STUDY PROTOCOL

Patient loyalty to HIV care in an HIV facility in Eldoret, Kenya: A mediated mediation [version 1; peer review: awaiting peer review]

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Abstract

Patient loyalty is the continuous commitment and engagement in care where patients can improve and sustain quality of life through continuous use of medical care. Identifying strengths and weaknesses in providing excellent quality care is a key measure of success of healthcare professionals and hospital management. However, few studies have examined patient loyalty from a strategic leadership perspective within HIV health care systems. The purpose of this study is to determine how patient loyalty to HIV care is influenced by multiple factors in a healthcare system environment. The study employs a mixed-methods approach guided by the complexity theory and the theory of planned behavior. A total of 444 surveys with (50 healthcare providers and 394 adult HIV-infected patients) currently on antiretroviral drugs, as well as 22 in-depth interviews with healthcare providers will be conducted. The study will be done at AMPATH Eldoret Kenya. We will use stratified proportionate and census sampling methods to select study participants for the survey while purposive and convenient sampling techniques will be used for in-depth interviews. Structured questionnaires and interviewer guides will guide data collection. Quantitative data analysis will entail hierarchical regression to test direct effects while multiple regression will test the mediation effects using the Hayes PROCESS Model No.6 in SPSS. Qualitative data analysis will be conducted using a thematic analytical method.

Keywords

Strategic leadership, Healthcare system factors, Relational Dynamics, Patient loyalty
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Introduction

Patient loyalty is a behavioral impulse that makes a customer engage with and repeatedly purchase a particular good or service for a long time, despite situational influences having the potential to cause customer switching behavior (Adhi Mahendrayana Putu et al., 2018; Mortazavi et al., 2009; Ngurah et al., 2018). It highlights the importance of both attitude (commitment) and behavior (repeat purchasing of services) aspects of loyalty (Roberge et al., 2001). Consistent with healthcare studies specific to HIV, loyalty implies retention in care, where HIV patients are continuously engaged in care regardless of whether the care is received from a different clinic to the one in which they were originally enrolled, and when patients return to the same clinic at a particular point in time (Kiplagat et al., 2018; van der Kop et al., 2018). In Kenya, like in other countries, most studies on patient loyalty focus on the antecedents, including satisfaction, quality, hospital brand image and trust, because it increases treatment effectiveness and intentions to revisit (Ageyi et al., 2014; Kim et al., 2017; Kikiprong Tarus & Rabach, 2013; Zhou et al., 2017); however, there is a literature gap on how patient loyalty to HIV care is influenced by these antecedents. Little is known on the role of multiple factors within the healthcare system environment on patient loyalty to HIV care.

Most studies that have discussed the importance of healthcare system leadership (Gilson & Agyepong, 2018; Gilson & Daire, 2011) describe the role of a clinical leader (Daly et al., 2014) as demonstrating clinical knowledge and establishing a good atmosphere for collaboration (Larsson & Sahlsten, 2016), which has the potential of determining whether patients remain loyal in care. The adaptive leadership framework (Heifetz et al., 2009) explains the importance of leadership within healthcare organizations, particularly in helping people to adapt and transcend challenging situations such as chronic diseases. However, there have been insufficient investigations to establish the role of leadership at the point of care where the interaction and relationships between patients and healthcare providers take place (Bailey et al., 2012), where a clinical leader plays a critical role in working with other providers (Edmonstone, 2011). Furthermore, clinical leadership studies emphasize on individual leaders at senior levels, overlooking those at the middle levels who deliver health care in practice in a way affected by their health care context (Nzinga et al., 2018). Moreover, a comparative qualitative study in Kenya and Indonesia revealed challenges in ensuring good governance for health (McCollum et al., 2018), while an evaluation of the Kenyan health system established a requirement to improve healthcare systems and institutions, specifically at the county level, since they have reported challenges like unclear homogeneous management structures, insufficient capacity to develop health laws that can incorporate the civil society in the process of decision making (Mulaki & Muchiria, 2019). Similarly, a weak leadership framework influenced healthcare delivery in South Africa (Govender et al., 2018). This creates a gap in how clinical leaders utilize strategic attributes at the operational level, to influence healthcare system performance, provider-patient relationships, and loyalty in an HIV care facility in Eldoret Kenya.

Studies on various health system building blocks indicate that health system factors such as distance to the facility, patient waiting time, used means of transport, perceived quality of service and attitude of a healthcare provider were statistically significant predictors of the number of antenatal visits in Kisumu county, Kenya (Kilowua & Otieno, 2019). Similarly, a Kenyan qualitative study found healthcare system factors constrain HIV care providers in delivering high-quality care to HIV patients (Genberg et al., 2019) while in Zambia, like in Pakistan, both health system hardware and software factors such as infrastructure to protect privacy, inflexibility in visit schedules influence patient disengagement among lost to follow up (LTFU) patients (Fatima et al., 2018; Mwamba et al., 2018). Whereas this is evident, little is known about how the healthcare system factors mediate the relationship between strategic clinical leader attributes and patient loyalty to HIV care in an HIV facility in Eldoret, Kenya. Previous studies demonstrate that manager transformational leadership influences patient-nurse relationships and patient outcomes independently of supportive practice environment particularly on patient falls with statistically significant effects, but the study did not capture clinical outcomes which could have provided a clear picture of other patient outcomes (Higgins, 2015). Besides, organizational climate mediates the relationship between transformational leadership and patient safety in Saudi hospitals (Alotaibi et al., 2015), while the hospital environment was a significant mediating factor in the relationship between empathy, assurance, and customer loyalty in the Yemeni capital (Hamoud & Alshehari, 2018). Besides, the quality of the healthcare healing environment mediated the relationship between patient satisfaction and core health delivery in Ghana. This implies that the better the healthcare environment, the more the patients are satisfied with the delivery of care (Amankwah et al., 2019).

As leadership plays a critical role in ensuring healthy relationships between patients and providers within a healthcare system (Stevenson et al., 2019), there is a need for strategies to effectively help providers, patients, and families develop and manage relationships in clinical encounters; however, the changes health care systems require to support providers as adaptive leaders must be elucidated (Anderson et al., 2015). Relational dynamics can attract and retain patients to an organization through friendship and partnership (Sexton & Sen, 2018), and HIV is a condition that requires intermittence of patience to care, a unique relationship with service providers with understanding, tolerance and continuous assessment (Bucciardini et al., 2015). In most cases, patients lose loyalty when an ongoing relationship with primary doctors and personal trust is lost due to sharing and use of patient clinical information by others (Waibel et al., 2018), provider-patient relationships structural factors (Wachira et al., 2018) that can predict negative patient outcomes including patient...
dissatisfaction and late presentation to care (Alipoor et al., 2017; Kawonga et al., 2016; Kiplagat et al., 2018). However, there is insufficient literature on how patient-provider relational dynamics directly and indirectly mediate patient loyalty-leadership relationships in the HIV setting in terms of trust, communication, and bonding. Previous studies found a stronger mediation effect of patient trust on patient-centered communication (PCC) as the frequency of patient hospital visits increased (Hong & Oh, 2020) and a partial mediation effect of patient trust on the relationship between nurses’ cultural competence and patient satisfaction (Tang et al., 2019). Patient satisfaction mediates nursing service quality and patient loyalty and between the physical environment, customer-friendly environment, and patient loyalty (Fatima et al., 2018; Schaal et al., 2016). There is, however, scant information on the mediation role of patient-provider attachment and particularly in HIV care.

Methods
Study design and area
This study will be conducted at Academic Model Providing Access to Healthcare (MTRH-AMPATH) in Eldoret, Kenya. AMPATH is in partnership with MTRH and the College of Health Sciences (MUCHS), Moi University in Eldoret Kenya, and a consortium of North American academic medical centers (Einterz et al., 2007). AMPATH serves a catchment area of 4 million people and has supported HIV care delivery for over 180,000 patients at nearly 150 Ministry of Health (MOH) sites across western Kenya. The AMPATH model leads in promoting and fostering a comprehensive approach to HIV/AIDS control that complements and enhances the available health infrastructure. It provides free antiretroviral therapy (ART) to all patients qualifying for therapy, as well as comprehensive nutrition services, psychosocial support, and economic development training. Importantly, AMPATH collaborates with healthcare providers at all levels of government to community health workers (CHWs) in providing effective care that is culturally sound (Karwa et al., 2017). For this reason, AMPATH forms a healthcare system with all the infrastructural arrangements that provide a basis for studying the healthcare system leadership, patient-provider relational dynamics, and loyalty of patients in HIV care.

Target population
The study involves adult HIV-infected patients and healthcare providers (clinicians, nurses, social workers, HTCs, nutritionists, and retention workers) in MTRH-AMPATH. This population interacts with patients within the healthcare system environment that are organized into care modules (1–3) for adults; each module is headed by a clinical officer who plays a leadership role. At the end of July 2019, the total population of adult HIV-infected persons (aged ≥18) receiving ART medication both in the active and the lost-to-follow-up (LTFU) categories was 26,064 (MTRH-AMPATH records, July 2018) and corresponding 50 healthcare providers (MTRH-AMPATH records, July 2019).

Inclusion and exclusion criteria
The inclusion criteria are adult HIV-infected patients under the AMPATH care treatment plan, currently on ART in classified care modules (adult modules 1-3), aged 18 years and older, and voluntarily willing to participate in the study. The healthcare providers in the corresponding care modules must also have at least 1 years’ experience in HIV care. Patients who present with severe illness or psychological cases will be excluded from the study. Similarly, healthcare providers that have busy schedules at the time of the study will be excluded.

Sampling design, sample size, and procedures
Sample size. To generate the sample size for the patients, the Yamane (Yamane, 1967) formula below was used to compute the sample size with a relative precision of ±5% and a 95% confidence level, where n is the sample size, N is the population size and e is the level of precision.

\[
 n = \frac{N \cdot e^2}{1 + N \cdot e^2}
\]

In this formula;

N= Population size (26,064) of active and LTFU patients in care modules 1-3 are treated as strata

e= Sampling error (0.05)

n= Sample size (394)

To sample the patient categories from the total sample size (n=394) (Table 1), a proportionate sampling approach is used to categorize patients into adult care (modules 1-3). The sampling approach allows stratification of the active and lost to follow-up (LTFU) patients proportionately. To ensure an equal chance of participation from each of the three strata care modules, a fraction of the population from each stratum is multiplied by the total sample to get the respective sample population for each module. This generates (for module 1, n = 128, module 2, n = 135 and module 3, n = 131) respectively. From each module, the study sample size (n=394) is divided by the estimated population size to obtain a systematic random starting point. In this case, every 3rd patient will be systematically selected to participate in the study until the desired sample is achieved. Notably, clinicians in each of the adult care modules attend to at least 80 patients per day (MTRH-AMPATH daily clinical records). For the healthcare providers (HCPs), the total population sample is 50 in the HIV facility; a census will be used to enroll all of them from their various departments. They play a critical role in the provision of HIV patient care, interact and build relationships with HIV patients and other providers including their leaders in charge. Based on their HIV care experience, they understand the healthcare system structures and patient-provider relationship dynamics hence will respond to the issues of strategic leadership.
and healthcare provision. For the qualitative methods, purposive and convenient sampling strategies will be used to select 22 healthcare providers to obtain an in-depth understanding of healthcare system leadership until data saturation.

Recruitment of study participants
Patients will be recruited from two points. First, clinicians will be requested to refer them to a room where this study will be done after examination and be approached at the point of entry (at the triage section). The patient flow in each of the care modules is systematic where patients are first triaged before they see a clinician or directed to the right point of care. The healthcare providers will be approached individually in their respective care modules, requested to fill in a questionnaire and participate in in-depth interviews at a convenient date and time. Those who accept to participate will first consent.

Variable measures
Patient loyalty (dependent variable). Patient loyalty will be measured using five behavioral items obtained from customer loyalty and patient loyalty measures that had been utilized by previous studies on a 5-point Likert scale ranging from (1=strongly disagree to 5= strongly agree) and showed good reliabilities of $\alpha \geq 0.70$ (Hacettepe et al., 2016; Juhana et al., 2015; Lee, 2019; Ngoma & Ntale, 2019). The items will be subjected to principal component analysis (PCA) to extract factors $\geq 5$ through an orthogonal rotation (varimax with Kaiser Normalization) (Chan & Idris, 2017; Kim et al., 2017), to assess validity. Next, a data transformation procedure will be conducted to determine the means that will be used for multivariate analysis and this process will be applied to all the variables in the study.

Strategic leader attributes. Two dimensions will be used (the adaptive leadership framework and clinical leader attributes). The Adaptive Leadership Framework developed by Heifetz (Heifetz & Laurie, 1997) for business does not only focus on the leaders’ capabilities but also on the leader-follower relationship as well as internal and external factors that impact the organization. This framework has been applied in the healthcare setting e.g. in chronic illness, (Anderson et al., 2015; Bailey et al., 2019), focusing on the leadership attributes to influence the healthcare system where the adaptive and collaborative work takes place between the patients and the healthcare providers and other stakeholders. Seven items adapted from the framework were modified and simplified to suit the current study. The items use a 5-point Likert scale ranging from (1=strongly disagree to 5= strongly agree). While clinical leader attributes, 10 questions on a 5-point Likert scale ranging from (1=strongly disagree to 5= strongly agree) are a collection of measures from previous studies.

<p>| Table 1. Population sample and sampling frame. Population sample =26,064; sample size = n = 394. |
|---------------------------------------------|-------------------------------------------------|-------------------------------------------------|-------------------------------------------------|</p>
<table>
<thead>
<tr>
<th>MTRH Care Module</th>
<th>Total per module</th>
<th>Proportionate Sample Distribution ($x$) &amp;=&amp; (=$a/N x n$)</th>
<th>Systematic Sampling (sample size/total $\Sigma(x)$) = &amp;($=$n/$\Sigma(x)$)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Module 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>3541</td>
<td>54</td>
<td></td>
</tr>
<tr>
<td>Lost to follow up (LTFU)</td>
<td>4873</td>
<td>8414</td>
<td>74</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>128</td>
<td>3.08</td>
</tr>
<tr>
<td>Module 2</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>4450</td>
<td>67</td>
<td></td>
</tr>
<tr>
<td>LTFU</td>
<td>4522</td>
<td>8972</td>
<td>68</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>135</td>
<td>2.92</td>
</tr>
<tr>
<td>Module 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Active</td>
<td>4173</td>
<td>63</td>
<td></td>
</tr>
<tr>
<td>LTFU</td>
<td>4505</td>
<td>8678</td>
<td>68</td>
</tr>
<tr>
<td>Total</td>
<td>26064</td>
<td>131</td>
<td>3.01</td>
</tr>
</tbody>
</table>

including the clinical leadership competency framework assessment tool (NHS Leadership Academy, 2011), attributes of clinical leadership (Mannix et al., 2013) and Victoria Quality Council. These items have been widely used in other studies in clinical settings and have demonstrated good reliabilities (NHS Leadership Academy, 2011; Nicol, 2012).

**Healthcare system factors (mediating variable).** Healthcare system factors are measured by the use of non-health aspects of care that relate to the care environment and the way healthcare is offered to clients. The 10 items from the WHO healthcare system framework measuring healthcare system responsiveness and performance will be used. Studies that have utilized these measures borrowed from the WHO health system responsiveness framework and modified to suit the relevant context and asked questions in a 5-point Likert scale (Chao et al., 2017; Miller et al., 2015; Murray & Frenk, 2000; Rachlis et al., 2016; Rashidian et al., 2011) showed good reliabilities. Like other variables, the items are measured on a 5-point Likert scale ranging from (1=strongly disagree to 5= strongly agree).

**Patient-provider relational dynamics (mediating variable).** To measure relational dynamics, patient trust in the healthcare provider and the healthcare system, patient-provider communication, and patient-provider relational bonding/attachment assesses patient-provider relational dynamics. To assess patient trust, 10 items that have been utilized in previous studies will be used. These questions will ask patient trust in the healthcare system to give the possible best care, patient confidence in the healthcare system to provide possible care, trust in the provider to provide accurate medical information, make an excellent medical judgment on behalf of the patient, provide treatment options for the patient, prioritize patient medical needs and worrying less by putting their lives in the hands of the providers. Also, providers caring for their needs than those of the patients and the chances of not keeping patient information private. All questions will be asked on a 5-point Likert scale, ranging from strongly agree to strongly disagree. The measures indicated good reliabilities of >0.85 (Anderson & Dedrick, 1990; Dugan et al., 2005; Thom et al., 1999).

**Patient-provider communication.** To measure patient-provider communication, a collection of measures from the perspectives of patient-centered communication, physician communication, and provider-patient communication will be utilized and particularly from the core functions of patient-centered communication. A total of eight questions, including the provider greeting the patients to make them feel comfortable, providing a chance for the patient to ask health-related questions and the provider answering them, involving the patient in decision making concerning their health, spending enough time with the patient in explaining things for better understanding, helping the patients to deal with feelings of doubt by encouraging them to express their thoughts concerning health problems and, checking to see if the patient treatment plan is acceptable. These questions will be asked on a 5-point Likert scale (1=strongly disagree to 5= strongly agree) to assess this construct from previous studies that showed acceptable validity and reliability of >0.80. (Jiang, 2017; Wachira et al., 2014).

**Patient-provider bonding/attachment.** Attachment theory has been used as a model of doctor-patient interaction framework for clarifying, measuring, and training medical personnel in the advancement of patient-centered care (Cassedy et al., 2015). To measure patient-provider relational bonding/attachment, 10-items from the Relationship Style Questionnaire on a 5-point Likert scale ranging from (1=strongly disagree to 5= strongly agree) will be used. The framework has been used to assess diverse healthcare issues that focus on experiences in close relationships. For example, in HIV care, HIV + patients with insecure attachment styles are more likely to experience higher levels of stress and worse adjustment to illness than those with secure attachment styles (Koopman et al., 2000). This tool was also administered in a low-income country with good reliabilities (Holmes & Lyons-ruth, 2006).

**Reliability and validity**

The reliability of the instrument will be tested using the Cronbach alpha coefficient to assess the internal consistency of the scale (Portillo, 2011). Accordingly, reliability values of greater than 0.70 indicate the data instrument is reliable (Masa’deh et al., 2016). Exploratory factor analysis (EFA) will also be used to assess convergent validity by assessing the factor loadings of items on specific constructs and assess goodness of fit of the model in predicting the primary outcome using statistical indices (Masa’deh et al., 2016). Normally, factor loadings of greater than 0.50 indicate a variance in the respective measurement items. The study will also examine the quality of data by testing regression assumptions as a pre-requisite for multivariate data analysis to avert potentially severe effects on the ability to draw inferences from the analysis of data (Ernst & Albers, 2017). These include normality, linearity, autocorrelation, and multi-collinearity statistical tests. The data instruments will first be pre-tested before data collection by administering the survey questionnaire to ten participants, including six patients and four healthcare providers, to determine the suitability of the questions. Likewise, for the interviewer guide, four healthcare providers stratified by gender will be interviewed. The pre-testing exercise will take approximately an hour in the HIV facility. Any suggestions and amendments arising from the respondents, will be incorporated in the instruments before final administration and the pre-tested data will be excluded in the final data analysis.

**Study conceptual framework**

The conceptual framework in this study consists of domains that influence the aspects of patient loyalty to HIV care including strategic clinical leader attributes, healthcare system factors, and patient-provider relational dynamics. The assumption is that a clinical leader in charge who possess strategic attributes can influence the healthcare system environment characterized by complex and dynamic factors, where the patient-provider relational dynamics take place. Both the providers and patients have unique characteristics that enable them to
engage in relational dynamics which in turn influence patient loyalty to HIV care directly or through mediation. This conceptual framework is supported by the Theory of Planned Behavior (TPB) advanced by Ajzen (1991) and the complexity theory by George A. Cowan, the head of research at the Los Alamos nuclear laboratory in the mid-1980s (Golash-Boza et al., 2012). TPB provides that an individual’s behavior is driven by desires or intentions that are motivated by the attitude toward the behavior, subjective norms, and perceived control of behavior (Sniehotta et al., 2014) (Ajzen, 1991), in this case, loyalty to HIV care behavior. In most HIV studies, TPB has been used to predict behaviors such as condom use (Espada et al., 2016; Semungus et al., 2017), HIV testing intention (Ayodele, 2017), intentions to adhere to ART (Saal & Kagee, 2012). The complexity theory, on the other hand, is described based on the interrelatedness of components of a system on each other where the complexity increases with the number of components and the unique relations between them (Kannampallil et al., 2011), which may be explained by the interactions of multiple factors within the healthcare system that may influence patient loyalty to HIV care. For example, in leadership studies, complexity theory is used to manage complex situations (Marion, 2008) by utilizing the adaptive leadership framework in implementing culture change in nursing homes, (Corazzini et al., 2015), adaptive leadership and person-centered care (Corazzini & Anderson, 2015). While TPB has inspired numerous health research, studies have been criticized for their static explanatory nature, which does not provide a clear understanding of behavioral evidenced effects on participants’ cognitions and future behavior (McEachan et al., 2011), while complexity theory assumptions remain murky despite much description, which hinders the development of its implications for leadership (Schneider & Somers, 2006). In the present study, the theories support the prediction of patient loyalty to HIV care considering the complexities that occur within the healthcare system when different elements interact with each other creating tensions that may hinder patient loyalty to HIV care (Figure 1).

Data analysis and statistical plan
For quantitative data, data processing and management shall be done which will include developing codes in SPSS for easy data entry, data cleaning, and test for regression assumptions before testing hypotheses. A paired statistic from the patients and healthcare providers will be computed and used to test the hypotheses utilizing the hierarchical regression method for direct effects and Hayes PROCESS Macro Model No.6 (Hayes, 2013) for serial mediations in SPSS vs.23 following the

![Figure 1. Conceptual Framework.](image-url)
dissemination of study outcomes
Study findings will be shared with the Moi Teaching and Referral Hospital, HIV facility leaders, the study participants, in the Moi University Library as a thesis document for future knowledge sharing, in refereed journals and book chapters.

Conclusions
Patient loyalty is well researched in areas of marketing and healthcare studies in examining patient outcomes such as safety and mortality. This study provides an opportunity to extend investigations beyond the patient loyalty antecedents to determine how multiple factors such as strategic clinical leadership within a healthcare system, factors surrounding the care system and patient-provider relational dynamics influence patient loyalty to HIV care in an HIV facility in Eldoret, Kenya directly or indirectly through mediations utilizing statistical models to test interactions and relationships among the variables.

Data availability
No data are associated with this article.

Author contributions
FA: Conceptualization, methodology, writing the original draft, review, and edit
JW, MK & VB: Conceptualization, methodology, supervision, review, and edit of the final draft

References

Ethical considerations
This study has received ethical approval from the Institutional Research Ethics Committee (IREC) in Moi Teaching and Referral Hospital (MTRH) (Approval No.0003485), a permit letter from the MTRH-AMPATH HIV facility and, a research license from the National Commission for Science, Technology, and Innovation (NACOSTI No NACOSTI/P20/3253), to collect data from the adult HIV-infected patients and the health care providers in MTRH-AMPATH HIV facility. Before signing informed consent, participants will be given sufficient information explaining the study purpose and procedures. Participants who do not understand English will be explained in Swahili. To ensure the privacy and confidentiality of the participants, a private room within the HIV facility will be kept confidential by only using it for the study and de-identifying data that may link the participants to protect anonymity. Overall, participants will be treated equally and fairly during enrollment and participation.

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