Population-based Interventions to Improve Sexual Health: Development and Evaluation

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First, just a brief bit of background. Y2000 estimates are that there are 18.9 million new cases of STI's in the US every year. This shows the rough breakdown by specific STI's.

More STI's among young adults – 50%

Serious Health consequences -

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### How many people get new STI’s in the U.S. every year?

<table>
<thead>
<tr>
<th>Disease</th>
<th>New cases/year</th>
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<tbody>
<tr>
<td>All STI’s</td>
<td>18.9 million</td>
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<tr>
<td>HPV (Genital warts)</td>
<td>5.5 million</td>
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<tr>
<td>Trichomoniasis</td>
<td>5 million</td>
</tr>
<tr>
<td>Chlamydia</td>
<td>3 million</td>
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<tr>
<td>HSV (Genital herpes)</td>
<td>1 million</td>
</tr>
<tr>
<td>Gonorrhea</td>
<td>650,000</td>
</tr>
<tr>
<td>Syphilis</td>
<td>70,000</td>
</tr>
<tr>
<td>HIV</td>
<td>&gt;40,000</td>
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</table>
Note that these are direct medical costs of 8 STI’s alone (HIV, HPV, HSV2, HepB, Chlamydia, Gonorrhea, Syphilis, Trichomoniasis). These are in Y2000 dollars. In today’s dollars, these costs would increase (by ~20%). There are substantial costs to quality of life and distress in addition. – (40-70% costs among 15-24 y.o.)

(94% Viral STI’s + 6% Nonviral STI’s)

Chesson et al., 2004
This model is one you’re probably not too familiar with, so I’d like to make a couple of important points. First, this is a model of \textit{intentional behavior change}. Integrates some common variables with IMB and TRA (especially decisional balance / attitudes + intentions).

When this work started in the late 1980’s/early 1990’s, the model had been applied well to smoking, but not to many other risk behaviors. Also, this is a \textit{multivariate model} – (sometimes reduced it to stages of change), all variables important for intervention purposes. Finally, one less well appreciated aspect of this model is that it \textit{arose out of studies of self change behavior}, that is those who were able to change behavior on their own. I say that b/c I want to emphasize here that this model is quite consistent with many aspects of Positive Psychology – that is \textit{studying how people change successfully on their own and then applying that knowledge to develop interventions to help them change} more effectively and efficiently, based on what we learned from self change.

So, \textit{breaking the behavior change process down into discrete stages of change has turned out to be very useful}.

One intervention platform we have developed is called an expert system. Just what is an expert System? An expert system is an intervention delivery system built into a computer program that mimics or codifies the reasoning of a human expert. The program uses standardized algorithms for assessment and providing feedback and applies those algorithms consistently. So, those pilot samples I just told you about can be used to develop explicit decision rules that are then coded into the system. EG How much of some process var. differentiates PC from C? Then, set a cutoff that provides feedback in response to the data provided…

One note here for real computer programming experts, true expert systems continue to learn or develop algorithms as they work and therefore they change. This is one feature of expert systems which we do not employ here, since we need to study an intervention delivery system which is constant. (It would be very difficult to study a computer program that kept changing, like trying to hit a moving target!)
Different Levels of Targeting/Tailoring

- **Group Level**: Same intervention for all
- **Stage Level**: Targeted interventions
  - Precontemplation
  - Contemplation
  - Preparation
  - Action
  - Maintenance
- **Intermediate Level**: Tailored interventions
- **Individual Level**: Expert system interventions
<table>
<thead>
<tr>
<th>Stage-targeted</th>
<th>TTM-Tailored</th>
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<tbody>
<tr>
<td>univariate</td>
<td>multivariate (10-15)</td>
</tr>
<tr>
<td>group feedback</td>
<td>individual feedback</td>
</tr>
<tr>
<td>clinical decisions</td>
<td>empirical decisions</td>
</tr>
<tr>
<td>5 different types</td>
<td>normative comparison</td>
</tr>
<tr>
<td></td>
<td>ipsative comparison</td>
</tr>
<tr>
<td></td>
<td>thousands of types</td>
</tr>
<tr>
<td></td>
<td>interactive</td>
</tr>
<tr>
<td></td>
<td>algorithms vary by Stg</td>
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</table>
Population-based – can program as much knowledge in as you find… Confidential is especially important in this area – studies have found that people self report more accurately about risky sexual behavior using a computer assisted survey than they do in response to an interviewer, for example.
Efficacy of TTM-Tailored Interventions for Single Health Behaviors

- Smoking Cessation
- Healthy Diet
- Physical Activity
- Sun Protection
- Medication Adherence
- Stress/Depression Management
- Mammography screening
- School Bullying

We have demonstrated effective TTM-tailored interventions (most in print and some in multimedia formats). Here are many of the citations:


What I want to focus on today is the Intervention development process that I have used over the past decade to develop and evaluate a population-based intervention to increase condom use in at risk populations. There are many steps of this process. Focus groups. Pilot samples to evaluate measurement structures and to create normative databases that we could then use in the intervention. I want to highlight this process b/c it exemplifies the scientist-practitioner model.
This project is one that was conducted within a large collaborative team with grant funding - included many colleagues and much expertise, in addition to my own.

Grant funded.
HPV is very prevalent, especially among young women, HPV is causally associated with cervical and other genital cancers.
We name this project Step by Step: Steppin’ for Healthier Teens — Steppin’ refers to dancing and of course step by step is a reference to the model. Our name needed to be sensitive to women’s need for privacy so we could not use sexual or smoking behavior in the title.
We were able to recruit a diverse sample, although it primarily includes young Black women, consistent with urban Philadelphia demographics. We also included about 7% White/Euro-American and about 8% Hispanic or Latina.

### Sample Diversity (N=831)

<table>
<thead>
<tr>
<th>Race/Ethnicity</th>
<th>%</th>
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<tbody>
<tr>
<td>Black / African-American</td>
<td>81.0</td>
</tr>
<tr>
<td>White / European-American</td>
<td>7.3</td>
</tr>
<tr>
<td>Hispanic / Latina</td>
<td>7.8</td>
</tr>
<tr>
<td>Native American</td>
<td>1.4</td>
</tr>
<tr>
<td>Other / Multiracial</td>
<td>1.8</td>
</tr>
</tbody>
</table>
This sample was at substantial behavioral risk for STI’s and unplanned pregnancy:

<table>
<thead>
<tr>
<th>Condition</th>
<th>%</th>
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<tbody>
<tr>
<td>Age of sexual debut ≤13-14 y.o.</td>
<td>62.7</td>
</tr>
<tr>
<td>Hx. Chlamydia</td>
<td>20.5</td>
</tr>
<tr>
<td>Hx. Gonorrhea</td>
<td>10.3</td>
</tr>
<tr>
<td>Hx. HPV, Herpes, or Syphilis</td>
<td>9.4</td>
</tr>
<tr>
<td>Hx. Pregnancy (at least one)</td>
<td>36.0</td>
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</table>
Stages of condom use - baseline sample. Good news - 40% of the sample reported using condoms consistently already – the Bad news - 60% were not.

Some thought, since this was a clinic-based sample, that we may get a sample that was highly prepared to use condoms already. That was clearly not the case and the range of readiness apparent here support using stage-tailored strategies to intervene with these young women.
This is a well studied construct.
T-scores (M=50, SD=10) X SOC across 48 health behaviors


I showed you the previous graph so you could appreciate the beauty of this one.

This includes the entire baseline sample and nicely replicates most of the relationships observed before, except the Cons are a bit flatter and the cross-over happens between C/PR instead of between PR/A before.

This kind of replication is very nice. However it is still cross-sectional
This shows baseline Confidence in Condom use X SOC
So, we used data like what I just showed you to develop expert system interventions for both condom use and smoking.
TTM Tailored Intervention Package

- Interactive assessment and expert system feedback (onscreen & printed)
  - Condom Use Promotion
  - Smoking Cessation OR Prevention
- Tailored feedback based on:
  - Stages of change
  - Pros & Cons
  - Confidence or Temptation
  - Processes of Change
- Stage-Matched Counseling
The comparison group in this study was standard care. They got the same assessment and generic feedback/advise to use condoms. They also got standard family planning counseling.
Stage-matched Counseling

- Can be used with teens at all stages of change, not only those ready for action
- Comparable to Motivational Interviewing
- Counselors match Process exercises to stage using Manual
- Counselor received printed output from computer with client’s stage of change and processes to work on

Interesting model for other settings – very minimal feedback to counselor (stage and processes to work on) – counselors did talk about condoms, but not much about smoking (of course)
These are the nuts and bolts of interventions and intervention designs, since they are literally what people think and do differently to change their behavior.
I'm not going to go over all of these today, just want you to realize that some POC are used more in early stage people (exper) and the behavioral set are used more for later stage individuals.

Definitions:

**Consciousness Raising** - increasing awareness
**Dramatic Relief** - motivating emotional experience; awareness of own risk
**Self-Reevaluation** - self reappraisal; looking at own self image with respect to health behavior
**Environmental Reevaluation** - impact of behavior on others / being role model
**Social Liberation** - impact of environment on behavior
**Self-Liberation** - will power, commitment, choice to engage in health behavior
**Helping Relationships** - seeking & accepting help with behavior change; social support
**Reinforcement Management** - rewarding new health behavior
**Counter Conditioning** - substitution of healthier alternatives for the old behavior
**Stimulus Control** - keep reminders available, avoidance of tempting cues
Some **new processes** that were conceptualized and added. Initial attempts to examine some the **interpersonal aspects of condom use**.

We did find support for these as distinct psychometric concepts and they were found to be important across the stages as well, as I’ll show you.
I don’t want to go through all of these, but I want to draw your attention to the two highlighted lines in pink and blue. Pink here is DR which reflects feeling at risk. This goes up from PC to C and then remains rather flat, so we’d only intervene on it in the PC stage. Contrast that with the blue line, which reflects SR, or self reevaluation, (looking at one’s own self image with respect to condom use – so, what does it mean about me?) Here, we can see that this process is used both from PC to C and from C to PR, so we’d intervene in both PC and C for that process. This is just one example of how we determine which processes to intervene upon in which stages.
Here are those interpersonal processes I told you about across the stages and I want to highlight 3 of them in pink (Condom Assertiveness), green (Communication about condom use), and yellow (Partner support for condom use). Not only do they need to increase a lot in the early stages, but in the later stages as well, so we’d definitely intervene on these not only at C, PR, but also at A and M.
Long story short – these are the rates of retention in the trial.
Rates of retention during the intervention phase disappointing, but not too surprising, given that they had to come into the clinic to work on the computer.
About: 75% of the sample got 2 sessions, 50% got 3 sessions and about 34% got all 4 sessions.

Rates did not vary by intervention group.
All available Data - the 60% of the sample Not using condoms at baseline (n=494).

% at A or M at each timepoint by group.

**Significant differences at 6 (n=236) + 12 months (n=284), but not 18 months (n=266)** (p < .05).

Missing Data – LOCF show comparable patterns
ITT - same slide assuming loss to follow-up did not progress. % at A or M at each timepoint by group.

**Significant differences at 6 (22 vs. 17) + 12 months (26.5 vs. 18.8), but not 18 months (23.5 vs. 20)** ($p < .05$).
Differences in rates of relapse between groups for the 40% of the sample using condoms consistently at baseline (N=334).

Again, significant differences at 6 (N=198) and 12 months (N=210), but not 18 months (N=195).
Quit rates among smokers – 29 vs. 23% (20% smokers at baseline, n=166 – by 18 mos, N=88)
Not statistically significant, but replicates results found with adults and with other teens – so this reflects more of a power problem than a lack of effect.
In the sample who were nonsmokers at baseline (n=589), the rate of smoking uptake was not different.
9.9 vs. 9.4 % @ 18 months (n=362) = NS
Step by Step Conclusions

- Results support the efficacy of the TTM Tailored expert system intervention & stage matched counseling package to increase condom use and reduce condom relapse in this high risk sample.
- Despite lack of statistical significance, smoking cessation results at 18 months replicated prior results with adults and adolescents.
- No support for effectiveness of the smoking prevention intervention.
- Significant initial increases in condom use were sustained over 18 months, however, control group caught up.
Remaining Questions?

- Would these results generalize to at risk adults?
- Would condom use results hold up without the counseling component?
This was a grant funded effort with many excellent collaborators.

Published in AJOG (2008) - Tailored intervention to increase dual-contraceptive method use: a randomized trial to reduce unintended pregnancies and sexually transmitted infections
Condoms + Hormonal contraception
PROTECT Study Timepoints

- Baseline – full exam
  - TTM group - 1 + 2 months sessions
  - Standard Care – no additional sessions
- 6 & 18 months phone survey
- 12 & 24 months – full survey & exam
PROTECT Baseline Sample Characteristics (N=542)

- Median Age = 22 years
- 90% Single
- 25% < H.S. Education (*unbalanced)
- 22% Black & 17% Hispanic
- 47% History STI (*unbalanced)
- 49% History unplanned pregnancy
- 34% No contraceptive use
- 33% Hormonal contraceptive use
- 48% smokers

< HS Education> Tx – 21% vs. Ctl. – 29% (p < .05)
Hx. STI > Tx. = 43% vs. Ctl.=51% (p < .05)
Propensity score adjusted for All main effects and most 2-way interactions
Looked at predictors – Hx of unplanned pregnancy was associated with unplanned pregnancy in this study

Hx of STI was associated with STI in this study
Again, as before this study involved a lot of hard by a lot of dedicated and talented professionals, listed here and Grant funding.
RI Project RESPECT

- 9 local sites in urban areas
  - Drug Tx. Programs, STD Clinics
- 1 site in the Bronx, NY Blood Center
- RCT
- TTM-Tailored ES Feedback compared to Generic feedback alone
- Intervention at Baseline, 2, 4 months
- Follow-up at 6, 12, 18 months

Again, no counseling component
Participation Criteria

- 18 - 44 years old & English speaking
- Heterosexually active in past 3 months
  - unprotected vaginal or anal sex
  - At least one opposite sex partner
- Not pregnant or trying to get pregnant
- Self report - HIV Negative
Bottom line these criteria sought to establish that the sample was AT SEXUAL RISK for STI's
We were able to recruit a fairly diverse, mostly unemployed sample. We had less gender balance than we would have wanted.

<table>
<thead>
<tr>
<th>Baseline Sample (n=315)</th>
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<tbody>
<tr>
<td>Age mean = 32.2 years (s.d. = 8.1)</td>
</tr>
<tr>
<td>Gender</td>
</tr>
<tr>
<td>28% Male</td>
</tr>
<tr>
<td>Employment</td>
</tr>
<tr>
<td>65% Unemployed</td>
</tr>
<tr>
<td>21% Full-time work</td>
</tr>
<tr>
<td>11% Part-time work</td>
</tr>
<tr>
<td>3% Other</td>
</tr>
<tr>
<td>Education</td>
</tr>
<tr>
<td>42.5% &lt; H.S.</td>
</tr>
</tbody>
</table>
We had pretty good diversity, matching rates of HIV in RI, mostly unmarried adults, but a few in more serious relationships and fairly sexually active.
14% in past year and 34% prior to that (STI)
Avg. of 3 sex partners in last month, median = 1
Here is the stage distribution for the baseline sample. Mostly not ready to use condom, consistent with our eligibility criteria…
Expert System Enhancements

- New background pictures + recorded new adult male and female audio.
- Gender-matched systems
- Added new sections for main and other partner readiness to use condoms.
We did have some difficulty maintaining the sample over time.
Outcomes

- DVs:
  - # times unprotected sex in past 30 days (n = 267)
  - % of times safe (includes those not sexually active in past 30 days) (n=296)
  - % A/M consistent condom use (N=292)
  - Any Stage Progress (N=305)

RM MANOVA found Significant Effect
• N= 267 – Outliers Removed

RM ANOVA found Time X Group Effect-  F = 4.10,  p = 0.044
Outliers removed – N=296 – This analysis allowed us to include those who were not sexually active in the past 30 days in both groups (~30 more people)
RM ANOVA on % Time Safe = F =5.11, p = 0.025
All available Data included (N=292).
Progress to A/M as the criterion, (among those were in early stages at baseline).
24.6% A/M in the Tx. Group compared to 14% in the control group. $z = 2.31, p = .010$ (one-tailed)

This is significant, but we worried about bias resulting from study attrition, so…
Intent to Treat analysis that assumes that all baseline pre-action individuals missing at 6 months did not progress and then recalculates the effect. So this analysis has more sample size and power, but a smaller effect (7% difference), and yet, it still finds a statistically significant difference between groups.

\[ z = 2.276, \ p = .011 \text{ (one-tailed)} \]

This increases our confidence in our treatment effect.
All available data - Another way to look at these data that counts progress to any stage. N=305 –looks better for both groups – still only 10% differential.  

\[ z = 1.731, \; p = .042 \text{ (one-tailed)} \]
Again, the ITT analysis (including baseline participants not retained at 6 months + assuming no progress) has more sample size (N=448) and power, but a smaller effect size (7%), yet we still find a significant effect of the tx.

\[ z = 1.770, \quad p = .038 \text{ (one-tailed)} \]

looks better for both groups.
Still need to do complicated missing data analyses on 12 + 18 month timepoints such as Multiple Imputation.

2 Multiple Risk Behavior Studies: Peipert - Dual Methods (Condom + Contraceptive use) & Step X Step – Condom Use + smoking

2 Adult studies – Protect + Respect
Here are just a few ideas for future work.

- Process to outcome research
- Compare cross-sectional to longitudinal findings
- Examine predictors of changes over time
- Enhance intervention outcomes
- Enhance retention
- Generalize to additional at risk samples + settings
- Dissemination & Translation
This iterative intervention development process is and must be driven by a scientist-practitioner model. Both components (the scientist and the practitioner) are integral to the success of the other. We need good methods and we need good clinical skills (listening/communication/message development) to develop and enhance effective interventions. This work exemplifies this model, and I’d like to continue to build on it.