Do interventions to improve adherence to antiretroviral therapy recognise diversity? A systematic review

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The research was funded by a grant from the University of East Anglia to support cross-disciplinary research.

Running head: Diversity of adherence trials
Abstract

People living with HIV (PLWH) are often culturally and linguistically diverse populations; these differences are associated with differing barriers to antiretroviral therapy (ART) adherence. Cultural competence measures the extent to which trial design recognises this diversity. This systematic review aimed to determine whether adherence trial participants represent the diversity of PLWH.

Randomised Controlled Trials in Organisation for Economic Co-operation and Development countries to improve ART adherence were eligible. We searched MEDLINE, EMBASE, and Cochrane Database of Systematic Reviews. For all included trials, we searched for their development, testing and evaluation studies. We compared trial participant characteristics with nationally reported PLWH data. We appraised trial cultural competence against ten criteria; scoring each criterion as 0, 1 or 2 indicating cultural blindness, pre-competence or competence respectively.

For 80 included trials, a further 13 studies presenting development/testing/evaluation data for the included trials were identified. Only one of the 80 included studies reported trial participants representative of the country’s population of PLWH. The median (IQ) cultural competence score was 2.5 (1.0, 4.0) out of 20. HIV adherence trial participants are not reflective of the population with HIV, which may be due to limited adoption of culturally competent research methods.

**Key words:** HIV; generalisability; diversity; trial reporting guidelines; transferability
Introduction

Sub-optimal adherence to Antiretroviral treatment (ART) in people living with HIV (PLWH) has led to numerous adherence interventions (Kanters et al., 2017). Implementation of these interventions into routine care has been limited (Simoni et al., 2017) and may reflect poor acceptability and feasibility in the real world environment (de Bruin et al., 2010).

PLWH are often culturally and linguistically diverse populations (Hernando et al., 2015) with differing barriers to ART adherence (Croome, et al. 2017; Shubber et al., 2016). Socio-cultural factors such as low levels of social support, poor health/medical knowledge, culturally mediated negative beliefs about ART and stigmatisation are all associated with sub-optimal ART adherence (Ammassari et al., 2002). In most Organisation for Economic Co-operation and Development (OECD) countries, HIV/AIDS disproportionately affect migrants. Whilst accounting for less than 16% of the European Union population, 40% of PLWH in the European Union are migrants (Hernando et al., 2015). Similar disproportionate representation is observed in the USA (Prosser, Tang, & Hall, 2012). ART adherence interventions should therefore recognise this cultural diversity during the research development, evaluation and implementation phases.

Trial reporting guidelines specifying the need for baseline demographics do not adequately reflect the complexities of cultural identity and how it is socially constructed in language (Schulz et al., 2010). However, these demographics are the best available data for assessing cultural diversity.

Cultural competence is as an “ongoing capacity of healthcare systems, organizations, and professionals to provide for diverse patient populations high-quality care that is safe, patient and family centred, evidence based, and equitable” (National Quality Forum 2008). Gibbs et al. (2007) report a cultural competence research framework comprising nine criteria spanning
the processes of study design, recruitment, analysis and dissemination all being in partnership with the target population. This framework has been applied to evaluate observational studies (Riggs et al., 2014) but it is yet to be applied to randomised controlled trials (RCT). The need for brevity in RCT trial reporting may prohibit full characterisation of intervention development and subsequent evaluation. However, facilities for publishing protocols, feasibility, pilot and process evaluation studies allows ample opportunity for researchers to report additional data. Trials, as a component of CONSORT reporting, routinely provide the demographic characteristics of participants (Schulz et al. 2010) thus providing the minimum necessary data to evaluate the extent to which participants reflect the population with HIV.

This study aimed to characterise the extent to which ART adherence intervention trials conducted in OECD countries are designed and implemented in recognition of the diversity of the population for which the intervention is intended.

**Materials and Methods**

**Phase 1. Identifying relevant RCTs**

The study followed the Preferred Reporting Items for Systematic reviews and Meta-Analysis (Moher et al., 2009) and was registered in PROSPERO (CRD42017077501). RCTs reported in English of any intervention to improve adherence to ART by adults were eligible. The review included all health care settings in OECD countries. We limited to OECD countries through manual searches of identified RCTs. We excluded studies using real-time monitoring for measuring adherence as they are subject to reactivity bias and thus less likely to be used to inform policy and practice.

RCTs were identified through searches of MEDLINE, EMBASE, and Cochrane Database of Systematic Reviews. Supplementary file 1 provides the search strategy adapted for each
database to accommodate different syntax rules. Two researchers (XW and NW) independently screened all titles and abstracts for relevance using an abstract screening tool (supplementary file 2). All retrieved articles were assessed for eligibility. Conflicts were resolved by discussion between the two reviewers and any disagreement by adjudication of a third independent reviewer (DB).

**Phase 2. Identifying development, testing and evaluation studies related to included RCTs**

Articles were eligible if they reported development, feasibility/piloting, evaluation or implementation of one or more intervention components from RCTs included at phase 1. We used the UK Medical Research Council definition of these research phases to determine eligibility (Craig et al., 2008).

BA undertook individualised searches for every author of RCTs included from phase 1. This identified any related publications on Pubmed, ResearchGate and Google Scholar. BA and DB independently reviewed all retrieved articles for eligibility.

**Data extraction**

An Excel data extraction sheet was developed for capturing participant socio-demographic characteristics and trial conduct data. Data were extracted verbatim thus terminologies for socio-demographic characteristics may have been specific to the country in which the study was conducted. Data were independently extracted by (XW, NW and BA); any discrepancies resolved by a third reviewer (DB).

**Quality assessment**

Definitions for each of the nine Gibbs et al. criteria for culturally competent research were adapted by the research team to better reflect the language of RCTs. The criterion ‘analysis/evaluation’ was split into two separate criteria for RCT conduct (Figure 1).
Data analysis

For each included study, if the reporting of socio-demographic characteristics enabled them to be attributed to individual countries, then these were compared with the sociodemographic characteristics of the country’s population with HIV, providing that these data were publicly available. This enabled us to establish the extent to which the trial population represented the diversity of the PLWH population.

For each of the ten criteria, XW and NW independently rated included studies on a scale of 0 to 2 for each of the ten criteria (Figure 1); any disagreements were referred to DB for arbitration. Lack of reporting prohibits the reader from evaluating the likely applicability of the research findings for any given population hence this was categorised as 0.

Results

Figure 2 provides the flow of studies; of the 80 studies retained in this systematic review, 66 (83%) were conducted in the USA, three in France (4%), two in Spain (2.5%), and one each in Canada (1%), Holland (1%) and Switzerland (1%). The remaining six (8%) were conducted in multiple OECD countries. Adherence interventions were wide ranging and included reminder devices, electronic communication such as short message service and face-to-face consultations. From the 13 relevant articles identified in phase 2 searches, five focussed on post-trial evaluation, however only one of these studies contributed extra data for assessing cultural competence (Garland et al., 2007). All eight of the trial developmental studies from the phase 2 searches contributed extra information to assess cultural competence. They provided details of early engagement and/or intervention refinement resulting from engaging
with the target population (Altice et al., 2004; Dilorio et al., 2003; Golin et al., 2016; Ingersoll et al., 2014; Macalino et al., 2004; Moore et al., 2013; van Servellen et al., 2003; Wohl et al., 2004).

[Figure 2 about here]

**Trial participants**

Table 1 provides the extent to which trial participants represent the country’s population prescribed ART. Only one study was representative based on the reported characteristics, however, this study did not report sexual orientation and/or mode of HIV acquisition (Enriquez et al., 2015). Supplementary file 3 provides details of trial participant characteristics. Only 35 (43%) studies reported sexual orientation and for eight of these studies, men who have sex with men contributed over 70% of participants (Antoni et al., 2006; de Bruin et al., 2010; Johnson et al., 2011; Kurth et al., 2014; Ramirez-Garcia & Côté, 2012; Roth et al., 2012; Safren et al., 2001; Wagner et al., 2013).

[Table 1 about here]

**Cultural competence assessment**

No studies achieved the maximum cultural competence score of twenty. The median (interquartile) cultural competence score was 2.5 (1.0, 4.0). Table 1 provides the summary scores for each study’s cultural competence assessment. The highest score was 12 and this was the only study reporting participants representative of the country’s HIV population. Figure 3
illustrates the limited number of studies adopting culturally competent methods across the ten criteria. Studies generally performed better for the criteria of ‘identifying the target population’ and ‘developing the intervention’ whilst reported involvement of the target population in disseminating trial findings was absent.

[Figure 3 about here]

**Forming partnerships and defining research questions**

Limited patient involvement was reported during the stage of conceiving the research ideas. Figure 2 indicates slightly better performance in forming partnerships relative to defining research questions. Three studies were rated as culturally competent as they involved participants during the design stage to consider their preferences (Ingersoll et al., 2015; Ingersoll et al., 2011; Safren et al., 2012). One trial was rated as culturally pre-competent because even though they did not reach out to the target community, the research team comprised PLWH and they were involved in the design, implementation and evaluation of the trial (Enriquez et al., 2015).

**Identifying the target population**

A medical setting such as HIV clinics were the recruitment source for 54 (68%) trials. These trials were characterised as pre-competent as the involvement of health care providers in the recruitment process may introduce bias. Recruitment from community settings including community outreach (Antoni et al., 2006) and primary care providers (Collier et al., 2005; Ingersoll et al., 2011; Kalichman et al., 2011; Kurth et al., 2014; Parsons et al., 2007; Pellowski et al., 2016; Remien et al., 2005; Safren et al., 2016; Safren et al., 2003) was adopted in ten studies whilst nine studies adopted multiple strategies including various combinations of HIV
clinics, primary care providers, and local advertisements (Dale et al., 2016; Duncan et al., 2012; Enriquez et al., 2015; Gwadz et al., 2015; Huhn et al., 2017; Johnson et al., 2011; Johnson et al., 2007; Safren et al., 2001; Williams et al., 2006).

**Appointing staff**

Representation of the target population in the research team was limited to seven (9%) studies. For five studies, PLWH were directly involved in intervention delivery (Enriquez et al., 2015; Gwadz et al., 2015; Simoni et al., 2007; Simoni et al., 2009; Williams et al., 2006). For the remaining two studies, research teams included community representatives and relevant bilingual workers guiding the research conduct (Floris-Moore et al., 2016; van Servellen et al., 2005).

**Recruitment of sample**

Most of the studies included recruitment restrictions such as ‘must provide written informed consent’. Two studies translated consent materials to make them accessible to the target populations of both English and Spanish speakers (Enriquez et al., 2015; Wohl et al., 2006). One study explicitly commented that their driver for excluding potential participants who could not read and speak English was the challenge of creating research and intervention materials for diverse populations (de Bruin et al., 2010).

**Data collection**

The data collection processes for only 22 (27%) studies catered to a culturally and linguistically diverse population. These included translating project materials (Collier et al., 2005; Samet et al., 2005); engaging bilingual community workers for data collection (Garland et al., 2007; van Servellen et al., 2005; Williams et al., 2006; Wohl et al., 2006); flexible session times (Kurth et al., 2014; Reynolds et al., 2008; Robbins et al., 2013); tailoring intervention activities based
on individual patient needs (Antoni et al., 2006; Gwadz et al., 2015); flexible locations (Garland et al., 2007; Johnson et al., 2011; Johnson et al., 2007; Macalino et al., 2007; Roth et al., 2012); providing male-female facilitator pairs (Kalichman et al., 2011); and flexible intervention delivery methods (Murphy et al., 2007; Pellowski et al., 2016). Others provided childcare (Holstad et al., 2011); matched project peers to participants on the basis of ethnicity, sex, and sexual orientation (Simoni et al., 2007; Simoni et al., 2009); and included patient participation in the intervention (Moore et al., 2015).

**Development of intervention**

Almost half of the trials (53%) customised the intervention for the target population such as varying intervention content (Johnson et al., 2011; Johnson et al., 2007; Kalichman et al., 2011; Kurth et al., 2014; Mannheimer et al., 2006; Parsons et al., 2007; Wagner et al., 2006; Wagner et al., 2013; Weber et al., 2004), location (Garland et al., 2007; Macalino et al., 2007; Roth et al., 2012) and frequency (de Bruin et al., 2010; Dilorio et al., 2008; Tuldra et al., 2000) according to participant preference or feedback. Enriquez et al. (2015) partnered PLWH with the researchers to translate a nurse-led intervention to a peer-led format (Enriquez et al., 2015). Other studies tailored the intervention for participants with lower health literacy skills (Pellowski et al., 2016; Rawlings et al., 2003). Several studies included consultation with patients (Robbins et al., 2013; Safren et al., 2016; Simoni et al., 2007; Simoni et al., 2009) and evaluation mechanisms to inform the next stage of the intervention (Holzemer et al., 2006). Preliminary needs assessment of participants (Wohl et al., 2017) and co-designing intervention materials were reported Moore et al (2015). Other cultural considerations were translation of written materials (Collier et al., 2005) and bilingual community workers (van Servellen et al., 2005).

**Analysis and Evaluation**
Two studies reported involving the target population in data analysis (Enriquez et al., 2015) (Macalino et al., 2007). Eight studies invited feedback from participants, primarily using post-trial intervention satisfaction surveys (Arribas et al., 2017; Rathbun et al., 2005; de Bruin et al., 2010; Garland et al., 2007; Himelhoch et al., 2017; Ingersoll et al., 2015; Ingersoll et al., 2011; Kurth et al., 2014). Some conducted post-trial evaluations with staff involved in intervention delivery (de Bruin et al., 2010; Himelhoch et al., 2017).

**Dissemination**

No studies reported disseminating findings back to the participants or target population.

**Discussion**

This review confirms that most HIV adherence trial participant populations are not representative of the target population. Notable differences are lower representation of ethnic minorities, females and heterosexual males. As differing sociodemographic factors are associated with differing barriers to ART adherence (Shubber et al., 2016), trial findings should be interpreted with caution when considering implementation into the real-world environment. The review also demonstrates that it is feasible to evaluate the cultural competence of RCTs but trial reporting quality prohibits comprehensive evaluation.

Cultural competence criteria align better with feasibility and process evaluation rather than RCT reporting standards (Schulz et al., 2010). However, few studies of these types were identified in this review. Due to inadequate reporting, we are therefore unable to conclusively state that trials are not adopting culturally competent methods. The limited diversity observed in trial participants, however, supports the conclusion that trials are failing to adopt culturally competent methods. Poor reporting also prohibits commissioners evaluating the extent to which trial findings are generalisable to their population. This may have contributed to the
limited adoption of novel adherence interventions into routine care (de Bruin et al., 2010; Simoni et al., 2017).

Our synthesis of studies spanning 17 years indicates no observable trend in either improvement or decline in reporting of culturally competent research methods. A range of OECD countries are represented but the majority of studies were conducted in the USA. The general disproportionately high representation of males in the USA trials with lower cultural competence scores is of concern particularly as the rate of females diagnosed with HIV has shown a smaller decline than males (Centers for Disease Control and Prevention, 2017).

Whilst characteristics relating to ethnicity, gender, sexuality and class specified in CONSORT criteria (Schulz et al., 2010) do not adequately reflect the complexities of cultural identity, there is limited reporting of even these characteristics. The message regarding fulfilling CONSORT standards may need strengthening. This may be achieved by specifying the minimum characteristics reported for behavioural intervention studies.

The relatively good performance of most studies for identifying the target population and data sources was due to using the clinical environment for recruitment and data collection. As the target population is people prescribed ART and HIV clinic attendance is a pre-requisite for receiving ongoing ART treatment, this provides a relatively comprehensive sampling frame for recruitment. In contrast, few studies achieved trial participants representative of the country’s population diagnosed with HIV in terms of ethnicity and sex; poverty of reporting precludes drawing conclusions regarding representation in terms of sexual orientation, mode of HIV acquisition and migrant status. As the procedure for identifying the target population was largely appropriate, the poor representation of the population with HIV may be a facet of inadequate research design across other criteria leading to certain populations declining trial participation.
Few studies engaged the target population to develop the research questions and intervention. This can result in misaligned questions and sub-optimal intervention design (Gibbs, 2008) due to insufficient researcher understanding of the problem (Brett et al., 2014).

Social, cultural and personal differences influence the balance of power and hierarchy between the researcher and those being researched, especially in terms of intersectionality (DeVault and Gross, 2012). Consequently, hierarchical relationship between patients and healthcare team members who were mainly used for recruitment purposes introduces potential for consent bias (Nnaji et al., 2018). This may explain the observed poor representation of females and migrants (Hughson et al., 2016). Bias in recruitment processes may have been further compounded by the limited evidence of tailored consent processes such as language translations (Hunt & de Voogd, 2007). Incongruously, several studies reported translation of material and multi-lingual research staff for data collection processes. This discordance may reflect inadequate reporting rather than poor trial methods. Adherence to international guidelines for reporting patient and public involvement (Staniszewska et al., 2017) would enable confirmation of the extent to which the target audience were involved in the design, conduct and reporting of the research, however no studies acknowledged this guidance. Whilst the reasonable level of target audience involvement in designing and tailoring interventions is encouraging, approaches were far removed from the growing co-design literature that positions end users as integral to the innovation process (Bate & Robert, 2006).

A dissemination approach that garners support from the target patient/public population provides a driving force for implementation (Shippee et al., 2015). The almost non-existent presence of patients prescribed ART or their representatives in the analysis, evaluation and dissemination processes may therefore provide some explanation for the limited implementation of interventions (de Bruin et al., 2010; Simoni et al., 2017).
Assessing the cultural competence of HIV adherence trials or any RCT is innovative. Implications for future research are that culturally competent research methods should be adopted. This required change may be supported by refining trial reporting standards and evaluating the cultural competence of trial methods.
References


patients with severe immunosuppression: A 48 week, non-comparative, randomized, multicentre trial (IMEA 040 DATA trial). *Journal of Antimicrobial Chemotherapy, 71*(8), 2252-2261. doi:http://dx.doi.org/10.1093/jac/dkw103


Assessment criteria
The following ten criteria for culturally competent research were used to assess the quality of included studies:

1. **Forming partnerships**
Did the researchers work through gatekeepers to establish relationships with the target population?

2. **Defining research questions**
Was the intervention identified and initiated in consultation with the target population?

3. **Identifying the target population and data sources**
Did the research team frame data collection to facilitate the target population?

4. **Appointing staff**
Does the research team include representation of the target population?

5. **Recruitment sample**
Was the consent process tailored for the target population including awareness of within cultural variations?

6. **Data collection**
Was the data collection process tailored for the target population?

7. **Development of intervention**
Were the target population involved in the development/customisation of the intervention?

8. **Analysis**
Were research team members representing the target population involved in the analysis and interpretation of data?

9. **Evaluation**
Was there feedback from participants to confirm interpretation of the results?

10. **Reporting/Disseminating findings**
Did dissemination allow the target population to discuss trial findings and generate solutions?

**Rating**
These criteria were rated on a scale of 0 to 2 as follows:

- Awarded 0 if – Culturally blind, which describes methodological approaches underpinned by the belief that neither colour nor culture influence behaviour and that all people are the same

- Awarded 1 if – Culturally pre-competent, which describes approaches recognising that the dominant race or culture of a country is not universally applicable but fails to fully attend to cultural differences

- Awarded 2 if - Cultural competent, which describes approaches recognising the cultural diversity of the intended population

Criteria were adapted from Gibbs, et al. (2007)
Operational definition adapted from Cross, Bazron, Dennis and Isaacs (1989).
Figure 1. Flowchart of study selection process

Phase 1
Records identified (n = 559)
Records after duplicates removed (n = 553)
Records screened (n = 553)
Full-text articles assessed for eligibility
Articles included (n = 80)
Records excluded (n = 459)
- Full-text articles excluded (n = 14)
  - Not OECD country (n= 1)
  - Not adult population (n=1)
  - Abstract (n=11)
  - Not RCT (n= 1)

Phase 2
Developmental or evaluative articles screened (n = 52)
Articles included (n = 9)
Records excluded (n = 43)
- Unrelated (n=39)
- No additional information (n=4)
Figure 2. Performance of studies across cultural competence assessment criteria
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<th>First Author</th>
<th>Publication Year</th>
<th>Country</th>
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<th>Sex</th>
<th>Sexual Orientation and/or mode of HIV acquisition</th>
<th>Cultural competence score*</th>
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<td>Javanbakht, M.</td>
<td>2006</td>
<td>USA</td>
<td>Not</td>
<td>Not</td>
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<tr>
<td>de Bruin, M.</td>
<td>2010</td>
<td>Holland</td>
<td>100%</td>
<td>Not</td>
<td>Not</td>
<td>Int: Homosexual (78%)</td>
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<tr>
<td>Holstad, M.</td>
<td>2011</td>
<td>USA</td>
<td>Not</td>
<td>Not</td>
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<tr>
<td>Williams, A. B.</td>
<td>2006</td>
<td>USA</td>
<td>Not</td>
<td>Not</td>
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<tr>
<td>Miro, J. M.</td>
<td>2015</td>
<td>Spain</td>
<td>65%</td>
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<td>Not</td>
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<tr>
<td>Goujard, C.</td>
<td>2003</td>
<td>France</td>
<td>NA</td>
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<td>Not</td>
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<td>Rathbun, R. C.</td>
<td>2005</td>
<td>USA</td>
<td>Not</td>
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<td>Rawlings, M. K.</td>
<td>2003</td>
<td>USA</td>
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<td>Rosen, M. I.</td>
<td>2007</td>
<td>USA</td>
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<td>Moore, D. J.</td>
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<td>Kalichman, S. C.</td>
<td>2011</td>
<td>USA</td>
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<td>Duncan, L. G.</td>
<td>2012</td>
<td>USA</td>
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<td>Gross, R.</td>
<td>2009</td>
<td>USA, Puerto Rico</td>
<td>Not</td>
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<tr>
<td>Pellowski, J. A.</td>
<td>2016</td>
<td>USA</td>
<td>Not</td>
<td>Not</td>
<td>Not</td>
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<tr>
<td>Brunetta, J.</td>
<td>2015</td>
<td>Canada, Spain, Italy, France, USA, UK</td>
<td>Not</td>
<td>Not</td>
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<td>Wilkins, E. L.</td>
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<td>Canada, Germany, UK</td>
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<tr>
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<td>USA</td>
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<td>Himelhoch, S.</td>
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<td>USA</td>
<td>Not</td>
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<td>Konkle-Parker, D. J.</td>
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<td>USA</td>
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<td>Tuldrà, A.</td>
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<td>Spain, Holland</td>
<td>NA</td>
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<td>Antoni, M. H.</td>
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<td>USA</td>
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<td>Not</td>
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</table>
information not reported in the study/relevant data reported in the study presented where national HIV statistics not found. National HIV statistics were
obtained from CDC HIV surveillance report and HIV/AIDS surveillance in Europe (WHO) report. *Scored as 0 (culturally blind), 1 (culturally pre-competent) or 2 (culturally competent) across 10 criteria; total score can range from 0 (culturally blind) to 20 (culturally competent).