

Selecting and Implementing Information Systems to Support HIV Care

Overview

September 2007

About the Document and the Author

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This document focuses on the complex problem of health information systems to support HIV care. As such, it draws on recent experience with paper and electronic health information systems that have been designed or adapted to this purpose primarily in Africa. This experience has been tremendously useful in defining the needs, pitfalls, and ultimately successful strategies for implementing the broad information needs of HIV care. The combination of improving information and communications technology and the insights we have gained over the years have converged to create successful HIV care information systems.

I have had fourteen years experience with health information systems in developing countries. Country experience includes Malaysia, Sri Lanka, Pakistan, India, Bangladesh, Papua New Guinea, Thailand, Nigeria, Ethiopia, Kenya, and South Africa. This experience covered a broad range of activities which include design and implementation of health information systems at the patient, facility, district, and national levels as well as use of the information at the national policy and planning level. As an indication of the breath of interest in health information systems, the work in these countries was performed for the Asian Development Bank, World Bank, World Health Organization, UNDP, USAID, and AusAID. Many of the projects were part of broader coalitions of donors united in the need for better health information. The work draws on this developing country experience as well as my earlier experience in designing and implementing health information systems for the private sector in the U.S.

This document was originally developed under the sponsorship of the US Government Global AIDS Program through the CDC and the USAID Measure Evaluation program. Later work on the document took place at the World Health Organization where I am currently employed. The document has gone through numerous revisions and enhancements over the past three years and is the result of constructive feedback and suggestions from numerous individuals as the result of presentations in many forums. I am particularly indebted to Xen Santas and Steven Yoon of the CDC for their guidance and many constructive suggestions. However, I must take full responsibility for the final text.

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1Overview

HIV is a chronic, complex, multifaceted disease with a lifetime duration. HIV patients require a wide variety of care and support services throughout their lives and the various stages of the disease from diagnosis to late stage care. Information on individuals must be recorded longitudinally and it must be accessible to the people who will be responsible for providing care. In addition, responsible health managers, planners, and researchers need to have access to aggregate information to monitor services and care, evaluate the effectiveness of treatment programs, and plan human and material resource supply.

This paper gives an overview of HIV care information systems so that those responsible in government, aid agencies, and private organization can understand how to select appropriate information systems for their programs and direct their implementation.

It includes the following sections:

Introduction to HIV Care Programs

This chapter discusses the use of information for patient care, disease management, program monitoring and evaluation and operations research. It describes the basic categories of health information and relates these to their use in HIV care.

HIV Care Spectrum and Work Flow

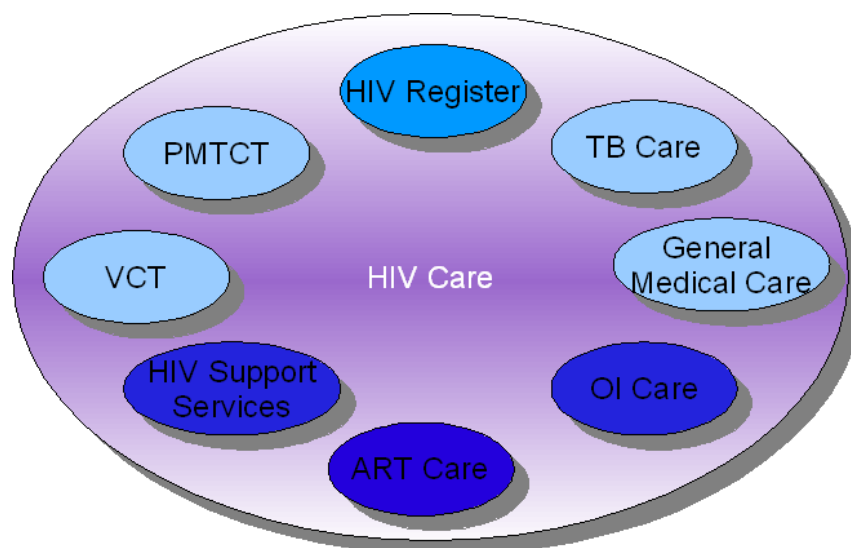
HIV infection is a chronic condition with a distinct course that requires unique care and support at each stage. This section outlines this disease course and the various programs that have been developed to deal with the infection at each stage. It discusses the data category requirements of each of these programs and the information flow between programs and over time.

HIV Care Information System Design

This chapter discusses the basics of HIV care information system design so that you can understand the principles in order to manage system selection and implementation. It outlines the process of health information system design in the HIV care context starting with information requirements, data requirements, data definition, and data sets (with examples). It then discusses data capture, storage, analysis and communications. Basic information system concepts and design principles including the data dictionary, metadata, and the minimum data set are discussed. If you understand these principles, you will be able to understand the information system selection process and ask the right questions at each phase.

Throughout this paper, we will argue for sharing information. We should make it clear that this does not mean homogeneous information systems. The information environment in every country is complex with multiple organizations providing various services. Each organization will select software based on its needs and experience. Rather than specify standard software applications, integrated information systems rely on standard definitions and standard methods of data representation and communication. This allows disparate software applications to communicate clearly. Data standards permit a diverse information application environment that gives everyone access to the information they need to provide services and monitor performance.

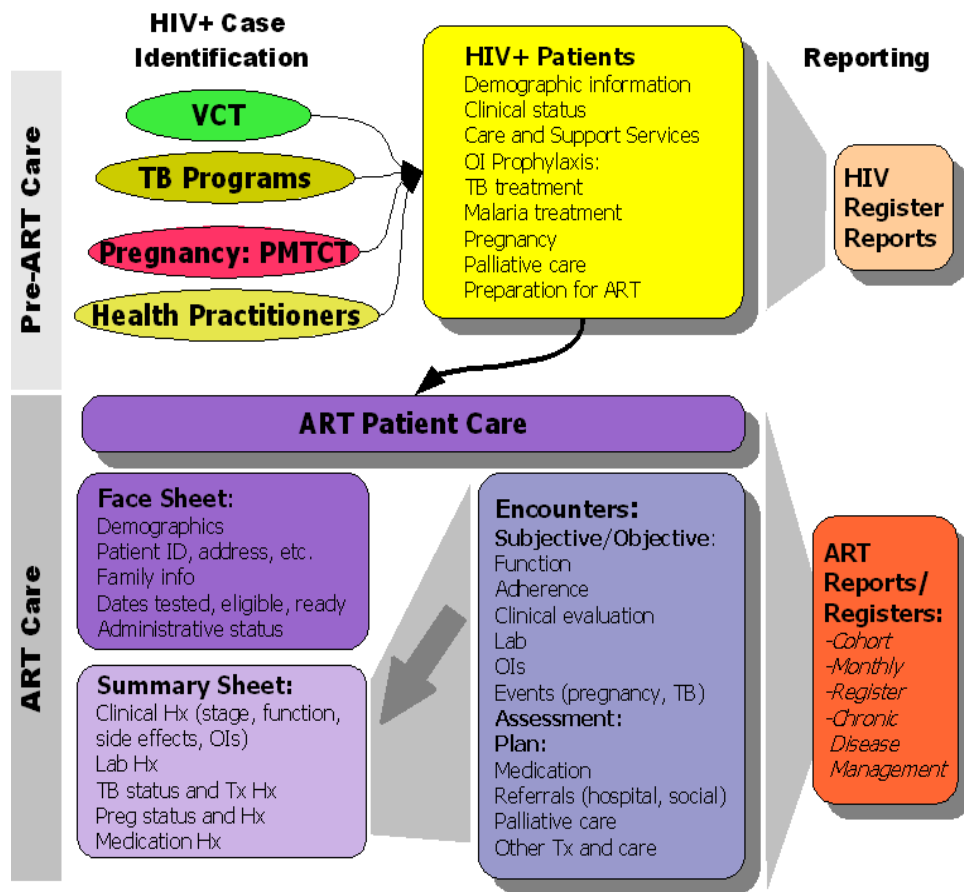
2 Introduction to HIV Care Programs



HIV care encompasses all stages and aspects of care and support for individuals with HIV. Voluntary counseling and testing first identifies infected individuals. Care and support services for all stages of the disease, opportunistic and co-infections, and palliative care follows. HIV care also includes preventing transmission during pregnancy. Because HIV is a complex disease with a long course and many personal and social ramifications, there are many advantages to gathering and sharing information at all stages. These advantages accrue to individual patients and to society.

This document will give an overview of the information system requirements for HIV care at all stages and through the perspective of the various programs that have been developed to provide care. It will emphasize “essential” or “minimum” data sets using standard definitions for each of the stages and programs and will define information flows among the programs. Information use is, of course, the goal and this document will describe and justify information collection and communication for the benefit of individual patients and for use in monitoring and evaluation of HIV care activities.

It is useful to first get an overview of the course of HIV and the programs that have been established to identify and treat individuals at each stage. This diagram shows the programs, information flow, and uses of information at various stages.



Starting with “Pre-ART Care”, HIV+ individuals are commonly identified through voluntary counseling and testing (VCT) programs, TB programs, and in pregnancy (often through prevention of maternal to child transmission, or PMTCT programs). Individual health practitioners also identify and refer HIV+ persons.

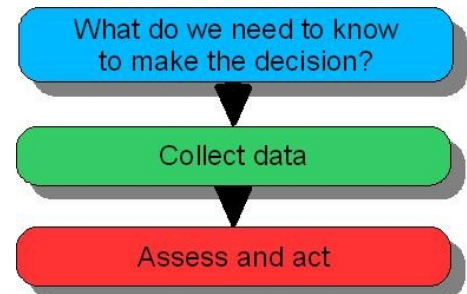
Once identified, HIV+ individuals may require and be eligible to receive various services and treatments. For this reason, it is useful to have a register of infected people that can be used to coordinate care and support services. This register can track their clinical status and be used to arrange appropriate services. This register is also a valuable resource for monitoring and evaluation of patients and programs. As the infection progresses, individuals can be monitored for eligibility for antiretroviral therapy (ART) and receive appropriate preparation for starting treatment.

Once a patient starts ART care, the information requirements increase significantly and the patient is enrolled in an ART individual patient care record system that may be paper based or an electronic medical record. Most of the “Pre-ART” information can be of use during ART so this information should follow the patient. ART care typically consists of identification and demographic information and a series of “encounters” with various service providers who assess clinical and social status and provide treatment and services as appropriate. It is important to track the details of clinical and social status as well as services provided. ART itself is complex and requires conscientious recording of drug

treatment, laboratory and clinical condition over time. It is useful to summarize encounter information in a format convenient for easy reference during individual patient care. The details of the ART care record are useful for monitoring and evaluation and research.

2.1 Use of Information

The purpose of an information system is to collect data that can be analyzed to provide information that is used to make decisions regarding both individual and population-level care. We need to have an understanding of the difference between data and information. Data consists of raw observations whereas information is data that has been analyzed and structured to facilitate action. Creating information from data requires consideration of a context, relationships, and the organizational or programmatic goals. Information needs can change as the goals evolve. A good information system will adapt to those changing needs.



The first step in information system design is determining what information is needed. There are several potential users of information and all of these should be consulted: people involved in direct patient care, people managing programs, and people who are working to improve care. They each have requirements for information oriented to their functions. All of these users should be taken into account when designing an information system.

One word of caution. It should be obvious that one would start information system design by looking at the needs of the users of information. However, the real world often has other forces and considerations that sometimes take precedence. Sometimes data is collected just because it can be even though it is not particularly relevant or useful. Sometimes data is collected because “we have always done it” even though it has not been used.

Every piece of data collected incurs cost. Often people will justify collection of more data using the rationalization that “it doesn't really cost anything to collect more data once we've set up the system so we might as well put in everything we might need”. This is a slippery slope to a bloated data collection system that often saps time and focus and deters both the collection of good quality data and the delivery of good care. In information system design, every piece of data collected should justify its collection by its use. Good information design transforms data into information by establishing relationships within the data and with the broader use context.

Let us look at the main categories of use of information with a view to consider what information would meet the needs of these groups.

2.1.1 Individual Patient Care

What information do practitioners need to treat each patient properly?

Each patient has a history and an environment. The patient's history includes past medical problems and care. It also includes the social and family history as these have an effect on health. The patient's current and past environment may include exposure to toxins or improper nutrition which will affect their response to disease.

Even acute medical problems have a history and this can go back for a period of time. Recurrent episodes of acute illness can point to underlying problems that need to be addressed. A history of successful resolution of a past illness can guide current therapy.

This illustrates how one must have access to the relevant medical and social history in order to properly treat a patient. The general term for this is “longitudinal medical record” (LMR) – a medical record that is maintained over time. This record can be paper or electronic, and can be kept by a clinic or hospital or carried by the patient. It contains a valuable trove of information that is in many cases of crucial importance in properly treating patients.

The LMR becomes even more important in the case of chronic illness such as HIV infection. Here a method called “disease management” is a valuable method to organize care.

2.1.1.1 Disease Management

It is worth spending time to study the best way to deliver care to patients with chronic diseases since these take enormous resources and the patients benefit from better care. HIV/AIDS is a particularly good candidate for disease management since it has a long course and there are many useful interventions that can be applied at various stages of the disease to improve the quality of life, treat threatening complications, and delay the progression of the disease.

Disease management (DM) is a discipline that has the goal of improving the quality of life of individuals with chronic disease through optimum application of resources. This often reduces cost and resource requirements by preventing complications and improving health. It has been used in developed countries for such common diseases as hypertension, heart failure, diabetes, asthma, and cancer. According to Mercer Management, in the U.S., over 60% of group health care plans offer disease management services. HIV/AIDS is a good prospect for the application of disease management principles since it is a chronic disease that responds well to proper treatment.

The tools for disease management are common across all diseases but, of course, the individual content of the tools will be customized for each disease. These tools include assessment instruments, clinical guidelines, health risk assessments, outreach, patient education, best practices, and triage. Monitoring and quality improvement processes are integral to the program. The individuals providing care in a disease management system may include physicians, nurses, nutritionists, social workers, and other therapists. Often epidemiologists, statisticians, and human resource professionals are involved in developing and maintaining disease management programs. Communication among providers and patients is an important aspect of disease management.

The principle goal is to improve the patient's quality of life and activities for daily living and to ease the disease path. For most chronic diseases, cure is not an option and is not a goal of the program.

Disease management programs have been extensively developed and studied in countries with advanced health care systems and found to be effective in improving the management and control of chronic disease. They provide improved adherence to evidence-based standards of care.

The advantages of a disease management program for HIV/AIDS in developing countries include the development and adherence to optimum treatment protocols that can assist providers of care where training and resources may be limited and providing integrated social, nutrition, and support services through improved organization and coordination.

2.1.2 Program Monitoring and Evaluation

How are we doing at executing our plan for treating patients?

Monitoring is the routine tracking and reporting of information about a program and its intended outputs and outcomes whereas evaluation is a rigorous collection of information about program activities, characteristics, and outcomes that determine the merit of a program. Monitoring can be thought of as day-to-day operational information and evaluation as a more thorough periodic assessment of an entire program.

Program managers need information to monitor the effectiveness of their activities. Collecting this information in a systematic way allows objective analyses to be performed and reviewed. This is important to ensure that the program is effective and having the desired result. It is also important to have feedback to improve the program. The information required will be determined by the program and commonly fits into the categories of: inputs, process, outputs, outcomes, and impact. Information on each of these categories monitors different aspects of performance which, in a properly designed information system, mirror the work flow of the project.

As an example, *inputs* are resources used in a program such as drug supply, *process* is the program implementation of drug use in the program, *outputs* are the immediate products or deliverables of the program such as the number of people treated. *Outcome* is the effect of the program activities such as access to drug treatment. Finally, *impact* is the longer-range, cumulative effect of the program such as improved health.

2.1.3 Operations Research

Can we do this better? Can we deliver services better? Can we treat patients better?

A third major category of information users would be those people doing research looking to improve programs. We are not referring here to people doing “basic” research but rather people looking at the processes, work flows, protocols, and treatment modalities. This is often referred to as operations research. This applies systematic research techniques to improve service delivery by analyzing factors that are under the control of program managers such as quality of service, training and supervision, and service components of a program. It is designed to assess the accessibility, availability, quality, and sustainability of programs.

As an example, it is very useful to be able to look at information on results for patients who received different treatment at different sites or who have different underlying medical or social circumstances. The results of these studies can improve treatment protocols and program activities.

Electronic information systems for HIV care and support provide a wealth of information that can be used by operations researchers to study the effectiveness of the current system and to make improvements.

2.2 Categories of Information

During the discussion of individual programs, we will refer to the following categories of information. We will not list all of the specific data items in each of these categories since this varies by local context as well as with national and international standards. Together these categories of information make up a complete individual patient record.

2.2.1 Patient Identification

Information necessary to identify an individual patient consists of items such as name, birth date, and identification numbers. It is essential that a rigorous system be established for patient identification. Each patient must have a unique identifier to ensure that their records are available for care. Equally important, each patient must have only one identifier to ensure that all of their records can be assembled to provide a patient history during future visits.

Often, patients receive an identification card with their number. However, if this card is not available, there must be a method to find the identification number using other identifying information such as name, location, birth, and family information. If the patient identifier cannot be located, personnel may be tempted to create a new identifier and record, thus breaking the record continuity.

2.2.2 Demographic Information

Demographic information identifies patients by location and characterizes them by such data items as age, sex, marital status, and ethnic group. All of these factors can be used to improve patient identification and they are useful in data analysis.

2.2.3 Insurance and Payment Information

This is information on the source of payment for services for the individual. It may include health or social insurance as well as support from organizational donors. In many cases, it defines eligibility for certain services.

2.2.4 Medical History

A patient's medical history is typically organized by topics that include: allergies, hospitalizations, surgery, medications, social history, habits (including drug use), and occupational history. It also includes family history.

2.2.5 Longitudinal Medical Record

The record of an individual's encounters with health personnel over time is called the longitudinal medical record. For each encounter, it includes a date as well as the nature of the contact, exam, laboratory, x-ray, a professional assessment, and treatment plan or advice. One example of a method to organize encounters is the Weed system which divides this information onto *Subjective* (patient reported complaints), *Objective* (professional exam, lab, x-ray, other studies), *Assessment*, and *Plan*.

2.2.5.1 Domain-specific information

Each medical problem has specific specialized information that is necessary in order to provide detailed care for that problem. Prenatal care, for instance, tracks information on a patient's weight, blood pressure, and lab work such as urinalysis as basic specialized information at each visit. Other tests are performed if available and when indicated. This information becomes part of the detailed longitudinal medical record and is necessary for immediate care. However, all of the domain specific details are not necessary after the end of the pregnancy. A summary of the pregnancy course and any complications can be entered into the medical history and appear on the medical summary sheet.

2.2.6Ancillary Services

Patients with HIV infection will be eligible for and require many support services during the course of their disease. These types of services can be social service counseling, patient education in prevention, preparation for ART treatment, social support services, financial services, and family support. It is important to record these episodes of support services to ensure they are delivered consistently, help coordinate these services and also to help gage the effectiveness of the services. The record of these services would contain the date, the service description, any significant findings or outcome from the service, and recommendations for follow up services.

2.2.7Medical Summary Sheet (or Face Sheet)

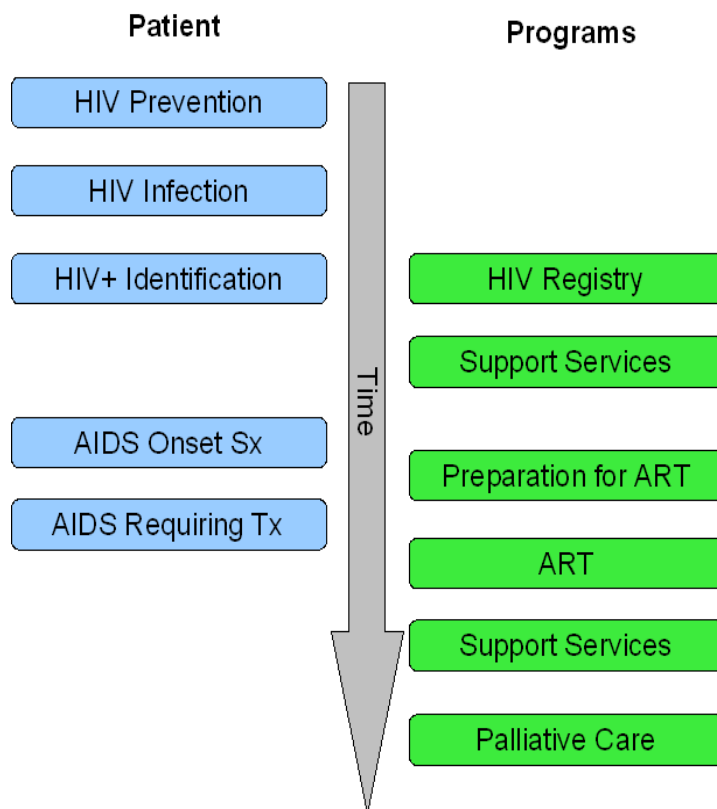
In medical care, it is very useful to have a summary of patient information that is important for immediate management. This summary sheet (sometimes referred to as a face sheet since it is the “face” of the record) pulls important information from all of the above areas and presents it in a structured format for easy access. This can include significant medical history. It usually contains a list of current patient problems, allergies, medications, recent care history, and significant laboratory or radiology findings.

When a patient is undergoing treatment for a particular medical problem, it will include pertinent information needed to care for that condition. For instance, when a patient is undergoing ART care, the summary sheet would contain significant indicators of the patient's condition (weight, CD4 count, etc.) as well as current medications and past medications that may have been discontinued due to problems.

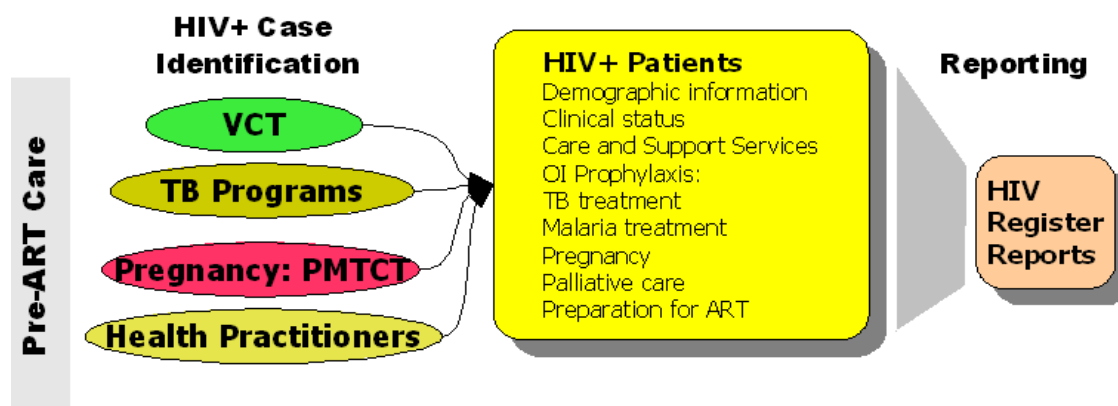
3HIV Care Spectrum and Work Flow

This section will follow the flow of patients and information over time. We'll start with the identification of HIV+ individuals then their entry into the HIV Registry. We then discuss HIV care programs and their information needs.

First, it is useful to recall the course of HIV infection and the structure of HIV care programs that are set up to deal with each phase of the disease.



3.1 Identification of HIV+ Individuals



There are three main formal programs that identify HIV+ patients. We will discuss each of these in some detail. In addition to these three sources, HIV+ patients are also identified through public and private health practitioners and other sources.

3.1.1 Counseling and Testing

Most areas have set up voluntary counseling and testing programs (VCT) to help people identify their HIV status and, once identified, to provide services. In addition, other programs in countries test individuals and refer them for counseling. Individuals who are identified as HIV+ are counseled on what to expect from their infection, how to avoid spreading the infection to others, and the availability of care and support services.

The basic information requirements for VCT programs include individual person identification and demographic information as well as HIV status. Additional information that can be useful is social connections (sexual partners), injection drug use. Depending on local protocol, the VCT program may want to keep a record of individuals who have been tested and found HIV negative. At a very minimum, the number of patients tested should be recorded.

The HIV patient registry is used to monitor status, provide support services, provide prevention information for partners, and prepare for care and support services.

3.1.2 Prevention of Mother to Child Transmission (PMTCT)

PMTCT programs are set up to identify pregnant women who are HIV+ and to provide these women with treatment to prevent the transmission of their infection to their children. Typically, all women presenting for prenatal care services will be offered testing for HIV infection and if positive, counseling and medical treatment to prevent transmission.

Pregnancy itself is a complex process and requires its own longitudinal record. Typically, PMTCT programs are integrated with prenatal and delivery service programs. Prenatal care itself requires monitoring of physical condition, vitals, laboratory, and medications.

The information that should be retained and communicated from the PMTCT program includes patient identification number, demographic data, HIV status, pregnancy complications, and medication given to prevent HIV transmission.

3.1.3 Tuberculosis Programs

There is a high percentage of co-infection with TB and HIV. Many patients who are under treatment for TB also have HIV infection. Patients who are HIV positive often have TB infection that may be masked by poor immune response. Historically, TB programs precede HIV care programs and have their own institutional structure. Patients must often be transferred between TB and HIV care programs. Many ART programs have a protocol that specifies that TB will be treated before ART will be started. All HIV patients should be tested for TB and, of course, treated if positive.

All of this calls for a robust communication of information back and forth between TB and HIV programs. They each must know the patient's history, prior treatment, current medications, clinical status of TB and HIV infection as well as other medical conditions. The information that must be tracked and communicated includes patient identification number, demographic data, medical history, longitudinal medical record, and ancillary services. In other words, the entire range of medical information.

3.2 HIV Registry

Once patients have been identified from VCT, PMTCT, TB programs and other sources such as public or private practitioners, they should enter an HIV registry. This registry may be maintained locally within specific programs or may be broader in scope. Privacy and security issues are extremely important in the management of HIV information and this should take precedence in designing the scope and use of this sensitive information.

A register of HIV positive persons is the foundation for the broad range of services necessary for HIV care. At various stages of infection, individuals will have different needs for care and support services. These services may be provided by different organizations but it is essential that they be coordinated. These services typically include prophylaxis for TB and malaria, pregnancy prevention and counseling, education, social services, and financial assistance.

At each stage of HIV infection, each individual patient will have special requirements and will have a unique social situation. Ideally, the services provided by various organizations should be tailored to needs of each individual. The HIV registry provides a single source of information on each individual's status and needs as well as a place to record and coordinate the services provided.

Prophylaxis treatment and monitoring for malaria, TB, and pregnancy can also be coordinated from the HIV registry so the patient can receive appropriate services.

The information that may be recorded in the HIV registry includes:

- Patient identification
 - demographic information
 - family and social connections
- Longitudinal record of encounters
- Medical information:

HIV+ Patients

Demographic information
Clinical status
Care and Support Services
OI Prophylaxis:
TB treatment
Malaria treatment
Pregnancy
Palliative care
Preparation for ART

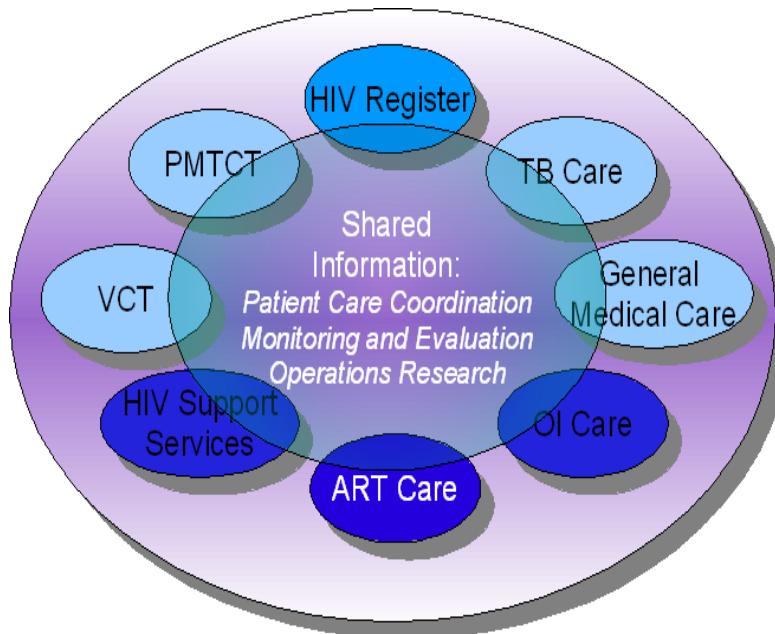
- HIV status
- physical status (vitals and exam)
- additional laboratory test results
- medical care delivered
- services record
- other? individual needs
- services received

One can see from this that the ideal information requirements for the HIV registry are for a longitudinal medical record which can be either a paper based record or an electronic medical record.

Again, we should emphasize that HIV care is a complex process of monitoring and service provision that will take place over many years. The individual longitudinal record of this entire course is necessary to deliver optimal care through all stages of the HIV infection. It is appropriate to ensure good information design from the beginning so that care providers at every stage have good information to provide the best quality care.

3.3 HIV Care Programs

This diagram shows the range of programs that are concerned with HIV+ patients. Typically, each of these is run as a separate program but they all need to share information on patients. The diagram indicates that each program may maintain its own detailed information and share the relevant part of that information with other programs to assist them in their care of the patient.



Since the various programs are in many cases run by separate organizations, it will be common to have a wide variety of information systems. Historically, it has been very difficult (if not impossible) to mandate a single software information platform for all of these programs and in many cases this is not

desirable since each program has unique information requirements.

However, all of these programs need to be able to share information. This can be done by developing a common “data dictionary” (standard definitions of data elements) and a minimum data set that takes into account the data sharing needs of all of the programs. This information is then coded into a communication protocol which is commonly based on a standard such as HL7 messaging. A messaging protocol is ideal since it allows the various programs to request and receive the specific information they need to perform their functions. The HL7 messaging protocol is a health industry standard that is well defined. There exists a wide variety of software tools to implement the standard which means that a lot of the work has already been done and it will be easier to implement.

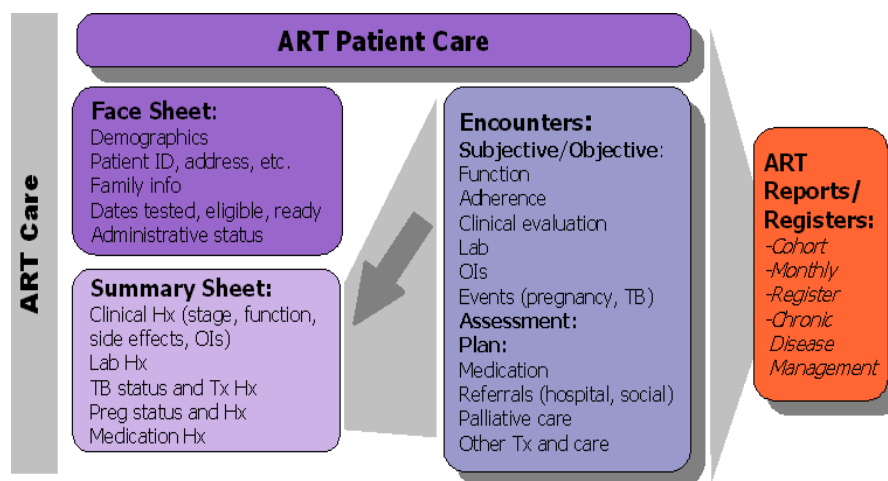
In summary, the work that will need to be done includes:

- develop a minimum data set for the HIV care universe (this will include the data requirements for each program)
- develop a data dictionary for the data items
- develop an HL7 interface for each program that needs to send or receive data
- implement an HL7 messaging system (using standard tools)

An implementation guide for generating messages associated with ART for HIV infection has been developed jointly by WHO and the U.S. President’s Emergency Plan for AIDS Relief, describing the steps and process needed to implement these tasks. Additional HIV-related data will be incorporated into this guide in the future.

Antiretroviral therapy (ART) is the mainstay of care for HIV+ patients once they develop symptomatic AIDS. Treatment with antiretroviral medications as well as treatment for common opportunistic infections (OI) requires significant resources and a good longitudinal medical record. In addition, there is a wide variety of additional support programs that can benefit HIV patients. We'll discuss these programs and their information requirements next.

3.3.1 ART Care



ART is the main contact point for most patients once they have qualified for and started antiretroviral medication. ART is complex and requires good information about the patient's current condition as well as past medical history. It is particularly important to have information on prior treatment and adverse reactions and resistance to prior treatment regimens. ART consists of treatment with a combination of medications which are selected based on the patient's condition and history. The patient's response to their drug regimens needs to be monitored carefully to ensure that they are responding to the treatment and are not having any untoward reactions or show signs of development of resistance. Monitoring is by clinical examination, vital signs, and specific laboratory tests. All of this needs to be recorded over the patient's entire course of the disease and available for review. In addition, since patients may move from one area to another (typically from city to home area as they become more ill and possibly back to the city as they recover and are able to work, or from treatment at large urban medical facilities to smaller, community-based clinics as ART delivery is expanded to cover a larger geographic area), their record must be portable.

ART care programs typically also include prophylaxis and treatment for common opportunistic infections such as TB and malaria.

Tuberculosis is common in patients with HIV infection. ART care programs may not treat patients for TB but refer these patients to TB programs where they can receive optimal care. However, it is important that these patients are not lost in the transfer from one program to another and it is important to have good communication of patient treatment and status between these programs so that the patient is treated for TB and then returned to the ART care program.

3.3.2 Palliative Care and Additional Patient Support Services

There are a wide variety of programs that provide additional support services to patients. These can be social service programs that provide individual and family counseling, financial programs which help with the loss of income and ensure food and shelter, or additional medical therapy such as physical therapy or end-of-life palliative care.

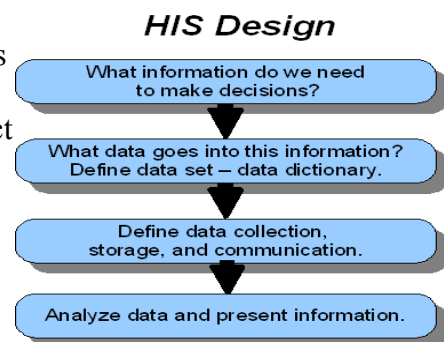
Each of these programs has unique information requirements depending on the services that are provided and program and donor requirements. However, each of these programs has information needs in common such as patient demographics, condition and treatment history, and status information. Each of the programs also should be able to report on the services that it provides so that others providing services can be aware of what is being done for the patient. This can avoid duplication of services when more than one program is providing similar services. Reporting can also avoid gaps which may occur when programs inadvertently assume that the needs are being met by another program.

Good communication can improve coordination of care which improves efficiency and improves the delivery of patient services.

4HIV Care Information System Design

The process of designing an information system begins with deciding which information is needed to make decisions at various functional levels (patient care, program management, monitoring and evaluation) and then determining what data you need to collect to derive that information. You then need to carefully define the data set (data dictionary); determine the data collection, storage, and retrieval methods; specify the data analysis that will be done; and determine how the data will be communicated to each entity that will use it.

This section will discuss each of the steps in more detail.



4.1 Information for Decisions

Data is just a collection of bits. In order for it to be useful, it must be organized. The process of data analysis uses aggregation, trend analysis, thresholds and presentation techniques such as graphs and charts. After transformation into a useful form, we can call it information.

The important first step is to determine just what information people need to make decisions. There are several natural audiences for information. At the patient care level, providers need information on individual patient condition as well as current diagnosis and treatment protocols in order to determine the proper course of action. Again, at the clinic level, managers need information on patient volume and character in order to manage resources for staffing, supplies, and drugs. Outreach workers and their support supplies also need to be managed. At the district level, managers also need information on the level of services and patient condition to manage clinics and supplies. At the national level, program managers need aggregated information from clinics to monitor the delivery of services as well as evaluate programs. Often some aggregated data is also reported to international organizations so that they can monitor disease, treatment, and programs.

After you have decided on the information that is necessary, the data elements that are necessary to derive the information can be determined easily.

The result of this first crucial step will ideally be a reasonable amount of data that will not overburden the workers and whose value they should recognize. This “minimal” or “essential” data set will be our foundation for the next step.

4.2 Data Dictionary and Metadata

The data dictionary is a listing of the collection of the data items in your data set. The data dictionary specifies the definition, type of data, possible predefined values, constraints, and the relationships among the data items. Collectively, this information is known as “metadata” (or “data about data”).

The data dictionary is essential to ensure that everyone using the data is assigning the same meaning to each data element. The data dictionary should be maintained by a data architect and data stewards and have a formal process to review and update it as needed.

It is useful to define a data dictionary at the national level to include all of the data elements that are used in the national health context. A national data dictionary can take advantage of the work that has

been done at the international level to develop standards. In addition, they can consult efforts in other countries. Finally, they should undertake a consensus process to ensure that all necessary and relevant local data elements are included in the data dictionary.

4.3 Define the Data Set

The data dictionary should be populated with the essential data set that was determined from the information requirements. In doing this, it is prudent to consult international standards since many data items have common definitions. It will be useful if the national data definitions correspond to international standards so that data can be compared. In addition, international standard data definitions have often benefited from a thorough process of vetting to ensure a clear, unambiguous definition. Use of international standards can also shorten the time needed to develop the data dictionary, as many of these standards can be imported directly into your system's code base.

In the field of HIV care, there has been defined a “minimum data set” that should be consulted as a starting point for the national data set.

We also an example of an approaches to representing and communicating health data that should be considered in health information system design. d

4.3.1 ART Care Minimum Data Set

The World Health Organization has defined a minimum data set for ART care. A minimum data set is the smallest amount of data that is necessary to provide ART care. Since collecting, storing, and using data has costs in terms of time and other resources necessary to enter, store, and retrieve the data, it is useful to keep the amount of data to a minimum. Of course, the minimum data set must include all of the data elements that are necessary for the care of the patient as well as provide program monitoring and evaluation. The minimum data set includes the data elements necessary to provide clinical care and for program monitoring.

Individual implementations of ART care software may want to add additional data elements to meet local requirements. However, as discussed above, each additional data element has a “cost” in terms of time to collect, verify, process, and analyze so the additional data elements should be limited to essential data items. Each data element should be questioned closely since it can often be collected as part of a specific survey, when needed, at much lower cost.

Another important concept is that the data must be easily understood without resorting to complex secondary manipulation. For this reason, data that is coded using standard vocabularies and definitions is preferable to free text which requires “interpretation” and is subject to miscommunication. The WHO ART minimum data set uses ICD and CPT for procedures and LOINC for laboratory tests and results.

The minimum data set includes data elements capturing medical history, physical exam, diagnostic test results, and treatment (drugs, procedures, physical therapy, and counseling). Diagnoses are recorded along with dates for each event including conditions, complications, and adverse events. Patient transfer and provision of ancillary services are also included.

4.3.2 Medical Information Standards

Medical care requires complete and accurate information about the patient's condition and history.

Medical care depends vitally on information. Medical information that is trapped in an obscure format or that is inaccessible cannot contribute to good medical care. Therefore you should try and use standards to represent and communicate health information.

The representation of medical concepts is a particularly difficult problem because of the broad range of medical and health concepts and because there is inherently some imprecision in understanding and describing these. A large number of standard description systems have been developed to address these problems. The WHO International Classification of Diseases (ICD), now in its 10th major revision, is probably the best known method to describe diagnoses. Other systems such as Read and SNOMED approach the problem differently and with a different scope. Diagnostic and Statistical Manual of Mental Disorders (DSM) is concerned with psychiatric diagnoses. Medical procedure coding is a separate area where we have the CPT, RBRVS. For laboratory data, we have LOINC. Drug names and drug reactions have their own terminologies.

The U.S. National Library of Medicine has a project to relate as many coding systems as possible using a meta-thesaurus. The project is called the Unified Medical Language System (UMLS) and incorporates over 100 vocabularies in various versions and languages. It organizes these vocabularies using a meta-thesaurus of over 1 million biomedical concepts (with over 5 million concept names. A semantic network connects these concepts using 134 semantic types and 54 relationship types. Finally, these concepts are related to specific vocabularies using a lexicon. The point of this is that medical coding is complex but standards exist and it is important to use these standards to represent and communicate information. The choice of a specific vocabulary and representation depends on the local context. Further, tasks such as analysis of data by others – including at the regional, national, and international level – or for research or evaluation, are nearly impossible without use of standard definitions and coding schemes. Transfer of patients to other jurisdiction is also more labor-intensive.

The best known standard for health information communication has been developed by Health Level 7 (HL7), a non-governmental industry-sponsored organization supported by the health-care industry. It has developed a widely-used standard which exists in several versions. The important point is that one needs to decide on a communication standard so that the receiver of the message can understand it.

4.3.3HL7 ART

The WHO ART Minimum Data Set has been defined under the HL7 communication standard. The HL7 format is a method of defining the data elements as well as a format for communication of the information. The HL7ART definition is extensible in that it can be expanded to include additional data elements to accommodate local requirements.

The data elements of HL7ART are divided into two categories: demographic (registration, scheduling, and practice management) and clinical. The fundamental unit of observation is the clinical encounter. Each encounter is identified by the patient's unique identifier, the visit date, the clinic site, and the identifiers of the provider(s) seen. Additional information is collected depending on the specific type of encounter.

Demographic: Registration, Scheduling, and Practice Management Data Elements

Key to managing patient data in an electronic medical record is establishing an unique patient identifier. Different systems will take unique approaches. However, care should be taken to ensure that the identifier is unique to that patient and also that each patient has only one identifier. Patients can be identified by a combination of first, middle, and last (family) names, date of birth, and mother's first

name.

Similarly, to ascribe care to individual providers, a unique provider identifier (with check digit) should be included as well. Because many of the treatment and prevention activities for comprehensive HIV/AIDS care involve family interventions, there should also be an identifier for the patient's family (defined as appropriate for each site).

Most of the registration data will not change for individual patients and need only be entered once. Addresses can also be included (to the degree possible in developing countries which often lack street addresses) to assist subsequent patient contacts, but this information often changes and has to be updated.

Payment program identifiers and charges, billing data, and payment information will need to be entered at each visit.

Clinical Data Elements

The clinical data elements included in the minimum dataset reflect the activities likely to be undertaken in most clinical venues providing care to HIV-infected patients. Such activities include preventing HIV infection, screening patients, caring for patients with HIV but without frank AIDS, and caring for patients with AIDS and their families.

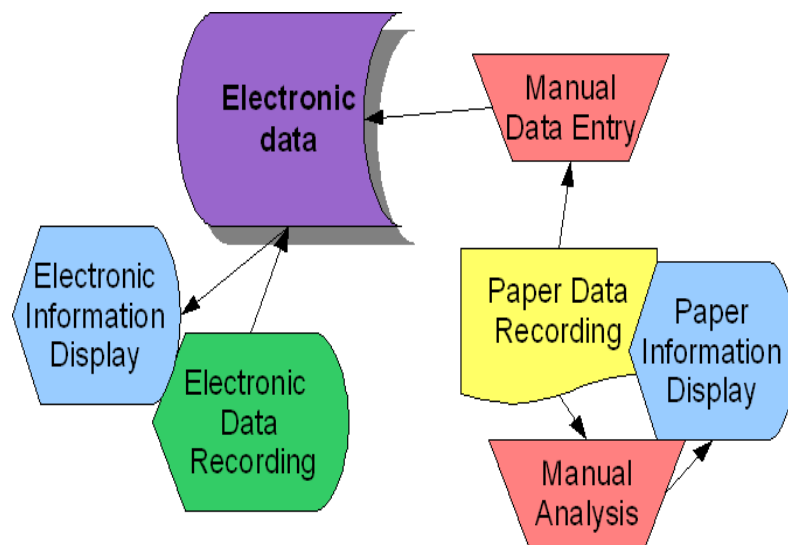
Assessing patients at initial and subsequent visits is necessary for making treatment and monitoring decisions and prescribing appropriate follow-up care. The minimum dataset should accurately reflect a basic comprehensive assessment and should include data elements capturing medical history, results of the physical examination, diagnostic test results, and treatment (drugs, procedures, physical therapy, and counseling). In addition, diagnoses for that visit must be recorded separately to identify the dates of first occurrence of each condition, complication, adverse event, and outcome of HIV/AIDS care. Including data elements to record medication adherence is of critical importance to HIV/AIDS care, because even minor lapses in adherence can result in the development of HIV resistant to antiretroviral drugs. Finally, there need to be data elements recording patient disposition (referral to another clinic, hospitalization) and date and cause of death.

In a later section, we'll discuss the useful HL7 role in data communication.

4.4Data Capture, Storage, and Communication

After you have decided what data you want to capture, you need to design the process which captures the data, stores it, then sends it to the point where it will be used.

4.4.1Data Capture - Paper and Electronic Systems



Information systems often have both paper and electronic manifestations. Information can be collected and displayed at various points on paper or electronically. If electronic systems are not available, then the paper system becomes primary. It is important to think of the information system as having data collection properties and data display properties. Data display can be either the unprocessed data or can be of derived, summarized, or aggregated data. In electronic systems, the data can be automatically analyzed and presented. However, in paper systems, analysis is a manual process which can introduce errors.

Data is often collected and displayed on paper. However, paper has many deficiencies in that it is easily lost or damaged, it is cumbersome to duplicate, and it must be physically transported from one place to another which is expensive and subject to loss and delay. However, the most serious shortcoming of paper is that it is extremely difficult to retrieve information. Individual records are easily lost in a pile of poorly filed records. Aggregating data from many records is time consuming and error prone.

Electronic data storage addresses most of these problems but requires computer hardware, software, and procedures and training to ensure accurate, timely data entry. A good information system will have carefully planned procedures for collecting information, entering it into the computer, and displaying the information on paper or electronically.

There are numerous techniques to help ensure accurate collection and entry of data. We won't have a complete discussion of this topic here but there are a few standard methods. Data entry close to the point of capture (in both time and space) is helpful. Using paper forms that mirror computer screens can improve accuracy. In addition, the computer can check data as it is entered to ensure that it is in an appropriate range and that it is consistent with related data.

When evaluating systems, look closely at the data entry work flow and the interface between paper and electronic data. A well designed system will be much easier to use and provide higher quality data.

4.4.2 Data Storage and Retrieval

Data storage is usually not a problem. In either paper or electronic format, it is easy to dump the data in any convenient corner. However, the point of storage is retrieval and if you want to retrieve your

data, then storage must be carefully designed.

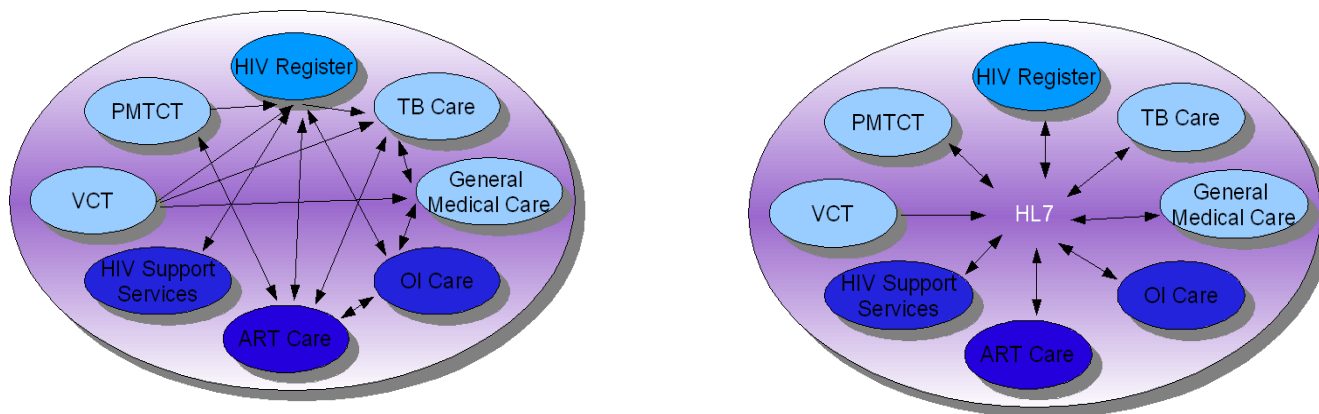
For paper or electronic individual medical records that are used in HIV care, the usual practice is to designate a unique “patient identifier” which can be sorted and filed alphanumerically. Each patient must have a unique identifier and only one identifier to ensure the integrity of medical records. The main problem is to develop a mechanism that matches the patient with the identifier. This is usually an identification card. Problems arise when the identification card is lost so there must be a backup system to lookup and match the patient's name, address, birth date, and other information with the identifier.

Paper retrieval is always problematic. Small amounts of paper that don't need to move far or be shared widely can be managed. However, once you need to store and retrieve any significant amount of data, you must have a carefully designed system. Paper records are often stored in a central location and filed in alphanumeric sequence so they can be retrieved. However, in order for the records to be useful, they must be removed from storage and transported to the point of patient care or analysis. This is another problematic area since paper records can only be in one place at a time, the record that is sitting on a desk because it is awaiting analysis or waiting for the provider to record observations is not available. Careful thought and attention must be placed on proper record management to avoid “lost” records. In spite of this, many carefully designed and managed medical record stores are still unable to locate as many as 25% of their records at any given time. For ART, data must be stored for many years, and be accessible from different facilities.

Electronic data storage overcomes many of the problems of paper records but it must be carefully designed and managed. One still needs a patient identifier. However, an electronic system can more easily search for and match patients if they have lost their identifier. Electronic systems overcome a fundamental flaw of paper records in that they can be viewed and updated from more than one place at a time and at the same time they exist in just one place where you can always find them. Electronic data can also be easily copied and transported. Another advantage of electronic data is that it can be automatically analyzed, aggregated and presented as useful information.

4.4.3 Communication with HL7

One problem with HIV care data is that there are numerous creators and consumers of data. Each of these programs have their own internal data needs and have most likely developed their own internal systems for collecting the data. Each program will usually need to interact with multiple partners. If this is done with paper, there will be a plethora of forms that each must be filled in at one end of the communication and then “translated” at the other end. Electronically, the problem is the same with a plethora of individual interfaces between all of the pairs of programs.



The solution to this for electronic systems is to develop a common electronic data format. The standard can specify the source, destination, and content of the data as a “message”. In health care, the common standard for health messages is called HL7 which specifies the data in detail. The advantage of using a common standard format such as HL7 is that each program only needs to develop one interface between their internal information system and the HL7 standard. They can use this interface to send information to any of the other programs. They also only need to develop one standard interface to receive information from other programs. This turns a “many to many” problem into a “one to one” solution.

4.5 Data Analysis

In order to make decisions, you need to turn your raw data into information. Data analysis takes data and makes connections and correlations; it looks for trends and thresholds. Programs have protocols that specify certain targets for performance or criteria for action. Patient care protocols specify what action to take based on a patient's condition. Data analysis takes these protocols and turns the data into actionable information.

Electronic information systems have a large advantage here in that they can be programmed to automatically perform complex analysis and present the information in a easy to understand format. They can take many pieces of data from many sources and distill these into a simple presentation such as a chart or graph.

In individual patient care, providers need to know the patient's current condition and the relevant history. The specific information and presentation will depend on the function of each provider. It is important to present the relevant information in a simple, clear, concise format that is easily understood. Numerical data such as laboratory values or measured parameters such as weight are best presented as a graph over time. Significant events such as episodes of opportunistic infections and supportive care services can also be represented on a time line.

In program management, monitoring and evaluation, aggregate information on patient volumes, treatment, interventions, and outcomes are most useful. An electronic information system can easily create these reports and present the information graphically so that it can be clearly understood.

5Conclusion

This overview should have given you a good understanding of the data and information requirements and rationale for HIV care programs. In addition, we covered basic information system design and implementation issues.

The remainder of the HIV care document set covers these subjects in more detail with specifics on data, information, and communication capabilities.