WHO/HIV/2013.132

HIV and adolescents: guidance for HIV testing and counselling and care for adolescents living with HIV

ANNEX 7: Evidence summaries and findings

PICO 1 - HTC

EVIDENCE SUMMARIES: RCTs

HIV testing and counselling for adolescents in generalised epidemic settings (randomised controlled trials)

Outcome: STI incidence (follow-up 6 months)

- In 1 trial (VCT 2000) with 6 months follow up, STI incidence decreased (non-statistically significant) among those individuals who received VCT compared to standard health information (OR 0.80, 95% CI 0.53 to 1.20). The quality of evidence is very low and was downgraded for indirectness due to an adult population and very serious imprecision (very small number of events).

Outcome: Survival at 6 months (follow-up 6 months)

- In 1 trial (Wanyenze 2011) with 6 months follow-up, fewer hospitalized HIV-positive adults who received VCT as inpatients were still alive, compared to HIV-positive patients referred for VCT post-discharge (RR 0.83, 95% CI 0.68 to 1.0). The quality of the evidence is very low. The evidence was downgraded for indirectness (adult population) and because the population were sick, hospitalized inpatients. The evidence was downgraded for imprecision due to few participants and events. Of note, 171/249 in the control group (VCT referral post discharge) and 3/251 in the inpatient intervention group were not tested for HIV.

Outcome: Attended HIV clinic (follow-up 6 months)

- In 1 trial (Wanyenze 2011) with six months follow-up, fewer HIV-positive patients in the control arm attended a HIV clinic compared to the intervention arm (RR 0.76, 95% CI 0.59 to 0.98). The quality of the evidence is very low. The evidence was downgraded as noted above.

Outcome: Uptake of pre-ARV care (follow-up 5 months)

- In 1 trial (Muhamadi 2011) with five months follow-up, uptake of pre-ARV care increased significantly in adult HIV-positive patients who received the intervention (enhanced post-test counseling by trained staff with combined with home visits by community support agents for extended counseling) compared to standard post-test counseling (RR 1.75, 95% CI 1.44 to 2.14). The quality of the evidence is low. The evidence was downgraded for indirectness (adult population) and for imprecision (few participants and events).

Outcome: Unprotected sex with non-primary partner (follow-up 6 months)

- In 1 trial (VCT 2000) with 6 months follow up, unprotected sexual intercourse with a non-primary partner was significantly decreased among both men (RR 0.74, 95% CI 0.6 to 0.91) and women (RR 0.72, 95% CI 0.56 to 0.93) who received VCT compared to those who received basic health information only. The quality of the evidence is very low. The evidence was downgraded twice for indirectness (adult population, self-reported outcomes), and for imprecision (few

participants and events).

Outcome: Sexual risk behaviour (follow-up 4 weeks)

- In 1 trial (Olley 2006) with 4 weeks follow up, the mean number of adults reporting sexual risk behavior was lower in participants attending four-session VCT, compared to those in the wait-list control group (MD 2.47 lower, 95% CI 3.17 to 1.77 lower) . The quality of the evidence is very low. The evidence quality was downgraded for study limitations (randomisation process unclear, allocation not concealed, not blinded), very serious indirectness (adult population, self-reported outcomes), and for very serious imprecision (very few events).

Outcome: Depression (follow-up 4 weeks)

- In 1 trial (Olley 2006) with 4 weeks follow up, the mean number of adults reporting depression was lower in participants attending four-session VCT, compared to those in the wait-list control group (MD 8.45 lower, 95% CI 9.44 to 7.46 lower) . The quality of the evidence is very low. The evidence quality was downgraded for study limitations (randomisation process unclear, allocation not concealed, not blinded), very serious indirectness (adult population, self-reported outcomes), and for very serious imprecision (very few events).

HIV testing and counselling for HIV adolescents in low-level epidemic settings (randomised controlled trials)

Outcome: STI incidence (follow-up 12 months)

- In 1 trial (Bolu 2004) with 12 months follow-up, STI incidence decreased in adolescent key populations in settings with a low-level epidemic undergoing HIV counselling vs. control (no counselling) (RR 0.65, 95% CI 0.49 to 0.86). The quality of evidence is low. The evidence was downgraded for significant study limitations, and for serious indirectness (counselling-only intervention).

Outcome: Attended STI clinic

- In 1 trial (Apoola 2011) with 1 week follow-up, attendance at STI clinic increased in adolescent key populations in settings with a low-level epidemic undergoing HIV testing vs. control (no testing) (RR 3, 95% CI 0.91 to 9.88). The quality of evidence is very low. The evidence was downgraded for significant study limitations, for very serious imprecision (very few participants/events), and for serious indirectness (testing-only intervention).

Outcome: Uptake of HIV, HBV, and HCV testing

- In 1 trial (Apoola 2011) with 1 week follow-up, uptake of HIV, HBV, and HCV testing increased in adolescent key populations in settings with a low-level epidemic undergoing HIV testing vs. control (RR 8.77, 95% CI 4.73 to 16.26). The quality of evidence is very low. The evidence was downgraded for significant study limitations, for very serious imprecision (very few participants and events), and for serious indirectness (testing-only intervention). Although the effect size was large, the quality of the evidence was not upgraded due to the significant study limitations and very few participants/events.

Outcome: Received all 3 doses of HAV and HBV vaccines

- In 1 trial (Apoola 2011) with 1 week follow-up, receipt of all 3 doses of HAV and HBV vaccines decreased in adolescent key populations in settings with a low-level epidemic undergoing HIV testing vs. control (RR 0.90, 95% CI 0.43 to 1.85). The quality of evidence is very low. The

evidence was downgraded for significant study limitations, for very serious imprecision (very few participants and events), and for serious indirectness (testing-only intervention).

EVIDENCE SUMMARIES: OBSERVATONAL STUDIES

HTC for HIV prevention and linkage to care among adols in generalised, concentrated and key population/low-level epidemic settings

Outcome: Linkage to care, generalised epidemic setting

- In one observational study (Naughton 2011) with 2-14 months follow-up, none (0%) of the 7 HIV-positive adolescents identified subsequently attended the clinic for care. There was no control group, and the relative effect was not calculable. The quality of the evidence is very low. The quality of evidence was downgraded for serious study design limitations (no comparator), and downgraded for very serious imprecision (very few participants/events).

Outcome: Linkage to care, key populations

- In one observational study (Gwadz 2010), 23/89 (26%) HIV-positive adolescents subsequently attended the clinic for care, vs 29/83 (35%) in the control group (RR 0.74 , 95% CI 0.47 to 1.17). The quality of the evidence is very low. The evidence was downgraded for serious indirectness (testing-only intervention) and very serious imprecision (very few events).

Outcome: Concurrent sexual partnership, men, generalised epidemic setting

- In one observational study (Kabiru 2010) with 6 months follow-up, significantly more men from the intervention group (had an HIV test in past 6 months) reported concurrent sexual partnerships compared to men in the control group (HR 3.18, 95% CI 1.51 to 6.72). Although the evidence was graded up for a strong association, the quality of the evidence is very low. The evidence was downgraded for very serious indirectness (adult population, patient self-report), and very serious imprecision (very few participants/events).

Outcome: Concurrent sexual partnership, ever pregnant women, generalised epidemic setting

- In one observational study (Kabiru 2010) with 6 months follow-up, more ever pregnant women) (non-statistically significant) from the intervention group (had an HIV test in past 6 months) reported concurrent sexual partnerships compared to women in the control group (HR 1.67, 95% CI 0.51 to 5.48). The quality of the evidence is very low. The evidence was downgraded for very serious indirectness (adult population, patient self-report), and very serious imprecision (very few participants/events).

Outcome: Concurrent sexual partnership, never pregnant women, generalised epidemic setting

- In one observational study (Kabiru 2010) with 6 months follow-up, fewer never pregnant women (non-statistically significant) from the intervention group(had an HIV test in past 6 months) reported concurrent sexual partnerships compared to women in the control group (HR 0.69, 95% CI 0.07 to 7.12). The quality of the evidence is very low. The evidence was downgraded for very serious indirectness (adult population, patient self-report), and very serious imprecision (very few participants/events).

Outcome: "Risky" sexual partner, men, generalised epidemic setting

- In one observational study (Kabiru 2010) with 6 months follow-up, more men (non-statistically significant) from the intervention group (had an HIV test in past 6 months) reported having had a "risky" sexual partner in the past 6 months, compared to men in the control group (HR 1.11,

95% CI 0.61 to 2.01). The quality of the evidence is very low. The evidence was downgraded for very serious indirectness (adult population, patient self-report), and very serious imprecision (very few participants/events).

Outcome: "Risky" sexual partner, ever pregnant women, generalised epidemic setting

- In one observational study (Kabiru 2010) with 6 months follow-up, more ever pregnant women (non-statistically significant) from the intervention group (had an HIV test in past 6 months) reported having had a "risky" sexual partner in the past 6 months, compared to women in the control group (HR 1.18, 95% CI 0.33 to 4.16). The quality of the evidence is very low. The evidence was downgraded for very serious indirectness (adult population, patient self-report), and very serious imprecision (very few participants/events).

Outcome: "Risky" sexual partner, never pregnant women, generalised epidemic setting

- In one observational study (Kabiru 2010) with 6 months follow-up, significantly more women from the intervention group (had an HIV test in past 6 months) reported having had a "risky" sexual partner in the past 6 months, compared to women in the control group (HR 3.54, 95% CI 1.48 to 8.45). Although the evidence was graded up for a strong association, the quality of the evidence is very low. The evidence was downgraded for very serious indirectness (adult population, patient self-report), and very serious imprecision (very few participants/events).

Outcome: Had unprotected sex in the past 6 months, men, generalised epidemic setting

- In one observational study (Kabiru 2010) with 6 months follow-up, fewer men from the intervention group (had an HIV test in past 6 months) (non-statistically significant) reported having had unprotected sex in the past 6 months, compared to men in the control group (HR 0.98, 95% CI 0.75 to 1.28). The quality of the evidence is very low. The evidence was downgraded for very serious indirectness (adult population, patient self-report), and very serious imprecision (very few participants/events).

Outcome: Had unprotected sex in the past 6 months, ever pregnant women, generalised epidemic setting

- In one observational study (Kabiru 2010) with 6 months follow-up, fewer women (non-statistically significant) from the intervention group (had an HIV test in past 6 months) reported having had unprotected sex in the past 6 months, compared to women in the control group (HR 0.59, 95% CI 0.47 to 0.75). The quality of the evidence is very low. The evidence was downgraded for very serious indirectness (adult population, patient self-report), and very serious imprecision (very few participants/events).

Outcome: Had unprotected sex in the past 6 months, never pregnant women, generalised epidemic setting

- In one observational study (Kabiru 2010) with 6 months follow-up, more women (non-statistically significant) from the intervention group (had an HIV test in past 6 months) reported having had unprotected sex in the past 6 months, compared to women in the control group (HR 1.64, 95% CI 0.94 to 2.83). The quality of the evidence is very low. The evidence was downgraded for very serious indirectness (adult population, patient self-report), and very serious imprecision (very few participants/events).

Outcome: Number of sexual partners (N=0-1), concentrated epidemic setting

- In one observational study (Müller 1995) with a median of 23 months follow-up, adolescents in the intervention group (after VCT) were significantly more likely to report having had fewer sexual partners in the past six months, compared to control (RR 1.82, 95% CI 1.53 to 2.15).

Although the evidence was graded up for a strong association, the quality of the evidence is very low. The evidence was downgraded for indirectness (patient self-report) and for serious imprecision (few participants/events).

Outcome: Condom use during the last 3 episodes of sexual intercourse, concentrated epidemic setting

- In one observational study (Müller 1995) with a median of 23 months follow-up, adolescents in the intervention group (after VCT) were significantly more likely to report condom use during the last 3 episodes of sexual intercourse, compared to control (RR 3.78, 95% CI 2.65 to 5.39). Although the evidence was graded up for a strong association, the quality of the evidence is very low. The evidence was downgraded for indirectness (patient self-report) and for serious imprecision (few participants/events).

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PICO 2 – Disclosure

References for PICOs 2-4 are found at the end of this annex.

What is the best way to help adolescents disclose HIV status?

CONTROLLED TRIALS - Adolescents

Outcome: Disclosed to sex partners at 15 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001a), adolescents participating in small group discussions were more likely to disclose their HIV status to sex partners (statistically non-significant), compared to those receiving standard care (RR 1.2, 95%

CI 0.79 to 1.6). The quality of evidence is very low. Evidence quality was graded down for risk of bias (non-randomised comparison between intervention attendees and controls), indirectness (study was conducted in the United States), and very serious imprecision (very few events).

Outcome: Number of missed appointments at 9 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001a), adolescents participating in small group discussions had more missed appointments, compared to those receiving standard care (MD 0.6 higher, 95% CI 0.18 to 1.02 higher). The quality of evidence is very low. Evidence quality was graded down for risk of bias (non-randomised comparison between intervention attendees and controls), serious indirectness (study was conducted in the United States), and very serious imprecision (very few events).

Outcome: Emotional distress mean score at 9 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001a), there was no difference in the mean emotional distress scores (statistically non-significant) of adolescents participating in small group discussions, compared to those receiving standard care (MD 0 higher, 95% CI 0.42 lower to 0.42 higher) The quality of evidence is very low. Evidence quality was graded down for risk of bias (non-randomised comparison between intervention attendees and controls), serious indirectness (study was conducted in the United States), and very serious imprecision (very few events).

Outcome: Emotional distress mean score at 15 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001a), there was no difference in the mean emotional distress scores (statistically non-significant) of adolescents participating in small group discussions, compared to those receiving standard care (MD 0 higher, 95% CI 0.42 lower to 0.42 higher) The quality of evidence is very low. Evidence quality was graded down for risk of bias (non-randomised comparison between intervention attendees and controls), serious indirectness (study was conducted in the United States), and very serious imprecision (very few events).

Outcome: Physical distress mean score at 15 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001a), there was no difference in the mean physical distress scores (statistically non-significant) of adolescents participating in small group discussions, compared to those receiving standard care (MD 0.1 lower, 95% CI 0.52 lower to 0.32 higher) The quality of evidence is very low. Evidence quality was graded down for risk of bias (non-randomised comparison between intervention attendees and controls), serious indirectness (study was conducted in the United States), and very serious imprecision (very few events).

Outcome: Unprotected sex at 15 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001a), adolescents participating in small group discussions were less likely to report unprotected sex, compared to those receiving standard care (RR 0.15, 95% CI 0.03 to 0.73). The quality of evidence is very low. Evidence quality was graded down for risk of bias (non-randomised comparison between intervention attendees and controls), serious indirectness (study was conducted in the United States), and very serious imprecision (very few events).

Outcome: T-cell count at 9 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001a), adolescents participating in small group discussions had a higher mean T-cell count (statistically non-

significant), compared to those receiving standard care (MD 8.4 higher, 95% CI 12.58 lower to 29.38 higher). The quality of evidence is very low. Evidence quality was graded down for risk of bias (non-randomised comparison between intervention attendees and controls), serious indirectness (study was conducted in the United States), and very serious imprecision (very few events).

RANDOMIZED CONTROL TRIALS: Adults

Outcome: Unprotected sex at 15 months

- In one trial (Murphy 2011), adults participating in four-session, one-on-one counselling among other HIV-infected mothers were more likely to disclose their HIV status to sex partners, compared to those receiving standard care (RR 4.56, 95% CI 1.4 to 14.77). The quality of evidence is very low. Evidence quality was graded down for indirectness (study was conducted in the United States), and very serious imprecision (very few events).

Outcome: Disclosed HIV status to all children at 12 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001b), HIV-infected parents participating in small group discussions with their adolescent children were no more likely (statistically non-significant) to disclose HIV status to all children than those receiving standard care (RR 1, 95% CI 0.88 to 1.13). The quality of evidence is very low. Evidence quality was graded down for very serious indirectness (HIV-infected adult parents were study population; study was conducted in the United States), and serious imprecision (few events).

Outcome: Disclosed HIV status to at least one adolescent at 24 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001b), HIV-infected parents participating in small group discussions with their adolescent children were more likely (statistically non-significant) to disclose HIV status at least one adolescent than those receiving standard care (RR 1.04, 95% CI 0.96 to 1.14). The quality of evidence is very low. Evidence quality was graded down for very serious indirectness (HIV-infected adult parents were study population; study was conducted in the United States), and serious imprecision (few events).

Outcome: Disclosed HIV status to at least all children at 24 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001b), HIV-infected parents participating in small group discussions with their adolescent children were no more likely (statistically non-significant) to disclose HIV status to all children than those receiving standard care (RR 1, 95% CI 0.91 to 1.1). The quality of evidence is very low. Evidence quality was graded down for very serious indirectness (HIV-infected adult parents were study population; study was conducted in the United States), and serious imprecision (few events).

Outcome: Parental depression score at 3 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001b), HIV-infected parents participating in small group discussions with their adolescent children had higher mean depression scores than those receiving standard care (MD 0.28 higher, 95% CI 0.06 to 0.5 higher). The quality of evidence is low. Evidence quality was graded down for very serious indirectness (HIV-infected adult parents were study population; study was conducted in the United States).

Outcome: Parental depression score at 15 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001b), HIV-infected parents participating in small group discussions with their adolescent children had lower mean depression scores than those receiving standard care (MD 0.22 lower, 95% CI 0.44 lower to 0 higher). The quality of evidence is low. Evidence quality was graded down for very serious indirectness (HIV-infected adult parents were study population; study was conducted in the United States).

Outcome: Parental depression score at 24 months

- In one trial conducted in the pre-antiretroviral therapy era (Rotheram-Borus 2001b), HIV-infected parents participating in small group discussions with their adolescent children had lower mean depression scores (statistically non-significant) than those receiving standard care (MD 0.12 lower, 95% CI 0.34 lower to 0.1 higher). The quality of evidence is low. Evidence quality was graded down for very serious indirectness (HIV-infected adult parents were study population; study was conducted in the United States).

Outcome: Number of family members disclosed to at 3 months follow-up

- In one trial (Serovich 2011), adults (men who have sex with men, MSM) participating in group counselling among other HIV-infected MSM were no more likely to disclose (statistically non-significant) to a higher number of family members than were the wait-list control (RR 1.1, 95% CI 0.91 to 1.34). The quality of evidence is very low. Evidence quality was graded down for very serious indirectness (adult population, study was conducted in the United States, and self-reported data), and very serious imprecision (very few events).

Outcome: Disclosed HIV status to some sex partners at 6 months

- In one trial (Wolitski 2005), adults (men who have sex with men, MSM) participating in peer-led behavioural sessions among other HIV-infected MSM were more likely to disclose (statistically non-significant) to some sex partners, compared to participants receiving standard care (RR 1.06, 95% CI 0.85 to 1.32). The quality of evidence is very low. Evidence quality was graded down for very serious indirectness (adult population, study was conducted in the United States, and self-reported data), and serious imprecision (few events).

Outcome: Disclosed HIV status to all sex partners at 6 months

- In one trial (Wolitski 2005), adults (MSM) participating in peer-led behavioural sessions among other HIV-infected MSM were more likely to disclose (statistically non-significant) to all sex partners, compared to participants receiving standard care (RR 1.04, 95% CI 0.87 to 1.25). The quality of evidence is very low. Evidence quality was graded down for very serious indirectness (adult population, study was conducted in the United States, and self-reported data), and serious imprecision (few events).

Outcome: Unprotected anal intercourse at 6 months

- In one trial (Wolitski 2005), adults (MSM) participating in peer-led behavioural sessions among other HIV-infected MSM were less likely to report (statistically non-significant) unprotected anal intercourse, compared to participants receiving standard care (RR 0.87, 95% CI 0.69 to 1.1). The quality of evidence is very low. Evidence quality was graded down for very serious indirectness (adult population, study was conducted in the United States, and self-reported data), and serious imprecision (few events).

Outcome: Consistent condom use during insertive anal intercourse at 6 months

- In one trial (Wolitski 2005), adults (MSM) participating in peer-led behavioural sessions among other HIV-infected MSM were more likely to report (statistically non-significant) consistent condom use during insertive anal intercourse, compared to participants receiving standard care (RR 1.03, 95% CI 0.8 to 1.34). The quality of evidence is very low. Evidence quality was graded down for very serious indirectness (adult population, study was conducted in the United States, and self-reported data), and serious imprecision (few events).

Outcome: Intervention motivated me to tell my sex partners about my HIV status

- In one trial (Wolitski 2005), adults (MSM) participating in peer-led behavioural sessions among other HIV-infected MSM had a higher mean score in reporting that the intervention had motivated them to inform their sex partners of HIV status, compared to participants receiving standard care (MD 0.57 higher, 95% CI 0.41 to 0.73 higher). The quality of evidence is very low. Evidence quality was graded down for very serious indirectness (adult population, study was conducted in the United States, and self-reported data).

OBSERVATIONAL STUDIES: Adults

Outcome: Disclosure at 2 months follow-up

- In one observational study (Mundell 2011), more HIV-infected pregnant women who participated in structured support groups for HIV-infected pregnant women had disclosed their HIV status, compared to before attending the support groups (RR 1.2, 95% CI 1.09 to 1.32). The quality of evidence is very low. Evidence quality was graded down for indirectness (adult population), and serious imprecision (few events).

Outcome: Disclosure at 8 months follow-up

- In one observational study (Mundell 2011), more HIV-infected pregnant women who participated in structured support groups for HIV-infected pregnant women had disclosed their HIV status, compared to before attending the support groups (RR 1.18, 95% CI 1.09 to 1.28). The quality of evidence is very low. Evidence quality was graded down for indirectness (adult population), and serious imprecision (few events).

Outcome: Depression at 8 months follow-up

- In one observational study (Mundell 2011), HIV-infected pregnant women who participated in structured support groups for HIV-infected pregnant women were no different in reporting feeling depressed, compared to before attending the support groups (RR 1, 95% CI 0.92 to 1.08). The quality of evidence is very low. Evidence quality was graded down for indirectness (adult population), and serious imprecision (few events).

Outcome: Weight of keeping HIV status secret at 1-week follow-up

- In one observational study (Otis 2012), HIV-infected women who participated in workshops for HIV-infected women had lower mean scores (statistically non-significant) for the weight of keeping their HIV status a secret, compared to before attending the support groups (MD -1.07 lower, 95% CI -1.3 lower to 0.81 higher). The quality of evidence is very low. Evidence quality was graded down for indirectness (adult population), and serious imprecision (few events).

PICO 3 – Training to support adherence and retention

Training of healthcare providers in adolescent health for improving retention and adherence among ALHIV

EVIDENCE SUMMARIES: RCTs

Outcome: MORBIDITY

Asthma symptom days (follow-up 24 months)

- This outcome was defined as the number of days with any asthma symptoms (including cough, wheeze, limitation in activity, or night wakening) in the 14 days preceding contact
- In 1 trial (Lozano 2004) with 24 months of follow-up, children with asthma in the planned care intervention arm condition had 13.3 fewer asthma symptom days compared to the standard care control arm (95% CI -24.7,-2.1; p=0.02) and children in the peer leader intervention arm had 6.5 fewer days compared to the standard care control arm (95% CI -16.9, 3.6; p=0.20).

Oral steroid burst rate (follow-up 24 months)

- This outcome was defined as how frequently this medication was taken the past 4 weeks
- In 1 trial (Lozano 2004) with 24 months of follow-up, children with asthma in the planned care intervention care arm had 39% lower oral steroid burst rate per year compared to the standard care control arm (95% CI 11% to 54%) and children in the peer leader intervention arm had 36% lower oral steroid burst rate per year compared to the standard care control arm (95% CI 11% to 58%).

HbA1c levels (follow-up 12 months)

- This outcome is a laboratory blood test conducted to determine the amount of sugar in the blood that is used to determine the level of diabetes disease control
- In 1 trial (Robling 2012, Gregory 2011) with 12 months of follow-up, children with diabetes in the intervention arm had mean HbA1c levels of 9.7 (SD 1.7) compared to 9.5 (SD 1.7) in the control group and this difference was not statistically significantly different (intervention effect 0.01, 95% CI -0.02 to 0.04, p=0.50).

Outcome: ADHERENCE

Adherence (as measured by quality of life questionnaire)

- In 1 trial (Robling 2012, Gregory 2011) with 12 months of follow-up, children with diabetes in the intervention arm had mean adherence scores of 76.8 compared to 80.6 in the control arm (difference not statistically significant).

PICO 4 – Community-based approaches

Adolescent community-based approaches

RANDOMIZED CONTROL TRIALS – Low-middle income countries

Outcome: Mortality (26 months) in peer health worker interventions

- This outcome is represented by 1 study with 26 months of follow-up (Chang 2010).

- In this one study, the proportion of patients who died was 9.3% in the intervention peer health workers arm compared to 8.5% in the control standard of care arm for a non-statistically significant difference (RR 1.1 ,95% CI: 0.74 to 1.62) (Chang 2010).
- The quality of this evidence is very low.

Outcome: Mortality (26 months) in peer health workers interventions with mobile phone support

- This outcome is represented by 1 study with 26 months of follow-up (Chang 2011).
- In this one study, the proportion of patients who died was 8.3% in the intervention peer health worker with mobile phone support arm compared to 10.1% in the control peer health worker arm for a non-statistically significant difference (RR 0.82, 95% CI: 0.55 to 1.22) (Chang 2011).
- The quality of this evidence is very low.

Outcome: HIV-associated mortality (12 months) in peer health workers interventions with personal digital assistant (PDA) support

- This outcome is represented by 1 study with 12 months of follow-up (Selke 2010).
- In this one study, no patients in either study arm had died of HIV-associated causes at 12 months. The relative effect is not estimable. (Selke 2010).
- The quality of this evidence is very low.

Outcome: Viral failure (>400 copies/mL) (24 weeks) in peer health worker interventions

- This outcome is represented by 1 study with 24 weeks of follow-up (Chang 2010).
- In this one study, the proportion of patients with viral failure was 9.7% in the intervention peer health worker arm compared to 10.4% in the control standard of care arm for a non-statistically significant difference (RR 0.94, 95% CI: 0.56 to 1.57) (Chang 2010).
- The quality of this evidence is very low.

Outcome: Viral failure (>400 copies/mL) (24 weeks) in peer health workers interventions with mobile phone support

- This outcome is represented by 1 study with 24 weeks of follow-up (Chang 2011).
- In this one study, the proportion of patients with viral failure was 12.3% in the intervention peer health worker with mobile phone support arm compared to 7.7% in the control standard of care arm for a non-statistically significant difference (RR 1.59, 95% CI: 0.91 to 2.79) (Chang 2011).
- The quality of this evidence is very low.

Outcome: Viral failure (>400 copies/mL) (48 weeks) in peer health worker interventions

- This outcome is represented by 1 study with 48 weeks of follow-up (Chang 2010).
- In this one study, the proportion of patients with viral failure was 9.2% in the intervention peer health worker arm compared to 11% in the control standard of care arm for a non-statistically significant difference (RR 0.84, 95% CI: 0.5 to 1.42) (Chang 2010).
- The quality of this evidence is very low.

Outcome: Viral failure (>400 copies/mL) (48 weeks) in peer health workers interventions with mobile phone support

- This outcome is represented by 1 study with 48 weeks of follow-up (Chang 2011).
- In this one study, the proportion of patients with viral failure was 9% in the intervention peer health worker with mobile phone support arm compared to 9.4% in the control standard of care arm for a non-statistically significant difference (RR 0.95, 95% CI: 0.53 to 1.17) (Chang 2011).
- The quality of this evidence is very low.

Outcome: Viral failure (>400 copies/mL) (96 weeks) in peer health worker interventions

- This outcome is represented by 1 study with 96 weeks of follow-up (Chang 2010).
- In this one study, the proportion of patients with viral failure was 6.5% in the intervention peer health worker arm compared to 12.7% in the control standard of care arm with statistically significant fewer patients in the intervention arm experiencing viral failure (RR 0.51, 95% CI: 0.29 to 0.92) (Chang 2010).
- The quality of this evidence is very low.

Outcome: Detectable viral load (12 months) in peer health workers interventions with personal digital assistant (PDA) support

- This outcome is represented by 1 study with 12 months of follow-up (Selke 2010).
- In this one study, the proportion of patients with viral failure was 9.4% in the intervention peer health worker with mobile phone support arm compared to 11.6% in the control standard of care arm for a non-statistically significant difference (RR 0.81, 95% CI 0.36 to 1.81) (Selke 2010).
- The quality of this evidence is very low.

Outcome: 100% adherence, self reported (12 months) in peer health workers interventions with personal digital assistant (PDA) support

- This outcome is represented by 1 study with 12 months of follow-up (Selke 2010).
- In this one study, the proportion of patients with viral failure was 79.2% in the intervention peer health worker with mobile phone support arm compared to 84.8% in the control standard of care arm for a non-statistically significant difference (RR 0.93, 95% CI 0.82 to 1.06) (Selke 2010).
- The quality of this evidence is very low.

Outcome: Less than 95% adherence (26 months) in peer health worker interventions

- This outcome is represented by 1 study with 26 months of follow-up (Chang 2010).
- In this one study, the proportion of patients with less than 95% adherence was 1.4% in the intervention peer health worker arm compared to 2.4% in the control standard of care arm for a non-statistically significant difference (RR 0.57, 95% CI: 0.23 to 1.37) (Chang 2010).
- The quality of this evidence is very low.

Outcome: Less than 95% adherence (26 months) in peer health workers interventions with mobile phone support

- This outcome is represented by 1 study with 26 months of follow-up (Chang 2011).
- In this one study, the proportion of patients with less than 95% adherence was 0.5% in the intervention peer health worker arm compared to 2.1% in the control standard of care arm for a non-statistically significant difference (RR 0.24, 95% CI: 0.05 to 1.07) (Chang 2011).
- The quality of this evidence is very low.

Outcome: Less than 100% adherence (26 months) in peer health worker interventions

- This outcome is represented by 1 study with 26 months of follow-up (Chang 2010).
- In this one study, the proportion of patients with less than 95% adherence was 25.5% in the intervention peer health worker arm compared to 23.3% in the control standard of care arm for a non-statistically significant difference (RR 1.09, 95% CI: 0.87 to 1.37) (Chang 2010).
- The quality of this evidence is very low.

Outcome: Less than 100% adherence (26 months) in peer health workers interventions with mobile phone support

- This outcome is represented by 1 study with 26 months of follow-up (Chang 2011).

- In this one study, the proportion of patients with less than 95% adherence was 25.2% in the intervention peer health worker arm compared to 25.8% in the control standard of care arm for a non-statistically significant difference (RR 0.98, 95% CI: 0.78 to 1.23) (Chang 2011).
- The quality of this evidence is very low.

OBSERVATIONAL STUDIES – Low-middle income countries

Outcome: Mortality (1 year) with peer-delivered modified DOT

- This outcome is represented by 1 study with 1 year of follow-up (Pearson 2007).
- In this one study, the proportion of patients who died was 13.1% in the intervention peer-delivered modified DOT arm compared to 18.3% in the control standard of care arm for a non-statistically significant difference (RR 0.72, 95% CI: 0.44 to 1.18) (Pearson 2007).
- The quality of this evidence is very low.

Outcome: Mortality (1 year) with treatment-partner assisted therapy

- This outcome is represented by 1 study with 1 year of follow-up (Taiwo 2010).
- In this one study, the proportion of patients who died was 10.6% in the intervention **treatment-partner assisted therapy arm compared to 6.1% in the control standard of care arm** for a non-statistically significant difference (RR 1.74, 95% CI: 0.95 to 3.2) (Taiwo 2010).
- The quality of this evidence is very low.

Outcome: Mortality (2 years) multi-component community-based care

- This outcome is represented by 1 study with 2 years of follow-up (Munoz 2011).
- In this one study, the proportion of patients who died was 10% in the intervention multi-component community-based care arm compared to 8.5% in the control standard care arm for a non-statistically significant difference (RR 1.18, 95% CI: 0.49 to 2.85) (Munoz 2011).
- The quality of this evidence is very low.

Outcome: Mortality (2 years) in rural ART

- This outcome is represented by 1 study with 2 years of follow-up (Kipp 2012).
- In this one study, the proportion of patients who died was 17.3% in the intervention rural-based ART compared to 11.5% in the control urban-based ART arm for a non-statistically significant difference (RR 1.5, 95% CI: 0.91 to 2.47) (Kipp 2012).
- The quality of this evidence is very low.

Outcome: Mortality (3 years)

- This outcome is represented by 1 study with 3 years of follow-up (Grimwood 2010).
- In this one study, the proportion of patients who died was 3.7% in the intervention patient advocates for paeds arm compared to 8% in the control standard of care arm for statistically significantly fewer deaths in the intervention arm (RR 0.46, 95% CI: 0.26 to 0.82) (Grimwood 2010).
- The quality of this evidence is very low.

Outcome: Mortality (5 years)

- This outcome is represented by 1 study with 5 years of follow-up (Fatti 2012).
- In this one study, the proportion of patients who died was 9% in the community-based adherence support arm compared to 10.6% in the control standard of care arm for statistically significantly fewer deaths in the intervention arm (RR 0.85, 95% CI 0.81 to 0.89) (Fatti 2012).
- The quality of this evidence is very low.

Outcome: Mortality (10 years): one kind of support

- This outcome is represented by 1 study with 10 years of follow-up (Talisuna-Alamo 2012).
- In this one study, the proportion of patients who died was 15.7% in the intervention socio-economic support arm compared to 16.4% in the control no socio-economic support arm for a non-statistically significant difference (RR 0.96, 95% CI: 0.85 to 1.09) (Talisuna-Alamo 2012).
- The quality of this evidence is very low.

Outcome: Mortality (10 years): two or more kinds of support

- This outcome is represented by 1 study with 10 years of follow-up (Talisuna-Alamo 2012).
- In this one study, the proportion of patients who died was 8% in the intervention socio-economic support arm compared to 16.4% in the control no socio-economic support arm with statistically fewer deaths in the intervention arm (RR 0.49, 95% CI: 0.38 to 0.64) (Talisuna-Alamo 2012).
- The quality of this evidence is very low.

Outcome: Retention in care (5 years)

- This outcome is represented by 1 study with 5 years of follow-up (Fatti 2012).
- In this one study, the proportion of patients who were retained in care was 79.1% in the community-based adherence support arm compared to 73.6% in the control standard of care arm for statistically significantly fewer deaths in the intervention arm (RR 1.07, 95% CI 1.07 to 1.08) (Fatti 2012).
- The quality of this evidence is very low.

Outcome: Reduced viral load (24 weeks)

- This outcome is represented by 1 study with 24 weeks of follow-up (Taiwo 2010).
- In this one study, the proportion of patients with reduced viral load was 64.3% in the in the intervention treatment-partner assisted therapy arm compared to 55.5% in the control standard of care arm for a non-statistically significant difference (RR 1.16, 95% CI: 1 to 1.35) (Taiwo 2010).
- The quality of this evidence is very low.

Outcome: Reduced viral load (48 weeks)

- This outcome is represented by 1 study with 48 weeks of follow-up (Taiwo 2010).
- In this one study, the proportion of patients with reduced viral load was 69.2% in the in the intervention treatment-partner assisted therapy arm compared to 68.7% in the control standard of care arm for a non-statistically significant difference (RR 1.01, 95% CI: 0.89 to 1.14) (Taiwo 2010).
- The quality of this evidence is very low.

Outcome: Reduced viral load (24 months)

- This outcome is represented by 1 study with 24 months of follow-up (Kipp 2012).
- In this one study, the proportion of patients who died was 93% in the intervention rural-based ART compared to 87.3% in the control urban-based ART arm for a non-statistically significant difference (RR 1.07, 95% CI: 0.98 to 1.15) (Kipp 2012).
- The quality of this evidence is very low.

Outcome: Reduced viral load (2 years)

- This outcome is represented by 1 study with 2 years of follow-up (Munoz 2011).

- In this one study, the proportion of patients with reduced viral load was 67.3% in the intervention multi-component community-based care arm compared to 45.2% in the control standard care arm for a non-statistically significant difference (RR 1.49, 95% CI: 0.97 to 2.29) (Munoz 2011).
- The quality of this evidence is very low.

Outcome: Reduced viral load (6 months)

- This outcome is represented by 1 study (Fatti 2012).
- In this one study, the proportion of patients with a suppressed viral load was 76.6% in the community-based adherence support arm compared to 72% in the control standard of care arm for statistically significantly fewer deaths in the intervention arm (RR 1.06, 95% CI 1.05 to 1.08) (Fatti 2012).
- The quality of this evidence is very low.

Outcome: Reduced viral load (12 months)

- This outcome is represented by 1 study (Fatti 2012).
- In this one study, the proportion of patients with a suppressed viral load was 65.8% in the community-based adherence support arm compared to 55.8% in the control standard of care arm for statistically significantly fewer deaths in the intervention arm (RR 1.18, 95% CI 1.15 to 1.21) (Fatti 2012).
- The quality of this evidence is very low.

Outcome: Reduced viral load (24 months)

- This outcome is represented by 1 study (Fatti 2012).
- In this one study, the proportion of patients with a suppressed viral load was 53.1% in the community-based adherence support arm compared to 42.3% in the control standard of care arm for statistically significantly fewer deaths in the intervention arm (RR 1.26 (1.21 to 1.31) (Fatti 2012).
- The quality of this evidence is very low.

Outcome: >90% adherence (1 year)

- This outcome is represented by 1 study with 1 year of follow-up (Pearson 2007).
- In this one study, the proportion of patients with >90% adherence was 91.8% in the intervention peer-delivered modified DOT arm compared to 84.6% in the control standard of care arm for a non-statistically significant difference (RR 1.09, 95% CI: 0.99 to 1.18) (Pearson 2007).
- The quality of this evidence is very low.

Outcome: >95% adherence (48 weeks)

- This outcome is represented by 1 study with 48 weeks of follow-up (Taiwo 2010).
- In this one study, the proportion of patients with >95% adherence was 80.2% in the intervention treatment-partner assisted therapy arm compared to 67.3% in the control standard of care arm with statistically significantly more adherent patients in the intervention arm (RR 1.19, 95% CI: 1.07 to 1.33) (Taiwo 2010).
- The quality of this evidence is very low.

Outcome: >95% adherence (12 months)

- This outcome is represented by 1 study with 12 months of follow-up (Kabore 2010).
- In this one study, the proportion of patients with >95% adherence was 66.9% in the intervention integrated community-based services arms compared to 58.3% control standard arm for

significantly more adherent patients in the intervention arm (RR 1.15, 95% CI: 1.03 to 1.27) (Kabore 2010).
- The quality of this evidence is very low.

Outcome: >95% adherence (2 years)
- This outcome is represented by 1 study with 2 years of follow-up (Munoz 2011).
- In this one study, the proportion of patients >95% adherent was 88.5% in the intervention multi-component community-based care arm compared to 83.9% in the control standard care arm for a non-statistically significant difference (RR 1.05, 95% CI: 0.88 to 1.27) (Munoz 2011).
- The quality of this evidence is very low.

Outcome: Follow-up visits (6 months)
- This outcome is represented by 1 study with 6 months of follow-up (Futterman 2010).
- In this one study, the proportion of patients with 57.5% in the intervention HIV+ mentor mother arm compared to 35.5% in the control standard of care arm for a non-statistically significant difference (RR 1.62, 95% CI: 0.94 to 2.79) (Futterman 2010).
- The quality of this evidence is very low.

RANDOMIZED CONTROLLED TRIALS – High-income countries

Outcome: ≥80% adherence (6 months)
- This outcome is represented by 1 study with 6 months of follow-up (Altice 2007).
- In this one study, the proportion of patients with ≥80% adherence was 67% in the intervention community-based ART arm compared to 56.6% in the control self-administered ART arm for a non-statistically significant difference (RR 1.18, 95% CI: 0.9 to 1.56) (Altice 2007).
- The quality of this evidence was very low.

Outcome: Reduced viral load (6 months)
- This outcome is represented by 1 study with 6 months of follow-up (Altice 2007).
- In this one study, the proportion of patients with reduced viral load at 6 months was 70.5% in the intervention community-based ART arm compared to 56.6% in the control self-administered ART arm for a non-statistically significant difference (RR 1.18, 95% CI: 0.95 to 1.63) (Altice 2007).
- The quality of this evidence was very low.

Outcome: Reduced viral load (3 months)
- This outcome was represented by 1 study with 3 months of follow-up (Macalino 2007).
- In this one study, the proportion of patients with reduced viral load at 3 months was 58.1% in the intervention MDOT outreach worker arm compared to 34.1% in the control standard care arm for a statistically significant higher proportion in the intervention arm (RR 1.71, 95% CI: 1.05 to 2.76) (Macalino 2007).
- The quality of this evidence was very low.

Outcome: Still on first-line regimen (6 months)
- This outcome is represented by 1 study with 6 months of follow-up (Altice 2007).
- In this one study, the proportion of patients still on first-line regimen at 6 months 45.5% in the intervention community-based ART arm compared to 45.3% in the control self-administered ART arm for a non-statistically significant difference (RR 1, 95% CI: 0.69 to 1.46) (Altice 2007).
- The quality of this evidence was very low.

Outcome: 100% adherence: electronic drug monitoring (6 months)

- This outcome is represented by 2 studies with 6 months of follow-up (Simoni 2007, Simoni 2009).
- In one study, the mean was 37.7 (SD 36) in the intervention peer-support arm compared to 48.1 (SD 36.3) in the control standard care arm for a non-statistically significant difference (Mean difference -10.40, 95% CI: -22.57 to 1.77) (Simoni 2007).
- In the other study, the mean was 37.2 (SD 44.5) in the intervention peer-support arm compared to 41 (SD 44) in the control standard care arm for a non-statistically significant difference (Mean difference -3.80, 95% CI: -20.05 to 12.45) (Simoni 2009).
- Analyzed together there was no statistically significant difference found between the
- Overall the cumulative RR from these two studies showed no statistically significant difference was found between the intervention and control arms (Mean difference -8.03, 95% CI: -17.77 to 1.71).
- The quality of this evidence was low.

Outcome: 100% adherence: electronic drug monitoring (9 months)

- This outcome is represented by 1 study with follow-up at 9 months (Simoni 2009).
- In this one study, the mean was 32.3 (SD 42.5) in the intervention peer-support arm compared to 29.1 (SD 39.7) in the control standard care arm for a non-statistically significant difference (Mean difference 3.2, 95% CI: -11.9 to 18.3) (Simoni 2009).
- The quality of this evidence was very low.

Outcome: ≥90% adherence: MEMS cap (12 months)

- This outcome was represented by 1 study with follow-up at 12 months (Williams 2006).
- In this one study, the proportion with ≥90% adherence using MEMS cap measures was 21.8% in the community-based home visits arm compared to 14.3% in the control standard care arm for a non-statistically significant difference (RR 1.53, 95% CI: 0.79 to 2.95) (Williams 2006).
- The quality of this evidence was very low.

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