Electronic medical records and clinical Decision Support Systems in HIV care in resource-limited settings
Oluoch, T.O.

Citation for published version (APA):

General rights
It is not permitted to download or to forward/distribute the text or part of it without the consent of the author(s) and/or copyright holder(s), other than for strictly personal, individual use, unless the work is under an open content license (like Creative Commons).

Disclaimer/Complaints regulations
If you believe that digital publication of certain material infringes any of your rights or (privacy) interests, please let the Library know, stating your reasons. In case of a legitimate complaint, the Library will make the material inaccessible and/or remove it from the website. Please Ask the Library: http://uba.uva.nl/en/contact, or a letter to: Library of the University of Amsterdam, Secretariat, Singel 425, 1012 WP Amsterdam, The Netherlands. You will be contacted as soon as possible.

UvA-DARE is a service provided by the library of the University of Amsterdam (http://dare.uva.nl)
Chapter 8

General Discussion
8.1 Introduction

The main objective of this thesis was to gain new knowledge on the effectiveness of Electronic Medical Record (EMR) and Clinical Decision Support System (CDSS) on quality of HIV care and treatment in resource-constrained settings. In order to achieve this objective, we conducted several epidemiologic and informatics studies in Kenya around the specific research questions listed below:

(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?

The research questions were addressed in chapter 2 to chapter 7 of this thesis. In this final chapter, we present a synthesis and overview of the key findings of the studies included in the thesis. We discuss the strengths and weaknesses of our studies and compare the findings to published research conducted elsewhere. Implications of the study findings are also presented and we conclude by making some recommendations for further research.

8.2 Summary of key findings and comparison to related research

8.2.1 HIV epidemiology in Kenya

Research question (i) was addressed through an epidemiologic study based on the Kenya AIDS Indicator Survey (KAIS) 2007 and presented in chapter 2. The main objective of this study was to gain understanding of the correlates for HIV infection among sexually active adults in Kenya aged 15-64 years. The national HIV prevalence among sexually active adults aged 15-64 years was 7.4% while HIV prevalence in Nyanza province among a similar population was 16.9% - the highest infection rate in the country (1). The sub-analysis focusing on Nyanza province provided in-depth information on factors associated with HIV-infection among sexually active adults in this geographic region. The key correlates for HIV infection were Herpes Simplex Virus type 2 (HSV-II), multiple sexual partners, divorce/separation, consistent condom use with last sex partner among those who know their HIV-positive status, and lack of circumcision among men (1). In comparison to the Kenya Demographic Health Survey conducted in 2003 (KDHS 2003), there was a marginal increase in HIV prevalence but this was not statistically significant. The introduction of antiretroviral therapy (ART) which has been shown to reduce HIV-related mortality (2) may have contributed to the marginal increase in prevalence. Our study, however, did not report on HIV incidence. Condom use during sexual intercourse is known to reduce the risk of HIV transmission. HIV-infected persons who were aware of their HIV-positive status were four times more likely to use a condom (3;4).
Studies with similar findings used hospital-based data or targeted only one district in Nyanza province (5;6). The Kenya Demographic Health Survey (KDHS) which provided national and provincial level HIV prevalence estimates did not collect information on bio-behavioral indicators associated with HIV (7).

8.2.2 EMR use and compliance with HIV care and treatment guidelines

Research question (ii) was addressed in chapter 3 and chapter 4. In chapter 3, we showed that EMR use was associated with all three investigated outcome measures of quality for pre-ART care. EMR use was associated with a significantly higher rate of performing a baseline CD4+ T-cell count test compared to the paper system. Although the proportion of follow-up CD4+ T-cell count tests performed was low when using paper or EMR system, the rate was higher using EMR compared to the paper system. EMR use was associated with better compliance with the pre-ART guidelines which recommend performing a CD4+ T-cell count every six months. The study also showed that some follow-up CD4+ T-cell count tests were conducted earlier than 6 months – especially after the implementation of EMRs. Clinicians can order earlier CD4+ T-cell count if they suspect treatment failure or the previous test was conducted when the patient had an acute infection. EMR use also contributed to improved data quality. It was noted that data clerks add a layer of data quality checks during data entry into the EMRs and consult with clinicians whenever they encounter missing data.

Timely initiation of ART among eligible patients as recommended in the clinical guidelines improves treatment outcomes (8). In chapter 4, we showed that EMR use was associated with an increase in the likelihood of ART initiation among eligible patients receiving HIV care. Although there was a marginal reduction in time from ART eligibility to ART initiation after transitioning from paper system to EMR, this reduction was not clinically significant. Non-EMR factors such as clinician behavior (provider practice), time for patient preparation and the patient’s own readiness for ART could have contributed to the lack of time reduction to ART initiation (9;10). The proportion of ART-eligible patients receiving ART at the study sites (80%) was higher than The Joint United Nations Programme on HIV/AIDS (UNAIDS) 2011 estimate for sub-Saharan Africa (56%) (11). However, there is still a 20% under-treatment, which requires other approaches for patient tracing and pre-ART counseling to ensure that all eligible patients are initiated on ART. We did not encounter any cases of over-treatment in our studies (i.e. initiating ART among ineligible patients) as the ART-eligibility criteria are well defined in the guidelines and understood by clinicians.

8.2.3 CDSS and quality of HIV care

Chapter 5 and chapter 6 address research question (iii). The findings from a systematic literature review to identify original, published studies describing the association between EMR-based CDSS and quality of HIV-care as well as barriers to EMR implementation in resource-limited settings are discussed in chapter 5. Twelve studies met the inclusion criteria set in the systematic review – ten of which were conducted in SSA and two others in the Caribbean. Only three studies quantified the associations between CDSS and relevant outcome and process measures, including time to order CD4+ T-cell tests, patient waiting time and missed appointments. One of the findings from the systematic review was that CDSS was associated with improved data quality. The majority of studies showed that data capture is by paper-
based systems which are retrospectively entered into an electronic system with CDSS. Only one study reported direct data entry at the point of care.

Immunological treatment failure among HIV patients occurs when there is sub-optimal response by the immune system to ART. With the increasing number of HIV patients receiving ART, CDSS can potentially help in detecting treatment failure and recommend appropriate clinical action. In chapter 6, we showed that the use of CDSS was associated with a higher likelihood of clinicians taking appropriate action on immunological treatment failure as recommended in the HIV treatment guidelines. There was a substantial reduction in time from immunological treatment failure to appropriate action following the use of CDSS. CDSS was also associated with faster ordering of baseline CD4+ T-cell test (a key measure of the state of a patient’s immune system) and timely ordering follow-up CD4+ T-cell test. The recording of CD4 T-cell tests in CDSS sites was significantly higher compared to EMR only sites. Previous studies on effect of EMR on quality of HIV care reported low rates of recording of CD4 T-cell counts, hence room for improvement through innovative approaches such as CDSS (12;13). Although CDSS was shown to be an effective intervention in enhancing guidelines adherence, it is worth noting that there is still large room for improving the recording of actions taken by clinicians. Nearly 45% of patients experiencing treatment failure did not have a recorded action and it is unclear whether no actions were taken or actions were taken but never recorded. A larger proportion of patients in the intervention group compared to the control group had a recording of condition for treatment failure and the action taken (54.9% vs. 29.5%). Lack of data could potentially affect the continuity of HIV care, especially in cases where a patient is seen by different clinicians. The choice of decision rules in the CDSS was limited to the use of CD4+ T-cell to infer eligibility for ART and monitor immunological response to HIV treatment. However, other clinical decisions, including ART eligibility, are based on diagnoses and these require structured coded data for accurate inference.

The findings from our studies that relate to CDSS and quality of care were largely consistent with research done in developed countries (14-16). Studies by Williams, Were and Alamo – all conducted in resource-limited settings – showed that CDSS can enhance quality of HIV care through better adherence to guidelines and improved processes (e.g. reduced patient waiting time and timely ordering of laboratory tests) (17-19). The strength of associations demonstrated in the studies published in this thesis, especially the use of CDSS in HIV care (chapter 6), makes them stand out. Poor data quality was reported as a key hindrance to meaningful use of CDSS (19-21).

Barriers to CDSS implementation in resource-limited settings included weak infrastructure and human resource challenges e.g. unreliable electric power, poor Internet connectivity, inadequate computers, poorly trained health workers and low computer literacy (22;23). These challenges are unique to resource-limited settings, especially in SSA and are quite different from those experienced in developed countries e.g. inability to type quickly, reduced eye contact between clinician and patient during consultation and preference to write in long prose (24;25). Implementation of CDSSs and evaluation studies in resource-limited settings are generally premature as shown by the basic design of the studies included in the review. This is despite substantial investments by global health initiatives in health systems strengthening in SSA. It is important to note that the use of EMRs and CDSS is rising mainly due to these global health initiatives.
8.2.4 Structured recording of AIDS defining illnesses

To address research question (iv), a structured approach to deriving a reference set for AIDS Defining Illnesses (ADIs) based on an earlier published framework for developing interface terminologies (26) is described in chapter 7. The aim of this study was to improve data quality through standardized recording of ADIs using a terminology system (SNOMED CT) which has been shown to enhance data accuracy, completeness and reusability in developed countries (27;28). More than 1,000 concepts described by nearly 1,900 terms were derived from four different sources. SNOMED CT had a near-complete content-coverage of the pre-coordinated concepts currently used in clinical HIV practice of a Kenyan teaching and referral hospital. The resulting reference set was implemented as an interface terminology of OpenMRS EMR to standardize the recording of ADIs, and for automated inference of WHO clinical stage to determine ART eligibility based on HIV disease progression. Based on experiences elsewhere, it is expected that the use of a reference set will enhance the quality of data recorded leading to more accurate inference of WHO staging and appropriate decisions on clinical care (28). These solutions, however, do not entirely address the problem of missing data. Further qualitative studies are needed to understand reasons why clinicians do not record data and how these can be comprehensively addressed.

8.3 Strengths and weaknesses of the studies

The Kenya AIDS Indicator Survey (KAIS), which was a nationally representative, population-based survey with response rate above 70%, provided key epidemiologic data that helped inform the location of our evaluation studies (chapter 2). KAIS was powered to provide provincial level estimates and the survey showed that Nyanza province had the highest rate of HIV infection in Kenya. Our studies evaluating the effect of EMR and CDSS on quality of care were conducted in Siaya and Kisumu counties, both located in Nyanza province.

The studies were conducted in multiple clinics and had large sample sizes which improved the precision of estimates. The study on standardization of AIDS-defining illnesses benefited from data collection from a busy teaching and referral hospital that provides HIV care and treatment to a large number of patients with diverse conditions hence a broad coverage of terms used to describe ADIs. Another positive aspect of the studies described in this thesis is that all HIV clinics in Kenya use the same national HIV care and treatment guidelines adapted from the WHO guidelines. The Kenyan Ministry of Health (MOH) HIV treatment guidelines were revised just before the start of the study, raising the threshold for ART eligibility from 250 cells/µl to 350 cells/µl. This had the benefit of increasing the number of patients enrolled initiating ART and had a similar effect on the intervention and control sites. All EMRs with CDSS need to comply with a single set of national guidelines which are revised periodically. The launch of the new HIV treatment guidelines by WHO in June 2013 shifts focus on routine HIV treatment monitoring from CD4+ T-cell count to viral load. Kenya is currently in the process of transitioning from immunological to virological monitoring of patients receiving ART. The effect of the new guidelines was minimal on our studies since the Kenyan MOH guidelines were not revised until June 2014, more than six months after the completion of our data collection. Moreover, we believe that the strong effects demonstrated in our study are likely to be generalizable towards improved virological monitoring of
patients receiving ART as recommended in the new guidelines. The decision rule for detecting virological treatment failure is similar to that of detecting immunological treatment failure.

We did not have to replace any existing system in order to implement our studies. Although a number of EMRs are implemented in Kenya, all our studies focused on two systems, namely C-PAD for the studies in Siaya county (chapters 3, 4 and 6) and OpenMRS for the studies at the teaching and referral hospital in Kisumu county (chapter 7). The team, therefore, did not have to deal with stringent administrative bureaucracy, user training and change management involved in replacing systems.

Our studies had some weaknesses. A weakness of the KAIS is that the sexual-behavioral data reported were based on self-reporting by survey respondents. Due to sensitivities around sexual behavior, some of this information may be inaccurate. However, the interviewers were well trained on ensuring respondents’ confidentiality and on eliciting the most accurate responses, even to the most sensitive topics. The survey design was cross-sectional and may not show causality.

The design for two of our studies described in chapter 3 and chapter 4 was a “retrospective observational, before-and-after” and we were not able to determine a cause-effect relation between the use of EMR and the outcome variables. Similar limitations were reported in most evaluation studies conducted in SSA. In addition to the two studies, we conducted a prospective, cluster randomized controlled study to understand the association between EMR-based CDSS and detection and action on immunological treatment failure. The limitations of determining the cause-effect were addressed through the prospective, randomized design. Health workers’ low computer literacy and frequent transfer of clinicians and nurses trained on the systems were major impediments to the implementation and use of EMRs at the study sites. As the studies were conducted in MOH-owned clinics, policies around staffing were the prerogative of the MOH and beyond the control of the study team. In order to mitigate the effects of staff transfers, the clinicians and nurses were constantly trained to ensure that they were able to use the systems correctly in accordance with the study protocol. Poor data quality, especially in the retrospective studies described in chapter 3 and chapter 4, was a major problem. Missing data on key variables such as CD4+ T-cell test dates and results, enrolment date and ART eligibility date reduced the number of records that were included in our final analyses. A number of sites were excluded from our randomized controlled trial since they did not have reliable electric power or secure location to place the computers.

8.4 Relevance and implications of the study findings

Advances in the use of health IT, especially EMR-based CDSS in developed countries, have significantly contributed to improved quality of healthcare. This has been achieved through better compliance with guidelines, better diagnosis and reduced medication errors (29-31). SSA has particularly lagged behind in the adoption and use of health IT due to numerous challenges outlined in studies by Forster and Fraser (22;23). With the evidence from our studies which show that EMR and CDSS use can improve data quality and adherence to treatment guidelines, there is a compelling reason for further investments in addition to those by current initiatives such as the US President’s Emergency Plan for AIDS Relief.
(PEPFAR) and the Global Fund Against AIDS, TB and Malaria (GFATM) to strengthen health information systems in order to enhance continuity of high quality health care.

The studies included in this thesis were conducted through a partnership between the US Centers for Disease Control and Prevention (CDC) and the MOH through the Kenya Medical Research Institute (KEMRI) to generate evidence on the role of EMRs and CDSS in enhancing quality of HIV care. These evaluations are part of an ambitious project to implement EMRs at 600 health facilities nationally. As EMRs and CDSS were only introduced at the study clinics over the last 2-5 years, the findings from these studies will promote their use and justify further investments in EMRs in Kenya by the MOH and its partners. All stakeholders agreed that existing EMRs, none of which had a functional CDSS, would be upgraded at the end of the studies in case of positive results. The design of our studies, including a randomized controlled trial, was robust and we expect that the findings can be generalized to health facilities in resource-limited settings in SSA. The majority of HIV patients seek treatment at MOH-owned clinics, which also happen to be under-resourced compared to private hospitals.

Late initiation of ART among eligible patients results in poor outcomes including higher mortality (32). We showed that EMRs can improve the likelihood of ART-eligible patients getting initiated on ART hence better outcomes. Wide-scale use of EMRs will imply that more ART-eligible patients currently not receiving ART will be initiated on therapy. Additionally, timely performance of the routine laboratory tests for HIV treatment monitoring enables clinicians to make timely decisions on patient management. Patients who experience treatment failure are likely to be identified earlier and appropriate action taken according to treatment guidelines.

WHO’s 2013 consolidated guidelines for HIV prevention and treatment recommend the use of viral load monitoring of HIV treatment (33). As countries in SSA, including Kenya, continue to scale-up the use of viral load to monitor response to HIV treatment nationally, there is a critical need to use automated systems to inform clinicians of treatment outcomes such as viral suppression, loss to follow-up or death (33). We expect that our experience with the use of CDSS to identify patients who were experiencing immunological treatment failure can be readily applied to the new guidelines to identify patients experiencing virological treatment failure. Automated alerts to clinicians will enable them take appropriate clinical action.

Use of terminology systems such as SNOMED CT to support documentation has been shown to enhance data completeness and reusability which improves continuity of care (27;28). Automated inference of WHO clinical stage through accurate recording of diagnosis based on a terminology system ensures that patients are correctly classified based on HIV disease progression hence appropriate initiation of ART. The ADI reference set derived from one of our studies is being used to implement an interface terminology which will improve the documentation of ADIs at a busy referral hospital. With more complete reporting, we will be addressing the problem of under-reporting of ADI which is common in SSA countries as reported by Kiragga et al. (21). The introduction of a terminology system to support documentation of patient records was welcomed by the stakeholders and will be extended to other areas including the tuberculosis (TB) and maternal and child health (MCH) clinics to improve data reuse and automated generation of summary statistics. CDSSs will be implemented using standardized
recording of ADIs to support automated inference of WHO clinical stage and to alert clinicians on patient eligibility for ART initiation.

Our studies identified opportunities and challenges in implementing health IT in resource limited settings including infrastructural and human capacity. The inability to implement EMRs and CDSSs in real-time as a point of care system due to lack of reliable electric power at many of the clinics was a major challenge. The Government should invest in innovative methods of generating electric power such as those based on solar or wind energy to ensure reliable electricity. This was also recommended by Fraser et al (34). Government of Kenya initiatives such as the ongoing rural electrification program (REP) which aims at providing reliable electricity to hospitals and schools in rural areas will in the near future solve the electric power problem in many health facilities. We showed gaps in information on the benefits or problems of implementing EMR-based CDSSs due to inadequate research done in resource limited setting. Well-designed and rigorous evaluations will generate relevant evidence to inform investments in technologies that work in settings with unique challenges (e.g. SSA) in the way that studies conducted in developed countries and described in systematic reviews have informed the implementation of CDSS in those countries (14-16). Our study on early detection and action of immunological treatment failure among patients receiving ART (chapter 6) is a first example of such a rigorous evaluation study.

8.5 Recommendations for further research

There have been substantial investments in strengthening health IT in resource-limited settings, including SSA, over the last 5 years. However, there is inadequate evidence to show what technologies work and the barriers to the implementation of such technologies. There is need for more rigorous evaluations studies, including randomized controlled trials to assess associations between EMR-based CDSS and processes and outcomes for HIV care and other chronic illnesses (Figure 8.1). Such studies should take into account overall improvement in the health systems including additional laboratory capacity, increased computer literacy levels of health workers and improved Internet coverage - especially in rural areas.

Provider practice plays a critical role in provision of HIV care. Garg et al. showed that CDSSs can improve practitioner practice in developed countries (14). No such studies have been conducted in resource-limited settings. There is need for qualitative studies on clinicians’ perspectives in relation to usability of EMRs and CDSSs and barriers to their successful implementation. Noormohammad et al. described reasons why clinicians do not comply with CDSS recommendations in a study conducted in Kenya, but did not discuss issues around usability of the EMR or CDSS (35). Such studies would supplement the existing work which are largely based on quantitative methods.
Very few studies have been conducted to evaluate the effectiveness of terminology systems on data quality and quality of care. Although Shah et al. reported that use of a structured clinical terminology system contributed to improved data accuracy at clinics in the United Kingdom, similar studies are yet to be conducted in resource-limited settings as well as developed settings (28). We described the implementation of an interface terminology based on SNOMED CT but did not evaluate its effect on data quality and quality of HIV care indicators such as accurate clinical staging of patients and appropriate initiation on ART. This is recommended for a future study.

Prior to conducting the evaluation studies, more work needs to be done to improve the ICT infrastructure (including Internet connectivity) and human capacity on health IT in resource-limited settings as recommended in various chapters of this thesis and in studies by Forster and Fraser et al (22,34). The Kenya eHealth Strategy that was launched in 2011 highlights the strengthening of ICT infrastructure as a priority area (36). The Government of Kenya, together with private sector players, has continued to extend Internet connectivity to all districts, including remote locations that were previously not served. County governments are also providing computers to health facilities and ensuring adequate physical security of the computer equipment as a way of enhancing the use of computer systems to improve quality of healthcare. Policies on health IT capacity building for health workers, hinged on the eHealth strategy, should be promoted to ensure that there are adequate skills to meaningfully use EMRs and CDSSs to provide clinical care. We recommend an overall training program for health workers on the importance of recording high quality data alongside specific training on the optimal use of the EMRs they will work with. Initiatives which promote regular use of data at the point of generation may also help reduce the proportion of missing data. Formal training on medical informatics at post-graduate level in local universities is taking root while the use of eLearning platforms to train healthcare workers on various courses including IT and monitoring and evaluation are becoming increasingly common.
8.6 Conclusion

Our studies showed that Nyanza province has the highest HIV prevalence in Kenya. We evaluated EMR and CDSS use at health facilities in Nyanza province and found that EMRs were associated with enhanced quality of HIV care through better adherence to HIV treatment guidelines. We showed that a CDSS causes early action on immunological treatment failure among patients receiving ART in a resource limited setting. Finally, we found that different sources demonstrate complementarity in the derivation of concepts and terms for an interface terminology that is based on SNOMED CT in order to automatically derive WHO clinical staging of HIV.
Reference List


