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Assessing the STIRR Model of Best Practices for Blood-Borne Infections in Clients with Severe Mental Illness

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Abstract

Objectives—People dually diagnosed with severe mental illness and substance use disorders are at markedly elevated risk for HIV, hepatitis B and hepatitis C, but generally do not receive basic recommended services. Several barriers impede receipt of services, including lack of programs offered by mental health providers, and client refusal of available services. Clients from ethnic minority groups are even less likely to accept recommended services. The intervention tested was designed to facilitate integrated infectious disease programming in mental health settings, and to increase acceptance of such services among clients.

Methods—A randomized clinical trial (n=236) compared enhanced treatment as usual (Control) to a brief intervention to deliver best practice services for blood-borne diseases in an urban, largely minority sample of dually diagnosed clients. This intervention included *Screening, Testing* for HIV and hepatitis, *Immunization* for hepatitis A and B, *Risk-reduction* counseling and medical treatment *Referral* and support (*STIRR*) at the site of mental health care.

Results—Clients randomized to STIRR had high levels (over 80%) of participation and acceptance of core services. They were more likely to be tested for HBV and HCV; immunized for hepatitis A and B; increase their hepatitis knowledge and to reduce their substance abuse. However, they showed no reduction in risk behavior, were no more likely to be referred to care (81 vs. 75%) and showed no increase in HIV knowledge. Intervention costs were \$541 per client.

Conclusions—STIRR appears to be efficacious in providing a basic, best-practice package of interventions for dually diagnosed clients.

HIV/AIDS and viral hepatitis continue to represent major public health concerns, particularly among individuals at high risk due to injection drug use, homelessness, and severe mental illness (1,2). Along with risk for HIV and HCV, co-infection is markedly elevated for persons with severe mental illness, further increasing morbidity and mortality (3,4). The largest study to date found HIV prevalence of 3%, approximately 9 times the overall U.S. rate, and HCV prevalence was 20%: approximately 11 times the overall population rate (5). The majority of clients who tested HIV-positive (59%) were co-infected with HCV. Clients dually diagnosed with both mental illness and substance use disorders were at even greater risk. Early detection and treatment is thus crucial for clients with dual disorders (6,7).

The Centers for Disease Control and Prevention, the Veterans Administration and the National Institutes of Health all recommend the following key services for people at elevated risk for Hepatitis and HIV/AIDS: screening for risk; testing for infection; immunization for hepatitis A and B; risk reduction counseling; and referral and support for medical care. However, the great majority of clients with dual disorders do not receive these recommended services. First, most providers offer none of these services to clients, despite being their major point of access to health care. In New York, where prevalence is high and HIV services are mandated, less than half of the psychiatric providers routinely do risk assessment, and only 16% offer blood testing for HIV (8,9). Mental health providers appear to be reluctant to offer core services for the following reasons: limited financial resources; reluctance to inquire about risk behaviors; reluctance to promote testing for infection; lack of knowledge about blood-borne infections; inadequate skills and confidence in dealing with positive test results; inability to help clients access appropriate medical care (10).

Another important barrier to receipt of services is limited client motivation. Only 17-47% of people with SMI report HIV testing within the past year (11). Even when tested, most people in the general population do not return to receive their test results (12), nor to receive post-test counseling to guide risk reduction or access to care (13). No national data are available on testing for HCV and immunization for HAV/HBV among clients with dual disorders, and published data on HCV prevention programs for this population are not available. Data from other high-risk groups suggest that adherence to immunization is generally quite low. For example, in one study of urban patients receiving care in STD clinics, only 23% accepted an offer for HBV immunization, and less than 10% of those who accepted returned for the (necessary) second dose (13). Surveys suggest multiple concerns regarding immunization among high-risk groups, including: fears about the vaccine; underestimation of personal risk; stigma issues; and mistrust of government agencies, drug companies, and the health care system (14,15). In practice, minority group members are less likely to receive immunizations (16). Referral to appropriate level of care for infected, dually diagnosed clients also seems highly problematic, even in integrated health care systems like the Veterans Administration. A recent VA study found that more than half of HCV positive patients with a psychiatric disorder were not being treated for their infection, and 11% of the participants died during the study period without ever receiving care (17).

The STIRR intervention was developed to overcome these barriers to providing recommended services for HIV and HCV to dually diagnosed clients. STIRR brings infectious disease services to the clients' usual source of care: publicly funded community mental health providers. It includes: *Screening* for HIV and hepatitis C risk factors, *Testing* for HIV and hepatitis C infection, *Immunization* against hepatitis A and B, and *Reducing risk* and *Referring* for medical treatment for those testing positive for HIV and hepatitis C (*STIRR*).¹⁸ To overcome provider barriers, STIRR is delivered by an external team of specialists with the knowledge, skills and confidence to deliver these core services. To overcome client barriers, STIRR is brief, requiring about one hour of client contact over 3 sessions. It employs a health promotion, empowering approach, recruiting the client as partner and agent in improving their own medical well-being. We conducted an open trial in New Hampshire, and approximately 3/4ths of eligible clients agreed to participate, had blood testing, and had at least two doses of vaccine for HAV and HBV. Pre-post testing also showed increased knowledge about blood-borne infections and increased motivation to reduce risk (18).

To establish efficacy for this intervention, and to assure feasibility in an urban, ethnically diverse setting, we conducted a randomized controlled trial in urban Baltimore, MD. STIRR was compared to enhanced treatment as usual (Control) (i.e. existing brokered case management services augmented by education and referral) across 4 publicly funded

community mental health services sites. Our primary hypotheses were that clients randomized to the STIRR would be more likely to be screened, tested, immunized, referred and linked to the appropriate level of medical care than clients randomized to Control. Our secondary hypotheses were that clients randomized to the STIRR would have greater increases in knowledge about blood-borne diseases, reduced behavioral risk, and less substance abuse than clients randomized to Control.

METHODS

Overview

Between 2006 and 2008, we recruited 236 dually diagnosed clients receiving services at one of four publicly funded community mental health programs in Baltimore. Clients were offered participation by their primary therapists, directly by the research team, and through flyers in the site waiting rooms. Participants were randomly assigned to STIRR (n=118) or to Control (n=118). All participants were assessed at baseline and at 6 months later. STIRR participants who tested positive for HCV and/or HIV were also assessed at 12 months post-intervention. Subjects were paid for participating in the assessments, but not for participating in STIRR services.

Participants

Participants were between the ages of 18 to 65, and had one of the following psychiatric diagnoses (Table 1): schizophrenic spectrum disorder (DSM-IV 295.1-7); major depressive disorder (DSM-IV 296.20-36), or bipolar disorder (DSM-IV 296.0x, 296.4-7, 296.80 and 296.89). In addition, all participants had current or lifetime diagnoses of substance use disorder, were English speaking, and able to give informed consent.

Procedures

Before beginning our study, local providers and cultural competence experts assessed all STIRR procedures and materials for potential cultural barriers. An ethnographer specializing in urban, African-American culture also observed pilot cases in Baltimore, and conducted interviews with minority pilot participants. He found no significant cultural barriers to understanding STIRR materials, and good acceptance of the intervention by African-American clients.

The study began with informational meetings for the clinical staff at each site. Study details were explained to potential participants prior to obtaining written informed consent. Recruitment and consent procedures were approved by the Institutional Review Boards at the University of Maryland and Dartmouth and the boards associated with each study site. Prior to randomization, participants completed a standardized baseline assessment described below. Independently within each site, participants were then randomized to receive either:

Enhanced treatment as usual (Control) (n=118), including information about blood-borne diseases; referral information regarding local community health sources for blood testing, immunization for HAV and HBV, and treatment as needed. Participants were directed to either their health provider (if engaged in regular medical care), or to an accessible local clinic, for free testing and immunization; or,

The STIRR intervention (n=118), which provided services directly to participants at the site of mental health treatment. Those randomized to STIRR went directly to the first intervention session, which included the following: infectious disease education, screening for risk level, pre-test counseling, blood draw for testing (HIV, HBV and HCV), first immunization with Twinrix® HAV & HBV Vaccine; and personalized risk-reduction

education counseling, and distribution of safety reminders (e.g. condoms). Blood was drawn on site and shipped out for laboratory testing. A second session was scheduled, approximately one month after the first, to provide test results, post-test and risk reduction counseling, medical referral and linkage (if needed), and the second Twinrix® immunization. At the third and final scheduled session, 6-months after the initial dose of vaccine, risk level was re-assessed, risk reduction reinforced, the final immunization provided, and medical linkage reinforced.

At the 6 month point, a final research assessment conducted by a research assistant blinded to subject assignment.

We randomly selected 28 STIRR sessions to monitor implementation fidelity and found that core intervention components (e.g., education, review of risk behaviors, and medical referrals) were delivered in virtually all instances as per the STIRR manual.

Control participants attended a final research assessment concurrent with the final STIRR session and were, upon exiting the study phase, offered STIRR services.

We also collected data on the costs associated with STIRR. We tracked the resource costs of offering the intervention, including the costs of case management and transportation, the costs of blood draws and tests, vaccines and products provided to clients. Administrative overhead costs for use of clinic space were imputed. We used provider catalogues of client encounters, client medical records, patient interview data on utilization of medical services, encounter records of blood draws and immunizations, and purchase costs of materials distributed to clients (e.g., condoms).

Measures and variables

Data sources for this study include self-report measures, standardized observations, laboratory reports, medical and psychiatric records, time logs, mental health center financial data, participant interview data, and cost data on materials and services. Parallel sources were used to compare outcomes across the two groups.

Self-report instruments were used to assess demographics (including age, gender, marital status, education, living situation, legal history); and use of medical services (sources, types, and amount of care received including infectious disease services. Medical services items were drawn from either the National Health Interview Survey (NHIS) (19) or the National Health and Nutrition Examination Survey (NHANES-III) (20).

Risk for blood borne infections was assessed by the AIDS Risk Inventory (Modified), which assesses knowledge, attitudes and risk behaviors associated with acquiring and transmitting these infections. We added specific items on hepatitis. This scale has been reliable and valid in studies with similar populations (21-23).

Current alcohol use disorders and current drug use disorders were assessed with the Dartmouth Assessment of Lifestyle Instrument (DALI), an 18-item questionnaire developed for people with severe mental illness (24).

Clinician ratings for alcohol and drug use were also employed to provide ratings of abuse (DSM-IV criteria) on the Alcohol Use Scale (AUS) and the Drug Use Scale (DUS), which have demonstrated reliability in numerous studies (25-30).

In addition, we used the Substance Abuse Treatment Scale (SATS), which measures stages of substance abuse treatment (31), and has adequate reliability and validity in studies of dually disordered clients (32).

Chart reviews were used to assess treatment participation of infected clients, and laboratory tests for performed for HIV (ELISA and Western blot for confirmation), HBV (surface Ab, HBV surface Ag antigen and HBV core Ab) and HCV (Abbott HCV EIA 2.0, Abbott Laboratories, Abbott Park, Illinois), using HCV-encoded recombinant antigens. Positive HCV screens were verified by the recombinant immunoblot assay (RIBA®; Chiron Corporation, Emeryville, California). HCV viral load was assessed with HCV-PCR.

Statistical analyses

We used chi-squared and logistic regression analyses to examine differences between the groups both for the number of participants who self-reported having been tested for infection and the number who self-reported having been immunized. We compared the two groups at baseline and then assessed the number of additional participants who were tested or immunized at the six-month period to determine the effect of the STIRR intervention. We used analysis of variance on difference scores (between baseline and six months) to examine the impact of STIRR on HCV knowledge, risk behaviors and scores on the alcohol and drug abuse scales, all including site of treatment as an additional variable. All tests were carried out using SPSS.

RESULTS

Randomization and retention

The consent rate (76%; 240/314) and follow-up rate (92% ; 200/217) were high, and the latter did not differ across groups. Diagnosis, ethnicity, gender, age did not differ between groups (Table 1). Group assignment was not associated with either participation or retention.

Participant characteristics

Within the STIRR group, 25% (26/106) tested HCV-positive and 8% (8/106) tested HIV-positive. Half of those (4/8) with HIV were co-infected with HCV.

Participation, testing and immunization

Hepatitis testing was defined as participant self-report of a blood test for HCV within the last year. (In the STIRR condition, any participant tested for HCV was also tested for HBV and HIV.) There was no significant baseline difference between STIRR and Control clients in rates of testing (Table 1). At six months, 88% (77/88) of STIRR participants who had not been tested at baseline reported being tested in the interim compared to 14% (11/80) of Control participants (Table 2). Using change scores as the dependent variable in a logistic regression with treatment group and site as predictor variables, treatment group was highly significant and site was not significant. The laboratory data for STIRR participants show that 86% (102/118) were tested, providing credibility for the self-report data. Of the STIRR participants tested, 99% (101/102) returned two weeks later for test results and post-test counseling. Laboratory data were not available for Control participants.

At baseline, STIRR and Control groups reported comparable rates of immunization (Table 1). At 6 months, 76% (73/96) of STIRR participants not immunized at baseline reported receiving immunization as compared to 5% (4/86) of Control participants. These change scores were used as the dependent variable in a logistic regression with treatment group and site as predictor variables. Treatment group was highly significant and site was not significant (Table 2). STIRR records show that 95/117 STIRR participants (81.2%) were immunized with Twinrix®, again providing validation of the self-report data.

Referral to medical care

Referral to medical care for infected participants was assessed by self-report in both groups at six months, and by direct observation by case managers/chart review at the 12 month follow-up for STIRR participants. For those who self-reported HCV-positive status, 81% (17/21) of STIRR and 75% (12/16) of Control clients reported having a medical visit for HCV (ns).

We were able collect one-year post intervention follow-up data for 14/26 (54%) of the STIRR participants who tested HCV-positive by laboratory results. The remaining clients were lost to follow-up primarily because of leaving treatment services, relocating from the area, death or incarceration. Ten of the 14 participants (71%) followed had a follow-up medical appointment and all 10 of those had lab work (liver enzyme monitoring) completed during the follow-up period. Four of the 14 (29%) were newly identified as positive based on the STIRR study blood draw, and all newly identified HCV-positive clients completed a medical follow-up appointment, and received liver enzyme monitoring. However, none received advanced diagnostics (e.g. viral load assessment) or treatment (e.g. antiviral therapy), possibly due to the fact that such procedures were not medically indicated.

In the STIRR group, 8 individuals tested HIV positive, one newly identified by STIRR procedures. Of the 6 subjects available for one-year post-intervention follow-up data, all had a medical follow-up appointment and all had CD4 and viral load counts measured during the follow-up period.

Knowledge, Risk Behaviors and Alcohol/Substance Use

STIRR clients showed greater hepatitis knowledge gains than Control participants. Differences in knowledge gained were submitted to an analysis of variance with treatment group and site as factors. Treatment group was highly significant, as was the effect of Site (Table 2). Importantly, the interaction between treatment group and site was not significant. There was no difference between groups in HIV knowledge gain.

Groups did not differentially reduce risk as measured by the sum of seven items from the ARI including: needle sharing, unprotected sex, etc. However, STIRR was associated with modest significant improvements in the DALI Alcohol score. These changes in DALI scores were submitted to an analysis of variance with treatment group and site as factors. Treatment group was significant, but neither the effect of Site nor the interaction approached significance. In addition, STIRR participants improved relative to Control on the Clinicians Drug Use Scale. These changes in clinicians' ratings were submitted to an analysis of variance with treatment group and site as factors. Treatment group was significant, and neither the effect of Site nor the interaction approached significance. Neither the DALI Drug Scale nor the Case Manager Alcohol Ratings showed a significant change as a function of group.

Costs

The average cost of delivering STIRR was \$541 per client. The largest component (\$234 or 43%) was the cost of blood tests, followed by personnel costs (\$169 or 31%), vaccine costs (\$65 or 12%), training and other clinic setup costs (\$50 or 9%), and other expenses. Thus, STIRR intervention delivery costs, which exclude the costs of vaccine and blood tests (which are necessary in all hepatitis screening programs), were approximately \$240 per client. Nurse time accounted for 88% of personnel costs in STIRR, or approximately \$150 per client.

DISCUSSION

Provision of basic health services for people at high-risk for blood-borne infections continues to be problematic, posing both a health risk for those individuals, and a public health concern in regard to possible infection of others. Dually diagnosed clients represent a large and underserved group at demonstrated high risk, but no evidence-based interventions are available to provide recommended assessment and medical services to this group. Currently, even simple, basic procedures, such as risk screening and testing, are not typically offered to clients and when offered, are frequently refused. Results of the first randomized clinical trial of STIRR support its basic efficacy and feasibility in delivering these services, at a relatively modest cost, in typical community mental health settings. Moreover, the rates of adherence to the services provided in the intervention greatly exceed previously reported results.

STIRR provided screening for about 3/4ths of dually diagnosed clients, greatly increased rates of testing and immunization, increased knowledge of hepatitis, moderately reduced substance abuse and achieved high levels of referral to care. While behavioral risk did not appear to change, blood testing and immunization have tremendous importance for both primary and secondary prevention of hepatitis. The CDC has stated that immunization for HBV is by far the single most important prevention measure (33). No intervention strategy to date has been able to achieve such success in real world community settings. While the rates of medical follow up for those reporting that they were positive for HCV did not differ between groups, it is important to note that the study had very limited power to detect such differences. In addition, this comparison does not reflect the number of potential HCV positive Control clients who did not know they were infected because they had not received recent testing. Our inability to determine the rate of infection in Control clients is a limitation of the study. However in the post-trial phase, Control clients were offered STIRR services and 7 of 35 clients requesting STIRR services tested positive for HCV infection, of whom 5 were previously unaware. If these results are indicative, STIRR rates of referral would be superior to Control.

STIRR's association with evidence of reduced problematic alcohol and substance use may be especially important given the dangers of alcohol for liver function. These findings suggest that linking substance use treatment and information with STIRR may increase its impact on clients' decisional balance with respect to drug and alcohol use.

The other results regarding behavioral risk-reduction were disappointing. Given the efficacy of some other more intensive risk reduction interventions with high-risk populations, this aspect of STIRR should be reviewed for modification and possible enhancement. However, even if STIRR were not particularly effective in regards to overall behavioral risk reduction, it will likely prove a cost effective intervention for increasing testing, immunization and referral, and a possible gateway into behavioral risk reduction interventions for clients at a second stage.

In order for STIRR to become an evidence-based practice, it should be replicated in other sites, with more culturally diverse populations, and in situations in which the STIRR team is not recruited and paid by the study team. Cost-effectiveness of the intervention should be assessed, entailing evaluation of medical outcomes over time.

CONCLUSIONS

The STIRR intervention offers the potential to greatly increase receipt of best-practice services for HIV and HCV for people with dual disorders. It is designed to overcome

provider and consumer level barriers at a modest and specified cost, allowing policy makers to consider adoption for their agencies and systems of care.

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TABLE 1

Demographic and Baseline Characteristics as a Function of Group

	STIRR (N = 118)		Control (N = 118)	
Variable	n	%	n	%
Age (M ± SD)	46.6 ± 8.5		46.3 ± 9.3	
Female	48	41	42	36
Never married	76	64	76	64
High School Graduate	72	61	66	56
Race				
Caucasian	29	25	30	25
African American	85	72	86	73
Other	4	3	2	2
Diagnostic Category				
Schizophrenia	56	47	54	46
Schizoaffective	27	23	28	24
Bipolar	19	16	21	18
Major Depression	16	14	15	13
HCV Test at Baseline	22	19	27	23
HBV Test at Baseline	23	19	25	21
HIV Test at Baseline	93	79	99	84
Immunizations at Baseline	8	7	11	9
Hepatitis Knowledge % at Baseline	70 ± 19		71 ± 20	
HIV Knowledge % at Baseline	78 ± 25		79 ± 23	
DALI Alcohol Baseline ¹	-.40 ± 1.6		.50 ± 1.7	
Clinician Drug Abuse at Baseline ²	1.7 ± 1.1		1.6 ± 1.1	
ARI Risk Score at Baseline ³	1.2 ± 1.5		1.1 ± 1.6	

¹No baseline differences approached significance.

²DALI alcohol scores range from -4 to +4. High numbers indicate alcohol abuse.

³The Clinician Drug Abuse Scale scores range from 1 to 4. High numbers indicate alcohol abuse.

⁴ARI Risk Scores range from 0 to 7 and indicate the number of risky behaviors endorsed by the clients.

TABLE 2

Outcomes as a Function of Group

Variable ¹	STIRR		Control		Test Value	df	p value
	Available	N	Available	n			
Tested for HCV	81	70	86	69	Wald $\chi^2 = 57.6$	1	<.001
Tested for HBV	80	69	86	73	Wald $\chi^2 = 54.3$	1	<.001
Tested for HIV	21	18	86	13	Wald $\chi^2 = 6.4$	1	.011
Immunized	105	82	78	97	Wald $\chi^2 = 54.9$	1	<.001
Referral to Medical Care (for infected patients)	21	17	81	16	$\chi^2 = .19$	1	.63
% Hepatitis Knowledge gain	107	14.02 ± 20.04	103	1.38 ± 22.51	F = 15.68	1200	<.001
% HIV Knowledge gain	107	5.02 ± 19.92	103	.36 ± 17.19	F = .44	1200	.509
DALI Alcohol change ²	107	-.16 ± 1.33	103	.23 ± 1.43	F = 5.35	1200	.022
Clinician Drug Abuse Scale ³	107	-.12 ± .57	103	.05 ± .58	F = 4.54	1200	.034
ARI Risk Score Change ⁴	118	-.38 ± 1.57	118	-.42 ± 1.40	F = .61	126	0.44

¹ All of these variable are measured as change relative to baseline.

² DALI alcohol scores range from -4 to +4. High numbers indicate alcohol abuse.

³ The Clinician Drug Abuse Scale scores range from 1 to 4. High numbers indicate alcohol abuse.

⁴ ARI Risk Scores range from 0 to 7 and indicate the number of risky behaviors endorsed by the clients.