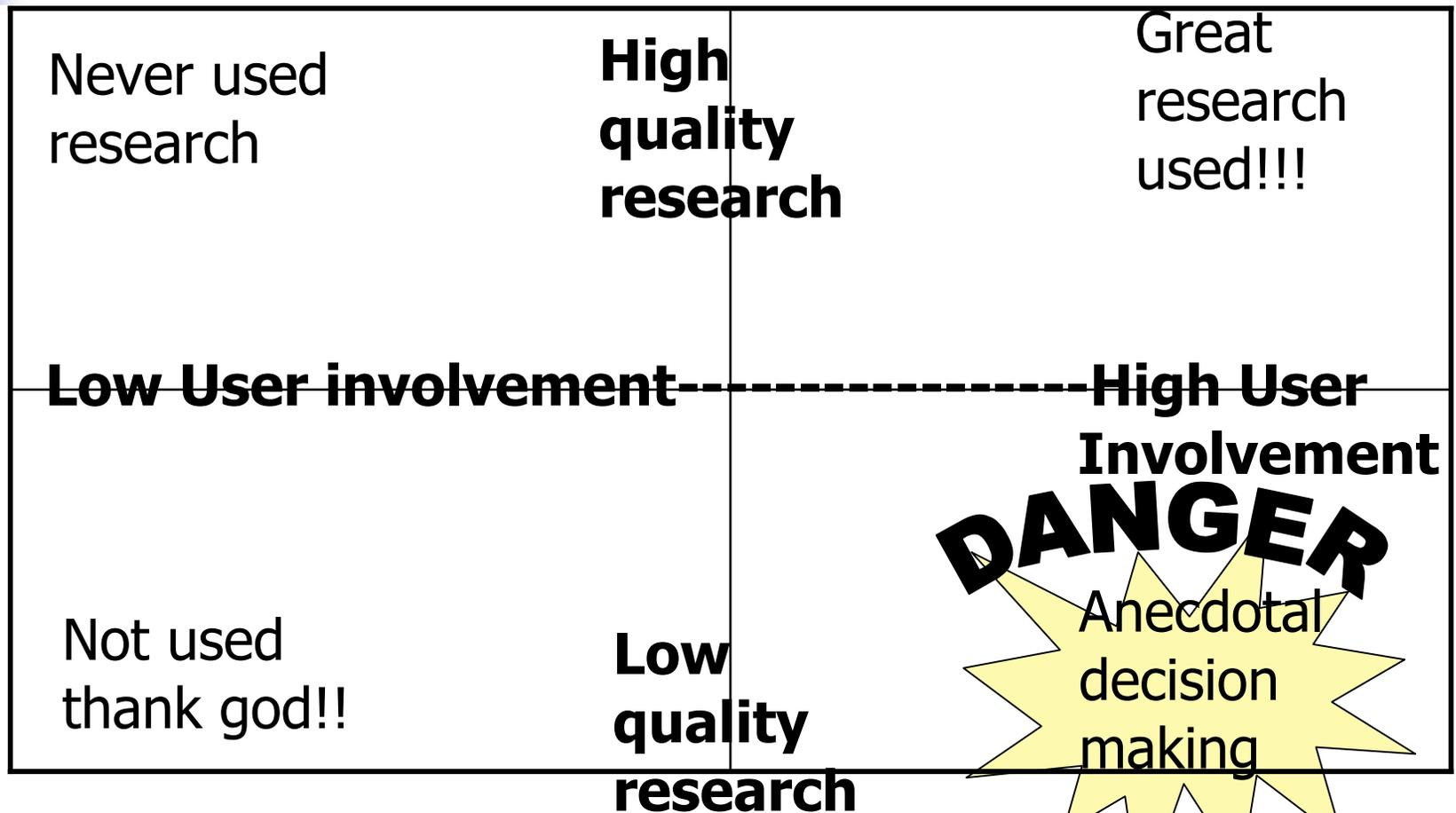
- Transfer from hothouse to real world
- Hothouse
 - University setting
 - Highly selected patients
 - Highly selected therapists
 - Rigorous supervision
- Real world
 - Regular clinic
 - Complex patients
 - Normal therapists
 - Normal supervision

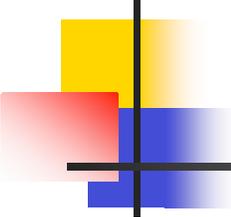


Alternative approaches

- Use methods to select sturdy hothouse candidates
- RE-AIM
 - Reach (who does it cover?)
 - Efficacy
 - Adoption
 - Implementation
 - Maintenance

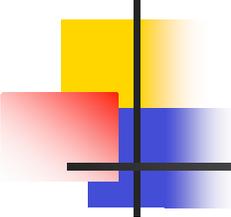
Involve decision makers at all stages of your trial





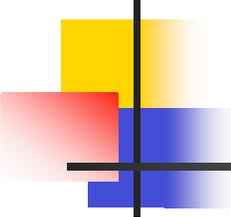
Who is a decision maker?

- Administrators/Managers
- Clinicians
- Politicians
- Patients



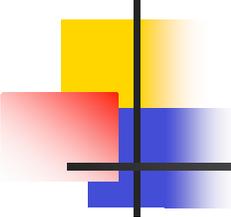
Administrators and Managers

- In health centres
- Managed care insurers
- Medicare, medicaid



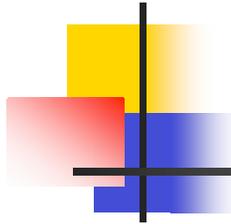
Clinicians

- Front line people
- Who might use your intervention
- Nurses, doctors, psychologists etc



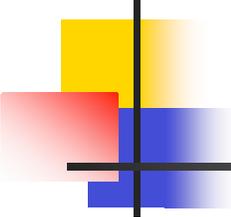
Politicians

- Politicians make decisions
- Difficult to know how to involve them
 - How do you do it?



Patients

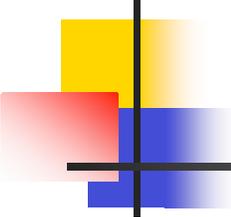
- Potential participants
- Successful participants



Reverse engineering

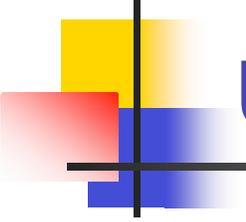
- Envision what you want to end up with
 - What are your goals (no more than 3, best with 1)
- Go backwards from there
- What is your goal?
 - In your research program (not just this study)

Make your goals as specific as you can



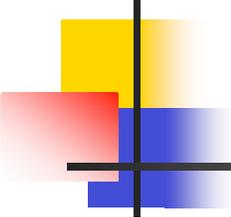
Use Goals to stay on message

- Use your goals in every decision about your RCT
- Description
- .
- Questions
- Target Subjects
- Measures
- Interventions



How you design a trial to be used

- Goal(s):
- Analysis of candidate products:
- Analysis of market:
- Competing Products:
- Funding:
 - NIH or other agency
- What
- Selling product:



Your goals should influence

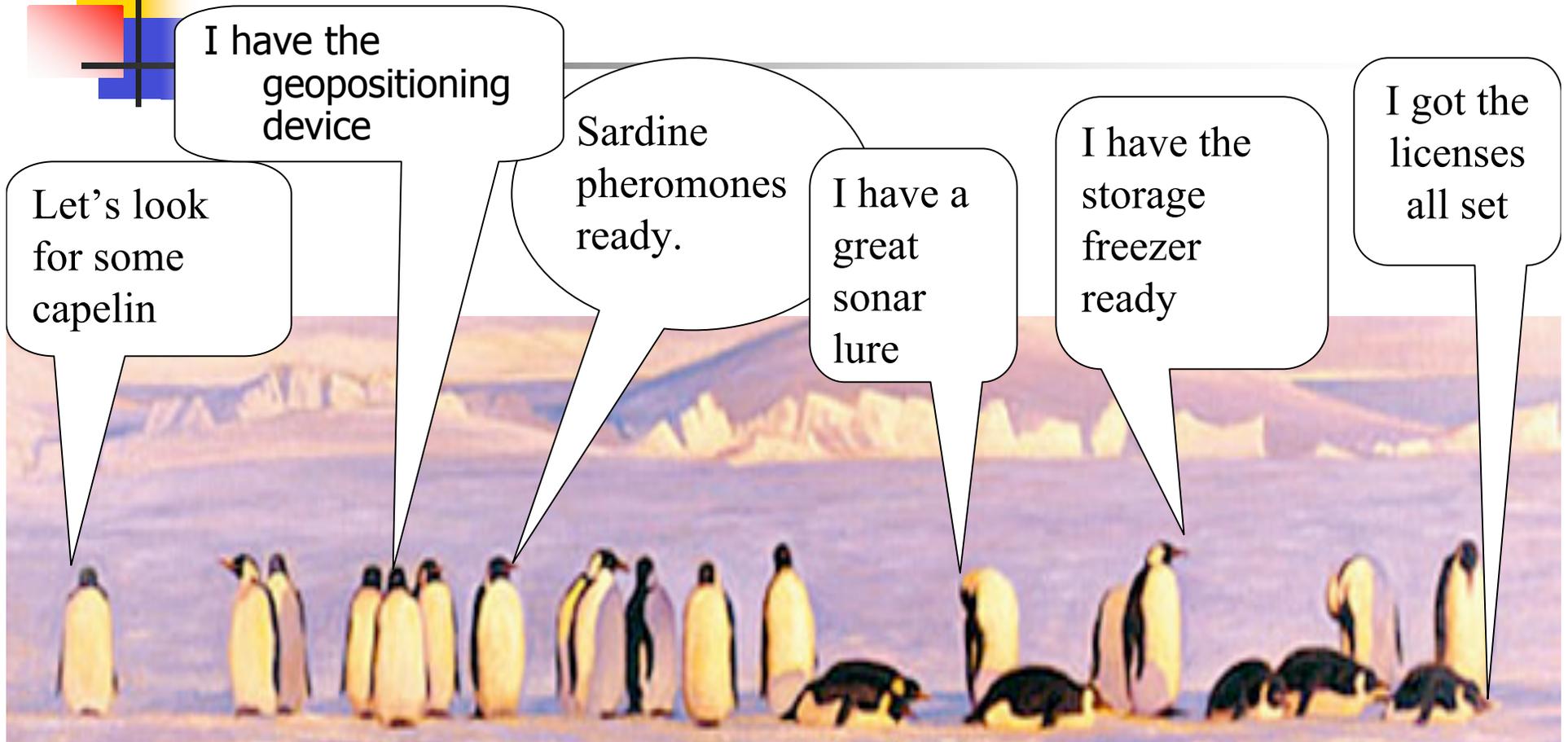
- Team
- Question to be asked
- Subjects
- Measures
- Interventions
- Analysis
- Dissemination plan

Need a team

- Be innovative
- Have fun!
- Cover the bases

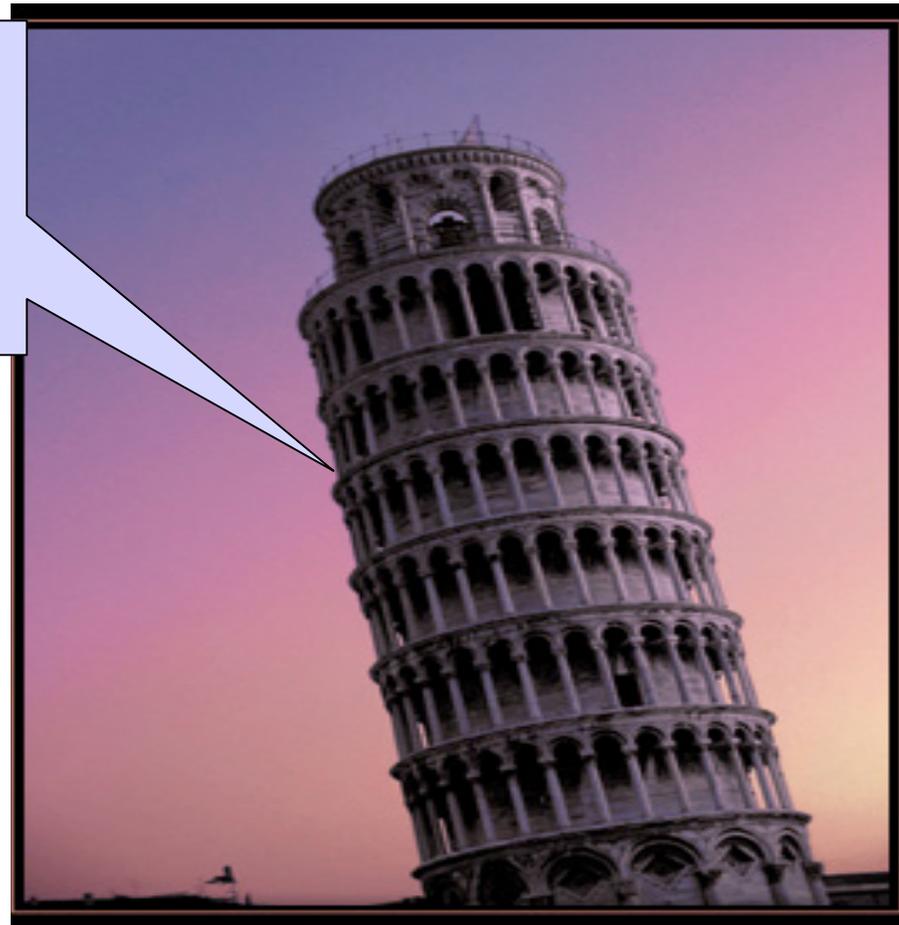


Why a team? Combines different skills and resources

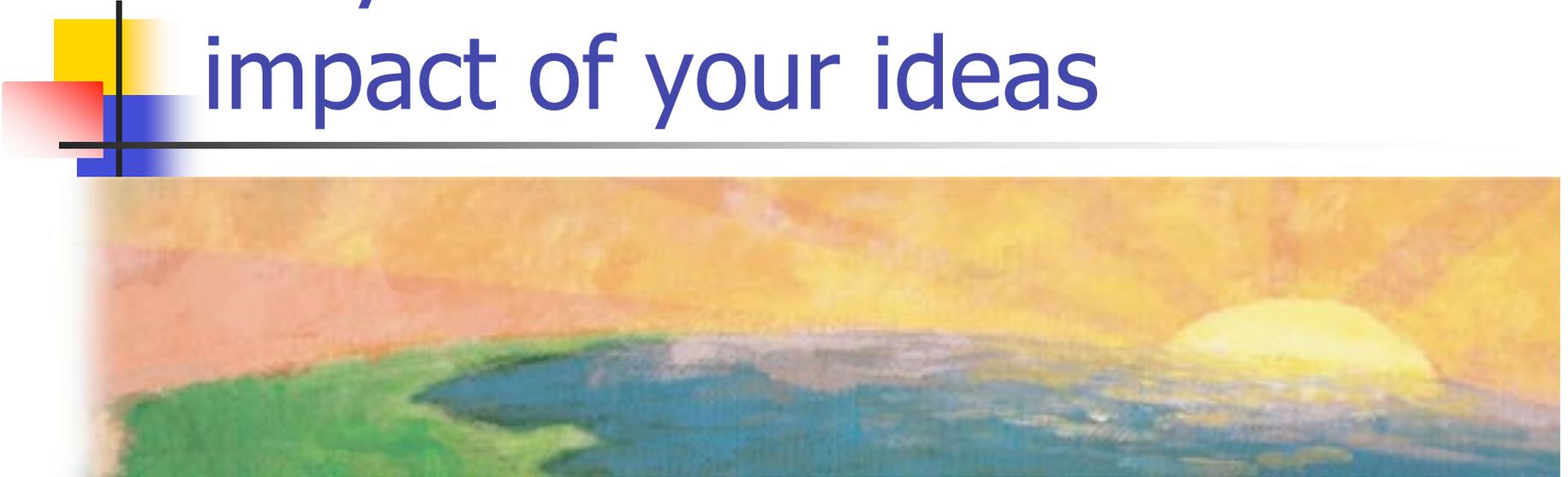


Why? Some mistakes can be avoided

Ok, I should have checked with a hydrologist



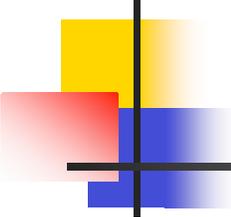
Why? Extends influence or impact of your ideas



Why does Big Pharma do trials involving dozens of centres?

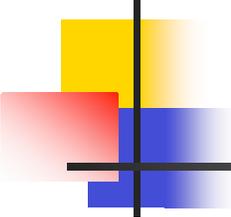
get subjects

prepare for later sales



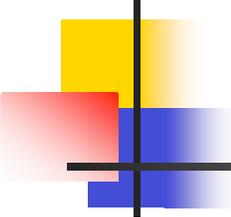
Point of intervention

- Primary care
 - continuity of care, widely distributed
 - **but** organization of services, skills for behavioral treatment, knowledge of behavioral science, interest are problematic
 - Shared care a variant but does not solve all problems
 - Insufficient primary care of child psychological and behavioral problems



Point of intervention

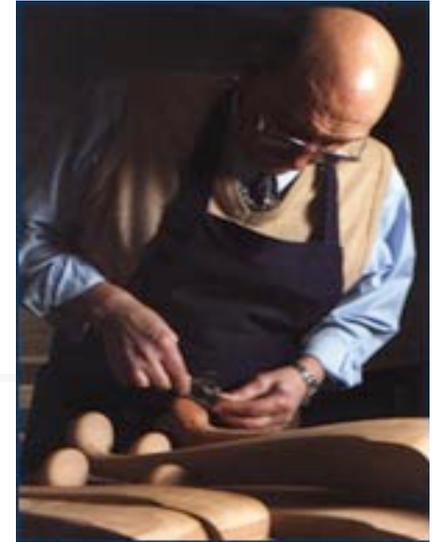
- Specialist care (e.g. psychiatrists, psychologists, social workers)
 - Not available except for the most difficult cases
 - Long waiting lists
 - Stigma
 - High costs to patients (even when free)



Point of intervention

- Novel approaches
 - Direct to patient
 - Via churches
 - Via community groups
 - Via workplace
 - Via schools

Models of intervention



■ **Craft model**

- highly-trained therapist e.g. MSW, Ph.D. or M.D.
- individual treatment planning, decision-making
- satisfying for therapist/patient
- Delivered in public or private settings

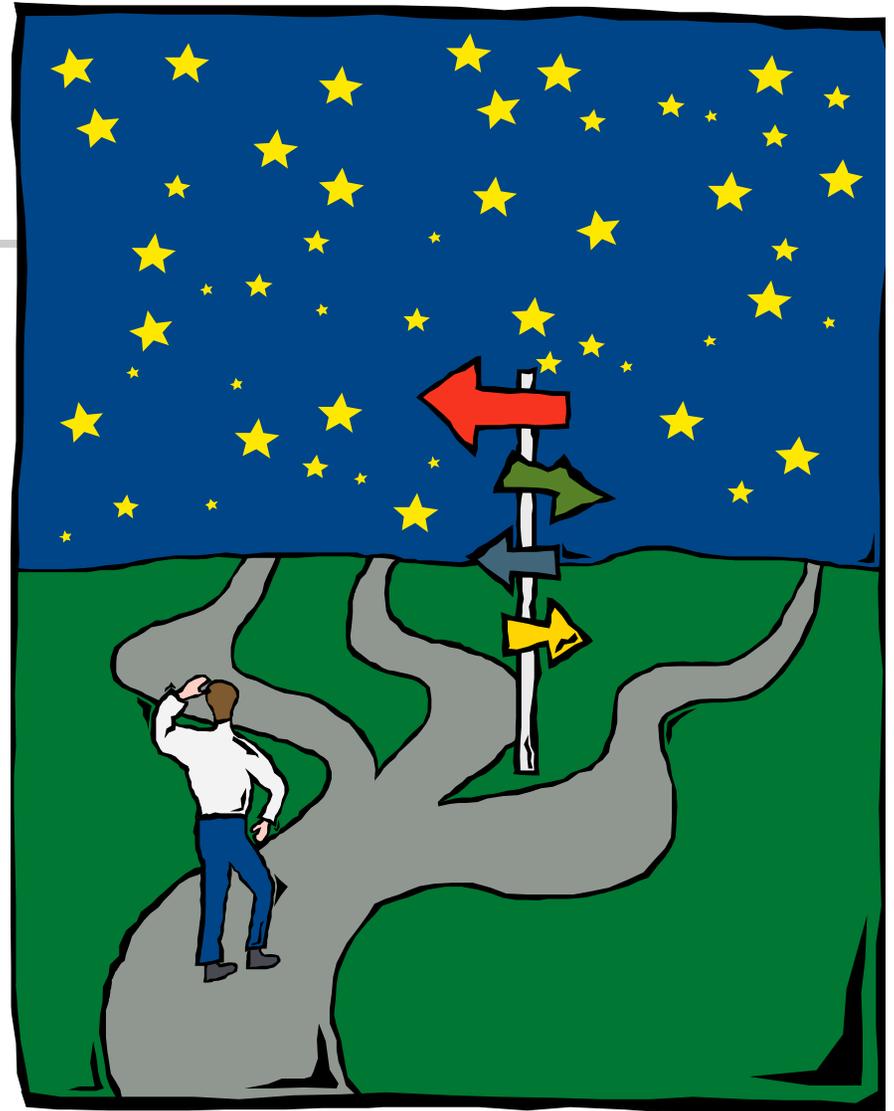
Problems with craft model

- Access
 - costs to patients
 - Monetary
 - Time
 - Travel
 - Stigma
 - costs to system
 - very few ever get treatment
- Poor results

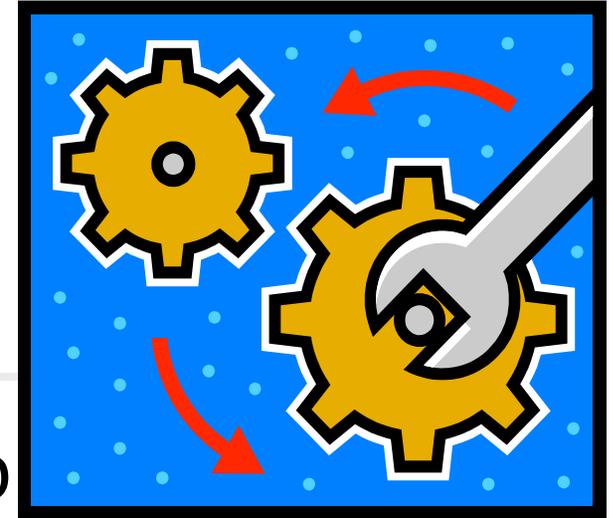


Crossroads

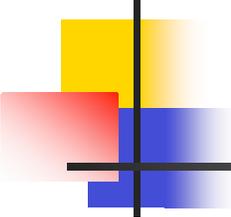
- Current situation
 - Very poor access
 - Poor outcomes
 - Hi cost/patient
- Continue same old
 - or
- Try new options



Industrial model



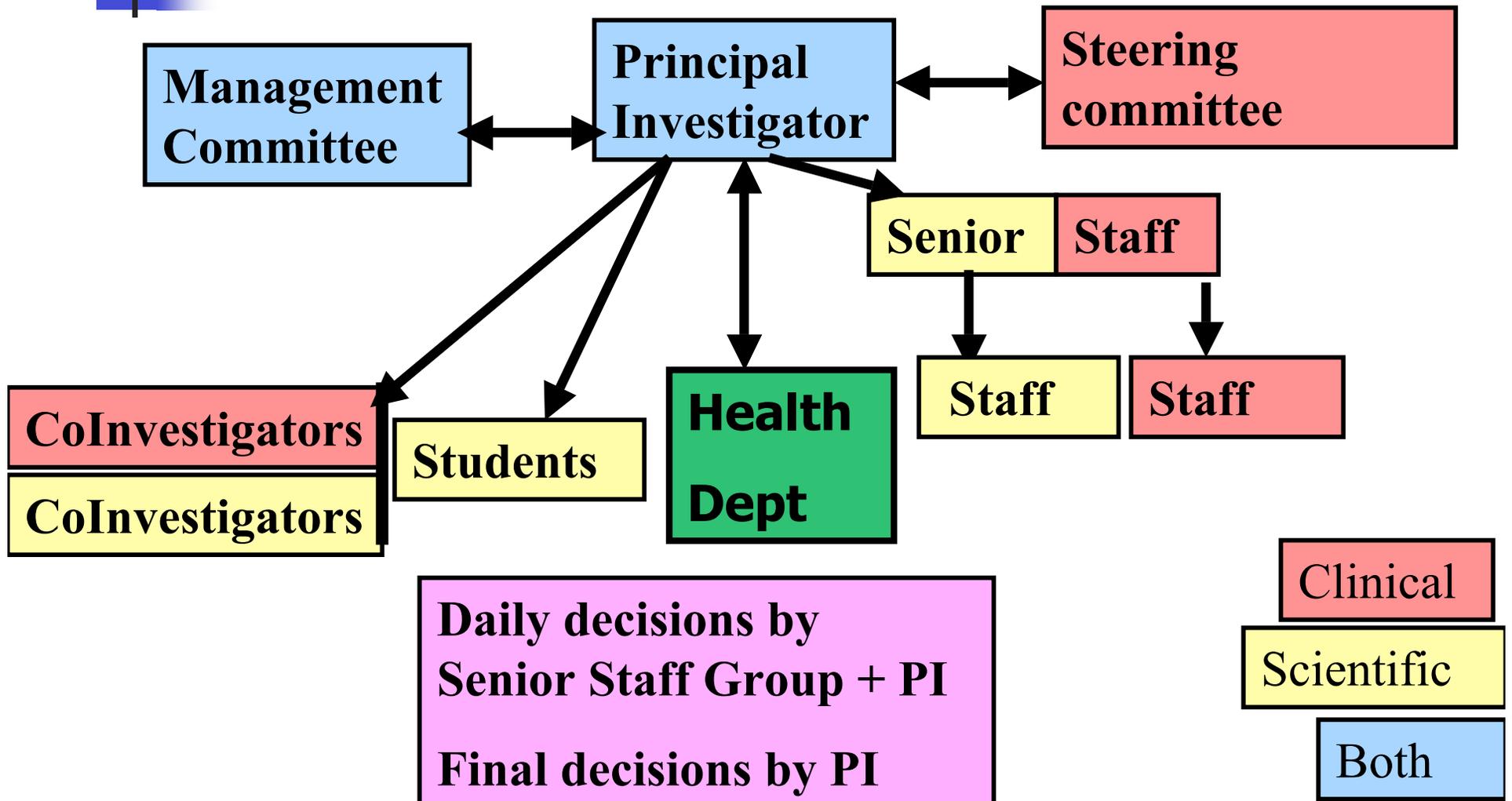
- make systems that do the job
 - use evidence to develop system
 - hone system via quality assurance
 - be cost effective
 - seek efficiencies with volume
 - use skill level required for job
 - use modern technology
 - Make widely available
 - Stepped care
 - Use craftspersons for more complex cases
 - Not dependant on personal whim of therapist

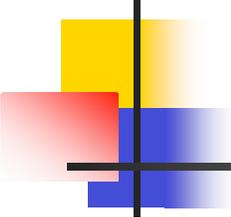


Family Help Team

- Some formal
 - As investigators
 - As Steering Committee
- Some informal
- From university, clinical services, funders of service
- Psychology, nursing, family medicine,

Management structure

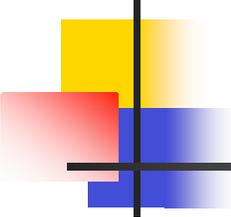




Family Help

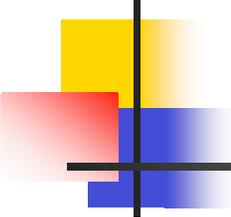
- Goal(s):
 - effective psychosocial interventions
 - Accessible to those who need them
 - inexpensively
- Analysis of candidate products:
 - Public system: accessible to all, no money
 - Private care:
- Analysis of market:
 - 18-20% of kids
 - How to make it accessible?
 - Underserved but no pressure to serve it





Family Help

- Competing Product
 - Regular care, parenting programs in community agencies
- \$\$\$\$: CIHR
- Selling product: must be packageable



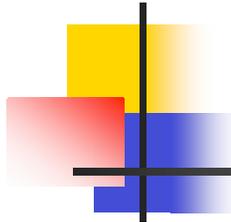
Barriers re Family Help 1

- Public health system in Canada
 - Underfunded
 - Waiting lists of 1 year for mental health problems not unusual
 - 4% of NS health budget for mental health

Provincial Health bureaucracy willing

But penniless

Standards for mental health care may help



Barriers

How to make treatment work in
clinics

Staff untrained in behavioral
methods overworked,

Only see horrendous cases

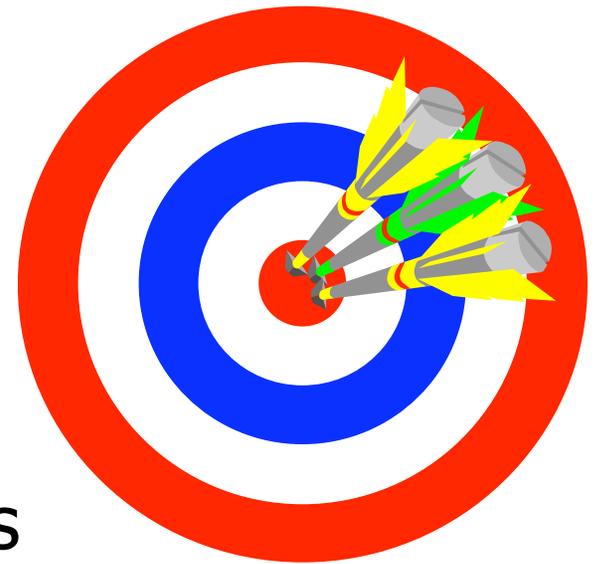
Psychological problems in children

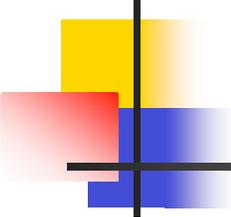


- Very Common
- Offord et al., Ontario Child Health Study
 - 18.1% have a **diagnosable** disorder
- Quebec Child Mental Health Survey
 - 19.9% have a **diagnosable** disorder
- Goodman & McGrath (1991)
 - 12-15% have chronic or recurrent pain

Good news: Treatments work

- Progress has been rapid
 - effective treatments
 - protocolized treatments
 - mostly behavioral
 - delivered by paraprofessionals

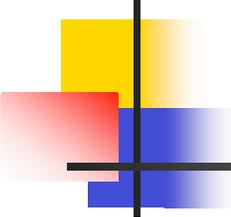




Bad news:

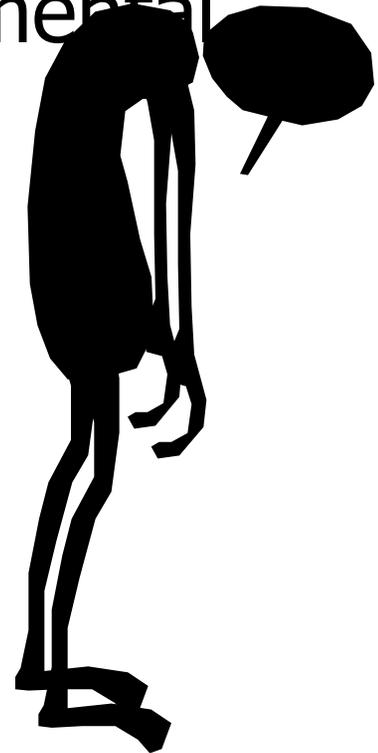
- Children not treated
- 16% of those with **diagnosable** disorders (OCHS)
 - seen by mental health specialist in previous 6 months
 - many seen, not treated

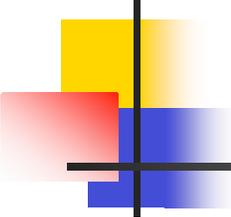




Bad news:

- Ineffective treatments often used
- Weisz et al. meta-analysis found NO EFFECT of clinic treatment (mental health)
 - unfocussed treatment
 - not on protocol
 - lack of knowledge
 - lack of training
 - “rugged individualism”,
 - boredom of therapists
 - poor monitoring of outcomes

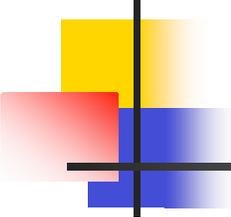




Utilization of treatment

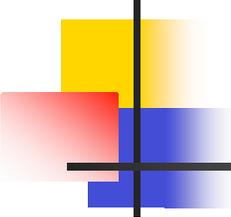
- POOR access to psychosocial treatments
 - Cost to system
- cost to patients
 - time
 - distance
 - office hours
- Stigma





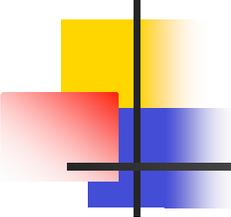
Family Help

- public relations to alert community
- family seeks help from family physician
- discusses problem
- physician completes 1 page referral
- **Family Help** contacts family for assessment (KSADS)



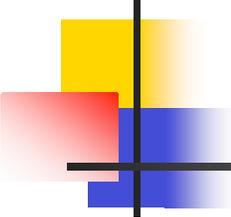
Areas of focus

- criteria
 - relative high prevalence
 - validated treatments
 - significant burden
 - amenable to distance treatment



Treatment

- evidence-based protocols
- specific problem areas
- delivered by manuals, telephone, videotapes/DVD, audio tapes/CD
- “coaches” supervised by professional

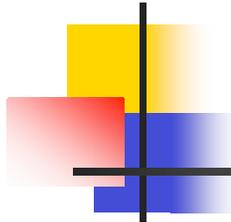


Modules

- age 3-7yrs, disruptive behavior
- age 8-12yrs, attention deficit
- age 5-12yrs, bedwetting
- age 9-16yrs, headache, abdominal pain
- age 6-12 years, anxiety disorders
- MOM, Managing our Mood
- Sleep problems

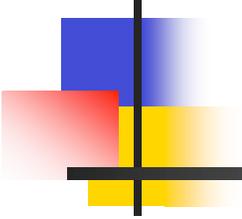


Trials Closed



Family Treatment Handbook

- written at low reading level
- graphics/drawings
- Interactive with video and coach
- Everything on audio



Disruptive Behaviour

Play Intro

Chapter List - Microsoft Internet Explorer

File Edit View Favorites Tools Help

Back Forward Stop Home Search Favorites Media Print Copy Paste

Address <http://142.239.47.100/content/parent/ch.asp> Go Links >>

The Family Help A TFC Program Bringing Health Home

Intro **Chapters** Help Discussion

Chapter List

Chapter Progress

	CHAPTER 1 Noticing the good
	CHAPTER 2 When there's more than one child - spreading attention around
	CHAPTER 3 Ignoring whining and complaining
	CHAPTER 4 Transitional warnings & using "When - Then"
	CHAPTER 5 Planning ahead
	CHAPTER 6 Charts and stickers
	CHAPTER 7 Time out
	CHAPTER 8 Planning ahead for community activities or times when you are absent
	CHAPTER 9 Working with the school - Daily report cards
	CHAPTER 10 Problem solving; PASTEing child management problems

Search Go

My Messages
You have 0 new messages!

My Bookshelf
View a list of pages that you wanted to remember.

My Tasks
Go here when you need to check what you have left to do in a lesson.

[Logout](#)
[Privacy Statement](#)

Done Internet

Start | Document1 - Mi... | **Chapter List - ...** | Document2 - Mi... | 1:26 PM

now the father and son play. Once you are done watching the scene, answer the questions below.



Questions, Chapter 1, Scene 4

1. So far in Chapter 1, you've learned a number of ways to pay attention to good behaviour in children. Put a check mark by all the things you saw the father doing in Scene 4.

- Noticed the good behaviour of his son.
- Asked questions or talked about what his son did.
- Named what his son was doing.
- Used body language.
- Made sure he was near his son.
- Kissed, hugged, or touched his son.
- Looked into his son's face.
- Didn't give too many controls and reminders
- Praised son as a reward for good behaviour.

2. What message do you think the father is giving his son?

- He is letting his son know that he enjoys seeing what the son is doing.
- He is giving his son attention and the boy will only want more attention.

3. If the father spends more time with the child and pays more attention to good behaviour, how do think it would change how the boy behaves in the long run?

message!

My Bookshelf

View a list of pages that you wanted to remember.

My Tasks

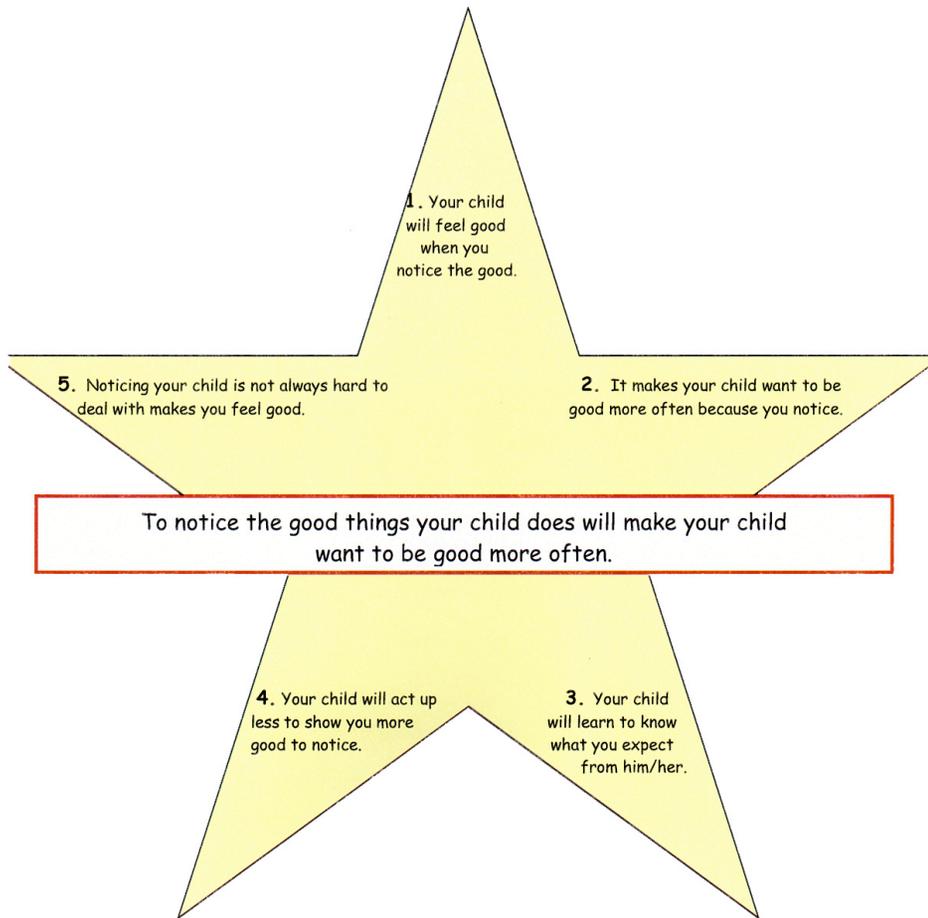
Go here when you need to check what you have left to do in a lesson.

Logout

Privacy Statement

From Disruptive Behavior Module

5 Reasons to Notice the Good



Tryout page

5



Step 1. **PICK** a problem.

List problems:

4. _____

5. _____

6. _____

What do I want to deal with first?



Step 2. Have **ALTERNATIVES**.

	Possible Alternatives	Good Points	Bad Points
1.		1.	1.
		2.	2.
		3.	3.
2.		1.	1.
		2.	2.
		3.	3.
3.		1.	1.
		2.	2.
		3.	3.



Step 3. **SELECT** the best alternative.

Who is going to put it in place?



Step 4. **TRY** out the alternative.

When will I start?



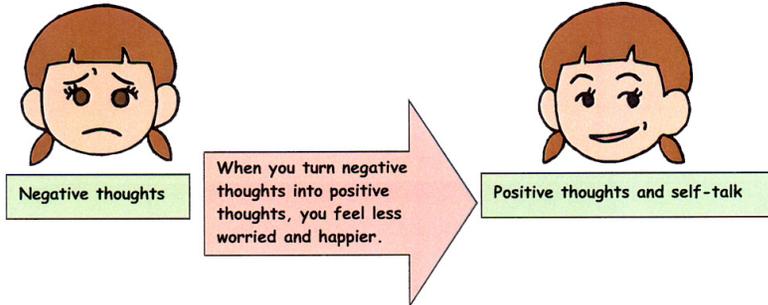
Step 5. **EVALUATE** the alternative.

Did it work?

Do I think something else would work better?

From Anxiety Module

Let's do an exercise that looks at how negative thoughts can be turned nice things you say to yourself.



Examples of negative thoughts turned into positive thoughts and self-talk

- I never do anything right. → Yesterday I helped my friend.
- Nobody likes me. → Terry and I are good friends.
- I'm stupid. → The teacher said I gave a good answer.

Now you try to do it -

- It won't work no matter what I do. → _____
- I can't do it. → _____



Now that you can see how negative thoughts can be changed to positive thoughts, let's go back to our example of Andrew. Watch the video Chapter 9, Scene 2 to see how Andrew's dad helps him to begin using positive self-talk.

My Notes:

Family Help Coach: 1-866-470-7111

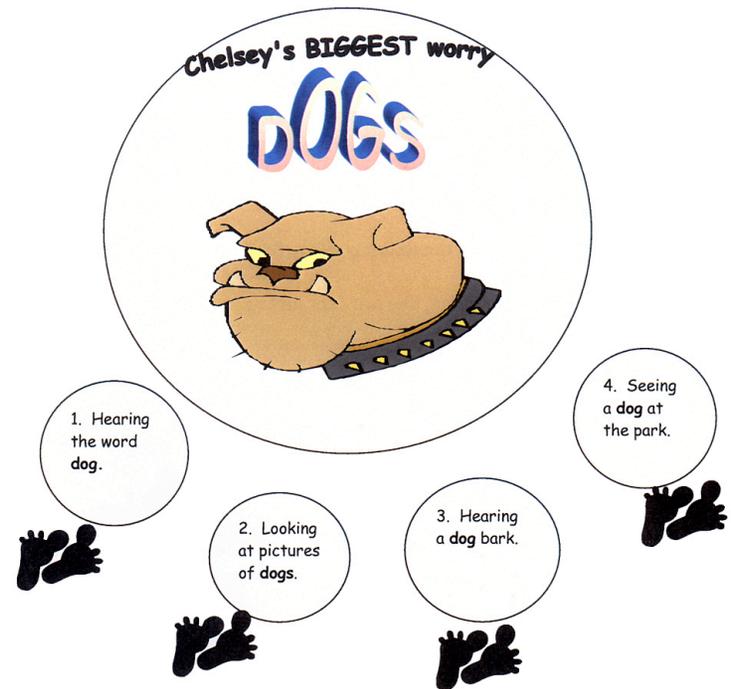
Facing your Worry

One way this Family Help program will help you is to teach you to face your worries but by taking little steps, not giant steps. Little steps towards what worries you the most will help you deal with your worry.



We are going to give you another exercise to do for next week. It will help you to learn more about your worry. Your Mom, Dad or coach will help you. We want you to draw, or write about, what worries you the MOST. Then we want you to tell us 4 things about that Big Worry that scares you the most.

Here's an example of how to do this.



Bedwetting

Step 5: It Takes Time



Comfort and remind your child often that it will take many, many days of using the alarm before he or she will learn to be dry. Learning new skills takes time, and learning to do new skills in your sleep can take even longer.

Encourage your child: "Mary, I know you have been trying really hard not to wet the bed. I know you are looking forward to being dry at night. The urine alarm will help you."

Step 6: Praise Any Improvement



Notice even the little things and praise your child

Remember to praise your child for waking up to the alarm, and for any other effort he/she makes. Do not be surprised if your child sleeps through the alarm the first few times, and if you find that you have a big puddle to clean up. The amount of urine passed before the alarm wakes your child will be less over time.

Step 7: DON'T GIVE UP!!!! Be Consistent



This kind of training takes time. It may be three months before there is a big change in the amount of urine your child passes at night. The more consistent you are, the better the progress will be. At times, you and your child will think it cannot be done. It may feel like an uphill climb! It takes a long time to learn an important skill like this. Nobody expects to be able to play the violin after only two months of lessons. Learning to stop bedwetting also takes time. So don't give up!

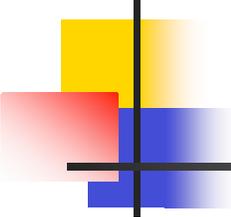
If discouraged, point out to your child the length of time he or she spent learning to ride a bicycle or play a video game. Skills which he or she can do easily now.



Benefits of Coach

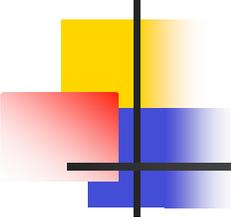
- Coach increases compliance, decreases drop outs, problem solves
- Bright, capable, personable
- Non-professionals
 - Lower cost
 - Follows protocol





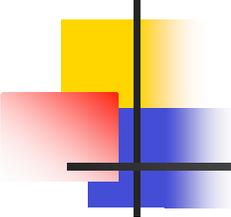
Progress

- Selling program to community
 - Public meetings
 - Detailing doctors
- Pilot studies impressive
- RCT's underway (3 studies closed)
- Interim Analysis wanted by partners
 - Showed strong effects
 - Pilot project in another province
 - Small amount of funding obtained for the intervention in Nova Scotia



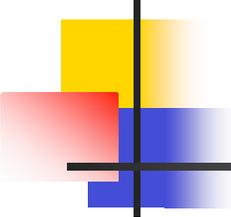
Pain in the Emergency Room

- Pain common
 - Disease or disorder
 - Procedures
 - Usually not treated



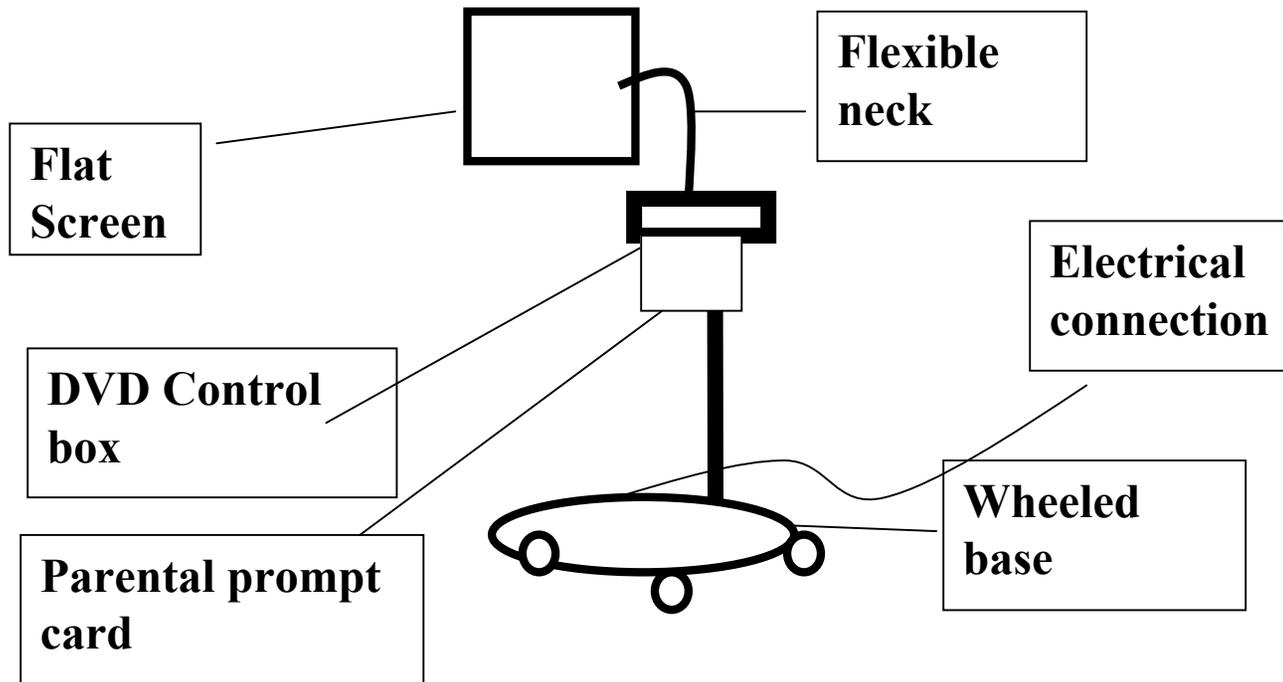
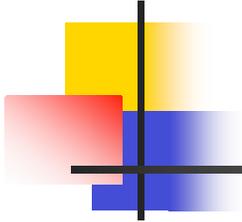
Criteria for ideal treatment

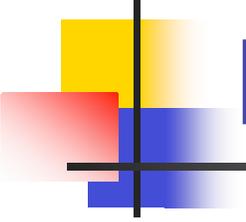
- Inexpensive:
- Fast acting:
- Minimal time
- Few negative side effects:
- Easily integrated



Pain Attack Treatment

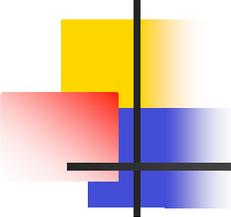
- Instructional video
 - Parent trained
 - to help child distract
 - No criticism or reassurance
 - Child trained
 - To deep breathe
 - To focus on video
 - To cooperate with nurse





Integration with Emergency Dept

- Chief, very much involved
- Nurse, research committee involved
- Integrated into National Association of Emergency Dept Research
- Policy studies underway



Conclusion

One shoe doesn't fit all



Think about your goals

Thanks

- Karina Davidson for the invitation
- You, the audience
- The parents and children
- Collaborators/Staff
 - Cathy Thurston
 - Cathy MacLean
 - Dan Washchbush
 - Sherry Stewart
 - Trish Pottie
 - Heather Robertson
 - Doug Sinclair





Thanks



MAYDAY
FUND



Health Districts
4,5,6



Human Resources
Development Canada

Développement des
ressources humaines Canada



Canada Research
Chairs

Chaires de recherche
du Canada

