

Patient Centered Care for Persons with HIV Disease: Protocol Review for CASA Study (Care and Support Access) Early in Chronic Disease Management

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Abstract

Background: In the US, more than 1.2 million adults are living with human immunodeficiency virus (HIV); gay and bisexual men account for 82% of new diagnoses annually. Young men of color account for 67% of this total. Despite advances in disease control, lack of retention in care itself remains a barrier and how outpatient staff members impact this has not been investigated. The palliative approach is patient-centered care targeting "relief of suffering" and "quality of life." This paper describes the original protocol for the Care and Support Access Study (CASA) where outpatient HIV staff members are challenged to improve outcomes for young men who have sex with men (yMSM) by integrating the palliative approach early (ePA) with HIV care delivery.

Methods: The hypothesis is that ePA can favorably impact outcomes for yMSM in one HIV clinic compared with treatment as usual (TAU) at a second clinic. In the era of HIV disease control, we use a quasi-experimental design with mixed methods to compare patient-level outcomes at 2 HIV clinics. The intervention fosters incorporation of the ePA with care provision using didactic and iterative education. We survey HIV staff members with regard to stress of care-giving. Qualitative interviews will highlight impact of the experience.

Objectives: This paper reviews the aims of the study including: 1) compare outcomes of yMSM receiving care from staff using the ePA to those receiving TAU; 2) compare work-related staff stress at a clinic receiving the ePA with staff providing standard HIV outpatient care; and 3) refine, deliver and determine the acceptability and applicability of interdisciplinary professional education to deliver the ePA in HIV management.

Discussion: We will measure the impact of the ePA on care delivery relative to patient-centered benefits. Lessons learned can contribute to a model for working with diverse patients facing challenging life transitions.

Keywords: HIV/AIDS; Palliative care; Education; Retention in care

Abbreviations ART: Combination Antiretroviral Therapy; yMSM: HIV Positive Young Men who have Sex with Men; ySGLM: Young Same Gender Loving Men; HIV: Human Immunodeficiency Virus; IOM: Institute of Medicine; POS: Palliative Outcomes Scale; McGill QoL: McGill Quality of Life Scale; WHO: World Health Organization

Introduction

Despite recent advances in human immunodeficiency virus (HIV) disease control, lack of retention of patients in care delivery remains a barrier to ending the epidemic [1]. The US Centers for Disease Control and Prevention (CDC) estimates that 1.2 million adults were living with HIV in 2011, including 14% unaware of their infection. Of HIV positive adults, 76% were male and 64% of new infections were

attributed to males who had sex with other men (MSM). Baltimore, Maryland ranks fourth in new infection rates and maintains the highest death rate from HIV among US cities [2]. HIV positive young African American men who have sex with men (yMSM), living in Baltimore, face challenges such as the co-morbidity of childhood trauma and coping with a chronic illness during evolving sexual identity that may render them at high risk for morbidity, or early death [3,4]. These behaviorally-infected individuals cared for in adult clinics resemble the surrounding culture of youth facing psycho-social issues, neurocognitive disorders, stigma, lack of health insurance, poverty, changing sexual identity, and need for HIV prevention; and their adherence with HIV management is documented to be poor [5,6]. Adherence with medication and clinic visits are critical to achieving disease control [7]. Factors associated with better retention in care at twelve months include discontinuing substance use, decreased structural barriers, decreased unmet needs, and no negative beliefs about HIV [8-10]. Targeted, age and culturally appropriate efforts to

decrease gaps in the HIV continuum of care are critical to addressing the HIV epidemic [11].

The Institute of Medicine has recommended team-based care as optimal for care delivery in a complex health system [12]. Both the Affordable Care Act and the National HIV/AIDS Strategy call for establishment of the patient-centered medical home to provide care coordination using a team approach central to this model [13]. Patient centered care views patients in the context of their own social worlds: being listened to, informed, respected, and involved in care delivery with their wishes honored [14]. Recently described as relationship science, there are multiple patient centered care interventions to be incorporated, such as effective communication, time to address individual needs, prompt scheduling of appointments, support through case managers [15] and outreach to improve retention in care [16]. While most US HIV care delivery has been delivered by a multidisciplinary team, evolving management has become narrowly focused upon achievement of viral suppression and prevention of serious toxicities. Despite the positive impact of combination antiretroviral therapy upon survival, people living with HIV disease (PLWH) continue to need care and support throughout the illness because of psychiatric and other co-morbidities [17,18]. The palliative approach (PA) combines patient centered care using the team approach with recognition of the importance of care for caregivers, including health workers, when working with patients and their families during emotionally stressful transitions [19,20]. A recent randomized controlled trial, demonstrates that improving the work life of health care workers prevents stress and burnout that may undermine patient-centeredness in care delivery while improving population health and reducing costs [21]. For PLWH the PA is a) patient-family-centered; b) delivered by an interdisciplinary team that develops a prognosis-driven care plan; c) focused upon control of symptoms as well as achievement of viral control; and d) incorporates self-care strategies for clinicians caring for complex patients.

The US Health Resources and Services Administration published a definition of palliative care adapted for HIV disease in 1998 and declared that health systems should attend to the alleviation of symptoms and suffering, along with provision of necessary HIV treatments [22]. Since then, the literature supports early implementation of the PA [23] and African clinical trials have demonstrated the effectiveness for the individual [24]. The CASA study aims to measure the impact of an educational intervention for multidisciplinary staff members of one outpatient HIV clinic. We hypothesize that training HIV clinical staff in palliative skills will improve care and clinical outcomes for yMSM [25]. The study intends to 1) assess the impact of the intervention on outcomes for two target populations: a) staff (work-related stress and burn-out) and b) patients (retention in care, mental health [26] and quality of life) and 2) refine a curriculum for non-palliative clinicians caring for PLWH to be introduced early in disease trajectory. Quantitative data will be augmented by information from qualitative interviews from selected staff and patients in the final year of the study to appreciate response to the intervention.

Efforts to control the HIV epidemic have proven successful in settings where infected persons have access to combination antiretroviral therapy and recommended follow-up. In international settings, viral suppression, a laboratory marker for disease control, was documented in 86-90% of randomly selected persons stable for 9-15 months on combination antiretroviral therapy (ART) [1]. HIV/AIDS can be a chronic illness for those able to access treatment. However,

despite this achievement, persons living with HIV disease (PLWH) in African countries continue to suffer from 10-26 simultaneous physical and mental symptoms exacerbated by poverty and stigma [2]. Palliative care can augment patients' outcomes, boost adherence to ART and improve life expectancy [3]. Based upon these experiences, we identified palliative content useful for non-palliative specialists to introduce in a US clinic [4]. Simultaneously in the US, the Affordable Care Act (ACA) has extended health coverage for all populations. In 2010, the Patient-Centered Outcomes Research Institute (PCORI) was established to develop an evidence base to support the concept of the patient-centered medical home (PCMH).

Methods

The research question is: "Does the early use of the PA, concurrent without patient HIV management, improve patient outcomes for difficult to engage and retain HIV populations compared with treatment as usual (TAU)?" We use a nonrandomized, longitudinal interventional design to describe the impact of PA education for outpatient HIV staff (OHS) caring for yMSM. The impact upon patients is being measured before and after the OHS is trained. We intend to offer the control site training at the end of the study. Sites compared at baseline are similar as they are supported with federal funding that requires uniform care delivery. Qualitative interviews will add depth to the analysis. The conceptual framework guiding the educational intervention is Johnson's self-regulation theory [27,28] previously used for developing interventions to assist individuals facing uncertainties and stress of threatening events [29]. Self-regulation theory proposes that individuals respond consistent with their own understanding of an experience and can be influenced by information. In the context of this study, HIV staff can learn to appreciate that their own behaviour may represent a threat to optimal patient outcomes for yMSM. The educational intervention is grounded in constructivist learning theory, meaning that learners participate in a learning process whereby new experience is added to, and modifies, their previous understanding [30]. Following approval by the UMB human research protections panel, participants in 2 cohorts complete the informed consent process. The larger cohort is 204 yMSM enrolled in outpatient HIV care at either of 2 HIV clinics who complete 3 serial surveys 4 to 6 months apart. The second cohort, OHS at these 2 HIV clinics will complete surveys before and after the intervention regarding work-related stress and compassion fatigue. The patient cohort is yMSM ages 18-35 years living in Baltimore in the era of availability of effective antiretroviral therapy (ART). Qualitative interviews from selected members of each cohort will be completed near the end of the study to understand the experience from the point of view of participants. There is a sub-cohort of staff made up of seven multidisciplinary members of OHS, identified as the CASA team, that will receive the educational intervention. We chose to replicate a usual model for diffusion of new knowledge in clinics consistent with the Train-the-Trainer approach augmented with on-site expert coaching over 18 months for this team and quarterly in-service for the whole staff of the intervention site. The intervention is educational offering elements of the PA observed to be acceptable to outpatient HIV service providers in resource constrained settings [24]. The original curriculum was grounded in US-based didactic and iterative educational methods [31,32]. Consistent with goals of the funder, members of an independent stakeholder advisory panel have been involved with each step of the study. The overall goal is to introduce use of the PA, not to educate palliative care specialists.

For the patient cohort, self-administered surveys will be completed using a touch-screen notebook with audio-CASI data collection software during regularly scheduled outpatient visits. Measures relevant to HIV care (attendance, adherence and viral suppression) and assessments of mental health and quality of life (QoL) will be collected. Personal health information regard biobehavioral, socio-demographic and situational factors will be collected using validated instruments that our own clinical and research experience suggest might impact outcomes either directly or through the experience of the intervention. In addition, disease/treatment characteristics will be extracted from the electronic medical record. Validated instruments include: self-report measures of adherence to ART developed and validated by the Adult AIDS Clinical Trials Group (AACTG) [33]; the HIV Symptom Index [34] and physical functioning assessed with measure of Performance Status [35]; psycho-social history from a 3-item alcohol/drug use and treatment history and a 3-item mental illness and treatment history (both of these were developed for use with PLWH from vulnerable populations) [26]; the Life Events Checklist [36] widely used to identify events associated with post-traumatic stress disorder (PTSD), the Sexual Behaviour Questionnaire (NHANES 2009-2010) [37] about sexual identity and activity plus sexually transmitted diseases, other than HIV, to document prevention behaviour reflecting engagement in care. We added one tested question related to having sex for money. To measure mental health and QoL, we used the Rosenberg Self-Esteem Scale [38,39]; McGill Quality of Life Questionnaire (MQOL) [40,41]; and the Palliative Outcome Scale (POS) [42]. To measure goal setting and care planning in the PATIENT cohort, we are asking if they have identified someone who might serve as their health power of attorney; and, to measure perceived satisfaction with treatment/care, we are using a modified FAMCARE Scale [43]. For the STAFF cohort there are 2 surveys to document socio-demographic/professional background and self-defined burnout [44] plus the AIDS Stress Scale [45].

For the analysis, we will use the RE-AIM Framework [46] that addresses acceptability, feasibility, and reach of the intervention to guide analysis of findings. This framework focuses attention and critical thinking not only on the content and outcome of a program, but guides examination of the service environments within the social circumstances, culture, and care needs of the diverse communities affected. It focuses the analysis on essential program elements that foster sustainable adoption and implementation of evidence-based programs and incorporates patient, setting and staff perspectives. Following a separate consent process, participant insights plus those of the stakeholder advisory panel will be utilized to suggest programmatic revision that will improve reach, implementation, and effectiveness of the program for other HIV clinics. The study is registered as a clinical trial (NCT02136680) and aims to gain culturally appropriate concepts and factors that might be used to develop future interventions for care and treatment of HIV positive yMSM. There are no pharmaceutical or imaging interventions. The PI and research team will review data yearly for safety in addition to monitoring the data collection progress.

Discussion

HIV disease is now a chronic illness for those able to access treatment. For HIV patients who are considered difficult to reach, or who have not achieved viral suppression in the era of effective treatment, there is a clear need to understand and address barriers to successful disease management. These barriers may be intrinsic to the

patient, but external factors must be reviewed and addressed. While the environment itself may pre-dispose younger patients to lack trust in the health care system, the potential role of OHS themselves in the loss of yMSM from the care cascade in the era of effective HIV disease management requires further attention.

The PA is grounded in: a) respect for racial, ethnic and cultural aspects that characterize the individual; b) open recognition of the impact of life transitions including acknowledgement of a remaining threat to survival in HIV disease despite therapeutic advances; and 3) clarification of the need for self-care by the health team faced with extending care to an emotionally challenging population. Our intervention aims to improve the illness experience for HIV+ yMSM by enhancing the relationship with clinicians where the interdisciplinary team itself represents the clinician. Scientific evidence exists for each palliative concept, but early integration in the HIV population has only been tested in the African setting. For OHS, the impact of self-care while implementing new patient care strategies is evaluated using pre- and post-intervention surveys and selected qualitative interviews. Another purpose of the CASA study is to highlight the publication of this description of the protocol affords increased transparency regarding the aims and objectives of the study and future analysis of generated data.

Conclusion

Here we present the initial protocol for the CASA Study that intends to offer patient centered, palliative skills education to a multidisciplinary group of HIV outpatient health workers to determine whether this educational intervention will be acceptable and enable staff members to improve engagement and retention of a difficult-to-reach population. Team coaching is augmented with quarterly in-service sessions for all staff members. Qualitative interviews will enhance quantitative data describing the current patient population in one high prevalence metropolitan service area.

Competing Interests

The authors declare no competing interests.

Authors' Contributions

CA, VR, DK and GP conceived of the original study with input from former and existing members of the Community Advisory Panel (CAP). CA, MCL, GP, VR, DK, and RB wrote the paper with critical review and input members of the CAP. All authors read, made comments and approved the final manuscript.

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