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Title: **The relevance of Data Management Systems in Research: The Case of KHRC**

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Abstract

Without an operational data management system (DMS) guided by a functional SOP designed per data management plan that conforms to study protocol, it will be quite difficult for researchers to produce high quality research data and research cannot be reproduced. DMS requires an accurate data capture and an efficient mechanism in managing research data. It will be vital to adopt modern technological tools to design the DMS which could automate some routine processes of the data lifecycle management (DLM) activities. Users are to be trained adequately to incorporate these techniques in the design of the systems to proficiently manage all DLM activities and train data collectors at the field to capture data appropriately. This paper highlights the significance of the management of data lifecycle of the at Kintampo Health Research Centre, history, experience, challenges and measures put in place to resolve them, this will serve as a guide for other researchers to produce high quality research data to inform policy maker's decision.

Keywords: Data management systems, data lifecycle management, high data quality, Kintampo Health Research Centre, data management plan and functional standard operating systems

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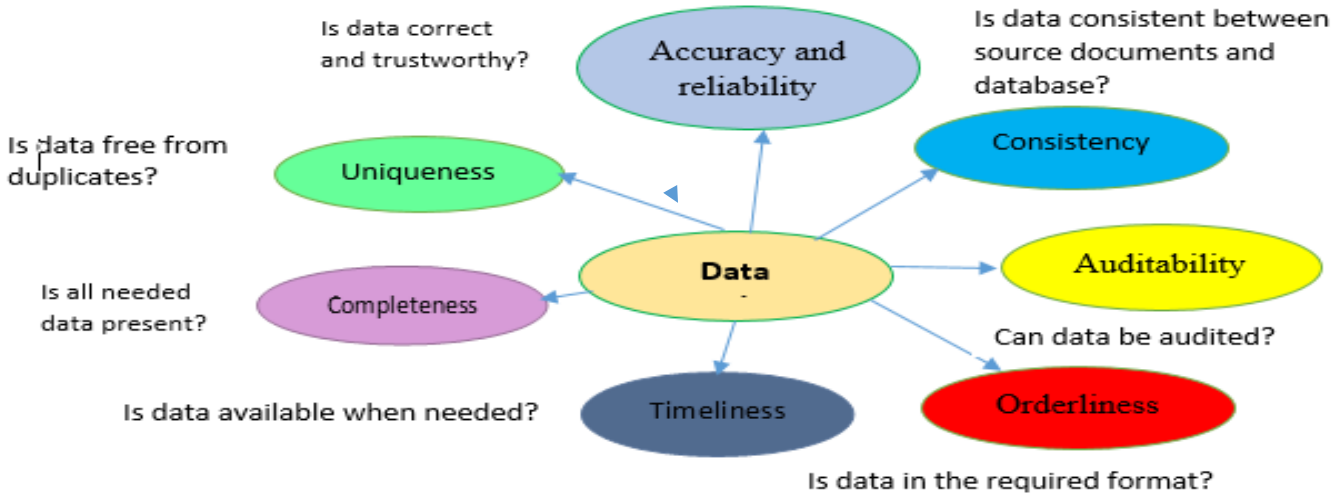
Introduction

Data is the heart of every organization which enhances proper decision making based on evidence (Whitman, 2011). Without good measures put in place to ensure high quality research data, outcome of data analyzed cannot be reliable. Data management is an administrative process which involves the use of cost effective, appropriate and modern technologies to design data management systems (DMS) to acquire relevant data. The cost of gathering data and processing it into information must be weighed against the benefits derived from using such information (Lin, 2008).

Data Management Systems

Good data management (Van Der Aalst, 1998) ensures that research data has high quality and possesses these attributes: Accuracy and reliability- data must correspond to reality; the data must be free from errors and must be dependable, for instance, the identification number of study participant on source document is wrongly entered on the dataset. Auditability- the data should have the ability to track possible changes. Completeness- the data should have no blanks; for instance, a require fields like date of birth or age is mandatory and should not be blank. Consistency- ensuring that data do not contradict; for instance, date of visit recorded on database is before the date the study commenced. Orderliness- the data should be in a required format per study protocol for example, the date March 4, 2019 should be in 03/04/2019. Timeliness and available- the data must be available when required per study protocol, for instance a delay in resolving a query (Wang, R. Y., & Strong, D. M., 1996). Uniqueness- the data should be free from duplicates. Figure 1.0 below shows seven attributes of high data quality in data lifecycle management (DLM).

Figure 1.0: Seven characteristics of high quality data



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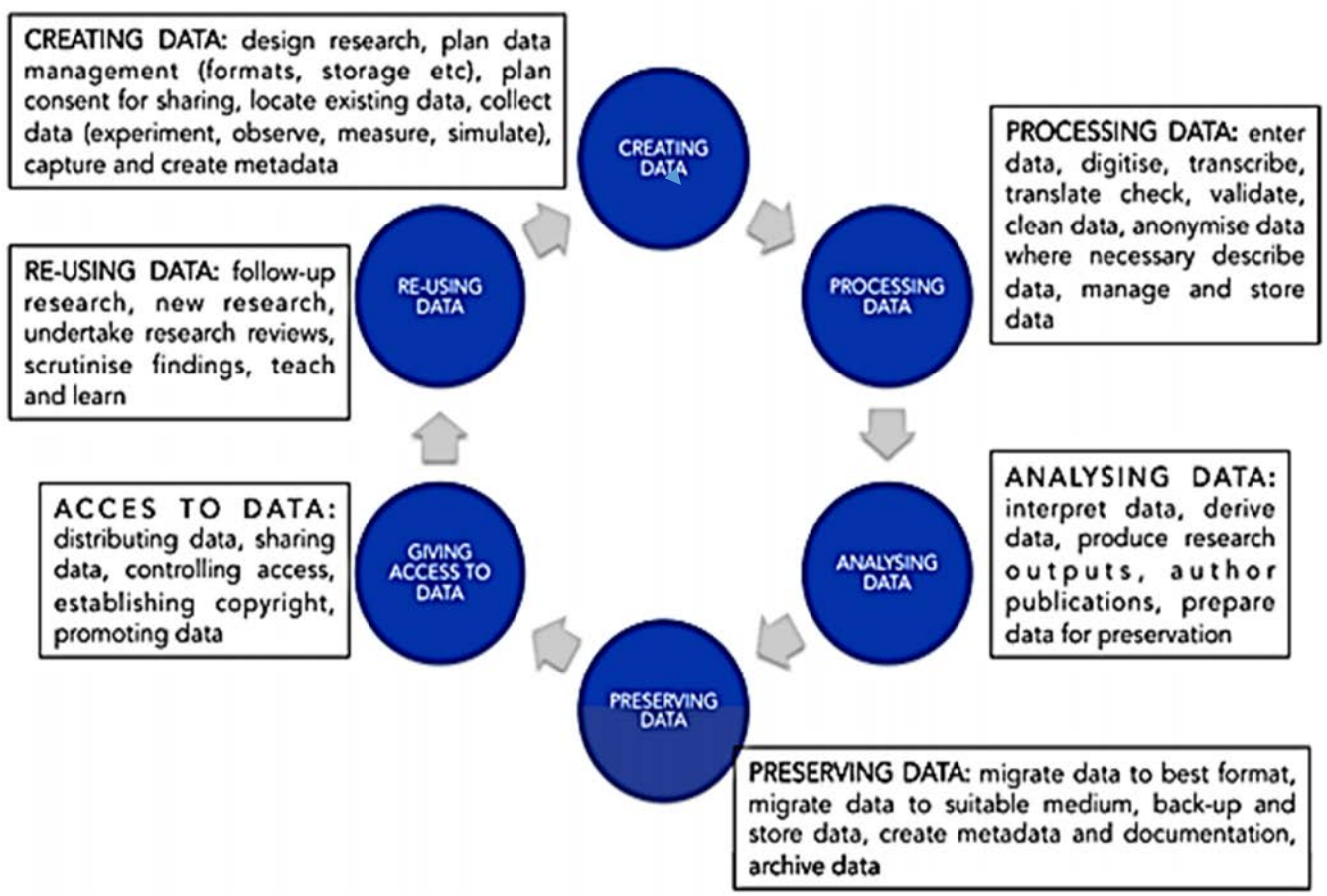
DLM is a routine data processes guided by policies and procedures, such as adopting universally, accepted, suitable guidelines and standards to design a functional standard operating procedure (SOP) that stems from data management plan (DMP). The DLM processes are as below: Creating data- this involves the design of the data capturing tools for instance electronic forms, DMP comprises the format of data to be collected, how data would be stored, the data dictionary, process of consenting and ensuring participants' privacy. Processing data- This has to do with data entry, verification, performing range and consistency checks, raising queries for appropriate resolution/ data cleaning and storage processes. Analyzing data- This covers the process of interpreting data, producing research outcomes, data publication and preservation. Preserving data- Transforming data into the right format into appropriate medium according to DMP, backup and storage of data, creating metadata, documenting the process and archiving of data. Giving data access - This entails the process of distributing, sharing and provide access to only those required. Re-using data- Data is secured for future follow up research works or new studies, reviews findings and lessons learnt are noted for subsequent studies. Figure 2.0 below shows the routine steps of the DLM.

Figure 2.0: Research data life cycle management



Incorporating a number of data quality audit mechanisms to ensure that data cannot be updated by intruders, standardizing available data for easy analyses and providing adequate training for data management staff including data collectors. Using a detailed SOP document to guide DLM processes would improve research data quality. Data quality processes involves: Policies and procedures- Globally accepted standards and guidelines are observed to design a functional SOP

to guide DLM processes. This is to standardize the DLM processes (Wandersman, A., et al, 2012). Standardization- SOP: This require a document with a set of written instructions having a repetitive activity that is followed by staffs within an organization to achieve their desired goals. The development and use of SOPs are an integral part of a successful quality system. It provides a uniformed information to perform a task properly and consistently to achieve pre-determined specification and a quality end-result. Leadership and Management- This is one of the key factors of improving data quality. Good leadership and management will ensure required policies and regulations are developed, ensure proper implementation and monitoring of the policies (Parvin, 2019). Data Quality Audit- This process is to enable problem identification within DLM processes and appropriate measures to be implemented to ensure data have the attributes of high quality and data integrity is not compromised using modern technologies to design automated audit trails may facilitate the process (Newgard, C. D., Zive, D., Jui, J., Weathers, C., & Daya, M., 2012). Training - This provides the DLM team to have the required professional skills, qualifications, competent resources and knowledge to govern DLM activities efficiently (Randhahn, S., & Niedermeier, F., 2017). Data Availability- Data should be readily available when ever needed using the appropriate channels for accessing data (Bretz, 1998). Data Quality Dimensions- High data quality is assured when improved measures are put in place by identifying various aspects of data definition, types, strategies, techniques are needed to equip methods and processes (Sidi, 2012). Decisions making in an organization is based on cleaned data obtained from data analysis. As data are significant resources in all organizations the quality of data is critical for managers and operating processes to identify related performance issues. Moreover, high quality data can increase opportunity for achieving top services in an organization. However, identifying various aspects of data quality from definition, dimensions, types, strategies, techniques are essential to equip methods and processes for improving data. Figure 3.0 below shows the processes of improving data quality assurance.

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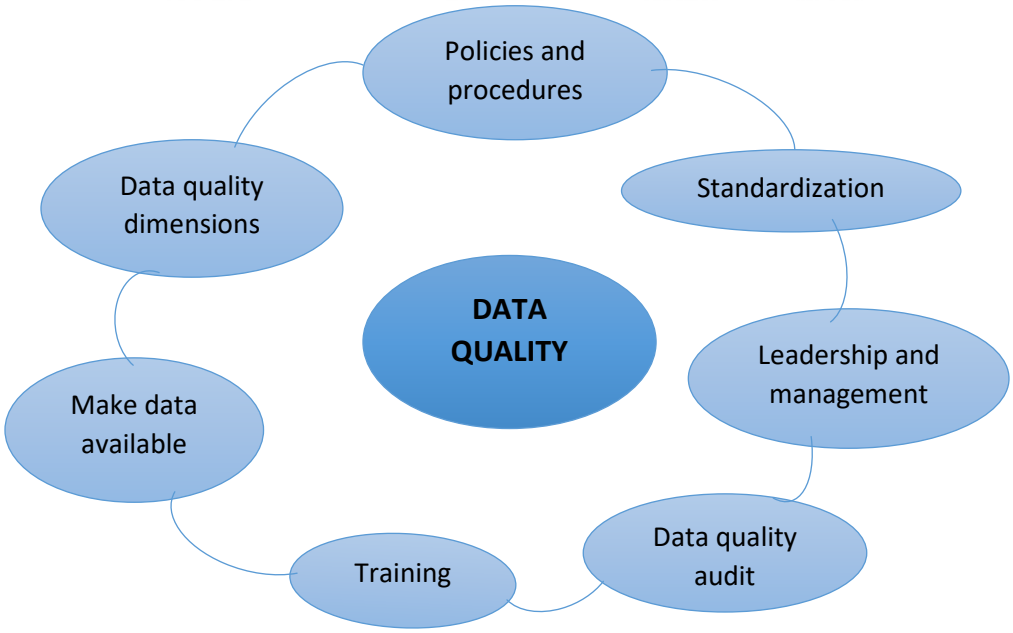
Figure 3.0: Data quality improvement steps



To achieve high data quality, a proper DMP is needed to manage the routine data life cycle. These are as follows: effective planning, controlling, providing clean data, practicing the disciplines in the development, execution, and supervision of plans, programs, policies and practices that protect, control, deliver and enhance the quality and value of data and information in the organization (Nerenz, 2009).

Benefits of effective data lifecycle management

The merits of data management include: Reduced potential errors and the damages caused by bad data. The greater occurrence of processes like copy-paste, drag and drop, and linking of documents, the greater the likelihood of data errors (Ameri, 2005). Effective security and protection- This aids in ensuring that data is never lost and is protected, also ensures staff are protected from various data losses, thefts, and breaches. Improve efficiency- when data is managed properly it could be easily updated, accessed and save a lot of productive hours. Improve data quality- using appropriate tools and suitable technologies to design data management systems (DMS) will help in improving data quality and will aid in proper decision making. Reduce cost and time-DMS will save you time, money and energy by automating all data management tasks, taking out the tediousness of doing it by hand, leaving more time for employees to attend to other important projects. Ensure compliance with requirements of the regulatory authorities. Increase research impact by maximizing data visibility and promoting transparency in research. Prevent unauthorized use - These are mechanism put in place to address privacy and confidentiality related issues throughout and beyond research. Improve accessibility- by ensuring the quality and integrity of data is maintained at all levels of research. Safeguard research data - by establishing appropriate backup and storage management. Secondary data- To enable research continuity and will permit innovative research to be a built on existing data.

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History

Kintampo Health Research Centre (KHRC) is one of three field research centres of the Research and Development Division (RDD) of Ghana Health Service established in 1994, located in the middle belt of Ghana in the Bono East Region with a total population of 156,145 of which male form 76,356 (48.9%) and female form 79,789 (51.1%) as at 2018 unpublished report. KHRC conducts high quality biomedical and public health research, develop research capacity guided by globally accepted ethical standards and good practices with the aim of contributing to reducing ill health and healthcare cost in Ghana and beyond. Houses within our study area have been numbered and digitized, facilitating tracing of potential study participants to their homes (Owusu-Agyei, 2012) to track progress towards Sustainable Development Goals (SDG) using indicators such as mortality levels, patterns and trends to shape local and international health policy, programs and practices. The research outcomes are published scientific journals both locally and internationally. We have several scale sets of staff with expertise from all discipline in the field of health research for the past 25 years. All our research project protocols and related documents are reviewed by our scientific review committee (SRC) and the Ethics Committee (EC); and give approval to all studies before commencement. Our main health focus are on these areas and some studies conducted are namely:

- Family Health/maternal and child research- The Obaapa study looked at the impact of vitamin A on maternal mortality which recruited 207,781 women in their reproductive age. This provided the largest platform for other maternal and child studies. Results was inconclusive but gave us a number of indices that are been followed up for pre-term and other burdens on maternal and child health. We conducted a child survival studies looking at impact of vitamin A on morbidity and mortality; whether Vitamin A reduces morbidity and mortality (Zlotkin, 2013). Another study was conducted to check the impact of delayed vaccination and low birth weight (Newton, 2007). Embrace study looked at how regular visits to be made by pregnant women and how it made impact on antenatal and postnatal care funded by JICA and GHS. Results revealed there was an increase in antenatal and postnatal care (Enuameh Y. A., 2016). Oxytocin study was to access the feasibility of using oxytocin uniject for community health workers used on pregnant women if there was bleeding, this was funded by PATH. Results revealed that uniject reduced bleeding among those who used the oxytocin uniject and there are still discussions how it would be rolled out in the community (Stanton, 2013). A cross- sectional study was conducted to test the use of contraceptives among adolescents in Kintampo, Ghana (Boamah, 2014). Another study was conducted to check the supposed facilitators and barriers to interventions aimed at reducing unintended pregnancies among adolescents in Kintampo (Enuameh Y. W.-A., 2012).

- Environmental research: National Institute of health, Trust Research Funds and Columbia University to investigate the impact of household air pollution (HAP) on low birth weight and pneumonia (Carrión, 2019). We distributed improved cook stoves to pregnant women who were identified in their first trimester and followed them till delivery, took their weights and that of the children, and followed the children till one year (Asante, 2013). The women were given either biolite which used wood or an improved stoves which used LPG. Results revealed there were no impact on the intervention low birth weight but with every interquartile increase in carbon mono-oxide, there was a reduction in birth weight of 50-54 grams. This is quite significant, yet to be published. We found average low birth weight was about 2.9gm, the prevalence was about 17% and birth length and head circumference; we did ultrasound scan for each of the pregnant women, with this were able to date the pregnancies and determine preterm births and 22% for gestational age and 4% for preterm birth (Asante K. P.-A., 2014) (van Vliet, 2018). We looked at the impact of carbon monoxide on hypertension and realized that the exposure of carbon monoxide was about 4 millimeter in mercury increase in systolic high blood pressure. These trials demonstrate the capabilities of been able to do pregnancy cohort studies to identify them from pregnancy and follow them up to age 7 (Lee, 2019).

- Malaria and Neglected Tropical- Vaccine trails, phase I and phase II, RTSS (Asante K. P., 2011), (Asante K. P.-A., Placental malaria and the risk of malaria in infants in a high malaria transmission area in Ghana: a prospective cohort study., 2013).

- Non Communicable Diseases (NCDs) - Diabetes and hypertension are the top 10 diseases in NCDs according to our routine data and that has been our main focus on NCDs. A prevalence study was conducted, where we found that about 24% of adults had hypertension and diabetes was 5.7% including pre diabetes, it shoot up to 39% which was quite high. About 50% adults having hypertension did not know they were hypertensive that was a huge problem for us to tackle. So one of our research agenda is to nail down on how to improve identification and referral of people with hypertension (Dosoo, 2019).

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TASH study, KHRC in collaboration with KNUST, blood pressure(BP) measurements and managements is done at the hospital level and not at the community level so this study test to see if it is feasible to manage people with hypertension using community health officers funded by National Institute of Health in USA (unpublished).

- Mental health research- Maternal depression study, was to determine correlation of depression cases among young pregnant women in Accra. We found 18% of young pregnant women had some levels of depression (Ae-Ngibise, 2015).

- Occupational research: Some studies have been done just to name a few- Innovative trials/tests, we worked with PATH to evaluate a number of tools we have, one of them was to evaluated rapid diagnostic test for GSPD among children less than 5 years (Adu-Gyasi, 2015). We have a slide bank for training for quality test and capacity building which people borrowing slides to South Africa to study from.

Our experience in data management

The data processing and management/computer centre unit is the brain behind all KHRC's success story for the past 25 years of our existence and there have been a lot of transitions. The unit collects and manages large datasets. Data collection was done using the physical questionnaire (paper/manual system). Response on questionnaire were double entered unto database designed using Visual FoxPro and Microsoft Access. Due to technological advancement, more data management tools were introduced in the designing and managing our data. With the aid of geographic information system (GIS) application and drone technology, the health and demographic surveillance system (HDSS) team can easily identify the compounds of the study participants in our catchment area. For instance, our HDSS application was formerly designed using Visual FoxPro but have migrated to SQL server, then to Household Registration System2 (HRS2) to Open Health and Demographic System (OpenHDS). OpenHDS is an open source android tablet application that enables effective and real time data capture offline on health and demographic information on residences in our catchment area and data uploaded to the OpenHDS server when they have mobile connectivity. Some data management systems are designed using C-sharp as front-end and SQL server for the back-end. After which, the electronic data collection were introduced on tablets/android applications. The data management applications were designed using Survey Solutions, Research Electronic Data Capture (RedCap) and Open Data Kit (ODK). REDCap software is used to collect virtually data aiming to support online or offline data capture for research studies and processes, which is compliant to HIPAA and other regulations. ODK is a free and open-source software for collecting, managing, and using data in resource-constrained environments. It allows for the collection of data offline and submission of the data when internet connectivity is available. These modern technologies have enhanced data management processes greatly by making routine processes more effective and efficient in real time; enable use save time and money. We have in place the barcoding system to support and enhance the tracking of forms in the storage and retrieval processes.

The data management unit processes involves: Propose- The data managers make input in the questions to be posed to participants and range and consistency checks (R & C)/skipping patterns, design the data collection and management applications where a number of checks are incorporated to improve data quality and write data management plan per protocols. Data

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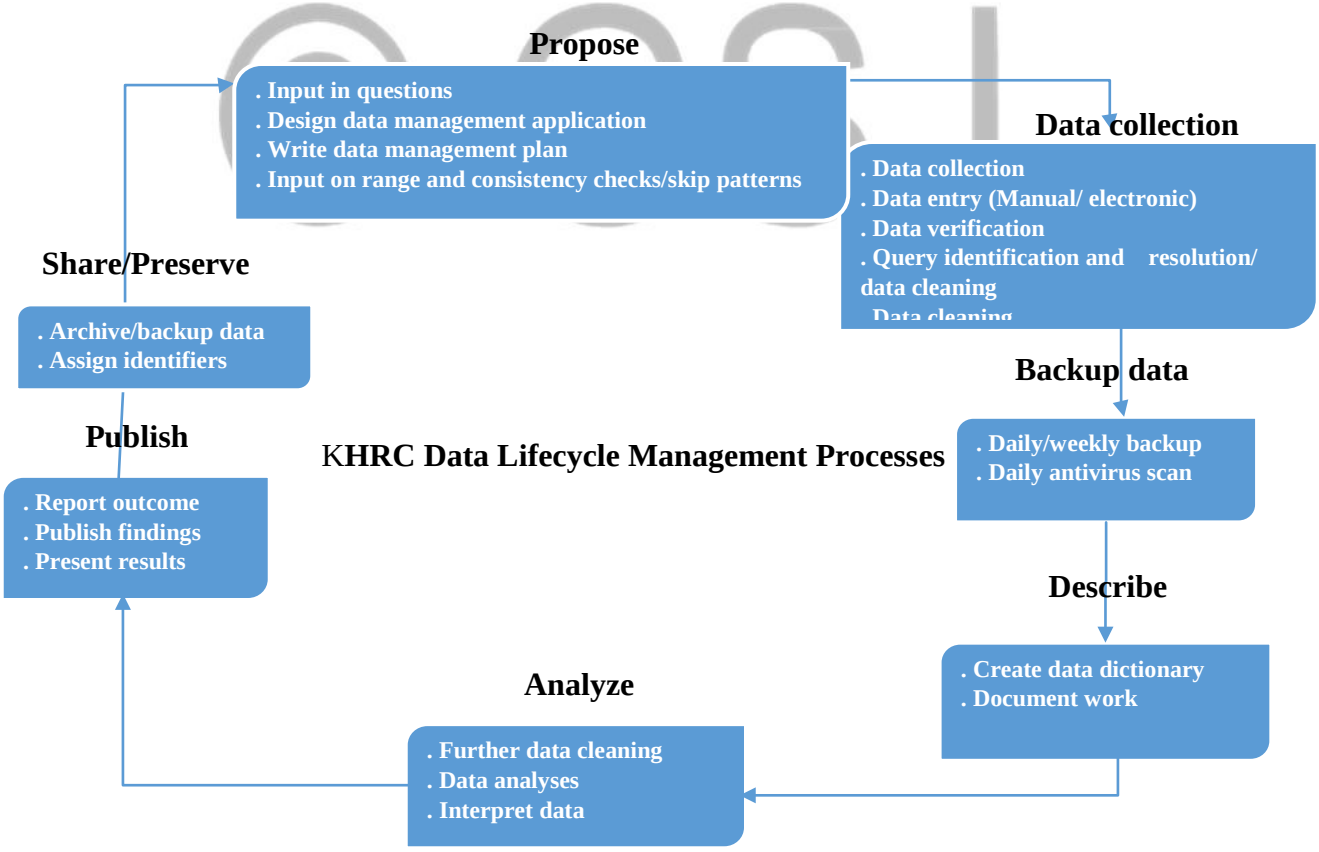
collection- We train the field team on how to collect data for electronic and paper-based data capture. For manual data capture - two data entry clerks enter exactly what the responses are on two different data entry screens like stream A and B without communication except their supervisor/data manager, after which data verification application is run to bring out discrepancies if any by comparing same data entered on the two streams for validity to prevent data entry errors for instance; a range check to avoid an input number that is greater/smaller than the specified range, discover outliers per the data verification and R & C, we raise them as queries back to the field team for appropriate resolution, after we make the required updates on the database this known as data cleaning. Data backup - This is to prevent data loss, copying or archiving data files for the purposes of restoring in case of data loss caused by a number of factors ranging from power outages, hardware failures, viruses and many more. We do daily and weekly backup to secure research data. We do automatic antivirus updates and scan from the servers where all our computers are connected to prevent, detect and remove malware. Describe - We create data dictionary/metadata and document our work to make our processes explanatory to us after several years. Analysis - After data cleaning process, further cleaning is done to test whether data is cleaned then data is then analysed and interpreted. Publish - Outcome of analysis and interpretation is reported, published in scientific journals and results presented to stakeholders. Share - Data is then prepared for sharing per our sharing policies by anonymizing all identifiers for the sake of privacy.

Figure 4.0: KHRC Data Lifecycle Management Processes



As a unit, we have SOPs that stems from our policies to guide us to achieve high research data quality. These include: Data authentication policy- This ensures all staff in the unit log unto our

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system with a username and secured password to gain access to our DLM application. Data capturing policy- this is to ensure certain procedures are followed routinely during data collection, for instance the participants are properly consented. Data entry policy- To guide the data entry processes according to study protocol. For example data entry team enter what they see, all fields are mandatory so any field with no response must be queried, logged into our query log book, sent back to study coordinators for appropriate resolution. Data quality assurance policy- This policy ensures DLM activities are followed to achieve high data quality to be reliable and evident for decision making. Data verification, range and consistency checks as well as data cleaning are some of the routine practices in the unit. Data backup policy- After close of work, data managers ensure data is backed up automatically on daily and weekly bases on some servers, selected external devices and Dropbox so that we do not lose data in anyway, this is our routine practices. Data sharing and access policy- The data is shared with only those authorized to access them. Data can only be shared upon request and approval of the Director. Data security- We have firewalls and antivirus which are automatically updated from our servers and computers to safeguard our data from all forms of threats. We have cameras fitted at vantage points to provide some level of monitoring to physically protect our asset like assets (tablets, computers, UPS, backup devices, etc.) from invaders. We also have mounted biometric verification system to physically secure our unit.

Furthermore, we analyze our data quantitative using Stata, r-studio and SPSS and use NVIVO to analyze qualitative data.

Challenges and the way forward

Challenges	Way Forward
Cost of licensed software/ hardware - Using advanced technology comes with cost of hardware example servers, software to storage, human resource and time.	By making informed decisions to conduct research with available resources and provide solutions which aligns with KHRC's goals. Several studies could use existing applications that were designed using advanced technologies. This will reduce cost.
Data cooking- Data produced from field team without visiting the study participant.	GPS is activated on tablets/android phones where GPS coordinates are captured during data collection to ensure field team truly visited the study participants. This could be verified to reduce invented/cooked data.
Data synchronization issues- At times data are unable to get synchronized.	Electronic data collection is done offline on tablets. Data is synchronized after fieldwork then fieldworkers notifies data managers on the number of records per id and date sent to the database for confirmation, if the records is not on database fieldworker is asked to resend.
Data Security- The rise of huge amount of data increases privacy and security concerns that could lead to high risk of exposure of the data, making it vulnerable.	Appropriate training is required by data management team to secure data by proper storage, which starts with encryption and constant backups. Automating security updates, backups, install operating system which often include better security, use firewalls and many more could improve data security.
Data storage – Saving data on several backup devices occupies large storage space over time. Missing data, inconsistent data, logic conflicts, and duplicates data all result	KHRC could look at the option google drive or cloud backup is a service in which the data and applications on servers are backed up, stored on a remote server to keep files and data readily available in the event of a system failure, outage or natural disaster.

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in data quality challenges	
Data loss- This could be as a result of power, technical or hardware failure.	More backup devices and regular backups are required to address this, to prevent data loss at any point due to a number of reasons. It's our policy for daily and weekly backup to be done. We plans to store our backups on cloud computers.
Data growth causes slowness- The amount of data produced makes it challenging to store, manage, utilize, and analyze it which slows down data management processes.	To reduce slowness during data processing regardless of size of data, all idle applications on the tablets have been locked except the data collection tools.
Power outage- Power failure is one of the concerns in our unit caused by loss of electrical power network supply.	To ensure we have adequate power for smooth running of our unit, the solar panels system available is switched on in case there is power failure to halt our routine work.
Insufficient understanding and acceptance of big data by some team members.	Using the expertise of in-house/hire staff to provide training to instill the skills data management team require for smooth running of the unit and employing useful information from the internet to make work less complex.
High cost of electricity	With the solar power system available in KHRC, we are hopeful to reduce the cost of electricity drastically.
Unresolved queries- Sometime it is quite difficult to find study participants for the clarity of some responses they provided earlier. This problem comes up in the paper-based/manual data collection.	This resolve this, field team are encouraged to submit all forms for data processing within 72 hours so in case there are queries and there is the need to get in connect with study participant is could be easier for them to be located.
High cost on human resource in data processing.	With the use of modern technologies to capture data electronically on android applications where more automated validation checks are incorporated DLM processes are quite easier and faster, errors are identified in real time and resolved which takes off the expense of data entry clerks.
Low Quality - Data with inconsistent format, missing data, inaccurate data and duplicates are data with low quality.	Our data management team have incorporated a number of validation checks during the design of our data management application for data with low quality to easy identification and appropriate resolution.

Conclusion

This paper highlights the significance of data management systems in the health research. For proper decision making, high quality data is required. Data should be reliable and evidence-based by the adoption of advanced technological applications to design an effective data lifecycle management applications in compliance with regulatory bodies. Data should be accurate and reliable, auditable, complete, consistent, orderly, timely and available; and uniqueness are some of the attributes of high quality data. The benefits of effective data management are reduction of potential errors/damages, reduction of cost and time, effective data security and protection, prevent unauthorized use, ensure compliance with requirements of the regulatory bodies, improved quality and accessibility of data, increase research impact by maximizing data visibility and promoting transparency in research.

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For over twenty five years, KHRC have conducted research in the area of family health/maternal and child, environmental, malaria and neglected tropical, non-communicable diseases, mental and occupational studies. We have a number of SOPs that stems from information assurance policies to guide our data lifecycle management processes where the data collected by the field team are processed and managed by data management team, analyzed by our statistical team and the findings are shared with policymakers for decision-making. Managing big dataset comes with a huge challenge, in KHRC we are faced with some data management issues such as: cost, invented/cooked data, data synchronization issues, data security, data storage, data loss, data growth causes slowness, power outage, insufficient understanding and acceptance of big data by some team members and unresolved queries however we have solutions to address these challenges by the aid of required team of experts and proper leadership skills. The data management team have employed adequate measures to ensure research data have high quality. Our effort have played a vital role in the success story of KHRC for data to be effective, efficient, reliable and evident.

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