National Electronic Health Record Bill

State of Electronic Health Record in Nigeria

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Introduction

The adoption of technology in healthcare delivery has ushered in innovations that are improving the quality of care and providing solutions to life-threatening conditions. Health records of patients have become an integral part of care delivery. Digitisation of the records has created ease and efficiency compared to the limitations imposed by paper records. Electronic health records are the digital version of orthodox paper records. Electronic health records have the capability to improve the quality of healthcare services, reduce medical errors, and create a more efficient use of time. "It can accurately capture the state of the patient at different stages and facilitate access to the entire patient history at an instant."[1]

It enables healthcare providers to treat patients more accurately by sharing all available health data on a patient. Access to health records is beneficial as it could provide valuable data on diagnoses or required medication.[2][3] Electronic health records help with time management, security of records, ease of retrieval of records, statistical summaries, and the presentation of clinic records. It provides a comprehensive view of the patient, better coordination of care, easier information sharing among care providers, increased productivity and efficiency, and personalisation of care.[4] Besides, it makes data available for research to develop life-changing solutions to life-threatening diseases.

The traditional system of storing health records makes storing and retrieving data a challenge. In Nigeria, there remains a substantial digital divide as health records are still primarily recorded and stored in paper-based forms. This traditional record system is often not only problematic to physically access; there is inadequate storage space to keep records, documents may become weak with age, there may be a colour alteration in them, some parts may be missing[5] and they may have become infested by pests or affected by other attacks.[6] However, healthcare technologies that are reliant on health records are growing in the country, and the government is recognising the need for a robust electronic records management system.[7]

[1] Kiri, 'Electronic Medical Record Systems: A Pathway to Sustainable Public Health Insurance Schemes in Sub-Saharan Africa' <https://www.npmj.org/article.asp?issn=1117-1936;year=2020;volume=27;issue=1;spage=1;epage=7;aulast=Kiri> accessed 9 April 2021.

[2] Divya Dugar, 'Benefits of Electronic Health Records | EHR Advantages & Disadvantages' (9 December 2020) <https://www.selecthub.com/medical-software/benefits-of-ehr-systems/> accessed 10 April 2021.

[3] For example, patient information or records stored electronically might be used to identify people at particular risk of being affected by a disease. Stoeger K and Schmidhuber M, 'The Use of Data from Electronic Health Records in Times of a Pandemic—a Legal and Ethical Assessment' (2020) 7 Journal of Law and the Biosciences <https://doi.org/10.1093/jlb/lsaa041> accessed 31 March 2021

[4] Anonymous, '7 Benefits of Electronic Health Records for Hospitals' (The University of Scranton Online, 20 November 2015) <https://elearning.scranton.edu/resource/health-human-services/7-benefits-electronic-health-records> accessed 10 April 2021.

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The growth of solutions geared toward electronic health records has largely been driven by private organisations and donor agencies. A good number of government healthcare facilities are yet to digitise their record-keeping processes. However, there is a growing effort to digitise the process, which is more visible with the growth of health insurance by both the National Health Insurance Scheme and Health Management Organisations.

In spite of the benefits of electronic health records, they are also fraught with shortcomings, primarily around security, privacy, and data protection concerns.[8] The slow adoption is also due to a lack of infrastructure like computers, internet connections, and power. The combination of lack of ICT skills by staff, paucity of funds, poor administration and corruption also adds to the factors limiting the adoption of EHR.[9]

[8] 'Legal Framework for EHealth' <https://www.who.int/goe/publications/legal_framework_web.pdf> accessed 10 April 2021.

[9] Ojodale Attah Ambrose , 'Implementing the Electronic Health Record in a Nigerian Secondary Healthcare Facility: Prospects and Challenges' <https://munin.uit.no/bitstream/handle/10037/12245/thesis.pdf?sequence=2&isAllowed=y> accessed 10 April 2021.

Towards a National Electronic Health Record System

The use of electronic health records is central to the plan of the Nigerian government to attain a progressive healthcare system.[10] This is evident in policy documents like the National Health Policy, the National Health ICT Strategic Framework 2015-2020,[11] and the Nigeria National E-Health Policy. In 2017, the Federal Ministry of Health conducted research on the digital ecosystem in Nigeria and the report showed wide use of electronic medical records.[12]

The absence of health records makes it difficult to provide quality and precise health care services. The immense benefit of electronic health records is makes it imperative not to be ignored by private and public stakeholders. Increasingly, some countries have adopted a National Health Record System. Consequently, the House of Representatives introduced a Bill in 2019 for a National Electronic Health Record System. The legislative proposition is modelled after some other countries in the world.

The National Electronic Health Record (NEHR) is a secure system that collects summary patient health records across different healthcare providers. This enables authorised healthcare professionals to have a holistic picture of your healthcare history.[13] NEHR is voluntary for citizens who want to be part of it. The summary of a patient's health record is securely stored in one place electronically, which enables multidisciplinary healthcare professionals across the country to work together to access it in real time and to provide enhanced care.[14]

[10] Laws and Policies Affecting Digital Health in Nigeria' (TechHive Advisory, 31 August 2020) <https://techhiveadvisory.org.ng/laws-and-policies-affecting-digital-health-in-nigeria/> accessed 10 April 2021.

[11] National Health ICT Strategic Framework 2015-2020' <https://health.gov.ng/doc/HealthICTStrategicFramework.pdf> accessed 10 April 2021.

[12] Nigeria Digital Health Landscape: An Inventory of Digital Health Solutions' <https://health.gov.ng/doc/eHEALTHINVENTORY.pdf> accessed 9 April 2021.

[13] Singapore National Electronic Health Record Brochure' <https://www.ihis.com.sg/nehr/Documents/Brochure/English_NEHR_PublicBrochure_A4online_05Feb18_R2.pdf>.

[14] 'About NEHR' <https://www.ihis.com.sg/nehr/about-nehr> accessed 10 April 2021.

Benefits of National Electronic Health Record

It helps to achieve a better health outcome. NEHR provides a better understanding of healthcare history. Healthcare professionals are able to deliver more effective care hinged on being able to make informed diagnoses for the best treatment strategy to improve a patient's health.

It improves patient safety. Healthcare professionals are able to view records of diagnosis, patient's allergies and prescription which supports safe care delivery, especially during emergencies. With this, incidents of wrong prescription, adverse drug reactions and other clinical errors can be reduced.

It enhances a patient's experience with seamless care. NEHR makes data portability easier across different healthcare facilities. This way, patients, regardless of location can access care with convenience, saving them valuable time and money, and minimizing duplication of diagnosis and test.

Availability of data for research. NEHR provides a rich resource and repository for research into developing solutions to life-threatening conditions and understanding diseases. The prevalence of emerging technologies like artificial intelligence and big data analytics can make use of the data to improve healthcare.

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The State of the Electronic Health Record Bill

The bill is currently pending before the House of Representatives Committee on Healthcare. In March 2020, the committee held a public hearing. During the public hearing, there were voices for and against the bill. One of the oppositions to the bill came from health records officers, who were of the opinion that the problem the bill is trying to address is already provided for under the Health Record Officers Act.

The deficiencies under the National Health Act also contribute to the necessity of the bill. The Act is insufficient to address the complex processing of health records for emerging technological trends like big data, predictive medicine, and artificial intelligence. Besides, the Minister of Health has failed to exercise its powers to make guidelines and regulations under the Act.[15] Consequently, this gap and the lack of a coordinated national policy and action make it necessary to enact the bill.
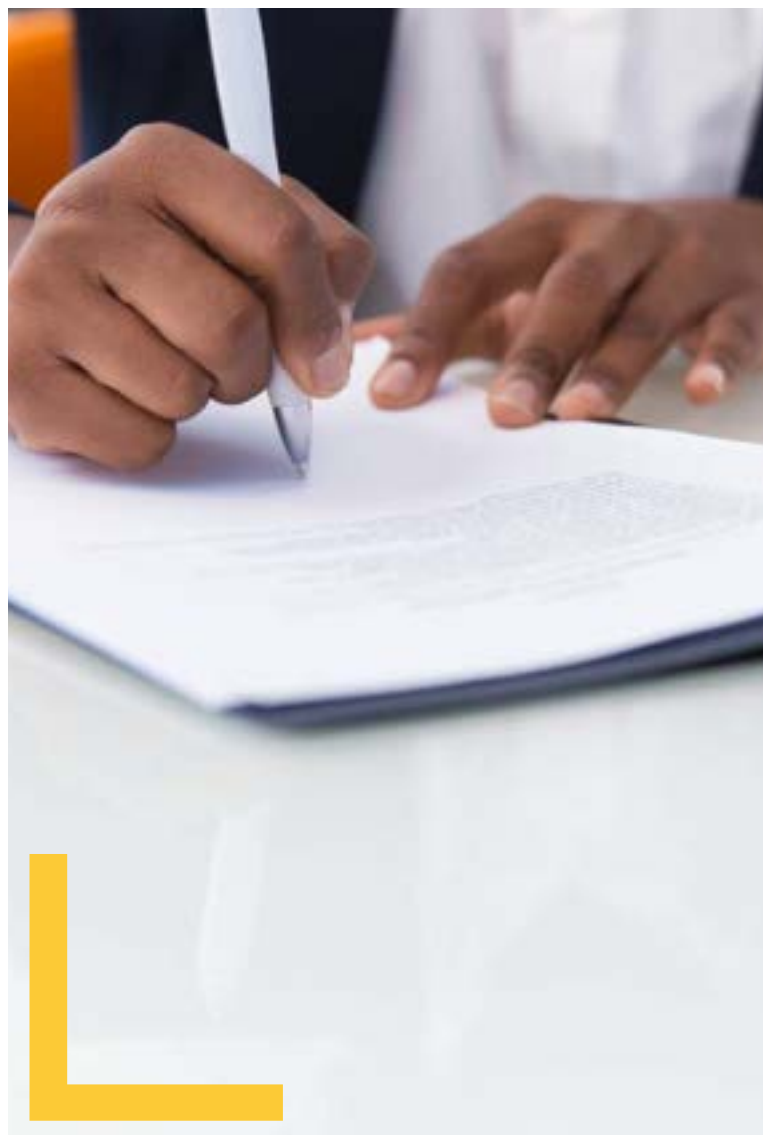
[15] Section 59 of National Health Act 2014

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Review of the Bill

The bill, which aims to address all of these perceived shortcomings, seeks to provide a framework for the operation and management of health records in electronic form. It will allow the voluntary collection of a patient's electronically-stored health information. It is intended to improve the availability and quality of health information and care across different health care providers.

The bill provides for the establishment and maintenance of an index service to ensure that health records of individual patients from different registered healthcare centres are connected to a registered record account.[16] It also provides for the establishment of a health repository service where health information of registered healthcare recipients is to be kept and retained for 30 years after the recipient's death or 130 years if the recipient's date of birth is unknown.[17]

Under Section 13, a registered healthcare recipient can set controls over who may access the recipient's information. The bill requires that default access controls be put in place where such a recipient does not set such controls. Section 14(1) places a penalty on persons who access health records without authorisation.[18] Under Section 11(1), the bill provides for the establishment of a national electronic health record system register where a healthcare recipient may register and, upon registration, be given a health record account where personal medical data would be stored.[19] Section 14(1) places a penalty on persons who access health records without authorisation.

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[16] Section 8(a) of the National Electronic Health Record Bill, 2019

[17] Section 9 of the National Electronic Health Record Bill, 2019.

[18] A fine not exceeding one million naira and an imprisonment term not exceeding two years for unauthorized disclosure of record. A breach of any provision of the Bill attracts a fine not exceeding one million naira and a term of imprisonment not exceeding two years. A corporation will be subject to a fine not exceeding ten million naira for a breach of the Bill.

[19] Section 12 of the National Electronic Health Record Bill, 2019.

Despite the innovative provisions in the bill, there are some perceived shortcomings in the provisions of the bill that need to be revisited and addressed by the legislators:

- The provision for default access controls under Section 13 is not specific enough on the data protection obligation on stakeholders. Consequently, the provision failed to impose sufficient safeguards for the protection of the health data.

- Concerning the establishment of a Board, the Constitution of the Board provided under the Bill is not diverse or reflective of modern realities. The powers given to the Board, the system operator, and the Minister to formulate policies are not stated to be limited by the Constitution. Also, the Bill does not explain how the approval of the Board will be obtained when there is a need to borrow or dispose of any property.

- The Bill does not prescribe a mandatory requirement that a healthcare recipient should display compliance with the data protection law or operationalise an efficient privacy program

Regarding appointments into the National Health Repository Service Operator's office, the criteria is not stated. Although the Bill defines who a contracted service provider is, it fails to mention the criteria for being employed as a service provider. There is also an omission as to the criteria and modalities for employing an international subject by the Board.

The Bill does not define what is meant by electronic health record nor does it mention data protection measures or principles, especially related to health data which are sensitive personal data.

The Bill only grants the Minister the power to issue the Regulation. As we have seen with the experience under the National Health Act 2014, the Ministers rarely exercise this power and typically leave a legislative lacuna.

The Bill states that the pre-action notice shall be served on the Health Record System, however this poses a problem because the Health Record System is not a legal person.[20]

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[20] Section 29 of NEHR Bill

Legal Frameworks Regulating Electronic Health Record in Nigeria

1. The 1999 Constitution of the Federal Republic of Nigeria [21]

Section 37 guarantees the right to privacy, and the privacy of their homes, correspondence, telephone conversations, and telegraphic communication. Preservation of privacy extends to healthcare records.

2. National Health Act (NHA) 2014 [22]

The Act is the principal legislation regulating the Nigerian healthcare sector. Under Section 26 of the Act, all information concerning a person's health status, treatment, or stay in a health establishment should be kept confidential. The section provides that health information can only be disclosed upon a court order or any law with the owner's consent in writing, and that non-disclosure will pose a severe threat to public health. Section 27 provides the basis for the disclosure of health records to a third party where disclosure is for a legitimate purpose within the ordinary course and scope of his or her duties and when such access or disclosure is in the user's interest.

Section 28 provides for the use of consent as the basis for obtaining patient health records for research, teaching, and studying. However, if the research data does not contain any personally identifiable information, consent will not be required. Section 29 places a duty on any person in charge of a healthcare facility to put necessary structures to prevent unauthorised access to patient records and protect such records online and offline.

[21] Chapter C23 Laws of the Federation of Nigeria 2004 < https://lawsofnigeria.placng.org/laws/C23.pdf> accessed 31 March 2021

[22] 'No 145 of 2014' <https://nigeriahealthwatch.com/wp-content/uploads/bsk-pdf-manager/2018/07/01_-Official-Gazette-of-the-National-Health-Act-FGN.pdf> accessed 31 March 2021

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3. Cybercrimes (Prevention and Prohibition etc.) Act 2015[23]

Under Section 5 of the Act, certain sectors are designated as Critical National Information Infrastructure (CNII), and any form of attack is an offence. Thus, any offence against a CNII is punishable with 10 years' imprisonment, and where the offence causes grievous bodily harm, it is punishable by 15 years. In both cases, the Act provides that there is no option of paying a fine. Where death occurs, the offender will be sentenced to life imprisonment. Part 7.5 of the 2014 National Cybersecurity Strategy,[24] designates the healthcare sector as a National Critical Information Infrastructure. The Act goes further to criminalise offences that could impact health records, like unlawful interception of electronic messages, identity theft, impersonation, and others.[25]

4. Medical Code of Ethics (Rules of Professional Conduct for Medical & Dental Practitioners)[26]

Under Section 22, the Code explicitly mandates the security of personal data at all times against unlawful interception. Section 42 regulates the sharing of patient health records among healthcare professionals. Also, Section 44 reinforces patient-doctor confidentiality, which is binding on healthcare professionals delivering service through health platforms. Any information about a patient must be kept confidential.

5. Nigeria Data Protection Regulation (NDPR) 2019[27]

The NDPR is the only general data protection law available in the country. Under the Regulation, health data is considered sensitive personal data requiring a higher degree of protection. The Regulation imposes obligations on data controllers and processors, grants rights to data subjects (patients), and prescribes penalties for non-compliance. The Data Protection Implementation Framework (DPIF) is an addendum to the NDPR, and it offers clarification where the NDPR is silent or unclear. The DPIF makes consent the only lawful basis to process sensitive personal data.[28]

[23] <https://www.cert.gov.ng/ngcert/resources/CyberCrime__Prohibition_Prevention_etc__Act__2015.pdf> accessed 31 March 2021

[24] National Cybersecurity Strategy 2014 <https://www.cert.gov.ng/ngcert/resources/NATIONAL_CYBESECURITY_STRATEGY.pdf > accessed 31 March 2021

[25] Administrator N, 'Ridwan Oloyede: Privacy and Security Issues Arising from the Digitisation of Nigeria's Healthcare Sector | African Law & Tech Network' <https://www.alt-network.com/ridwan-oloyede-privacy-healthcare-sector/> accessed 9 April 2021

[26] Medical and Dental Practitioners Act [CAP 221], Laws of the Federal Republic of Nigeria 1990

<http://www.mdcnigeria.org/Downloads/CODE%20OF%20CONDUCTS.pdf> accessed 31 March 2021

[27] Nigeria Data Protection Regulation 2019 <https://nitda.gov.ng/wp-content/uploads/2019/01/Nigeria%20Data%20Protection%20Regulation.pdf> accessed 31 March 2021

[28] Article 5.3.1 (b) of NDPR

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Challenges of not having a National Health Record

The absence of a national health record system comes with a lot of challenges for the administration of healthcare services. The inaccessibility of healthcare providers to accurate, timely, and adequate data often results in an inefficient system with poor quality healthcare. Also, the absence of a national health record system impedes research as healthcare researchers are unable to access data easily. This inability to access records and data for research means that innovative health products cannot be developed or may take a longer period of time.

Further, where there is no national health record system, the government cannot adequately conduct health planning, conduct disease surveillance, set its priorities, or know the areas in the healthcare system that resources should be channelled to. The lack of an integrated national health record also affects policymaking. This is because decision-making would be based on assumptions rather than evidence-based decisions. Lastly, the productivity and efficiency of health workers would be reduced due to the slow and time-consuming process of manually keeping records and extracting information. In this regard, a national record system will provide a structured pathway for the exchange of health information while enabling efficiency and the timely provision of healthcare services.

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National Health Record system Model in Select Country: Singapore as a Case Study

The benefits of a National health record system are currently being harnessed by some countries, notable among them is the application of the model in Singapore. Singapore

In Singapore, the National Electronic Health Record (NEHR)[29] has been progressively deployed in public and private healthcare institutions since 2011 to support the country's "One Patient, One Health Record". The scheme is owned by the Ministry of Health (MOH) and managed by the Integrated Health Information Systems (IHiS)[30]. The system securely collects patient health records across different healthcare providers. The arrangement allows the authorised healthcare professionals to access the NEHR to have a rounded insight about a patient's healthcare history. Citizens can access some of their health records by using the country's health portal[31] or using a mobile application.

National Electronic Record Bill and the National Health Information Management System (NHIMS)

"The NHIMS was established in 2007 to track progress made in all healthcare interventions.[32] It provides an evidence base for health sector reforms and helps address constraints in implementing health interventions. The NHIMS consists of provisions for appropriate infrastructure and the establishment of mechanisms and procedures for collecting and analysing health data to provide needed information. Planning, monitoring, and evaluation of health services are hampered by a dearth of reliable data.[33] It is managed by the Federal Ministry of Health's (FMOH) Department of Planning, Research, and Statistics (DPRS).

[29] 'About the National Electronic Health Record' <https://www.ihis.com.sg/Latest_News/Media_Releases/Pages/About_the_National_Electronic_Health_Record.aspx> accessed 10 April 2021

[30] ibid

[31] 'HealthHub' <https://www.healthhub.sg/> accessed 9 April 2021.

[32] 'NHMIS Monthly Analysis' <https://monthly-nhmis-analysis.fmohconnect.gov.ng/> accessed 9 April 2021.

[33] 'Nigeria Digital Health Landscape: An Inventory of Digital Health Solutions' <https://health.gov.ng/doc/eHEALTHINVENTORY.pdf> accessed 9 April 2021.

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The objective of the NHIMS include to monitor progress towards stated goals and targets of health service programmes, to provide information for decision makers, feedback for those who provided data and for the general public, to assess the health status of the population among other things.[34]

The health system benefits from the NHMIS through improved availability of appropriate information for decision-making, improved accessibility for all people, improved productivity of all health workers, improved cost-efficiency, improved utilisation of health care resources, improved quality of care, enhanced accountability and transparency, support for priority setting and resource allocation in health, help in the planning of health progralt is intended to improve understanding of diseases, reveal the efficacy of specific treatments, and demonstrate the efficiency of specific services. vices.

The NHMIS is a working example of how data collection can support public health planning and provide rich insight across the country. The creation of the NEHR will further improve the quality of the datasets available and will help improve decision making and the overall improvement of the healthcare system in the country. The availability of accurate, timely, reliable, and relevant health information is the most fundamental step towards informed public health action.[35]

The Bill and Health Record Officers

The bill in its present state may potentially conflict with the Health Records Officers (Registration, etc.) Act.[36] Section 8 of the bill creates a body named the Health Record System Operating Board, which may have similar responsibilities as those performed by record officers. [37] Health records broadly encompass both electronic and non-electronic health records. Creating a distinct body to do exactly the same thing under the Health Records Officers (Registration, etc.) Act will amount to duplication of effort and waste of resources.[38]

[34] Emmanuel C Meribole and others, 'The Nigerian Health Information System Policy Review of 2014 : The Need, Content, Expectations and Progress' (2018) 35 Health Information & Libraries Journal 285.

[35] 'National Health Information System Policy' <https://ehealth4everyone.com/wp-content/uploads/2015/09/Nig-Health-Info.pdf> accessed 10 April 2021.

[36] 'HEALTH RECORDS OFFICERS (REGISTRATION, ETC.) ACT' (LawCareNigeria, 15 September 2019) <https://lawcarenigeria.com/health-records-officers-registration-act/> accessed 10 April 2021.

[37] Temitayo Adebayo Tajudeen et al, 'Administration of Health Records/Information Practitioners of Nigeria: Requirements, Implementations, Prospects and Challenges of Health Records Officers' Act ' Library Philosophy and Practice (e-journal) <https://digitalcommons.unl.edu/cgi/viewcontent.cgi?article=6926&context=libphilprac>

[38] 'HEALTH RECORDS OFFICERS (REGISTRATION, ETC.) ACT' (LawCareNigeria, 15 September 2019) <https://lawcarenigeria.com/health-records-officers-registration-act/> accessed 31 March 2021

Policy recommendations

Given the shortcomings of the bill, it is imperative for the bill to be revisited and its provisions amended so it can support the demands of a digital health ecosystem. The stakeholders in the digital health sector should look at stronger collaborations. The following recommendations are put forward that could improve the quality of the bill:

The bill should define what is meant by default access control and recognise the principle of data protection by design and default. There should be a framework for transparency, data sharing and accountability. The requirement for transparency should make it mandatory that patients understand why they provide the data and there should be quantifiable and explicit benefit for the patient.

Concerning the Board, its constitution should include the National Health Research Ethics Committee (NHREC) and the Nigerian Institute of Medical Research. Although Nigeria does not currently have an independent data protection authority, the future commission should be included on the Board. The Bill should also specify what constitutes the 'approval of the board'. For instance, if the Board has to vote, is it by a simple majority?

There should be a mandatory requirement to display verifiable evidence of data protection compliance and implementation of privacy programs by healthcare provider organization, healthcare provider and other relevant stakeholders. NEHR requires stringent regulation because it is of public interest and it involves a special category of data.

The Bill should list out the criteria for the appointment of the National Health Repository Service Operator's office and a contracted service provider. For the latter, it should also state the requirement of privacy, security, and data protection measures as criteria for appointment. The modalities for employing an international subject should be mentioned for the purpose of clarity.

The power to make Guidelines and Regulations by the Minister of Health, who is a political appointee has been used sparingly. Consequently, we recommend the power should be exercised by a career officer in the Ministry who may also be able to ensure continuity of such policy or such power should be exercised by the Board to be created under the Bill.

The Bill should define what constitutes an electronic health record and it should state the data protection measures or principles, especially related to health data which are sensitive personal data.

Call to action

A national health record will not be possible if other challenges like the infrastructure deficit are not fixed. Electricity and the provision of information technology facilities need to be provided. In addition, the employees will need to be trained on the use of the facility. A maintenance structure would also need to be put in place to prevent a system collapse. Funding is crucial for a successful implementation.

There is a need for a national framework for data sharing in healthcare, the transfer and interoperability of data, and a code of ethics. Standardisation of integration should take place. Privacy, data protection, and security should be key components of establishing a NEHR. Existing policies and the legal framework for electronic health should be fully implemented.

Recommendation for further research
The findings and scope of this white paper are limited. There needs to be an impact assessment study done with the help of everyone involved.

Conclusion

The National Electronic Health Record Bill is definitely a good thing because it means that health records can be shared between different health care providers. This could make health care easier to get and more effective. However, the gaps in its provisions require that the bill be revisited and amended. A review of the bill could help us find the value in data and improve our health as a result. This review will provipolicymakersers and other key stakeholders with the foundation for making evidence-based decisions during the implementation of a National Health Record system. There must, however, be an impact study conducted in collaboration with all stakeholders, and a concerted stakeholder's collaboration must be present in the review process in order to develop and implement a better national electronic health record system.

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