New York Academy of Medicine Center for Adherence Support Evaluation (CASE)
SPNS Adherence Evaluation
Study design matrix -- December 3, 1999

	Johns Hopkins University School of Medicine	Mission Neighborhood Health Center	Chase Brexton Health Services, Inc.	North Broward Hospital District (NBHD)	Columbia University/Harlem Hospital Center	Action Point Adherence Project (UCSF Urban Health Study)
ADMIN						
Principal Investigator	Richard Moore, MD	Ricardo Alvarez, MD	David Butcher, MD	Stephen Bowen, MD, MPH, Kathleen Graham, PharmD	Sharon Mannheimer, MD, Wafaa El-Sadr, MD, MPH	Brian Edlin, MD
Lead Evaluator		Evaluation Consultant (TBH)			Sally Findlay, PhD, Evaluator - CSPH	
#/type service delivery sites	1/Moore Clinic (Hospital-based HIV specialty clinic serving 2300-2500 patients)	1/Mission Neighborhood Health Center's Clinica Esperanza (Community-health center based HIV clinic serving 328 patients)	2+/Chase Brexton Health Services (Community-health center HIV clinic, 800 patients) + satellite clinic + Mobile Pyschiatric Case Management	5/NBHD, a four-hospital healthcare system serving 3,100 HIV patients, comprising Comprehensive Care Center (1700 HIV patients), Children's Diagnosic and Treatment Center (600), Pompano Adult Center (300), Mills Family Center (500), 7th Avenue Family Health Center (100), as well as an HIV Clinical Research Unit	3/Harlem Hospital Infectious Diseases Clinic (Hospital-based HIV clinic + two affiliated methadone maintenance programs) serving 800 HIV patients	1/Action Point Adherence Project, storefront facility, located in supported-living SRO (# of patients?)
#/type recruitment sites	1/same	1/same	2+/same + referrals from prisons, pre-release centers, and drug treatment centers + outreach at STD clinics, prisons	5/same	5/same + African Services Committee; St. Mary's Day Treatment Program	12+/multiple bidirectional referral agencies
setting	Mid-Atlantic, urban (Baltimore)	West Coast, urban (San Francisco's Mission District)	Mid-Atlantic, urban (Baltimore)	Southeast, urban (Broward County/Ft. Lauderdale)	Northeast, urban (Harlem and surrounding areas, New York)	Pacific, urban (Tenderloin/South of Market areas of San Francisco)
population	77% African-American, 29% female, 51% SA history, 37% pysch history, 74% <$10K, 85% unemployed, 22% unstable housing	65% Latino/Hispanic, 95% male, 75% MSM, 50% monolingual, 68% below poverty, 92% uninsured, 25% SA and/or pysch history	85% dual/triple diagnosis (70% SA history, 50% pysch history), 39% female, 37% uninsured	72% minority, 40% female, 75% below poverty level, 20% Medicaid	77% African-American, 14% Latino, 32% female, 35% SA history, 15% homeless	multiply diagnosed, 27% homeless or marginally housed (of whom 30% pysch history, 30% current IDU, 80% SA history, 75% previous incarceration), poor
INTERVENTION						
# intervention arms	4	1	1	3	2	1

	Johns Hopkins University School of Medicine	Mission Neighborhood Health Center	Chase Brexton Health Services, Inc.	North Broward Hospital District (NBHD)	Columbia University/Harlem Hospital Center	Action Point Adherence Project (UCSF Urban Health Study)
standard intervention	Standard Intervention (SI): intensive case management (ongoing), nurse education (x4)	SI=Medication Adherence Protocol (MAP): provider education, ongoing assessment, case management, frequent follow-up; MediSet pill boxes, Visual MediSet, nurse confirmation of prescriptions; Adherence Protocol 1. Patient meeting with Medical Provider, initial readiness assessment (how?), prescriptions; 2. Patient meets with case manager, adminsters MAP Assessment Tool, develops treatment plan; 3. Follow-up meeting with case manager, entitlement enrollment, psychosocial support; 4. Meeting with Nurse or Treatment Advocate, recieves Mediset Timer, schedules follow-ups, med education; 5. One-week follow up with Medical Provider to assess adherence issues, side effects, CBC; 6 Four-week follow-up with Case Manager to assess adherence issues, CBC/VL;	SI=Comprehensive Adherence Protocol: 1. Client HAART preparedness program to reduce patient barriers; 2. Screening for substance abuse and depression; 3. Adherence education and support services; 4. Individual Adherence coordinator Adherence Protocol 1. Initial Visit: Case Management Intake Pyschosocial Assesement, to address urgent needs; Adherence Coordinator provides basic HIV and HIV adherence education; Case Manager (Addictions Counselor) screens patients for substance abuse (including urine sample among random 50%) and depression; 2. 1st Medical Visit: Medical Provider assesses HIV history, conducts HIV workup, refers non-adherent patients to Outreach Workers, as indicated; Case Manager initiates Substance Abuse and Mental Health Services and Referrals, as indicated; Dietician consult; Nursing Visit; Adherence Coordinator consult; 3. First Follow-up visit: Medical Provider develops treatment plan; Case Manager follow-up; Nursing	Standard intervention (SI): 1) physician education; 2) treatment plan; 3) multilingual pamphlets;	SI=Current Clinical Practice (CCP): patient education, support groups (e.g. Harm Reduction), frequent follow-up visits, social work, incentives (transportation), feedback on effectiveness of therapy,	SI=Individualized Adherence Plan (IAP), with optional components: dedicated staff; daily med discpensing or weekly visits w/Mediset filling; emergency prescription supplies; patient education (Medical provider, pharmacist); patient/staff contract w/goals; drug treatment, pysch treatment, medical care; practice regimen (using candy or gel-caps); acupuncture; hot meals or food delivery; case management; cash incentives; pager reminder system; weekly follow-up visits
enhanced intervention	SI+ peer advocate support (ongoing) and/or SI+ group education/support (x7)	n/a	n/a	1) Provider Enhanced Intervention (PEI): SI + pharmacist counseling (x2-3); meds adjustment (lifestyle and side effects); calendars, pill boxes, pagers; video/audio tapes or 2) Home-Based Intervention (HBI): SI + PEI + pharmacist home visits (x1-2), day calendars, HIV med delivery, discarding of out-of-date meds, caretaker instruction	SI+ 1) Peer-centered social support; and, 2) assistance in overcoming adherence barriers, tailored to meet individual clients' "stages of behavior change" (consistent with Transtheoretical Model of Change), including case management, appointment reminders, appointment escorts, rewards, and/or social activities	n/a
duration of intervention	12 months	16 months	24 months?	12 months	12 months	24 months

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Providers involved	Medical providers; Case Managers; Nurses; Peers; Pharmacists	Medical Providers; Nurses; Case Managers; Peers (Treatment Advocate)	Case Managers; Adherence Specialist (different?); Medical Providers; Nurses; Mental Health Providers; SA Providers; Peers; Outreach; Nutritionists; Pharmacists;	Medical providers; Nurses; Research staff; Pharmacists; Social workers	Medical providers Nurses; Case managers; Peers; Social workers	Medical providers; Nurses; Social workers; Case managers; Pharmacists
Adherence Intervention Quality Assurance Methods		MAP protocol is reiterated by multiple staff; readiness is assessed by multiple staff; nurse checks prescriptions; regular chart reviews to ensure documentation, protocol compliance; weekly meetings of evaluation team	Monitoring of client "no show" rates			APAP Medical Director reviews new patients charts; periodic random chart review; weekly supervision meetings;
incentive	$5 x 2 interviews			stipend (unspecified)	transportation support	$10/visit/week, $5 adherence assessment, $15 interview
EVALUATION						
n (evaluation)	600 (400 + 200 matched controls from clinic population)	168	Total? 500 current, 150/year new (for 24 months? Total 300 new?)	Quantitative Study: 600 (3 x 200/arm) (NOTE: proposal assumes 25% LTF, 150 evaluable patients/arm) Qualitative Study: 250 (5 clinics x 50 patients), oversampling for Hispanics (nested?)	260 (130 intervention, 130 control)	150 (100 currently in treatment, 50 treatment-naive)
Study design	prospective enrollment; randomized among 4 arms; pre- post-intervention study; matched controls (CD4, HAART use, missed clinic visits)	enrollment (prospective or cross-sectional?); observational study; (proposal suggests that number of clients who do not participate in MAP will be tracked, and that qualitative reasons for non-participation will be recorded)	Quantitative Study prospective enrollment--new; cross-sectional enrollment--current; observational study; Qualitative Study cross-sectional enrollment; stratified by adherence (low/high) and substance use history	Quantitative Study: prospective enrollment (HAART-naïve patients); cross-sectional enrollment (changing HAART regimen); block randomized into 3 arms; pre- post-intervention study; NOTE: Are patients who are currently taking HAART (and currently receiving enhanced interventions) randomized among 3 study arms? Qualitative Study: (nested or separate cohort?): cross-sectional enrollment; observational study	prospective enrollment (HAART-naïve patients); cross-sectional enrollment (current HAART recipients); randomized; controlled; pre - post-intervention study; longitudinal follow-up;	prospective enrollment (?); pre- post-intervention study; comparison group = from REACH cohort (matching criteria are not specified)

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Evaluation Goals	1) Among Moore Clinic patients, is Project LINK participation associated with greater HAART utilization? 2) Among Moore Clinic patients prescribed HAART, is Project LINK participation associated with greater HAART adherence? 3) Among Project LINK participants, is participation in any of four intervention groups associated with greater HAART adherence? 4) Among Moore Clinic patients, is Project LINK participation associated with improved health outcomes (CD4, VL, progression, mortality)? 5) Among Project LINK participants, what are patient characteristics associated with good/poor adherence?	1) Among Clinica Esperanza patients, is MAP participation associated with HAART adherence? 2) Among MAP participants, determine variables associated with good/poor adherence.	1. Evaluate effectiveness of Comprehensive Adherence Program to improve adherence, service utilization, medical outcomes, and client satisfaction among CBHS patients at high-risk for non-adherence; 2. Determine the degree to which adherence is associated with: substance abuse and utilization of addictions counseling; depression and utilization of mental health services; knowledge of HIV and the consequences of non-adherence; and, participation in individual adherence program components; various client characteristics; 3. Determine the degree to which perceived barriers to adherence are associated with program participation;	1. Among NBHD patients, evaluate effectiveness of two enhanced medication adherence interventions, compared to each other, and to standard intervention 2. Among NBHD patients, determine patient factors associated with good/poor adherence. 3. Among NBHD patients, determine system factors associated with good/poor patient adherence.	1) Evaluate the validity, acceptability, and feasability of a touch-screen interview instrument to assess adherence rates, compared to self-report interview; 2) Identify specific elements of peer interaction that influence adherence; NOTE: Is efficacy of adherence intervention evaluated in this study?	1. Is APAP participation associated with HAART utilization? 2. Among APAP participants on HAART, is APAP participation associated with adherence? 3. Is APAP participation associated with improved health outcomes? NOTE: comparison group?
Research Protocol	1. LINK-eligible Clinic patients referred (daily); evaluation-eligible patients (HAART-naive) referred to evaluation interviewer; 2. Evaluation is explained; informed consent obtained 3. Baseline interview 4. Enrolled patients randomized to 1 of 4 intervention groups 5. Intake assessment (questionnaire), care plan developed 6. Patients interviewed (every 3 months) 7. At 12 months, Close-out assessment (questionnaire)	1. Six-week follow up with Medical Provider to evaluate adherence, side effects, and to review CBC/VL. 2. Four, eight, twelve, and sixteen month follow up visit to evaluate adherence. 3. Provider satisfaction assessed. 4. Client satisfaction assessed.	1. Psychosocial surveys are administered every 6 months. 2. Data are abstracted from patient charts to assess adherence. 3. Pharmacy records are assessed to evaluate adherence. 4. Clinic visits assessed to evaluate adherence. 5. Structured interview every six months to assess adherence, barriers 6. In-depth interviews with patients to assess patient/provider relationship, adherence barriers. 7. Focus Groups with patients to assess patient/provider relationship, adherence barriers.	1. Physicians, nurses, research staff will identify prospective participants. 2. Evaluation staff will discuss protocol, obtain informed consent. 3. Patients stratified by disease stage and block randomized to one of three interventions. 4. Patients are interviewed at 0, 3, 6, and 12 months. 5. Patient knowledge questionnaire administered at 6, 9, 12 (?) months. 6. Qualitative interviews (patients and providers) to assess barriers	1. Potential participants are randomly selected from Clinic rosters, or are provider- or self-referred; 2. Potential participants are assessed by project personnel (?). 3. Informed consent. 4. TMC-based stage of behavior change questionnaire is administered. 5. Patients are randomized to standard or enhanced intervention, stratified by stage of behavior change. 6. Enhanced interventions are adapted for patients based upon stage of behavior change. 7. Adherence is assessed through self-report interview, peer and provider assessment, VL, HIV genotype, and clinic visits. 8. Provider(Peer)/patient relationship assessed through in-depth patient and peer interview, focus groups, and observation of support groups	1. APAP enrollees who return for second visit and develop an IAP will be offered study participation; 2. Study explained by nurse or adherence case manager, informed consent; 3. Weekly follow-up visits; 4. Monthly brief adherence assessment; 5. Quarterly bloodwork (non-diagnostic) and interview

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Assessment interval	Antiretroviral use, adherence: 0, 3, 6, 9, 12 Patient Satisfaction: 6, 12 (?) months Provider Satisfaction: 6 (?) months HIV antiretroviral knowledge: 0, 12 (?) or 0, 6, 12 VL, CD4: 0, 3, 6, 9, 12 Chart review, administrative database: monthly	Adherence + Medication Adherence Protocol compliance: 6 weeks (?), 4, 8, 12, 16 months Provider Satisfaction: 12, 24 months Client Satisfaction: frequency? NOTE: no baseline(?)	VL: 0, 4, 8, 12, 16, 22, 24 CD4: 0, 6, 12, 18, 24 Patient Satisfaction: 0, 12, 24 Adherence, psychosocial assessment: 0, 6, 12, 18, 24 In-depth client interviews: 0, 6, 12, 18, 24 Focus Groups: 0, 12, 24	Interview: 0, 3, 6, 12 Chart reviews (qualitative study): 7-22 VL, CD4 abstraction: 12 Patient HIV/ART knowledge questionnaire: 6, 9, 12 (?) Provider interview x1: 7-31 In-depth (qualitative) interviews x1: 7-31	HIV genotypic resistance: 0, 12, 18 VL: 0, 3, 6, 9, 12, 18 Medical visit adherence: 0, 3, 6, 9, 12, 18 Self-reported adherence, Utilization: 0, 3, 6, 9, 12, 18 Stage of Change, Decisional Balance: 0, 3, 6, 9, 12, 18 Provider-reported adherence: 0, 3, 6, 9, 12, 18 Peer-reported adherence: 3, 6, 9, 12 Patient self-efficacy, life events, HIV knowledge and beliefs: 0, 6, 12, 18 (or monthly) Patient Substance Use, QOL, Depression: 0, 6, 12, 18 Patient satisfaction: 0-18 (monthly) Focus groups: (?) Peer satisfaction: 0-18 (monthly) Support group observation: 0-18 (monthly)	VL, CD4: 0, 3, 6, 9, 12, 15, 18, 21,24 Adherence (brief): 0-24 (monthly) Adherence (comprehensive): 0, 3, 6, 9, 12, 15, 18, 21, 24 Structured interview: 0, 3, 6, 9, 12, 15, 18, 21, 24 APAP services utilization: 0-24 (monthly) Healthcare utilization (chart review): 0, 6, 12, 18, 24 AIDS Registry search: 12, 24 MICRS (medical encounter database): 0, 6, 12, 18, 24
KEY VARIABLES						
descriptive	Demographics; Mental Health Status; SA status; Health Attitudes & Beliefs; Housing; Social support; Insurance;	variables (unspecified) that contribute to non-compliance or improved compliance;	Demographics; Mental Health Status; SA status; Health Attitudes and Beliefs; Patient/Provider relationship;	demographics; Mental Health Status; SA status; Health Attitudes & Beliefs; social support;	demographics; Mental Health Status; SA status; Health Attitudes & Beliefs; stage of change; Provider(Peer)/Patient relationship	demographics; Mental Health Status; SA status; Health Attitudes & Beliefs; Housing; Social support;
process	program utilization; provider satisfaction; SA/psych utilization;	program utilization;	prescriptions; medical utilization; program utilization;	prescriptions; System factors;	medical utilization;	program participation; SA/pysch utilization; provider satisfaction;

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outcome	HAART utilization; HAART characteristics; HAART adherence; patient satisfaction; health attitudes & beliefs; SA patients achieving abstinence; enrollment in benefit/entitlement programs; VL, CD4; disease progression; mortality	HAART adherence; patient satisfaction… "will be assessed through a structured interview with the Project Coordinator."	HAART adherence; VL, CD4; disease progression; Physical Health Status; Patient Satisfaction;	HAART adherence; patient satisfaction; VL, CD4;	HAART adherence; VL, CD4; Physical Health Status; Patient satisfaction; Correlation between touch-screen interview and VL, HIV genotypic resistance (?); Correlation between touch-screen interview and self-reported adherence	HAART utilization; HAART adherence; VL, CD4; disease progression; physical health status; mental health status; SA; housing; patient satisfaction;
Enrollment criteria	1) missed 40% of past 10 appointments or 40% of all appointments for 6 months or out-of-care for 6 months; 2) HAART-naïve (or ART-naïve?); 3) CD4<500 and/or VL >20,000; 4) >=17 years; 5) consent.	none specified	1) ART is medically indicated; 2) agree to participate	1) >=18 years; 2) HAART-naïve or changing HAART regimen; 3) informed consent; 4) willing to participate; 5) BCHD pharmacy client.	1) ART is medically indicated; 2) informed consent; 3) willing to participate;	1) HIV infected persons who enroll in APAP (two visits); 2) informed consent; 3) willing to participate
Adherence defined		95% of doses as prescribed	"To be determined, based upon comparison with other HRSA sites"	90% (or other level) of doses as prescribed	90% of doses as prescribed	>=90% of doses as prescribed
Adherence measured	self-report via touch screen, 3, 14, and 30 day recall	patient self-report; viral load ("Undetectable viral loads or viral load reduced by two logs after initiation of treatment will be surrogate markers of compliance"); pharmacy refill records (from ADAP, mechanism not specified)	Client self-report via interview; comparison of expected/actual pharmacy refill records; patient compliance with care plan; VL (e.g., undetectable VL for medical outcomes, 2-log reduction in VL for adherence); chart review	Patient self-report of general and medical adherence (3- and 7-day recall); behavorial (appointment keeping, prescription refills); pill counts, electronic monitoring (MEMS caps); biological (VL, CD4)	self-report interview, via touch screen; interviewer-administered self-report, 3 day recall; "one-page confidential self-reported adherence scale (?);" provider and peer worker assessment; VL; HIV genotypic resistance; behavioral (appointment keeping)	self-report (3 day recall) via brief interview (monthly); structured interview (quarterly); pill count
Existing instruments	**Project LINK Intake Form** (enhanced?); **LINK Clinical and Intervention Information form**; patient satisfaction survey (to be adapted); **Assessment of Current Drug Use**; **Assessment of Current Antiretroviral therapy**; **Project LINK Close-Out form** (enhanced?)	**MAP Assessment Tool** Medication Adherence Assessment Tool (TBD) MAP Data Recording (Data Tracking) Tool (TBD - different from above?) Self-administered Provider Satisfaction survey (TBD)	**Case Management Intake Psychosocial Assessment;** **Adherence Education and Follow-up Checklist;** **Medication Adherence form;** **ALIVE Medications Questionnaire;** **Alcohol Use Disorders Identification Test (AUDIT);** **Risk Behavior Assessment (RBA, drug-related section);** **Center for Epidemiological Studies Depression (CES-D) Scale;** **Short-Form 36 Health Survey;** **Patient Satisfaction surveys by Handler et al;** Client-satisfaction self-administered survey (same as above, or TBD?) **Barrera's support network questionnaire (modified);**	**Medication Compliance interview form;** **Center for Epidemiological Studies Depression (CES-D) Scale;** **Perceived Availability of Support interview form;**	**Stages of Change questionnaire;** **Self-report Adherence Questionnaire (Chesney);** **Decisional Balance Questionnaire;** **Self-efficacy Questionnaire;** **Baseline Client Interview;** **Follow-up Demographics Questionnaire;** **Addiction Severity Index Substance Use Questionnaire;** **HIV Knowledge and Attitudes Questionnaire;** **Health Utilization Questionnaire;** **Rapid Assessment of Adult Literacy in Medicine (REALM);**	(None are included with proposal) **Medical Outcomes Study Short Form (SF-36);** **Diagnostic Interview Schedule (DIS-III-R);** **Patient Satisfaction questionnaire (REACH study);** Brief adherence assessment instrument (TBD?) In-depth interview (TBD?)
Existing relational databases (client level)	Moore Clinic Database (3000 patients; 10,000 person/years; longitudinal demographic, clinical, laboratory, therapeutic, and outcomes)		Client visit database (?); Pharmacy records database;	Pharmacy records database;	none specified	SFAF computerized information system; REGGIE (citywide) system; MICRS (medical encounter database)

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Data collection methods	structured interviews; chart review; administrative database;	chart review; structured interviews	chart review; structured interview; administrative databases (pharmacy records, medical visit records); participant observation; in-depth interviews; focus groups	chart reviews; administrative databases (medical visits, pharmacy records); structured interviews; in-depth (qualitative) interviews	structured interviews; in-depth interviews; focus groups; chart review; administrative databases (medical visits); observation (support groups);	chart review; structured interview; administrative databases (Medical encounters, program participation), vital statistics database;
Length of intervention + post-intervention followup	12 months + 0	16 months + 0	24 months + 0	12 months + 0	12 months + 6 months	24 months (or 3 months + 21 months) (NOTE: proposal suggests that intervention will be evaluated at 3 months, then followed for 18 months to assess duration of effect, but interventions continue during follow-up period.)
Duration of new client enrollment	17 months (6-22)	28 months (3-30) NOTE: Intervention is 16 months	24 months (?)	enrollment period is not specified	enrollment period is not specified	24 months (1-24? "100 during year 1, 50 during year 2")
Analysis plan	? -- see pp. 49-51	?-- see pp. 28-30	? -- see page 43	? -- see pages 36-38	? -- see page 47	? -- see page 55
KEY	<u>Study Design Variables</u> PROSPECTIVE ENROLLMENT: study enrollees have not yet received study intervention and are assessed at baseline; CROSS-SECTIONAL ENROLLMENT: participants are recruited from among those who are currently receiving or have previously received the study intervention; RANDOMIZED: participants are randomly assigned among enhanced intervention and control study intervention arms; LONGITUDINAL FOLLOW-UP: participants are evaluated for a period of time following the conclusion of the intervention; PRE- POST-INTERVENTION STUDY: participants are evaluated before and after receiving the study intervention; CONTROLLED: a group of study participants that does not receive the study intervention; MATCHED CONTROLS: the control group is comprised of individuals matched to study participants according to identified criteria	<u>Descriptive Variables</u> DEMOGRAPHICS: race, gender, sexual preference, age, education, country of birth, religion, literacy, language of choice, and/or income; MENTAL HEALTH STATUS: current depression, pysch diagnosis, and/or psych history; SOCIAL SUPPORT: presence of caretaker, caretaking responsibilities, HOUSING; INSURANCE; HEALTH ATTITUDES & BELIEFS: medication self-efficacy, HIV knowledge, and/or ART knowledge; SA STATUS: current substance use and/or substance abuse history SYSTEM FACTORS: waiting time, staffing ratios, hours of operation, telephone reminders, patient perceptions of providers, appointment convenience PATIENT/PROVIDER RELATIONSHIP: trust, rapport, communication, empathy, respect,	<u>Process Variables</u> PROGRAM UTILIZATION: Adherence intervention enrollment, retention, participation rates, completion rates, and/or duration of participation; PROVIDER SATISFACTION: with adherence intervention SA/PYSCH UTILIZATION: SA referrals, SA treatment, pysch referrals, and/or pysch treatment; PRESCRIPTIONS: expected v. actual prescription refills, refill rates; MEDICAL UTILIZATION: healthcare utilization, clinic show rate, ER visits, nursing visits, outside referrals (other than SA/pysch), and/or case management visits; COST: adherence intervention cost and/or healthcare cost;	<u>Outcome Variables</u> HAART UTILIZATION: proportion of patients for whom HAART is indicated who initiate and/or receive HAART; HAART CHARACTERISTICS: patient characteristics associated with receiving HAART; HAART ADHERENCE; VL, CD4: viral suppression, viral load trend, viral resistance, viral staging, CD4 trend, and/or CD4 staging ADHERENCE CHARACTERISTICS: patient and/or system characteristics associated with good/poor adherence PATIENT SATISFACTION: with adherence intervention and/or healthcare; HEALTH ATTITUDES & BELIEFS: medication self-efficacy, HIV knowledge, and/or ART knowledge; PHYSICAL HEALTH: physical health perception, comfort level, Karnofsky score, and/or QOL; MENTAL HEALTH: depression, psych diagnosis; SA: substance abuse, recovery relapse; HOUSING; DISEASE PROGRESSION: symptoms, opportunistic infections, and/or AIDS, ;	<u>Providers</u> MEDICAL PROVIDER: HIV specialist, physician; ADHERENCE SPECIALIST: intervention specialist, adherence coordinator, care coordinator CASE MANAGER: case manager, intensive case manager; NURSE: nurse, nurse educator; SA PROVIDER: addictions counselor, SA treatment provider; MENTAL HEALTH PROVIDER: mental health provider, counselor, wellness counselor, chaplain; NUTRITIONIST: nutritionist, dietician, lipids specialist; OUTREACH; PEER: peer advocate, treatment advocate, support groups, buddy; SOCIAL WORKER; RESEARCH: research staff	

	Dimock Community Health Center	**Washington University**	**AIDS Services Center, Inc.**	**Multnomah County Health Department (OR)**	**Columbia University School of Public Health**
ADMIN					
Principal Investigator	Steven Tierney, MD, Principal Investigator; Judith Steinberg, MD, Co-Principal Investigator; Ken Freedberg, MD, Cost-effectiveness Principal Investigator	Linda Mundy, MD	Barbara Hanna, MD	Barbara Glick, PhD	Nancy VanDevanter, DrPH
Lead Evaluator	Jeanne Day, MPH, Evaluation Team Leader - JSI	Cynthia Willey-Lessne, PhD, Evaluation and Design Consultant;	Jacksonville State University (JSU), evaluation team (TBH)		Cheryl Merzel, DrPH
#/type service delivery sites	2/Dimock Community Health Center (DCHC), serving 200 patients w/HIV; and East Boston Neighborhood Health Center (EBNHC), serving 100 patients w/HIV	1/Helena Hatch Special Care Center (HHSCC), University medical school-based health clinic, serving 248 adolescent and adult women with HIV	3+/AIDS Services Center, all-volunteer medical clinic serving 250 patients w/HIV + 2 satellites, plus Department of Health sites for DOT	1/Multnomah County HIV/AIDS Health Services Center (HHSC), public health department clinic serving 546 patients with HIV	6/Northern Manhattan Women and Children HIV Project (NMWCHP), multi-organization consortium with six clinics serving 1,356 patients with HIV (including 783 children); Control group will be recruited from Brooklyn Pediatric AIDS Network, multi-organization consortium serving 900 patients with HIV
#/type recruitment sites	2/same	1/same	3/same	1/same	/same + additional consortium members?
setting	Northeast, urban (Boston: DCHC serves the Roxbury, North Dorchester, Jamaica Plain, and Mattapan areas; EBNHC serves East Boston, Chelsea, Revere, and Winthrop)	Midwest, urban (St. Louis) and suburban/rural (Southeast Missouri)	South, rural (fourteen counties in Northeast Alabama)	Northwest, urban and suburban (six counties in OR and WA comprising Portland EMA)	Northeast, urban (Washington Heights, East and Central Harlem neighborhoods in New York City)
population	DCHC: 70% African-American, 15% Latino, 40% female; 51% IDU, 30% heterosexual;75% pysch history; 30% below poverty. EBNHC: 27% Latino, 44% female, 39% immigrants (Southeast Asian, Central/South American, Brazilian, North African, East European); 41% IDU, 35% heterosexual; 61% SA history, 71% mental health history; 16% below poverty.	100% female, 77% African-American, 92% single, 66% unemployed, 23% SA diagnosis, 25% pysch diagnosis, 33% unstable housing, 55% w/children <18	53% African-American, 25% female, impoverished (50% w/o steady income, 17% disability income, 44% w/telephones, 28% w/cars), 12% insured, 20% Medicare; 80% SA history;	45% SA history; 60% pysch history; 9% homeless;	51% African-American, 43% Latino, 23% infants (0-2), 35% children (2-12), 92% female (of adolescents, adults);
INTERVENTION					
# intervention arms	2	2	3	1	2

	Dimock Community Health Center	Washington University	AIDS Services Center, Inc.	Multnomah County Health Department (OR)	Columbia University School of Public Health
standard intervention	Standard Intervention (SI): multidisciplinary care (coordinated by an HIV Nurse Care Coordinator x 1-4 visits), HIV specialty care x 1-2 visits, literacy-leveled educational materials, weekly peer counseling (4-6 months), programmable watch, tailored interventions.	SI="usual care" (informal adherence support) -- ??? proposal suggests that "usual care" will comprise control, but also states that all clients receive Take Charge interventions	n/a (SI is not used as control; everybody gets one of three enhanced interventions) Standard Intervention (SI): provider education; counseling, encouragement; pill boxes, pill counts, med pickup monitoring; educational video, brochures; contract for non-adherent clients	Multidisciplinary HAART Adherence Assistance Program: health counseling w/clinical pharmacist (x4 pre-HAART, ongoing post-HAART), tailored regimens and treatment plan, special med packaging (designed for homeless), Spanish-language educational materials, pill boxes and alarms, daily calendar, Adherence Protocol 1. New clients are evaluated for current health status, need for special services; 2. 2x45 minute counseling sessions with clinical pharmacist; referrals as needed 3. HAART is or is not prescribed (if not, repeat step 1); referrals as needed 4. 2x45 minute counseling sessions with clinical pharmacist; referrals as needed 5. Worksheet for HAART is completed; HAART regimen is selected and recommended to medical provider; 6. Treatment Plan 7. 10-14 day follow-up visit with clinical pharmacist or medical provider; regimen adjustment as	Standard Intervention (SI): "the ordinary activities a provider engages in to assist clients with medication taking." ???
enhanced intervention	SI + HIV home care nurse visits, 1-2/week x 4-6 weeks	SI+Take Charge ADHERE Program: Assessment (ART indication, readiness, lifestyle) Tailored drug regimen; educational materials; nurse counseling; practice regimen (using candy); multiset pill boxes; pager/reminders; check-off charts; peer support (optional); social work/case management; chaplaincy support; reminder system; feedback on effectiveness of therapy; rewards (notes, flowers, hugs); monthly in-person or phone followup;	Intervention 1: SI+ daily in-person or telephone buddy (trained friend, family member, co-client, volunteer) or buddy team (trained church care team or other) contact Intervention 2: SI+ directly-observed therapy (once daily, 5 days/week); Intervention 3: SI+ monthly meeting with clinic adherence panel; monthly assessment; 30-day adherence plan;	n/a	SI+ Northern Manhattan Adherence Project (NMAP): optional interventions tailored to client's stage of change -- provider education; support groups, peer counseling, art therapy, therapeutic exercises, role-playing; videos, CD-ROM's, theatre; permanency planning, partner notification; practice regimens; treatment plans; home-delivered services; beepers, colored pill vessels; emergency meds; regimen adjustment; special formulations and interventions for children; caretaker support and counseling; rewards, social activities; treatment feedback; ??? q3 months, or interim referrals?
duration of intervention	6 weeks (enhanced intervention)	12 months	6 months	12 months	12 months

	Dimock Community Health Center	Washington University	AIDS Services Center, Inc.	Multnomah County Health Department (OR)	Columbia University School of Public Health
Providers involved	Medical provider; Adherence specialist; Nurses; Social workers; Case managers; Peers; Mental health provider; Nutritionist	Medical provider; Nurses; Social workers; Case managers; Pharmacists; Peers	Medical providers; Mental health providers; Nurses; Case managers; Peers	Medical providers; Pharmacists; Nurses; Mental Health Providers; Nutritionists; Social workers; Interpreters	Adherence Specialists; Interdisciplinary team (members are not specified)
Adherence Intervention Quality Assurance Methods	HIV specialist and HIV Nurse Care Coordinator visits are standardized through strict protocols; peer buddies are supervised by HIV mental health provider; clinic and evaluation staff training; direct observation (interventions)	staff training by TMC consultant;			Data quality monitored by evaluation team; scannable forms are inspected for completeness and consistency; project database is printed annually and returned to sites for accuracy review
incentive	$20 gift certificate for Stop & Shop (for all interviews or only baseline?)	lottery tickets for returned Multiset boxes;	1) telephone service, social events, food vouchers 2) unspecified incentives; 3) ?	$10/self-report survey; $15/ethnographic interview	none specified
EVALUATION					
n (evaluation)	120 (60 standard, 60 enhanced intervention)	140 + 22 control (delayed intervention) ???: proposal states different n's: 248 (p. 38), 184 (p. 48), 140 (p. 41),	160 (1=30; 2=20; 3=110); Of 250 clients, 40 are projected to be already adherent, 50 are non-HAART	280 (140 current, 140 new) 80 (qualitative study); LTF estimated at 10%; Patients for whom HAART is not indicated will be excluded from data analysis;	Quantitative Study 500 (250 each in intervention and control groups, including 190 HIV+ and HIV- caregivers, 25 HIV+ adolescents, and 35 HIV+ pregnant women) 20% LTF is estimated. Qualitative Study 50 (25 intervention, 25 control) stratified by adherence and population (caregiver, adolescent, pregnant women), 20 clinicians and 5 intervention specialists ?? provider/patient dyads
Study design	cross-sectional baseline analysis; prospective enrollment; randomized; pre- post-intervention study; longitudinal follow-up;	cross-sectional enrollment; non-randomized; pre-post intervention study; comparison group = geographically distinct, delayed intervention group	cross-sectional baseline analysis (n=200); prospective enrollment; non-randomized (patient choice); pre- post-intervention study; longitudinal follow-up (intervention stops?);	Quantitative Study: cross-sectional enrollment (current); prospective enrollment (new); observational study; Qualitative Study: random, cross-sectional enrollment (20 from each of 4 groups: 1) refuse HAART; 2) non-adherent; 3) inconsistently adherent; 4) adherent	prospective enrollment (pre-intervention?); non-randomized; pre- post-intervention study; matched control group (geographically distinct, but matched -- patients or cohort??? -- in terms of sociodemographics, illness??, HAART adherence??, and treatment setting);

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Evaluation Goals	1. Evaluate efficacy of enhance intervention, compared to standard intervention, to improve patient adherence. 2. Evaluate health outcomes (VL, CD4, QOL) associated with enhanced intervention, compared to standard intervention 3. Evaluate cost and cost-effectiveness of enhanced intervention, compared to standard intervention 4. Identify barriers to adherence and effective approaches to improving adherence	1. Evaluate efficacy of Take Charge ADHERE intervention to improve adherence, compared to "usual care" 2. Evaluate association of Take Charge ADHERE intervention with sustained VL suppression 3. Identify determinants of adherence/non-adherence	1) Among ASC patients on HAART, is participation in one of three interventions associated with improved adherence? 2) Are three interventions feasible to administer among rural HIV population? 3) Identify factors (patient, intervention) associated with good/poor HAART adherence.	1) ??? Among HHSC patients, is HAAP participation associated with greater HAART utilization? 2) ??? Among HHSC patients on HAART, is HAAP participation associated with greater adherence? 3) Identify factors associated with good/poor adherence, and to non-adherence characteristics	1) Among adolescents, HIV+ pregnant women on HAART, does participation in NMAP result in greater HAART adherence, compared to patients receiving SI? 2) Among HIV+ or HIV- caregivers, does participation in NMAP result in greater HAART adherence (among children?), compared to clients receiving SI? 2) Identify factors (environmental, system, patient) associated with good/poor HAART adherence.
Research Protocol	1. Chart reviews of Non-HAART patients, to assess proportion of patients for whom HAART is indicated; 2. Baseline interviews for a) patients currently receiving HAART; b) patients initiating HAART; c) patients changing HAART regimen; to establish pre-study baseline (?) 3. study explained, informed consent 4. patients are block-randomized (1:1) to standard or intensive intervention, stratified for clinic site and VL (<50K, >50K) 5. Intentive intervention participants recieve 1-2 home visits over 4-6 weeks 6. Patients have interim clinic visits every 6 weeks, study visits every 3 months 7. Patients invited to participate in focus groups (3 x 2 clinics) 8. Provider satisfaction interviews at month 4; follow up survey at month 12 9. Patient satisfaction survey at month 12	1. Informed consent. 2. Baseline medical, behavioral data. 3. Patients have clinic visits every 4-6 weeks. 4. Self-report adherence interview at months 1, 2, 3, 4, 7, 10, 13 5. Focus groups (who? When?)	1. All patients (n=200) have baseline adherence assessment; 2. All patients (n=200) undergo 3 month adherence evalution; 3. Non-adherent (<90%) patients (n=160) are assigned to one of three interventions (patients choice); 4. 6 month intervention period, w/monthly adherence assessments 5. 6 month post-intervention follow-up	1. All new and current HAART Adherence program patients are enrolled. 2. Baseline interviews 3. Adherence assessed through semi-structured interview, chart review, and prescription refills quarterly pre-HAART, monthly during HAART 4. Patient satisfaction, Health Attitudes and Beliefs, provider/patient relationship assessed through self-report surveys (interviews) 5. Qualitative (ethnographic) in-depth interviews to assess patient refusal to initiate treatment or patient non-adherence, monthly.	1. Informed consent. 2. Baseline Stage of Change (of caregiver?), demographic interview. 3. Interventions, based on stage of change, delivered during regular clinic visits (q3 months); referrals as needed; 4. Stage of change, adherence assessments (of caregiver?) at 6 and 12 months; 5. Patient satisfaction, health attitudes & beliefs, provider/patient relationship assessed by in-depth client interviews x50; 6. In-depth provider and Intervention Specialist interviews to assess their self-efficacy, patient beliefs; 7. Qualitative system and clinical encounter observations;

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Assessment interval	Self-reported adherence: q 6 weeks VL: 0, 3, 6, 12 CD4: 3, 6, 12 Patient self-efficacy, life events, HIV knowledge and beliefs; 3, 12 Patient QOL, depression: 3, 12 Patient satisfaction: 3, 12 Provider satisfaction (interview): 4 Provider satisfaction (survey): 12 Substance Use: 0, 3, 6, 12 Service utilization: 0, 3, 6, 12	self reported adherence: 4, 7, 14, 21 days; 1, 2, 3, 4, 7, 10, 13 months stage-based readiness for HAART: 1, 2, 3, 4, 7, 10, 13 pill counts, prescription refills: 1, 2, 3, 4, 7, 10, 13 VL: 1, 2, 3, 4, 7, 10, 13	Adherence (self-report, MEMScaps, physician report): months 0-12 CD4, VL, genotype: 0, 6, 12 Patient Satisfaction: 1, 3, 6, 12 Buddy interviews: 1, 3, 6 Adherence panel interviews: 6	Adherence (self-report): months 0-12 Adherence (chart review, prescription refills): 3, 6, 9, 12 Patient Satisfaction, Health Attitudes & Beliefs: months 0-12 CD4, VL: 0, 3, 6, 9, 12 Semi-structured interviews: months 0-12 In-depth interview:	Adherence (self-report -- caregiver?): 0, 6, 12 Stage of change (of caregiver?): 0, 6, 12 CD4, VL (of children?): 0, 3, 6, 9, 12 In-depth interviews (patient -- includes caregivers?): In-depth interviews (provider and IS): Clinical encounter observations:
KEY VARIABLES					
descriptive	demographics; Mental Health Status; SA status; Health Attitudes & Beliefs; adherence "issues" (environmental obstacles, problem-solving, strategies)	demographics; Mental Health Status; SA status; Health Attitudes & Beliefs; Behavioral Stage of Change;	demographics; Mental Health Status; SA status; Health Attitudes & Beliefs; Housing; Social Support;	demographics; Mental Health Status; SA status; Health Attitudes & Beliefs;	demographics; Health Attitudes & Beliefs (of caregiver?); Housing; Insurance; Social support; system variables (transportation time, Behavioral stage of change (caregiver?); other variables collected as part of Title IV reporting requirements (unspecified); Provider attitudes (beliefs about clients, philosophy of patient care, self-efficacy, self-perceived practices)
process	medical utilization; cost; SA/pysch utilization;	medical utilization;	program utilization;	program utilization; medical utilization;	System factors: waiting time, hours of operation, staff training, language proficiency, availability of support services, treatment planning; other variables collected as part of Title IV reporting requirements (unspecified);

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outcome	HAART adherence (self-report and electronic monitoring); patient satisfaction; VL, CD4; Cost, cost-effectiveness	HAART adherence (self-report); VL, CD4; disease progression;	HAART adherence (self-report and electronic monitoring); patient satisfaction; VL, CD4; physical health status;	HAART utilization; HAART adherence; patient satisfaction; adherence characteristics (length of time to first non-adherence episode, point of time of greatest non-adherence risk, characteristics associated with non-adherence, circumstances surrounding non-adherence);	HAART adherence (self-report, of caregiver?); VL, CD4 (of children?); other variables collected as part of Title IV reporting requirements (unspecified);
Enrollment criteria	1) initiating HAART; 2) changing HAART regimen; or, 3) currently on HAART and non-adherent (missed >1 dose/previous month)	1) informed consent	1) current HAART recipient; 2) currently <90% adherent; 3) Intervention 2 participants must a) live near ASC or health department; and, b) take med regimen max 2 doses/day;	1) HAART is indicated;	1) HIV+ or HIV- caregiver, HIV+ adolescent, or HIV+ pregnant woman (HIV+ non-pregnant, non-caregiver women are excluded) 2) informed consent;
Adherence defined	90% of doses as prescribed	90% of doses as prescribed;	95% of doses as prescribed	medication taken as prescribed on 90% of days;	100% of doses as prescribed
Adherence measured	self-reported adherence, 3 day recall; percentage of doses taken, as recorded by electronic watch monitor	self reported adherence, 2 day recall; VL: undetectable weeks 12-56 multi-set pill boxes in combination with MEMS caps (reminder goes in the box); MEMS caps; Pill counts; Adherence motivation; Clinic visits;	self-reported adherence; physician-reported adherence; pill counts; MEMScaps; VL/CD4; HIV genotype	self-report interview; physician-report via chart review; pharmacy refills	self-report interview (of caregiver?);
Existing instruments	(None are included in proposal)	TMC motivation, decisional balance, and tempatation assessment; **Medication History;** **Rapid Assessment of Adult Literacy in Medicine (REALM);** Adherence interview;	Adherence questionnaire ("developed by pharmaceutical companies???");	Adherence interview (TBD); In-depth (ethnographic) interview (TBD); **Worksheet for HAART**;	**Client Qualitative Interview**; Adherence assessment interview (TBD); Standardized instrument to rate quality of planning process (TBD);
Existing relational databases (client level)	EBNHC has a relational database with patient demographics, utilization, case management, SA, mental health, QOL, funded through SPNS grant (future funding is unclear)	"Logician" computerized medical records database, including behavioral and clinical indicators and interventions			NWMCHP project database

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Data collection methods	chart review, self-administered surveys, "surprise" telephone assessments, focus groups, electronic monitoring (HealthWatch 100);	structured interview, survey questionnaires, MEMS caps, pillbox counts, self-reports, administrative database (medical visits, pharmacy records), focus groups	structured interview, survey questionnaires, MEMScaps, pillbox counts,	structured interview; semi-structured interview; in-depth interview,	chart reviews, structured interviews, administrative databases, observation, additional data from Title IV reporting instruments (unspecified)
Length of intervention + post-intervention followup	6 weeks + 10.5 months	12 months + 1?	6 months + 6	12 months + 0	12 months + 0
Duration of new client enrollment	36 months ("40 patients/year") (p. 26); but "study enrollment 8-11 weeks total" (p. 42)	Intervention Group: 9 months? Control Group: ?	Clients are "assigned" all at once (month 9)	12 months	12 months
Analysis plan	? -- see pp. 47-50	? -- see page 48	none specified	? -- see page 49	? -- see pp. 43
KEY					