Patient loyalty to HIV care in an HIV facility in Eldoret, Kenya: A mediated mediation [version 2; peer review: 2 approved with reservations]

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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
Amendments from Version 1

In the abstract, the objectives of the study have been clearly stated and the population sample defined clearly. In the background of the article, empirical findings have been discussed that cut across disciplines including business, marketing, and healthcare studies providing diverse perspectives about patient loyalty in healthcare relationships. A detailed review of empirical literature discussing the objectives of the study has been provided. In addition, the conceptual framework has been shifted from the methods section to the end of the literature review section. In the methods section, the mixed methods research design has been described as a parallel mixed methods design that reflects the exploratory and explanatory designs. The exclusion criteria for healthcare providers exclude those who will not want to participate. Also, qualitative measures have been included. The practical implications of the study have also been discussed.

Any further responses from the reviewers can be found at the end of the article.

Introduction

The notion of patient loyalty has been extensively discussed in marketing and healthcare studies. In marketing literature, 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 (Mortazavi et al., 2009; Ngurah et al., 2018). The definition highlights the importance of both attitude (commitment) and behavior (repeat purchasing of services) aspects of loyalty (Roberge et al., 2001). In healthcare studies, patient loyalty is a behavior that is influenced by factors like commitment to parties, such as patient trust in the physician and the quality of interpersonal relationships (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). Retention is also conceptualized in terms of missed appointments, medical visits at regularly defined intervals, and a combination of those methods focusing on the use of the health care system (Horstmann et al., 2010). Scholars across disciplines consent that patient loyalty is a behavioral impulse that makes a customer engage and remain in the repeated purchase of a particular good or service for a long time (Ngurah et al., 2018).

In sectors such as banking, tourism, transportation, and healthcare, they all need loyal customers to survive in the challenging business environments where the number of hospitals has increased and patients are “customers”, hence they need to keep loyal patients to survive in the industry (Tosyali et al., 2019). Customer loyalty in perspective constitutes an underlying objective for strategic market planning, and this represents an important basis for developing a sustainable competitive advantage (Dick et al., 1994).

However, there is insufficient literature on what HIV-infected patients and clinicians perceive to be patient loyalty and its determinants in HIV care. 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 (Aguye et al., 2014; Kim et al., 2017; 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). Similarly, the strategic leader attributes that clinical leaders should have at the primary care and how they influence patient loyalty is less documented. 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 (Nzina 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 (Hamood & 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.

**Literature review**

1. **Determine the proportions of patients with patient loyalty to HIV care among patients receiving care at AMPATH-MTRH, Western Kenya**

Achieving patient loyalty to care is the ultimate goal for many health organizations (Kim et al., 2017), however, patient loyalty to HIV care is elusive in SSA. In marketing studies, customer loyalty is an important factor in the service business as it represents strong and positive relationships between customers and service providers (Chang et al., 2013). Patients who were treated at the Banyumas Regency Hospital expressed a high level of loyalty that was not due to the high quality of the relationship but because they were generally satisfied with the treatment process (Astuti & Nagase, 2016). Patient loyalty is one of the critical factors in ensuring the sustainability of hospitals and gaining a competitive advantage in the changing health sector (Amarat & Sen, 2018). Literature indicates that loyal customers are likely to use the same service provider repeatedly and spread positive word of mouth (Chang et al., 2013), patients who felt that the hospital valued them had high patient loyalty while service quality and emotional value and professionalism had relatively more effects on patient loyalty in a public university hospital in Turkey (Hacettepe et al., 2017). Moreover, treatment effectiveness and satisfaction positively influenced patient intent to revisit the hospital (Kim et al., 2017). However, the quality of the relationship between a patient and a healthcare organization can decrease patient loyalty which may make patients switch provider and potential loyalty is destroyed (Astuti & Nagase, 2014). Similarly, loyalty is vulnerable to erosion when a patient decides to try treatment elsewhere, experiences dissatisfaction, or receives negative information about the performance of services, and can result in a reduction in loyalty (Astuti & Nagase, 2016). While most studies on patient loyalty are influenced by or through patient satisfaction independent of service quality (Hacettepe et al., 2017; Mbuthia et al., 2017), however, there is insufficient literature on the proportions of patients who have loyalty to HIV care in Western Kenya that has a high population of HIV infected persons (UNAIDS, 2016) challenges of adult retention in HIV care (Kiplagat et al., 2018) and non-adherence to antiretroviral therapy (ART) (Mukumbang et al., 2017).

2. **Explore the perceptions of healthcare providers on the strategic leader attributes for clinical leaders**

In every organization, strategic leaders are required to perform specific roles including making strategic decisions regarding the overall direction of the organization, engaging with stakeholders, establishing follower trust, communicating organizational vision, and addressing conflicting strategic issues (Samimi et al., 2020). In healthcare studies, many
physicians are currently in leadership positions whether in their practice, hospital, or health system. They perform complex leadership roles that range from managing a small clinic to serving as the hospital CEO and regardless of the assignment, their success depends on teams and those who lead them. Hence, leadership training at some level is important for every physician leader (Kelley, 2021), and particularly in developing their strategic capabilities to manage the changing healthcare systems. The clinical attributes that shape a clinical leader include organization of care to support the well-being of patients (Boamah, 2018), collaborative, summative in providing overall direction and bringing other views together, flexible in decision making, approachable to all levels of medical and nursing staff, articulate, strategic planner, participative in executive policy (Heinen et al., 2019; Sonnenberg et al., 2018; Stanley et al., 2017; Stanley, 2017; Stanley, 2016). In digital healthcare leadership, similar leadership attributes were reported which include being proactive, visionary, and dynamic, leading by example to take the organization to the next level (Alanazi, 2022). Additionally, charisma, cognition, power, and motivation were identified as attributes of strategic leaders (Samimi et al., 2020). The medical leadership competency framework highlights personal qualities such as acting with integrity, self-development, self-management, and self-awareness, while working with others, the leader should be a team leader, build and maintain relationships, develop networks and be accommodative by encouraging contributions (NHS Leadership Academy, 2011). However, the conceptualization of leadership is shifting as individuals from other clinical disciplines see themselves as leaders (Shams et al., 2019). Similarly, physicians and clinicians who have leadership responsibilities should have core leadership competencies, emotional intelligence, build teams and manage change as their important attributes to lead, however, there is still a gap in their leadership competency and level of preparedness for significant leadership roles (Kelley, 2021). There is however, an observation of limited data on what patients and providers perceive to be clinical leader strategic leader attributes to improve healthcare system performance and impact patient care in the HIV care system.

3. Examine the provider’s perceptions of the relationship between strategic leader attributes and patient loyalty to HIV care

There is insufficient literature on how providers perceive the influence of strategic leader attributes in the healthcare system environment and patient outcomes. Most studies have highlighted how leadership attributes such as transformational, transactional, and clinical leadership influence patient outcomes (Huynh et al., 2018; Sfantou et al., 2017; Wong, 2015). However, little is known about the influence of leader adaptive capacity as a strategic leader attribute on patient loyalty to HIV care. While the adaptive leadership framework is useful to guide research about healthcare communication in addressing challenging issues in palliative care, however, communication approaches were often mismatched with parent needs (Neglia et al., 2013), indicating a gap in the utilization of the leader’s adaptive capacity attributes. Similarly, providers presented detailed medical information to patient family members who lacked the technical capacity to address the complexities of palliative care (Adams et al., 2013). While leadership framework provides a useful lens to explore practitioners’ leadership behaviors at the point of care, there is still inadequate evidence on what leadership at the individual level at primary care, particularly about the relationship between health care practitioners, patients, and their family’s caregiver (Anderson et al., 2015; Bailey Jr, et al., 2012), presenting a literature gap on strategic leader attributes that are necessary for clinicians in the HIV context. In addition, personal qualities of top leaders such as working with others improved healthcare services of both private and public hospitals in Pakistan, however, they only differed in terms of delivery strategy (Baloche & Siddiq, 2016). Furthermore, clinical leaders were perceived as having an impact on how clinical care is delivered, staff support, and leading change and service improvements to patients and the main attributes associated included effective communication and clinical competence (Stanley et al., 2017). Also, by encouraging healthcare teams to work effectively, clinical leaders can improve day-day hospital operations thereby improving the outcome quality of patient care (Chakraborty & Kayna, 2016), however, there is a clear gap on the influence of strategic clinical leader attributes on patient loyalty to HIV care in the HIV care system.

4. Determine the health system factors associated with patient loyalty to HIV care

a) Health system Capacity and Patient Loyalty

While most studies have discussed health system factors and patient retention in HIV care, there is limited evidence of patient loyalty in HIV care. A healthcare service quality study revealed that physical environment, responsiveness, privacy, and safety of patients are positively related to patient loyalty in Pakistan (Fatima et al., 2018). Furthermore, most qualitative studies found the facilitators of comprehensive HIV primary care included appointment reminder system, non-identifying clinical signs, women and family spaces, however, the multifaceted nature of the studies present challenges for isolating specific interventions most effective in improving access to care (Lam et al., 2016; O’Brien et al., 2018).

In Zambia, a qualitative study established that both health system hardware and software factors such as inadequate infrastructure to protect privacy, delayed opening time, inflexibility in visit schedules, influence patient disengagement among lost to follow up (LTFU) patients (Mwamba et al., 2018). In addition, the state of Kenya’s health system in terms of the WHO 6 building blocks established effective coordination between the national and county governments however there was inadequate infrastructure for service delivery, persistent geographic inequalities, inadequate adherence to clinical guidelines and human resources for health (Mulaki & Muchiria, 2019). In Western Kenya, healthcare system factors constraint HIV care providers in delivering quality care to patients (Genberg et al., 2019). Similarly, facility-level
factors influence the retention of HIV patients in care in East Africa (Rachlis et al., 2016). In South Africa, the current healthcare system is still fragmented and does not adequately meet the healthcare needs of its clients (Conny, 2018).

b) Patient Trust and Patient Loyalty. In organizations, trust refers to employees identifying with the organization and being willing to establish long-term relationships with the organization (Yu et al., 2018). In relationship marketing, trust is the key factor in building customer loyalty (Mayer et al., 1995). In healthcare studies, trust is the belief of the patient in the provider or the hospital, based on the concept that the care provider seeks the best for the patient and will provide suitable care and treatment for him/her (Platonova et al., 2008; Zarei et al., 2014). Trust in the health system and its institutions is of utmost importance however, little attention has been put on its impact on overconsumption (Krot & Rudawska, 2021). In addition, trust was identified as an important aspect in an empirical study relating to consultations in primary healthcare in the UK (Robb & Greenhalgh, 2006), but little is known about how trust influences patient loyalty in HIV care.

While trust leads to increased patient satisfaction and loyalty as well as recommending the healthcare provider to others (Chang et al., 2013; Ozawa & Sripad, 2013) however, consistency of relationship was not relevant to the patient when clinical information was shared and used (Waibel et al., 2018). Similarly, trust impacts patient loyalty (Sumaedi et al., 2014), however, when trust is breached, it may have negative consequences. Patients with positive trust in their physicians were loyal however, 16% and 29% agreed that doctors don’t pay full attention to what they are trying to tell them and care less about their medical needs (Yang & Chen, 2018). In HIV care, trust in physicians, in general, may not be a major barrier to HIV testing and linkage at the initial stages but is very important along the continuum of care due to later interactions with physicians and the healthcare system and thus influence retention in HIV care (Ahenkora et al., 2019; Graham et al., 2015). Whereas this is evident, there is insufficient literature on patient trust in the clinician and the healthcare system on patient loyalty to HIV care in Western Kenya.

c) Patient-Provider Attachment and Patient Loyalty. The role of attachment theory in the patient-provider relationship explains how patients get attached to their doctors, particularly for their medical needs (Ahenkora et al., 2019). In reality, the formation of strong relational bonds between service providers and customers predicts satisfaction, positive word-of-mouth, and loyalty (Berry & Parasuraman, 1991). The patterns of adult attachment associated with healthcare relationships and health outcomes include security, pre-occupation, dismissing, and fearfulness (Maunder & Hunter, 2009). According to (Turan et al., 2019), attachment-related avoidance predicted suboptimal ART adherence, viral failure, and low CD4 count while attachment anxiety predicted missed HIV care visits. This indicates the value of investing in patient-provider closeness and friendship to lessen tensions and improve the loyalty of patients. Moreover, a secure patient attachment was predictive of a better alliance, more perceived patient support, less general distress, higher levels of trust and satisfaction with the healthcare providers when compared to patients with an insecure attachment style, hence using an attachment theory framework, can improve the understanding of the patient-provider relationship (Palmer Kelly et al., 2019). Patients can get attached to their providers when the providers are supportive and safe and have frequent contact with them (Maunder & Hunter, 2016). However, this study lacked the perspectives of the providers who could provide a comparative perspective. Patients will more likely be engaged in care if they receive empathetic and caring atmosphere (Wood et al., 2018), however, patient-provider relational bonding or attachment is one area that is understudied in HIV care concerning patient loyalty to care.

d) Patient-Provider Communication and Patient Loyalty. Communication in healthcare is very critical in exchanging information between all stakeholders and it should be applied at all levels of a health system. However, communication breakdown occurs when the needs of the patients are not met or misunderstood in what is communicated, so patients get demoralized to engage in care (Vermund et al., 2017). In Pakistan, a study established a significant relationship between patient-provider communication and patient loyalty to their physician and loyalty to the hospital (Unal et al., 2018). Similarly, an HIV study in the US to improve patient-provider communication about HIV medication adherence established more dialogue about therapeutic regimen in visits with a group of patients and providers on intervention where the visits focused on brainstorming solutions to non-adherence compared to those in the control group (Beach et al., 2015). In Kenya, physicians engaged in a high number of communication behaviors in terms of listening carefully to their patients and patients were more likely to attend the clinic, and less likely to miss appointments and ART medication in Kenya (Wachira et al., 2014). Patients and providers in HIV care facilities in Bamako, Mali identified rapport as a foundation feature of patient-provider communication (Hurley et al., 2018). However, there will always be a challenge when communication does not meet the needs of the client. In HIV studies for instance, providers viewed themselves as the decision-makers in inpatient care and were louder than patients and others shouted at (Bofill et al., 2014) (Beach et al., 2015) (Madula et al., 2018), which is likely to instill fear among the patients because of inability to express themselves. These findings present a clear picture of the importance of prioritizing interventions and focusing on patient-provider communication to improve patient loyalty to care.

e) Patient Satisfaction and Patient Loyalty. Patient satisfaction is the judgment of perceived value and sustained response toward service-related stimulus before, during, or after the consumption of medical services by a patient (Kim et al., 2017). For hospitals, satisfied patients are more likely to keep using medical services, follow the prescribed treatment plan, maintain a relationship with a specific healthcare provider, and recommend the hospital to others.
However, the relationship between satisfaction and loyalty, decreased as the length of the relationship increased (Balaji, 2015). In HIV studies, patient satisfaction is a determinant of treatment uptake, adherence, and retention, and an important health system outcome (Chimbindingi et al., 2014), but the influence on patient loyalty in HIV care is less documented. Treatment effectiveness and patient satisfaction positively influenced patient intent to revisit (Kim et al., 2017). 68.50% of patients who were satisfied with service provision in the Karsa Husada general hospital said they will visit the hospital again however, quality improvement of pharmacy service and patient satisfaction had a positive effect but not with or towards patient loyalty (Insani et al., 2017). On the contrary, service quality was not significant to loyalty in public hospitals in Indonesia (Lestaraningsih et al., 2018). Furthermore, a patient at a clinic may have a general good feeling about the hospital, and a high level of satisfaction, but it doesn’t mean they will be loyal however, patients may become loyal after the clinic offers loyalty programs and encourages them to come back (Astiti & Nagase, 2016). Similarly, satisfaction does not necessarily influence patient loyalty, and therefore healthcare institutions should not depend solely on satisfaction to ensure patient loyalty while a dissatisfied customer is very likely to become disloyal (Chang et al., 2013; Sumaedi et al., 2014). There was a strong correlation between patient satisfaction and willingness of patients to return to the hospital after a primary total hip replacement (Schaal et al., 2016), however, patient loyalty remains a challenge when patients are dissatisfied and it provides an opportunity for healthcare institutions to rethink the primary care level strategies that will improve patient loyalty to care. In addition, the reactions of patients towards health system factors in other medical conditions such as HIV are not known.

5. The mediating effect of patient satisfaction on the relationship between patient trust in clinicians and the health system and patient loyalty

In most studies, satisfaction appears as either the antecedent or consequence of the variables under examination and literature indicates that much patient satisfaction is due to a general good feeling about the hospital, and a high level of satisfaction, but it doesn’t mean they will be loyal (Addo et al., 2020). Increased trust, commitment, and the ability to communicate did not automatically lead to patient loyalty; only an increased sense of satisfaction did so (Astiti & Nagase, 2016). A study that established whether patient experiences of examinations affect their word of mouth intention found that patient satisfaction with physicians mediated the relationships however, the limitation is that the evaluation of participants may have changed over time and their views may not reflect the current situation (Akbolat et al., 2021). Whereas healthcare quality has a strong and positive impact on patient satisfaction and patient trust in medical care, patient satisfaction mediates the relationship between health service quality and patient trust in healthcare service providers (Alrubaise & Alkaa’ida, 2011). It is possible to say that when patients are more satisfied, they develop more trust in the healthcare provider, which certainly leads to their loyalty. Patient satisfaction mediates the relationship between public trust in healthcare and patient overconsumption in healthcare systems (Krot & Rudawska, 2021). An observational study found patient satisfaction as a mediating variable between overall satisfaction with doctors and patients’ expectations and developing confidence or trust in the emergency department (Abidova et al., 2021). Therefore, when patients are satisfied with their doctors and when they feel their expectations are made, then they will feel satisfied and develop more confidence and/or trust in the doctors and the hospital. While studies have shown the mediation effects of patient satisfaction on the quality of service and patient loyalty, little is known about how patient satisfaction with the clinician and the health system mediates the level of patient trust in the clinician and health system in the HIV care.

6. The mediating effect of patient satisfaction on the relationship between patient-provider communication and patient loyalty

Enhancing effective communication and relationship building may improve retention in care (Flickinger et al., 2013; Wachira et al., 2014). However, the influence of patient-provider communication on patient loyalty to HIV care through patient satisfaction is understudied. Literature indicates that physician-patient communication determines patient loyalty to the physician and hospital while patient loyalty mediates the relationship (Unal et al., 2018). Moreover, patient trust and satisfaction positively mediated the relationship between face-to-face and online patient-provider communication which influence patients’ health-related outcomes (Akbolat et al., 2021). In addition, patient-provider communication influenced patient emotional well-being and was partially mediated by patient satisfaction (Jiang, 2020).

Fatima et al. (2018) argue that it is sometimes difficult to satisfy everybody because generally, individuals have diverse judgments and expectations. Their study found that the relationship between patient loyalty and physical environment, customer friendliness, and communication was fully mediated by patient satisfaction while privacy and safety, and responsiveness were partially mediated by patient satisfaction. Moreover, patient-perceived involvement not only had a direct positive impact on patient loyalty but also had an indirect effect on patient loyalty through patient satisfaction (Zhang et al., 2022). This implies that when patients are more engaged by their doctors through communication and other engagement strategies, they are more likely to get satisfied and engage in more medical visits. Patients were particularly satisfied with the qualities of doctors such as listening to complaints, explanation of their ailments, advice, and treatment, and their general behavior (empathy, respect, confidence, etc) (Addo et al., 2020), however, the influence of these factors on patient loyalty to HIV care through patient satisfaction with the health service is understudied.

7. The mediating effect of health system capacity on the relationship between perceived strategic leader attributes and patient loyalty

The goal of a healthcare facility is to promote the clients’ well-being by organizing the hospitals in a way to provide quality care to patients, however, there is scant literature on the mediating role of health system capacity in healthcare studies and
particularly connecting to HIV care. Health system capacity do not necessarily influence patient loyalty directly as a patient outcome. For example, physicians and nurses perceived teamwork climate (66.9%), working conditions (24.1%), and job satisfaction (9.0%) to fully mediate the relationship between managerial leadership and safety climate (Weng et al., 2017). Manager transformational leadership influenced patient-nurse and patient outcomes when mediated by a supportive practice environment particularly on patient falls (Higgins, 2015). Furthermore, the organizational climate mediated 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 empathy, assurance, and customer loyalty relationships in the Yemeni capital (Hamood & Alshehari, 2018). The quality of the healthcare healing environment mediated the relationship between patient satisfaction and the core health delivery in Ghana (Amankwah et al., 2019). From these studies, there is a gap in the literature on the mediating role of health system capacity which gives this study and timely opportunity to study the HIV care system and determine the role of strategic clinical leader attributes on patient loyalty to HIV care through the health system environment.

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, intentions to adhere to ART. 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., 2014), adaptive leadership and person-centered care (Corazzini & Anderson, 2014). 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).

Methods

Study design and area

This study employs a mixed-methods study design that integrate both qualitative (exploratory) and quantitative (explanatory) techniques for collecting, analyzing data, and reporting the findings. The type of mixed methods will be parallel where quantitative and qualitative datasets will be collected separately, analyzed and findings reported independently. None of the techniques will inform the other based on the specific questions to be answered by specific respondents. The 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
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 and only interested will be included. Patients who present with severe illness or psychological cases will be excluded from the study.

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.

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

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 and data collection procedures
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. Patients will be excluded from the interviews about the strategic leader attributes and the strategic role of clinical leaders in the health system. For the healthcare providers, they 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 to provide views on strategic clinical leadership. 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 $\alpha >0.70$ (Hacettepe et al., 2017; Juhana et al., 2015; Lee, 2019; Ngoma & Ntale, 2019). Patient loyalty assesses the commitment of the patient to repurchase products and services of an organization repeatedly, feelings toward the hospital, and willingness to recommend the hospital to others (Hacettepe et al., 2017; 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 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 have been used 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).

**Qualitative themes**

The themes will include questions on the understanding of leadership and the health system, strategic leader attributes for clinical leaders, strategic roles of clinical leaders in an HIV primary health care system, challenges of health system leadership and strategies for changing health system leadership.

**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 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
Hayes, 2013
Ernst & Albers, 2017

Patient demographic characteristics shall be kept confidential by only using it for the study and will be identified for collecting data. Also, participant data of the participants, a private room within the HIV facility in Swahili. To ensure the privacy and confidentiality of the participants, a private room within 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.

Data analysis and statistical plan
Quantitative and qualitative data analysis will be done separately and results reported independently. 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 conceptual framework (Figure 1). Patient demographic characteristics will be used to adjust for confounding effects. Descriptive statistics will also be analyzed to present participant and variable characteristics respectively. For the qualitative data, data analysis will be analyzed thematically which will include transcribing and translating the audio recorded data then, codes will be developed in N-Vivo software vs.11. Emerging themes will be identified that will inform thematic analysis of the data. Data will be presented in the form of narratives and the lifting of quotes.

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/P/20/3253), 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 identified for collecting data. Also, participant data shall 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.

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.

Practical implications
The findings of this study will provide valuable insights for healthcare practitioners, healthcare leaders, and managers. A leader who is equipped with strategic leader attributes influences the healthcare system environment and patient loyalty to HIV care. Therefore, there is a need for the HIV health facility leadership and management to develop the strategic leadership capacity for clinical leaders to back up their clinical expertise and cascade strategic leadership downward to drive quality HIV care. In addition, the study findings will contribute to strategic management and healthcare literature to provide evidence on the influence of strategic leader attributes and health system factors on patient loyalty to HIV care and the use of adaptive leadership framework for business to understand patient loyalty to HIV care. The study findings will also help the HIV leaders and managers to develop strategies and policies for addressing dynamics in the healthcare system environment and establish ways of improving health system performance to ensure good patient-provider relationships and provide strategic and efficient patient care that is satisfactory to enhance patient loyalty to HIV care.

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.
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Christel Protière

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○ It should be interesting to discuss similarities and distinctions between the concept of loyalty and others like adherence, patients empowerment or patient-physicians relationships. At least the authors should better define the way they considered patients’ loyalty (toward care, toward physicians or toward the hospital?).

○ Perhaps some "old" references about the patient-physicians relationships might help (Gafni et al. for example that defined the different models of patients-physicians relationships)

○ The objectives of the study protocol have to be clearly defined.

○ Using qualitative and quantitative data is not enough to define a mixed method. It should be interesting to know how they will be interconnected. Additionally, the general themes of the interviews have to be defined.

○ If it is clear that health care providers will fill in a questionnaire and will participate in an individual interviews, it is not so clear for the patients. If ever it was not planned, I strongly recommend considering to conduct individual interviews with patients to explore their expectations.

○ It would be easier to understand the objectives if the conceptual framework was presented earlier in the document.

○ Regarding the exclusion criteria for healthcare providers, excluding the ones who have busy schedules may introduce a bias (they probably will all have busy schedules, then the assumption could be that only interested ones rather than less busy will participate).

Is the rationale for, and objectives of, the study clearly described?
Partly

**Is the study design appropriate for the research question?**
Partly

**Are sufficient details of the methods provided to allow replication by others?**
Partly

**Are the datasets clearly presented in a useable and accessible format?**
Not applicable

*Competing Interests:* No competing interests were disclosed.

*Reviewer Expertise:* I'm a social scientist (economist and psychologist) working in the field of HIV

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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Author Response 11 Oct 2022

**Felishana Cherop**, Moi University, Eldoret, Kenya

Dear reviewer, The literature review has been updated to discuss patient loyalty and patient-provider relationships from diverse backgrounds such as marketing, business, HIV, and other healthcare domains. The study focuses on loyalty to the provider and the health system. The objectives have also been clearly defined and included. However, patients have not been considered in in-depth interviews but we will make recommendations to be included in future studies. The conceptual framework has been shifted to the literature review section after the empirical discussion and the exclusion criteria exclude providers who are not interested to participate in the study. Thank you.

*Competing Interests:* No competing interests were disclosed.

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Reviewer Report 02 December 2020

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Selim Ahmed
World School of Business, World University of Bangladesh, Dhaka, Bangladesh

The authors need to revise the paper according to the following comments:
1. The authors need to include the literature review as a separate section. Under the literature review the individual research variables and their relationships with empirical evidences must be defined.

2. The study proposed to use two units of data set to test the research model but the question is that how interview data (qualitative) will be used in the model along with survey data (quantitative). Another issue is that 22 responses (healthcare service providers) are proposed for the health service providers which is not acceptable in the statistical analysis.

3. The authors need to discuss practical implications as a separate section.

**Is the rationale for, and objectives of, the study clearly described?**
Yes

**Is the study design appropriate for the research question?**
No

**Are sufficient details of the methods provided to allow replication by others?**
Yes

**Are the datasets clearly presented in a useable and accessible format?**
Not applicable

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** Healthcare Management

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

**Author Response 11 Oct 2022**

**Felishana Cherop,** Moi University, Eldoret, Kenya

Dear reviewer, The literature review of the study has been included and the variables indicating the relationships discussed. Qualitative data will be obtained separately from the providers to gain an in-depth understanding of strategic leader attributes for clinical leaders in an HIV health system, hence the data will be analyzed separately and results reported independently. The practical implications of the study have been discussed and included in the article as a separate section. Thank you.

**Competing Interests:** No competing interests were disclosed.