Evidence Table 12. Trials of Case Management for Serious Chronic Infections

| **Author Year(Quality)** | **Study Purposeand/or*A Priori* Hypothesis (if stated)** | **Eligibility Criteria** | **Exclusion Criteria** | **Study Design/Type Duration of Intervention** | **Demographics:Age (Mean, Median and Range)Gender (% Female)Race and/or Ethnicity** **Socioeconomic Status** | **Primary Disease of Population****(and other medical comorbidities and/or coexisting mental illness)** | **Describe Factors of Complex care Needs** | **Payer/ Insurance Carrier** |
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| Hsieh 200840 (Fair) | To explore the efficacy of hospital-to-community level case management with DOTS to monitor the adherence of patients with pulmonary TB in Taiwan. Hypothesis: adherence, rate of completion, treatment success, sputum conversion, and chest X-ray improvement in experimental Group1 who received CM with DOTS would be significantlyimproved compared with experimental Group 2 and comparator group. | 18 years of age or older, no cognitive impairment, spoke Mandarin or Taiwanese, did not have atypical or extrapulmonaryTB, chronic hepatic or renal disease, and were willingto participate in the study for the entire 6 months. | Not specified | quasi-experimental design, using age and gender as matching factors, subjects were randomly assigned to one of threegroups; May 2002 to July 2003 | Mean age 68 years, 81% male, 80% lived with family or friends SES: NR (85% unemployed/ retired) | TB | Unclear (rate of TB medicine completion with DOT in Taiwan in 2001 was 74% according to authors) | NR |
| Husbands 200741 (Poor) | Among people living with HIV/AIDS, who and with what characteristics and circumstances, benefit most from case management vs. self-directed access to support services? Also what are the comparative costs to society?  | HIV+, > 16 years of age, new or current user of support services at the AIDS Committee of Toronto in Canada, able to understand spoken English themselves or with an interpreter, in touch with reality. | NR | Singled-blind randomized trialDuration 6 months | Age Mean 42.27 +/- 8.92 13% female; 1% transgender70% Caucasian/ white 84% spoke English89% > high school education | HIV/AIDS Comorbidities: 1) 73% depressed at baseline, mean CESD score of 28.4 (+13.1). 2) Means years since HIV/AIDS diagnosis 8.72 (+13.1) | 80% with annual income < $20K; 72% on disability10% worked full or part time51% lived alone | National Health Care Insurance (Canadian) |
| McCoy 199264 (Poor) | Is case management superior to one-timereferrals to services on demand as needed by HIV-positive IDUs? Will thecase-managed group receive higher numbers of services than the comparatorgroup? | HIV-seropositive IDUs who were involved in other studies at University ofMiami Comprehensive Drug Research Center  | NR | Randomized trial (Demonstration project)Duration: 1-year  | Age range: <25 (9%); 26-30 (22%), 31-35 (27%); 36-40 (29%), 41 (13%); 36% Female86% Black76% without regular employment | HIV+Comorbidities: NR | Low income IVDUs | South Florida AIDS Network (a program within the Public Health Trust of Dade County)  |
| Nickel 199679 (Poor) | To assess whether nurse case management, as compared to usual care, affects the QOL of AIDS patients on home care. | AIDS diagnosis; referred for home care to one of the seven participating agencies.  | < 21 years; those determined to be near death at the time of the CM first visit; refused home care. | Randomized trial Duration: 2.5 years (Jan 1990- June 1992) Note: Subjects followed throughout the course of home care or until project closure in August1992. | Age ranges: 20-29 (23%); 30-39 (53%); 40+ (24%)93% male79% white 63% were participating in Medicaid | AIDS Comorbidities: NR | NR | NR (63% were participating in Medicaid either at study entry or during followup)  |
| Nyamathi 200680 Nyamathi 200781(Fair) | 1) To compare the effects of an intervention program (conceptually based on ComprehensiveHealth Seeking and Coping Paradigm; Nyamathi, 1989), employing nurse case management against a comparator program with standard care on LTBI treatment completion in a homeless population, and 2) To compare the effectiveness of the two programs in improving TB knowledge over a 6-month treatment period. | Spent the previous night in one of the study’s homeless shelters; no self-reported history of completing TB prevention therapy; between the ages of 18 and 55, or >55 years of age, reported risk activation factors for active TB (diagnosis of immune compromising diseases or taking immunosuppressant medications), and willing to undergo further diagnostic testing at the John Wesley Community Health Medical Clinic at the Weingart Center LA. | Cognitive impairment (e.g., active hallucinations or stupor, refused chest x-ray, missed physical exam, excluded by PCP, refused DOT  | Randomized trial (conducted from 1998-2003)Duration= 6 months | Age mean (SD): 41.5 (8.5) 80% maleRace/ethnicity: Black (81%), Hispanic (9 %), White (7%) |  LTBI1) Comorbidities: NR | Homeless; 75% without health insurance | 10% Medicare |
| Sorensen 2003106 (Fair) | To address the question of the utility of CM in a population of substance abusers with HIV/AIDs. | Adults who met DSM-IV criteria for substance dependence, hadHIV infection as verified by their medical charts with CD4 > 50 in the last 6months, willing to provide informed consent and urine specimens. | Currently enrolledin substance abuse treatment or case management, diagnosed with medical conditions indicating they would likely be deceased within 6 months, nonresidentsof San Francisco, or in police custody. | Randomized trial Duration: 1 year  | Age: NR73% menRace: 43% African American, 7% Hispanic, 8% other/mixed ethnicity, 42% Caucasian7% employed | HIV+ Comorbidities: NR Coexisting mental illness: NR | Most with unstable living situations (e.g., homeless, living with friend/relative, halfway house, hotel/motel); substance abuse. | NR |
| Wohl 2006109; Sansom 2008110(Fair) | To evaluate the impact of a DAART program and IACM intervention onvirologic and immunologic response to HAART among patients at 3 public HIV clinics in Los Angeles County, California.  | Treatment-naïve and treatment-experienced persons for whom no more than 1 prior Cregimen had failed; MMSE score=23, live or work within the DAART workers’ catchment areas.  | Those with advanced liver or kidney disease, were receiving directly observed therapy for TB, or were participating in clinical trialsthat prohibited participation in an adherence-support program. | Randomized trialDuration: 6 months | 82% >30 years 75% Men 64% Latino; 24% were African American) 56% self-identified as heterosexual 73% Unemployed; 64% reported annual incomes of <$10,000  | HIV+ Comorbidities: NR | Challenges to HAART adherence (*authors note that adherence barriers were not assessed before randomization*) | LA County public-health HIV clinics |

| **Author Year(Quality)** | **Managed Care (Yes/No)** | **Characteristics of the Case Manager** | **Case Management Intervention** | **Preintervention Training** | **Primary Location of Case Manager** | **Primary Mode of Case Manager Contact with Patient** | **Caseload**  | **Frequency of Visits and Phone Calls** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hsieh 2008 40(Fair) | NR | NR |  Group 1: DOT under direct supervision of the case manager7 days/week for 2 months, self-administration after the second month with one unscheduled home visit per week by a casemanager; Group 2: self administered medicine with a monthly unscheduled home visit by a case manager. Both groups were offered clinical medical care and nursing instructionsaccording to the clinical pathway for TB during hospitalization. | NR | unclear  | in person | NR | Group 1: DOT daily times 2 months; weekly home visit times 6 months; Group 2: monthly home visit times 6 months |
| Husbands 200741 (Poor) | Yes, National Health Care Insurance (Canadian) | NR | Strengths-based model of CM where case manager works with the client to assess and prioritize the range and mix of their challenges and strengths in the areas of daily living, housing, finances, social supports, vocation, health, leisure or meaningful activity); The CM attempts to actively link the PLHAs with a range of services as needed.  | Manual used to train CM in of the strength-based model of case management.  | AIDS service organization | NR | NR | NR |
| McCoy 199264 (Poor) | No | Bachelor-level health educators with no social work training | 3 CMs with specific assigned caseload; CM model: needs identification through screening; regular, ongoing HIV prevention education; identified need for health and mental health care, social and economic services, and addiction treatment services; CM program used regular and frequent (every 2 weeks) monitoring of patients’ use of the above-identified services to determine access, compliance with treatment, and the reassessment of any needs or problems for treatment or intervention. | In-service training programs wereheld with CMs to familiarize them with the relationshipbetween drug addiction and HIV transmission and to demonstrate risk-reductioncounseling and behavioral skills, such as needle cleaning, for this population. | South Florida AIDS Network (a program within the Public Health Trust of Dade County)  | Unclear | 1:30 to 1:35 (CM: clients) | NR |
| Nickel 199679 (Poor) | No | Nurses specialized in HIV care | Direct services by the NCM and consultation to the agency nurse assigned to the patient; intervention protocol included: patient assessment, careplanning with monthly care review by an interdisciplinary team consisting of the NCMs, agency home care nurse and other specialists (e.g., infections disease, public health, social worker, clergy member); twice monthly review of subject needs by CM team and directed patient to community network for and authorization of services; ongoing case manager observation and monitoring of subject reports of service quality. | Training of the case manager *in study protocols* was conducted by thestudy investigators. | NR | Weekly phone calls, monthly visits.  | 1:12 or less | Weekly phone |
| Nyamathi 200680 Nyamathi 200781 (Fair) | No | CM included a research nurse (community-based nurse trained in thecare of homeless patients) and a trained outreach worker. | 8, 1-hour TB education sessions, by their nurse and outreach worker over the 24 weeks of treatment; provided with community resources; escorted to their medical and social service appointments; tracked by the outreach worker when they missed a DOT dose.Note: identical LTBI medical treatment, medical monitoring and incentives as the comparator group  | The research nurses and outreach workers received special training as extended care providers to ensure optimal skills in providing the intervention. | Unclear likely at the Weingart Center) | 8, 1-hour TB education sessions by their nurse and outreach worker over the 24 weeks of treatment; outreach worker tracked patients when they missed a DOT dose; escorted to their medical and social service appointments. | NR | 8, 1-hour TB education sessions by their nurse and outreach worker over the 24 weeks of treatment (otherwise number, length, and location of contacts not specified) |
| Sorenson 2003106 (Fair) | No | Paraprofessionals who were former consumers of HIV or substance abuse treatment services with a high school equivalency degree, certified chemical dependency counselors with a successful work history in treatment programs. | CM program was in place when the study began and included: service brokerage (advocating for client entry to programs) and counseling (continuingcontact with patients through a 1-year period); focused on linking patients with services; made appointments forevaluation and followup care and accompanied patients to appointments. | 1-week orientation to policies and procedures upon joining the CM program. Supervised by a licensed clinical social worker through direct observation, daily supervisory meetings, and weekly case presentations that were observed by the clinical social worker and a consulting psychiatrist. | CM program based out of a public teaching hospital. | Mode of overall contact: 57% calls; 43% visits | 1 per 20 | Phone calls and visits forthe year of treatment: 43.8 (SD = 50.3); median=30. *Seven participants had 100 or more activities. CMs provided 12 or fewer activities to about a fourth of the participants.* Total: 49% of activities (phone calls and visits) occurred in months 1–3, and 72% of activitiesoccurred in months 1–6. |
| Wohl 2006109; Sansom 2008110(Fair) | No | Described as "trained case manager" |  IACM patients self administered their HAART and met weekly for 6 months with a trained case manager to overcome barriers to HAART adherence while also engaging in traditional case-management activities including: referrals for health care payment issues, housing support, drug abuse treatment, legal services, and nutritional support. | NR | HIV clinic where participant received care | In-person clinic visits | NR | Scheduled to meet weekly for 6 months; *Average number of meetings with CM = 14* |

| **Author Year(Quality)** | **Location of Face: Face Time** | **Planning and Assessment** | **Patient Education** | **Self-Management Support** | **Coordination of Services**  | **Medical Monitoring and Adjustment** | **Integrated within Primary Care** | **Health IT** | **Describe Comparator** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hsieh 200840(Fair) | Group 1: DOT daily times 2 months; weekly home visit times 6 months; Group 2: monthly home visit times 6 months | CMs responsible for offering counseling, DOT, following up on the patient’s treatment status, and corresponding and communicating with public healthnurses. | Hospital clinic staff were responsible for providing health education information to subjects in Group 1 and 2 | "CMs responsible for offering counseling" | CMs responsible for offering counseling, DOT, following up on the patient’s treatment status, and corresponding and communicating with public healthnurses. | yes (see coordination of services) | hospital-based program | NR | Comparator group: routine hospital care withoutany additional intervention and a clinic followup visit with a case manager once per month |
| Husbands 200741 (Poor) | NR | "Case management records were developed for each client and served as evidence that strengths-based case management for each domain of life was indeed provided. Records included notes on intake, assessment and reassessment, service planning, coordination and referral, monitoring and followup and discharge and transition planning." | NR | NR | (See Planning and Assessment) | Both NR | No | NR | Usual care: Self-directed Use of Support Services Program which included psychosocial counseling, employment counseling, social support and support groups with or without practical assistance as needed (e.g. meals, furniture, good food box, buddies, drives to medical appointments, congregate dining, and referrals to other agencies). These services are provided if a PLHA asks; that is, services are provided on demand or at the request of the PLHA. |
| McCoy 199264(Poor) | NR | Occurred during intake (details not specified) | Educated patients about risk reduction strategies (average= 30 minutes) | NR | NR | NR; No adjustment | No | NR | The comparator group utilized the services of a bachelor-level, experienced social worker on staff at Comprehensive Drug Research Center who, on request and without a formalized needs assessment, during a brief intervention session, referred study participants to health and social services. |
| Nickel 199679 (Poor) | Monthly in-person visits | Yes | NR | NR | Yes | Yes, monitoring; no adjustment | Communication with PCP at least monthly  | NR | Usual care was provided by agency home care nurses who provided care toAIDS patients through procedures comparable tothose for patients with other diagnoses (e.g., needs assessment, care planning and revision, and delivery of care as needed). Included 24-hour on-call services.  |
|  Nyamathi 200680 Nyamathi 200781(Fair) | See previous cell | Unclear | 8, 1-hour TB education sessions by their nurse and outreach worker over the 24 weeks of treatment.  | Included 1) self esteem and attitudinal readiness for change; 2) TB and HIV risk reduction education; 3) coping, self management,and communication skills; 4) cognitive problem solvingto implement behavior change; and 5) positive relationships and social networks to maintain behavior change. | Provided with community resources and escorted medical and social service appointments. | LTBI treatment = twice weekly doses of 900 mg INH 50mg vitamin B6 over 6 months at a common medical clinic, monthly monitoring of side effects . Note: unlike comparator group, NCMI participants were tracked when they missed a DOT dose. | Those requesting assistance with non-TB health care problems were referred to the medical clinic located on site.  | NR | Standard of care included (received by both study groups) DOT at the research clinic twice a week over a period of 6 months administered by research nurses; a 10-min question and answer session regarding LTBI treatment before receiving the INH dose and time devoted to individualized needs, such as referral to treatments or services; a detailed directory of community resources and services of local agencies; $5 for each dose of INH received; referral on request to the medical clinic located on site; Comparator participants: received a single 20-min factual presentation on TB and the importance of being compliant with the LTBI treatment. |
| Sorenson 2003106(Fair) | Community (64%), hospital (16%), office (20%). | NR | Description of CM activities included risk reduction education | NR | 73% of programs contacted/ referrals made were defined as non-drug, 27% defined as drug. *Case managers focused on linking patients with services that included medical care, psychiatric treatment, legal assistance, and social service entitlements such as low-income housing and Supplemental Security Income (SSI).*  | No; No | No | NR | Brief contact with the department of psychiatry at SFGH provided brief contact and referral through ASAP. When ASAP workers (included both professionally trained individuals (e.g., social workers) and paraprofessionals (former consumers of substance abuse or HIV services)) received a referral from the research project, they met with the patient at the hospital program. They provided education about reducing the risk of HIV transmission, information about HIV services, and referrals to substance abuse treatment, social services, and HIV services in the community.  |
| Wohl 2006109; Sansom 2008110(Fair) | In person during clinic visit; A*verage meeting duration =30 minutes; Total time spent with CM = 7 hours.* | Yes (met weekly with CM to discuss) | Yes, regarding adherence to HAART  | Yes, support to adhere to HAART | Referrals for health care payment issues, housing support, drug abuse treatment, legal services, and nutritional support. | No; decisions were made by the medical staff in the clinics. | Yes | NR | Self-administered their HAART and continued to receive the services that were available to all clinicpatients, including quarterly contact with a case manager. DAART: received daily delivery of HAART, specially-trained, bilingual community worker observed the participant take 1 daily HAART dose. Community workers delivered evening, weekend, and holiday doses for self administration. At the next meeting, patients were queried about the self-administered doses, and empty packages were collected. Adherence problems were addressed by the community worker when possible, and participants were referred to the clinic staff when necessary. |

| **Author Year(Quality)** | **Results by Patient Health Outcomes** | **Results by Resource Utilization Outcomes** | **Results by Process Measure Outcomes**  | **Harms Reported** | **Number Screened/Eligible/ Enrolled** | **Number Withdrawn/Lost to followup/Analyzed (Overall)** | **Total** **Withdrawals; Withdrawals due to Adverse Events** | **Notes** |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| Hsieh 200840 (Fair) |  At 2 months, statistically significant difference in sputum conversion (87% vs. 75% vs. 53%) and CXR improvement rates (62% vs. 59% vs. 32%); treatment success rates were significantly better in Group 1 than in Group 2 or Comparator (94% vs. 69% vs. 69%); | NR | Statistically significant adherence rate differences among the three groups forthe third, fourth, fifth and sixth months (< 80% adherence ( range for 3rd through 6th months)): Group 1 (0-0%), Group 2 (13-22%), Comparator (19-28%); treatment completion rates were significantly better in Group 1 than in Group 2 or Comparator ( 97% vs. 69% vs. 69%) | NR | Screened: NR; eligible 114; enrolled 114; each group n=38 | 96 analyzed (32 in each group); (10 died, 8 not included because of the match procedure) | NR |   |
| Husbands 200741 (Poor) | 1) Depression: (CES-D scale scores divided into very depressed and less depressed)a) Mental Health Function Index Scores for very depressed (CM vs. usual care): 31% improvement vs. 1% deterioration (p=0.015)b) Social Function Index Scores for very depressed (CM vs. usual care): 45% improvement vs. 27% deterioration (p=0.001)c) Physical Health Summary Score (CM vs. usual care): 16% improvement vs. 7% deterioration (p=0.009)d) Mental Health Summary Score (CM vs. usual care: 30% improvement vs. usual care = 4% deterioration (p=<0.0001) | 1) Cost among the very depressed (CM vs. usual care): $17,901 vs. $20,839 (p=0.19)2) Among females (CM vs. usual care): $10,548 vs. $27,379 (p=NR) | NR | NR | 128 screened/ NR/ 99 enrolled  | Attrition and loss to followup (not differentiated) 20; completed 6-month followup = 79 (80%) | NR | 91% had used this AIDS service organization before; Those who completed the study (n=79) had, on average at baseline, a clinically significant 8-10 point higher (better) QOL score than those who did not complete the study (n=20). Unable to tell from data reported how many were randomized to each group/attrition rates from each group. |
| McCoy 199264 (Poor) | NR | NR | Number of services received (CM vs. comparator) 193 vs. 42 servicesChange in high risk behaviors:a) Number of different people with whom the study participant injected and had sex (fewer compared with baseline for CM/more compared with baseline for comparator); (p<0.01) | NR | Screened, eligible unclear; 100 enrolled in CM vs. 40 enrolled in usual care (randomization suspended "to fill case loads" and the reinstituted; project expired before number in comparator group could be equalized) | NR | NR |   |
| Nickel 199679 (Poor) | NSD in QOL or Quality of Well-Being between groups at 3 and 6 months  | NR | NR | NR | A total of 130 of the estimated 394 people with AIDS living in the catchment area (Columbus-Franklin County, Ohio) were referred for home care to one of the seven participating agencies at some time during the 2.5 years of the project. 45 were ineligible; 28 of the 85 eligible chose not to participate; 57 (67% of those eligible) enrolled (29 CM; 28 usual care)  | NR/NR/57 | NR | Duration of involvement in the interventionprotocols varied by individual, with suchevents as death (range: 5 to 815 days) |
| Nyamathi 200680 Nyamathi 200781(Fair) | NR | NR | 64% of NCM group completed LTBI treatment; 42% of comparator completed their LTBI treatment (OR 3.01 (CI 2.15-4.20); treatment completion was significantly associated with the NCM intervention (r=0.22, p<0.001; TB knowledge: At baseline, the mean knowledge scores were 7.3 and 7.6 for standard care and NCM groups, respectively (p>0.05). At followup, mean knowledge scores were 9.3 for standard care and 11.4 for NCM (p<0.001). |   | Screened 5442/ eligible 980 (PPD+); enrolled 520 (CM, n=278; comparator, n=242) | 5% overall lost to followup/followup data available for 494 | NR |   |
| Sorenson 2003106 (Fair) | The sex risk index was greater (i.e., more risk) for the brief contact group. NSD in substance use, HIV risk behaviors, physical and psychological status, quality of living situation.  | NSD were found in self-reporting of treatment services received.  | NR | NR | 371 screened; 281 eligible; 190 (68% of eligible) enrolled; randomized to either brief contact (n = 98)or CM (n = 92);  | A total of 160 participants (84% of total, 90% of living) were interviewed at 6 months, 150 (79% of total, 90% of living) at 12 months, and 151 (79% of total, 95% of living) at the 18-month followup.  | NR | The study occurred at San Francisco General Hospital, a public teaching hospital. Study recruitment occurred 1994–1996. Participants recruited from: inpatient medical wards (44%), outpatient heroin detox clinic (25%), and emergency department (22%); no other unit accounted for more than 4% of participants. |
| Wohl 2006109; Sansom 2008110(Fair) |  6 months: <400 copies/mL (NSD)1) DAART group, 54%2) IACM group, 60%3) Usual care group, 54% at 6 months: Co treatment analyses (NSD) of undetectable viral loads:1) 71% of the DAART patients2) 80% of the IACM patients3) 74% of the usual care undetectable viral loads at 6 months (P > .05). Note: NSD in viral load reduction, median CD4+ cell count, change in CD4+ cell count from baseline, or percentage of patients with a CD4+ cell counts <200 cells/mm3 or patients with new or recurrent opportunistic infections. | Study group vs. usual care: 1) IACM participants: 2.3 vs. 6.7 days/1000 person–days; incidence rate ratio [IRR]: 0.34, 97.5% CI 0.13–0.87, p<0.025; 2) DAART participants: 44.2 vs. 31.5/1000 person–days, IRR: 1.4; 97.5% CI 1.01–1.95) p<0.025. 3) Average participant health care utilization costs were $13,127, $8,988, and $14,416 for DAART, IACM, and SOC | At 6 months no missing dose:1) 97% DAART arm2) 92% IACM arm3) 97% Usual care AL6 | NR | 2797 screened; 416 (15%) eligible; 166 (40%) declined to participate; 250 enrolled: DAART arm (82), IACM arm (84), SOC arm (84);  | 78% (194/250) completed 6 months in the study, with equal rates of retention among the3 arms: DAART 79% (65/82), IACM 80% (67/84), SOC 74% (62/84); All were included in analysis of health outcomes. | NR | Recruited from3 public HIV clinics in Los Angeles County from November 2001 through March 2004; In addition to primary care services, the study clinics adherence support included provider adherence counseling at the time of clinic visits, meetings with a case manager every 3–4months, and access to community-based social support services, including adherence support provided by community based pharmacies and others.  |

Abbreviations: ASAP=AIDS and Substance Abuse Program, CI=confidence interval, CM=case management, DAART=directly administered antiretroviral therapy, DOT=directly observed therapy, HAART=highly active antiretroviral therapy, IDU=intravenous drug user, IACM=intensive adherence case management, LTBI=latent tuberculosis infection, NR=not reported, NSD=no significant difference, QOL=quality of life, SD=standard deviation, SES=socioeconomic status, TB=tuberculosis.