Electronic medical records and clinical Decision Support Systems in HIV care in resource-limited settings
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Chapter 1

General Introduction
1.1 HIV Epidemic in Kenya

The World Health Organization (WHO) describes the Human Immunodeficiency Virus (HIV) as a retrovirus that infects cells of the host’s immune system and destroys or impairs their function. Acquired Immune Deficiency Syndrome (AIDS) is the disease caused by infection with the HIV. AIDS results in severe damage of the body’s immune system causing vulnerability to life-threatening infections and tumors (1). Heterosexual sex between an HIV infected person and uninfected partner is the main mode of HIV transmission in many sub-Saharan African (SSA) countries (2;3). The WHO and The Joint United Nations Programme on HIV/AIDS (UNAIDS) joint report on global HIV epidemic showed that nearly two-thirds of the 34 million people infected with the virus resided in SSA in 2010 (4). Kenya is among the countries with high HIV prevalence in SSA. The Kenya AIDS Indicator Survey (KAIS) conducted in 2007 showed that HIV prevalence among adults aged 15-64 years was 7.1% (5). A similar population-based survey conducted five years later showed a decline in HIV prevalence to 5.6% (6). The two surveys showed that Nyanza province in western Kenya had the highest HIV prevalence in Kenya with 14.9% and 15.2% of adults aged 15-64 years having HIV-infection in 2007 and 2012, respectively (5;6).

In order to plan for effective interventions to respond to the HIV epidemic, it is necessary to understand the socio-demographic, behavioral and biological factors associated with the disease. Various sources of data including routine statistical summaries, surveys, surveillance, operational research and mathematical modeling are used to monitor the distribution and trends in the epidemic in response to prevention and treatment programs. UNAIDS and WHO have developed guidelines for measuring HIV prevalence in population-based surveys (7). The KAIS protocols were developed based on the UNAIDS/WHO guidelines to provide HIV prevalence data as well as factors associated with HIV infection in Kenya (5;6).

KAIS is a household survey that entails interviewing eligible and consenting respondents from sampled clusters of households. Blood samples are collected from consenting participants for central testing in the laboratory to determine HIV prevalence. Individual participants who wish to know their HIV status can collect their results at the nearest clinic six weeks after blood sample collection, or participate in a voluntary home-based HIV counseling and testing. Those confirmed to be HIV-infected are referred for HIV care and treatment services. KAIS also provides critical data on access to HIV prevention, care and treatment services, respondents’ perception of risk for HIV infection, risk factors for HIV infection and co-morbidities – including sexually transmitted infections.

1.2 HIV Care and Treatment Guidelines

As of December 2011, and to improve quality of lives of those infected with the virus and to prevent further transmission of the virus, approximately 7.9 million patients were receiving Antiretroviral Therapy (ART) globally with 75% (n=6 million) living in SSA (8). As with other diseases that affect global populations, WHO has developed guidelines for care and treatment of persons infected with HIV. Many countries, including Kenya, have adopted these guidelines and customized them to be most appropriate in addressing the local epidemic. In June 2013, WHO launched The Consolidated Guidelines on the Use of
Antiretroviral Drugs for Treating and Preventing HIV Infection: Recommendations for a Public Health Approach (9). Among other things, the consolidated guidelines address HIV diagnosis and antiretroviral drugs for HIV prevention; linking people diagnosed with HIV to clinical care and treatment; indicating when to start ART, and what ART regimen to start treatment-naive patients on (first-line ART), monitoring the response to ART and diagnosis of treatment failure; and managing common infections and co-morbidities (including opportunistic infections, which are referred to in this thesis as AIDS Defining Illnesses).

Guidelines released by WHO in 2010 recommended the use of CD4+ T-cell count to assess eligibility for ART and to monitor the immune system’s response to ART (10). CD4+ T-cells are white cells that are an essential part of the body’s immune system. Various studies have shown that CD4+ T-cell count and viral load are the key prognostic factors for HIV disease progression to AIDS and death (11;12). Early mortality is higher among patients enrolling on HIV care with low baseline CD4+ T-cell count (13). The WHO guidelines recommend a baseline measurement of CD4+ T-cells immediately after the HIV patients have a confirmed HIV-positive result, and follow-up measurements every six months (10). The latest guidelines recommend initiating ART when a patient’s CD4+ T-cell count drops to 500 cells/µl (9). Previous revisions of the WHO guidelines recommended initiating ART at CD4+ T-cell counts of 250 cells/µl (10) and 350 cells/µl (14).

The 2006 revision of the WHO guidelines recommended the use of clinical presentation of patients to classify the progression of HIV infection. These guidelines classify common co-morbidities known to be associated with HIV into four clinical stages based on the severity and prognosis that reflect HIV disease progression from asymptomatic to conditions where presumptive diagnoses can be made on the basis of clinical presentation or simple investigations (10). The documentation of these stages helps clinicians in resource-limited settings (mainly in Africa and Asia) with no immediate access to CD4+ T-cell count testing to make decisions on ART eligibility (10).

Immunological treatment failure occurs when there is sub-optimal response by the immune system to ART. One of the main causes of HIV treatment failure is non-adherence by patients to the prescribed drug dosages leading to sub-therapeutic concentration of ART in plasma (15). Treatment failure should be detected at the earliest opportunity and appropriate action such as adherence counseling, viral load test or repeat CD4 test taken.

1.3 Treatment of HIV

Standard ART is a combination of at least three drugs that are taken to suppress the HIV and progression of HIV disease (14). Before a patient becomes eligible for ART, they receive pre-ART care which includes medications to prevent opportunistic infections, multi-vitamins and education on how to stay healthy and avoid infecting others (4). Newly diagnosed HIV patients or those newly enrolled on ART should visit the clinic monthly, while stable patients are expected to attend the clinic every three months for review and medication refills. AIDS, like other chronic diseases, requires lifelong treatment and ongoing collection of longitudinal data to monitor the response to treatment at individual patient level and for
routine statistical reporting. The rapidly increasing number of patients enrolling on HIV treatment in SSA annually, coupled with a limited number of health workers, can potentially compromise the recording of patient data (16) and thereby their care. In order to address this, there is urgent need for innovative solutions such as Electronic Medical Records (EMRs) for the management of the large amounts of longitudinal data, and Clinical Decision Support Systems (CDSS) for providing feedback to health care workers to improve guideline adherence. In particular, studies in developed countries have shown that EMRs and CDSSs are associated with better diagnosis, reduced medication errors, improved data quality and better practitioner performance (17-19).

1.4 Electronic Medical Records

SSA has lagged behind in adopting EMRs and the majority of health facilities still use paper forms to manage patient records. Health facilities in SSA face unique challenges including infrastructural and human capacity limitations. Infrastructural challenges include unreliable or unavailable electric power, inadequate computers and poor or no access to the Internet. Health workers often have limited computer skills. This, coupled with inadequate technical skills to install and maintain computer systems, especially in rural areas where the majority of the patients seek treatment, reduces the ability to utilize information technology (IT) interventions in health care to improve its delivery (20).

Various countries in SSA have benefitted from the support from multilateral (e.g. WHO and UNICEF) and bilateral partners (e.g. The US Government through the President’s Emergency Plan for AIDS Relief - PEPFAR) to access resources for strengthening health systems, including EMRs (21). Since 2010, PEPFAR has funded the implementation of EMRs at approximately 600 health facilities in Kenya, of which a majority is owned by the Kenyan Ministry of Health (MOH).

1.5 Clinical Decision Support Systems (CDSS)

A CDSS is a computer program that applies sets of rules to data, often stored in EMRs, in order to offer patient-specific and actionable recommendations to improve clinical decisions (22). Recommendations of a CDSS are communicated to the EMR user as alerts or reminders. The set of rules implemented in a CDSS often represents guidelines. CDSSs have been shown to have the ability to improve quality of care through better adherence to clinical guidelines, improved patient safety, more efficient clinical processes, and better patient outcomes in developed countries (23;24).

1.6 Quality of Care and of Data

Quality of medical care is difficult to define and measure as it is determined by conceptual and operationalized characteristics of what quality is (25). Process and outcome indicators are often used to measure quality of health care (25;26) and various methods have been adopted to improve the quality of health care through better compliance with clinical guidelines. In HIV care, for example, timely initiation of ART, timely performance of appropriate treatment monitoring measurements using laboratory tests such as CD4+ T-cell counts and viral load are factors that enhance quality of care.
Unstructured collection and recording of free-text key data elements such as diagnoses limits data quality and data re-usability for decision support or statistical analysis as the diagnoses are not uniquely defined and identified with a code (27). A terminology system such as SNOMED CT can contribute to data accuracy and re-use through concept-based definition of diagnoses and coded storage of data (28) hence improved quality of care.

1.7 Problem Statement

The majority of published studies so far that have used rigorous scientific methods to evaluate associations between health IT interventions, such as EMRs and CDSSs, and selected quality of care outcomes were conducted in developed countries. Countries in SSA, which bear the greatest burden of HIV, also have the weakest health systems making it difficult to provide care of high quality. With the increasing investment in health systems including EMRs and other systems in SSA, there is a critical need to evaluate the effect of such systems on quality of care. These evaluations would inform appropriate investments in solutions that address context-specific problems while taking into account unique challenges of implementing health IT interventions in resource-limited settings.

The research work published in this thesis describes HIV epidemiology in Kenya, a systematic review on EMR-based CDSS in resource-limited settings and associations and effects between EMR/CDSS and quality of care in Kenya.

1.8 Research Questions

This thesis addresses the following research questions:

(i) What are the socio-demographic, behavioral and biological risk factors associated with HIV infection among sexually active adults in Kenya?

(ii) Are EMRs associated with enhanced quality of HIV care and treatment in resource-limited settings?

(iii) What is the effect of CDSS on quality of HIV care and treatment in resource-limited settings?

(iv) Does SNOMED CT cover AIDS defining illnesses and can it be used to develop and implement an interface terminology in an EMR in a busy HIV clinic in sub-Saharan Africa in order to automatically derive WHO clinical staging of HIV?
1.9 Thesis Outline:

The research questions listed above were addressed through several studies that were conducted in the Nyanza region in western Kenya. Additionally, a national population-based survey provided epidemiologic data. The findings from these studies are presented in the chapters described below.

In chapter 2, we describe an epidemiologic study that was designed to address question (i). It provides a broad overview of the distribution of the HIV epidemic and factors for HIV infection among sexually active adults in Kenya.

Research question (ii) is addressed through two chapters. Chapter 3 describes the findings of a study on adherence to pre-ART guidelines following the introduction of an EMR in 17 clinics in western Kenya. In chapter 4, we present the results of a multi-center study evaluating the association between EMR and appropriate placement/initiation of HIV-infected patients on ART. The study was conducted in the same 17 health facilities described in the previous chapter. Research question (iii) is addressed through chapters 5 and 6. In chapter 5 we describe the results of a systematic review of published papers on the effects of EMR-based CDSS on quality of HIV care in resource-constrained settings. Chapter 6 describes the findings of a multi-center cluster randomized controlled trial to assess the effect of EMR-based CDSS on early detection of immunological treatment failure among HIV-infected patients at 13 clinics in western Kenya. The study presents the implementation of a CDSS to detect immunological treatment failure in compliance with the treatment guidelines and recommending appropriate clinical action.

To address research question (iv), chapter 7 describes the development of a SNOMED CT-based reference set for AIDS-Defining Illnesses (ADI) and its implementation as an interface terminology for OpenMRS EMR at a Kenyan teaching and referral hospital.

Finally, the overall synthesis of the key findings from the studies presented in this thesis and recommendations for further research are presented in a summary discussion in chapter 8. Figure 1.1 shows the stages at which the studies in this thesis support patient care.

Figure 1.1: The flow of patients from HIV infection to monitoring treatment and the stages at which various studies in this thesis were conducted.
Reference List

(10) World Health Organization. WHO Case Definitions of HIV For Surveillance and Revised Clinical Staging and Immunological Classification of HIV-related Disease in Adults and Children. 2006.


