

Digital Health Technologies in Ghana: An Integrative Qualitative Analysis of User Preferences, Regulatory Concerns and Information Sources

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Abstract

Background

Digital Health Technologies are increasingly used to improve health outcomes worldwide. In Ghana, the Christian Health Association of Ghana (CHAG), in collaboration with Medtronic Labs, launched the Akoma Pa project to enhance the diagnosis and treatment of hypertension and diabetes in rural areas through digital health solutions. This study assessed the sources of information on the regulation of digital health technologies, user preferences, and regulatory concerns among patients participating in the Akoma Pa intervention.

Methods

The study was conducted from February to April 2024 at selected CHAG facilities merging quantitative and qualitative data to provide understanding of user preferences, regulatory concerns and information sources on digital health technologies. Multistage and purposive sampling techniques were used for the quantitative and qualitative components, respectively. An integrative qualitative analysis using descriptive statistics in STATA version 16.0 for the quantitative data, while qualitative data were transcribed and analysed thematically, supported by Microsoft Excel version 2016.

Results

The mean age of the quantitative study participants was 63.4 years (± 11.8). Nearly two-thirds (61.7%) were unaware of regulations or guidelines governing digital health technologies in Ghana. Nearly half of the participants (48.4%) knew their health information was anonymised before sharing and about 73.1% were unaware that their health information might be shared with third parties without consent. More than one-third (38.8%) identified data confidentiality and privacy as major concerns. Participants expressed dissatisfaction with restricted access to their health information. In the event of a breach of confidentiality, most (83.0%) would report to health professionals or the health facility. Health professionals and facilities were the primary sources of digital health regulatory information for patients (97.1%), followed by television and radio (32.3%).

Conclusion

The study identified primary sources of digital health information among study participants. However, data privacy, confidentiality, data protection and sharing, and violation of patients' rights were identified as regulatory issues and challenges associated with digital health. This suggests an urgent need to heighten patients' education on digital health interventions with a special focus on regulatory issues and concerns. Additionally, regulations and laws should be available to govern digital health usage in Ghana.

Introduction

Digital technology is now pervasive throughout social institutions in the modern period. The emergence of digital devices like smartphones, tablets, and wearables, and the use of digital technologies to monitor people's movements in public spaces, have all facilitated the digitisation of health interventions and care [1]. The general population and those working in the healthcare and public health industries have been significantly impacted by these advancements in digital technologies. In recent years, the adoption of digital technologies for health and well-being has grown steadily. The idea of digital health is still under development [2], and it primarily includes internet-based software and media aimed at enhancing medical connectivity, commerce, and content [3]. Prior studies show that such innovations can improve healthcare access for at-risk populations and enhance individualised care [4].

Digital health is increasingly being used to refer to a broad range of health-related technologies [5]. Digital health now incorporates a broad range of scientific concepts and technologies aimed at improving patient care, enabling early diagnosis, and supporting disease prevention [6]. These tools are increasingly used across healthcare domains—including diagnosis, therapy, clinical decision-making, care administration, and delivery—while improving clinical research, reducing healthcare costs, and enhancing care effectiveness [7]. These advances have transformed how health professionals collect, share, and analyse patient data to improve clinical decisions and health service delivery [8]. Simultaneously, patients now have a greater ability to track their health and medical records through digital means [9]. For instance, digital technologies have demonstrated improvements in morbidity and mortality outcomes in patients with cardiovascular disease (CVD) when used in practice [10].

While fostering ongoing innovation, some specific adaptations could improve current regulatory oversight. A global strategy on electronic health (eHealth) and mobile health (mHealth) for 2020 to 2025 was released by the WHO in 2021 [2]. Digital health has the potential to revolutionise the way healthcare is delivered, particularly in resource-limited settings such as Ghana. Digital treatments that comply with the Food and Drug Authority definition of software as a medical device are currently approved and subject to regulation (SaMD) [11]. According to the WHO's action plan on digital health, Member States and the Secretariat are required to dynamically monitor the maturity level of digital health in nations and institutions and to evaluate how well digital health strategies are being implemented using standard metrics [7]. Digital health is a fast-growing field that offers promising opportunities for innovation and improvement with the objective of effectively making healthcare more efficient, accessible, and effective by leveraging the power of digital technology to collect, analyse, store and share health data [12].

The fragile nature of the health systems in Africa, coupled with the scarcity of health resources, is a potential affront to the successful implementation of sustainable health interventions to combat disease [13]. Following technological advancements, digital health/mHealth has become an increasingly popular and indispensable strategy in the management of patients [14], with a paradigm shift of focus from healthcare professionals to patient-centric. However, this does come with some significant challenges, including questions regarding the quality of data, security and regulatory concerns, especially in low-

resource settings. Additionally, patient data is highly sensitive, and there are concerns that data anonymisation may not be enough to preserve privacy [15].

Akoma Pa (“healthy heart”) is a public health intervention in Ghana that integrates a digital health platform, the Spice App, to address the increasing prevalence of hypertension (HPT) and diabetes mellitus (DM). [16]. The initiative adopts a cost-effective, integrated care model that provides free, high-quality healthcare services and medications to patients, particularly targeting low-income and rural populations facing barriers such as high treatment costs, limited access to quality medicines, and inadequate healthcare infrastructure. By incorporating digital health technology, the program facilitates the storage and management of patient data, improving diagnosis, treatment adherence, and overall disease control. Despite its promising outcomes, further research is required to examine digital health information systems, regulatory frameworks, and patient preferences to enhance sustainable adoption and large-scale implementation of such interventions in Ghana [17].

Despite the importance of digital health technologies in managing health conditions and improving healthcare utilisation, in Ghana, the source of digital health regulatory information remains unclear. To the best of our knowledge, there is a paucity of literature in Ghana on the sources of information on digital health technologies regulation, as well as user preferences and regulatory concerns among patients. Meanwhile, issues of regulations and preferences need to be addressed to heighten patient adoption and scale-up. This study aimed to understand the patient perspective on the regulation of digital technologies in Ghana. More specific objectives were: (1) to assess sources of information on digital health technologies, (2) to understand patients’ knowledge about the regulation of digital health technologies, and (3) to explore their concerns and recommendations for better regulation of health technologies.

Methods

Study design

The study employed an integrative qualitative analysis [18] using both quantitative and qualitative data collected from February to April 2024 at selected CHAG facilities to provide understanding of user preferences, regulatory concerns and information sources on digital health technologies. Quantitatively, an institution-based cross-sectional study design was chosen to solicit information on digital health in Ghana. An ethnographic design was adopted in the qualitative study to help provide a detailed and in-depth understanding of the issues surrounding information sources, user preference and regulatory concerns among patients in Ghana.

Study setting

This is a nationally representative study conducted in Ghana to understand digital health information sources and regulatory concerns among users. Ghana is a country in West Africa that borders Cote

d'Ivoire, Burkina Faso, and Togo. Ghana borders the Atlantic Ocean and the Gulf of Guinea and has a land area of 238,535 sq km. According to the 2021 Population and Housing Census, Ghana has a population of 30.8 million people [19]. In the country, the population of females (50.7%) outnumber the males (49.3%) by 0.4 million. Ghana's population has grown fivefold since independence [19]. The official language of Ghana is English, but different ethnic groups, such as Akan, Ewe, Dagbani, and Ga, also speak many local languages. Ghana's economy is a middle-income economy that is mainly based on exporting natural resources, especially cocoa, gold, and oil. Ghana is the world's second-largest producer of cocoa beans, after Côte d'Ivoire. Ghana also has a vibrant agricultural sector that employs about 40% of the labour force and contributes 18% of the gross domestic product (GDP). Other important sectors include services, manufacturing, and mining.

The Akoma pa intervention was implemented by the Christian Health Association of Ghana (CHAG) facilities in eight (8) out of the sixteen (16) regions: Ashanti, Ahafo, Western, Western-North, Bono, Bono-East, Central, and Eastern regions, with the intention of future scale-up. Hence, to accurately assess the sources of digital health information among patients, using Akoma pa as a case study, the study was conducted across eight (8) regions in Ghana.

Study population

The study population was diabetic and/or hypertensive patients enrolled in the Akoma pa intervention.

Inclusion criteria

Adult (≥ 18 years) diabetes and/or hypertension patients who were currently benefiting or have benefited from the Akoma Pa intervention.

Exclusion criteria

Patients on Akoma pa intervention with complications of diabetes and/or hypertension who were unable to participate.

Sample size

Using the Taro Yamane method (1976), $n = N / (1 + Ne^2)$, where N is the total population, given as the targeted patients enrolled on the Akoma pa project (N = 78,600 patients) [16], and 'e' is the precision level (significance level at 0.05), a sample size of 398 was estimated. However, a total of 10% was added to account for non-response (10% of 398 = 48). Hence, the total sample size for the study was estimated to be 446. Notwithstanding, to ensure a fair distribution of sample size, a probability proportional to size (PPS) was utilised to distribute the participants among 46 CHAG health facilities across 8 regions in Ghana. Table 1 below shows the sample distribution for the study.

Table 1
Distribution of sample size

Region	Number of facilities	Estimated sample
Bono	4	39
Bono-East	2	19
Ahafo	2	19
Ashanti	22	213
Eastern	3	29
Western	3	29
Central	6	59
Western-North	4	39
Total	46	446

For the qualitative research, saturation was achieved after conducting six (6) Focus Group Discussions (FGDs), which were used as the sample size for the qualitative study.

Sampling methods

A multi-stage sampling technique was employed to solicit information from participants for the quantitative study. Firstly, the eight (8) regions were purposively selected because these are the regions where the Akoma pa intervention was implemented. Following the regional selection, with a computer-assisted randomiser (random number generator), 46 health facilities were selected from the 85 CHAG facilities where the Akoma pa intervention was implemented. Following the facilities selection, simple random sampling techniques were employed to recruit participants for the study. Selected participants were then issued the questionnaire and were guided to answer accordingly. The average number of respondents needed per day for the quantitative segment was estimated based on the number of expected attendees and the data collection period. The health facilities had clinic days for diabetic/hypertensive patients (mostly Tuesdays and Wednesdays). The data collection spanned two weeks (10 working days).

For the qualitative study, purposive sampling was used to select participants. The sampling process was guided by respondents' key theoretical knowledge, characteristics relevant to the study, and practical experience with the Akoma pa intervention.

Data collection technique and tools

The quantitative data were collected using a structured questionnaire (see *supplementary file 1*). These completed questionnaires were designed and saved digitally on the Kobocollect online database. These online questionnaires were subsequently administered for data collection. The online questionnaire on the Kobocollect server was linked to Android devices for data collection. Trained research assistants entered the responses from the patient on the Kobocollect application on the Android device, stored locally, and synchronised regularly to the Kobocollect virtual server, which was managed personally by a data manager. During the data collection, respondents were approached individually and asked to participate in the study. The researchers guided the consenting clients in answering the research questions and ensured their rights were not violated, coupled with helping them to choose appropriate venues to ensure privacy. The questionnaire encompassed socio-demographic characteristics of patients, source of digital health information, regulatory issues and concerns of digital health among patients in Ghana

Focus group discussions were conducted among patients on Akoma pa who were not involved in the quantitative survey. This was used to solicit participants' regulatory concerns and issues using a Focus Group Discussion Guide (see *supplementary file 2*). In total, six (6) FGDs were conducted within two weeks. Each FGD had between 6 and 8 patients participating. To minimise interference, the researchers cooperated with respondents to schedule meeting dates, times and venues. The FGDs were conducted in a Ghanaian local language (Twi), and each lasted for about thirty (30) to forty-five (45) minutes. At each FGD, with respondents' permission, the researchers audio-recorded the responses, whilst taking written notes to complement the audio recordings. Written notes included observations of both verbal and nonverbal cues and communication as they occurred, coupled with immediate personal reflections on some questions. When participants needed to attend to emergency issues, the audio recorder and discussions were paused and resumed when they returned.

The structured questionnaire and the FGD guide were piloted at the Church of God clinic in Essienimpong, Ashanti Region. The pretesting was conducted to check the instruments' validity and reliability. Following the pretesting, necessary changes were made, and questions that seemed ambiguous or sensitive to patients were rephrased.

Data management and analytical procedures

The completed structured questionnaires were downloaded from the Kobocollect server, and the data were managed using self-written commands. Data was extracted into the STATA statistical software package version 16.0 for analysis [20]. Descriptive data were presented using tables and charts. The recorded FGDs were transcribed and translated into English. The data were analysed using Thematic-Content analysis with the assistance of the Microsoft Excel application using the variable matrix, flow charts and relevant quotes to highlight results.

Ethical consideration

Ethical clearance was sought from the Committee for Human Research, Publication and Ethics of the Kwame Nkrumah University of Science and Technology with reference number (CHRPE/AP/257/24). Additionally, because the study was conducted in CHAG facilities, additional ethical clearance was sought from the Institutional Review Board of CHAG with reference number (CHAG-IRB04072023). Moreover, permission was requested from the Heads of Departments at the various diabetic/hypertensive clinics and was granted. Before data collection, the research procedures were explained to respondents, including the potential risks and benefits inherent in the study, the study duration, the right to participate or withdraw, and the assurance of confidentiality and anonymity of information, using an information sheet. Those who agreed to take part in the study were asked to sign or thumbprint a consent form.

Results

Table 2 presents the socio-demographic characteristics of the 446 respondents who participated in the study. Nearly two-thirds of the participants (60.5%) were over 60 years, and nearly a quarter of them (24.7%) were in the age category of 51–60 years, with a mean age (S.D) of 63.4($\pm$ 11.8), ranging from 25 to 95 years. The majority of the participants (80.5%) were females, more than half of them (52.9%) were married, and nearly one-third of them (30.5%) were widowed. A little over half of them (50.7%) had basic education, and nearly half of them (46.4%) were unemployed. Among those who are employed, nearly one-third of them (31.8%) were self-employed and a little over a quarter (26.7%) were into agriculture/farming. Almost all the participants (91.7%) were Christians, and close to half of them (42.8%) were dwelling in rural communities. Majority of the participants (89.9%) were Akan, and more than one-third of the participants (41.7%) had between 6 and 10 household size. More than three-fourths of the participants (78.9%) earned below GHC 1,000.00 per month, and very few of them (2.0%) earned more than GHC 3,000.00 monthly.

Table 2
Socio-demographic characteristics of respondents

Socio-demographic characteristics	Frequency (n = 446)	Percentage (%)
Age group [in years]		
≤ 40	10	2.2
41–50	56	12.6
51–60	110	24.7
≥ 61	270	60.5
Mean± (S.D)	63.4 ± 11.8	[25–95]
Gender		
Female	359	80.5
Male	87	19.5
Marital status		
Never married	18	4.0
Married	236	52.9
Separated/divorced	56	12.6
Widowed	136	30.5
Educational level		
No formal education	128	28.7
Basic education	226	50.7
Secondary	65	14.6
Tertiary	27	6.0
Employment status		
Employed	176	39.5
Pensioner/retiree	63	14.1
Unemployed	207	46.4
Occupation, if employed (n = 176)		
Agriculture/farming	47	26.7
Artisan (e.g driver, masonry, tiler)	9	5.1

Socio-demographic characteristics	Frequency (n = 446)	Percentage (%)
Age group [in years]		
Civil/public servant	16	9.1
Entrepreneurship	9	5.1
Private sector employment		
Sales and services	34	19.3
Self-employed	56	31.8
Religion		
Christian	409	91.7
Islam/Moslem	34	7.6
No religion/atheist	3	0.7
Place of residence		
Peri-urban	166	37.2
Rural	191	42.8
Urban	89	20.0
Ethnicity		
Akan	401	89.9
Dagomba/Mamprusi	17	3.8
Ewe/Krobo	16	3.6
Ga-adangbe	3	0.7
Other	9	2.0
Household size		
≤ 2	46	10.3
3–5	180	40.4
6–10	186	41.7
≥ 11	34	7.6
Monthly income (GHC)		
< 1000	352	78.9
1000–2000	65	14.6

Socio-demographic characteristics	Frequency (n = 446)	Percentage (%)
Age group [in years]		
2001–3000	20	4.5
≥ 3001	9	2.0

Figure 1 is a graphical presentation of the duration of patients on the Akoma pa intervention. More than two-thirds of the participants (69.7%) had been on Akoma pa intervention for 1–2 years, a little over a quarter of the participants (25.8%) had been on Akoma pa intervention for less than a year, and very few of them (4.5%) had been enrolled on Akoma pa intervention for 3 years.

Table 3 presents the sources of digital health technologies' regulatory information among patients on Akoma pa. More than one-third of the participants (38.1%) had ever searched for digital health regulatory information. More than one-third of them (40.6%) indicated their source of regulatory information on digital health was family and friends, almost all the participants (97.1%) indicated health professionals were their major source, and very few of them (3.8%) indicated social media (Facebook, YouTube, Twitter, Snapchat, among others). Also, nearly one-third of them (32.3%) indicated television and radio were their sources of regulatory information, very few of them (1.1%) indicated print media (newspaper, magazine, etc), less than one percent of them percentage (0.4%) indicated dedicated websites and forums, very few of them indicated their sources of digital health regulatory information were internet searches (3.4%) and other sources (1.6%) .

Table 3
Sources of regulatory information about digital health technologies in Ghana

Variable	Frequency (n = 446)	Percentage (%)
Searched for digital health regulatory information		
No	276	61.9
Yes	170	38.1
Family and friends		
No	265	59.4
Yes	181	40.6
Health professional and facility		
No	13	2.9
Yes	433	97.1
Social media [e. g Facebook, Twitter]		
No	429	96.2
Yes	17	3.8
Television/radio		
No	302	67.7
Yes	144	32.3
Print media [newspaper, magazine, etc]		
No	441	98.9
Yes	5	1.1
Website, forums, reviews		
No	444	99.6
Yes	2	0.4
Internet search		
No	431	96.6
Yes	15	3.4
Others		
No	439	98.4

Variable	Frequency (n = 446)	Percentage (%)
Searched for digital health regulatory information		
Yes	7	1.6

Note: *Multiple responses

Table 4 presents the regulatory issues of digital health technologies among patients in Akoma pa in Ghana. Nearly half of the participants (48.4%) were aware that their health information is anonymised/protected before it is shared/ transmitted, and nearly two-thirds of the participants (60.1%) were unsure whether their health information can be deleted from the Akoma pa Spice APP upon discontinuation from accessing care at the facility. More than one-third of the participants (39.2%) were moderately sure that assurance of confidentiality would influence their decision to use digital health technology, and more than half of the participants (54.7%) indicated they had to seek permission before they could access their personal data or information on the Akoma pa Spice App. More than three-fourths of the participants (78.3%) trust health information on the Akoma pa Spice App, nearly three-fourths of the participants (73.1%) are unaware if their health information is shared with third parties without their consent, and more than three-fourths of the participants (77.8%) indicated they consented before they were enrolled on the Akoma pa intervention/Spice App. Nearly half of the respondents (45.3%) agreed that their health information is kept confidential from unauthorised persons, and the majority of respondents (83.0%) indicated they would speak to a health professional/facility in the event there is a breach of confidentiality of health information/data. More than one-third of the respondents (39.2%) indicated that pricing moderately influences their trust in using digital health technologies, nearly half of the respondents (46.6%) indicated they had no concern with their enrolment on the Akoma pa Spice App, and more than one-third of the respondents (38.8%) indicated their major concern is confidentiality/privacy of health information. Nearly two-thirds of the participants (61.7%) do not know any regulatory body for digital health in Ghana, and a little over one-third (34.3%) claimed they know about a regulator in digital health in Ghana.

Table 4
Regulatory issues of Digital Health Technology among patients on Akoma pa in Ghana

Variable	Frequency (n = 446)	Percentage (%)
Aware data is anonymised before sharing/transmitting		
No	32	7.2
Not sure	198	44.4
Yes	216	48.4
Health information can be deleted from Spice App when you discontinue treatment		
No	41	9.2
Not sure	268	60.1
Yes	137	30.7
Assurance of confidentiality influence decision to use DHT		
Not at all	53	11.9
Slightly	127	28.5
Moderately	175	39.2
Significantly	91	20.4
Request permission before accessing personal data/information		
No	202	45.3
Yes	244	54.7
Trust health information on the Akoma pa Spice App		
No	97	21.8
Yes	349	78.3
Aware health information is shared with third parties without consent		
Data is anonymised before sharing	69	15.5
I am not aware	326	73.1
No data shared with third parties	51	11.4
Consented before I was enrolled on Akoma pa/Spice APP		

Variable	Frequency (n = 446)	Percentage (%)
Aware data is anonymised before sharing/transmitting		
No	99	22.2
Yes	347	77.8
My health information is kept safe and private		
Don't know	185	41.5
Yes	261	58.5
My health information is kept confidential from unauthorised persons		
Strongly agree	106	23.8
Agree	202	45.3
Neutral	133	29.8
Disagree	2	0.4
Strongly disagree	3	0.7
In case of confidentiality breach, what would be your action		
Go for support	22	4.9
Report to family and friends	23	5.2
Report to regulatory authorities	8	1.8
Speak to health professional	370	83.0
Seek legal counsel	17	3.8
Other	6	1.4
Pricing affects your trust in digital health technology use		
Significantly	146	32.7
Slightly influence	70	15.7
Moderately influence	175	39.2
Does not influence my trust	55	12.3
Aspect of Akoma pa Spice APP which is a concern to me		
Confidentiality/privacy of health information	173	38.8
Data erasure	15	3.4

Variable	Frequency (n = 446)	Percentage (%)
Aware data is anonymised before sharing/transmitting		
No concern	208	46.6
Security of data	27	6.1
Other	23	5.2
Aware of a regulator who supervise data privacy, confidentiality, anonymity, and security of health data		
Don't know	275	61.7
No	18	4.0
Yes	153	34.3

DHT, Digital Health Technology

Qualitative Findings

Digital Health Regulations-Patients' Focus Group Discussions

This section reports the qualitative findings among patients enrolled in the Akoma pa intervention with diabetes and/or hypertension covering the under listed themes.

Familiarity with digital health technologies

The study revealed that most of the participants were familiar with the use of devices such as computers and tablets, as well as the dramatic shift from paper-based records to paperless or electronic-based health records, where the patient only presents their hospital card to the healthcare facility to obtain effective healthcare:

"Now we are aware of the shift to digital services. At first, you will be holding your folder and moving from one point to another. But now, because of the digital system, the enter your card at the OPD and then you are cool to move to all department" [DM/HPT patient, FGD-2]

'We were not allowed access to the tablets and device and we don't know what they were imputing, but they were entering whatever we were saying'. [DabaaHope FGD 1]

The participants averred that digital technologies in healthcare fast-track up health seeking processes, care for the patients, and aid in the enjoyment of comfort and luxury. Below are excerpts from the FGDs:

"What I have noticed and makes me so happy is that at first you were supposed to queue to retrieve patient folders, but with the introduction of computers and the use of tablets, all that has been eliminated now so, it makes everything fast. Now when we get here, we do not spend as much time as it used to be" [DM/HPT patient, FGD-3].

"At first, we used to carry folders around but now we use only the card and the doctor types everything on the computer" [DM/HPT patient, FGD-2]

Knowledge of policies, regulations or guidelines that oversee digital health technologies usage in Ghana

The FGDs revealed that all participants had no knowledge of policies, regulations or guidelines that oversee digital health technologies usage in Ghana. These are what participants had to say:

I am not aware of any policies, regulation or guidance concerning Digital Health Regulation in Ghana. We can only testify from the enjoyment of effective healthcare by the usage of digital health technology [DM/HPT patient, FGD-3].

'We were only told at some point in time that the old system has been changed so we are no longer using folders rather computers, but as to whether there are any rules or regulations, I am not aware' [DM/HPT patient 8, FGD-4].

'I am not aware of any policies, regulation or guidance concerning Digital Health Regulation. All we know is they using it to care for us to get well' [DM/HPT patient 5, FGD-5]

Major regulatory gaps or challenges needed to be addressed.

Participants pointed out that the lack of efficient communication between healthcare practitioners and the patients, as well as the lack of rules or laws to punish avoidable mistakes made by healthcare practitioners, are the major regulatory gaps or challenges that still need to be addressed.

'What I said was that punishment should be meted out to doctors who commit avoidable mistakes [DM/HPT patient 5, FGD – 6].

'I want the government to make a law that as you have taken our information, you should be able to prevent others from having access to it' [DM/HPT patient 6, st. patricks FGD]

Patient Safety

The qualitative study revealed divergent views where half of the participants listed several reasons to suggest that indeed Digital Health Technology may compromise patient safety. The participants expressed fear that in a case where one device has to be used by a lot of practitioners, there is a possibility of patients' information being ignored or being left out, if new practitioners do not take enough time to review patients' old history stored on these digital devices, which could lead to poor

diagnoses and could be detrimental to their health and might compromise patient safety. On the other hand, the remaining half argued that Digital Health Technologies may not compromise patients' safety because there has never been a risk, such as leakage of patients' information, associated with the initiative ever since it was implemented. Again, the technology has a lot of positive impacts ever since it was implemented, and the practitioners are competent enough to handle and ensure their health information is well protected, hence it appears very promising for the future.

'It is a machine so it's a bit scary, because I may come tomorrow and not meet the doctor who attended to me today and the machine can also develop fault. So, if it happens like that, I will have to tell the doctor my history before he can attend to me. So, it is not that safe' [DM/HPT patient 2, St. Patricks FGD]

'They are very competent at the work, and we have never heard of any information leak. If you don't go to them there is no way you would hear from someone else talking about another person's condition' [DM/HPT patient 3, Nkoranza FGD]

Privacy and Data Protection

Participants expressed being much more comfortable sharing personal information digitally because they believe their health information will be used solely to improve their health and the healthcare system. They are, however, unsatisfied with options available to protect their health information, such as password locks on computers and tablets, which are made only accessible to practitioners. Hence expressed their worry of possible exposure or leakages of their health data to a third party.

'I am equally excited that you will ask about my health conditions because it will enable practitioners to keep proper track record and speeds up the general health seeking process for us' [DM/HPT patient 4, St. Patrick's FGD].

'I am with the notion that our information will not be used for anything but to know and monitor our progress. So, I believe it for our health's sake and nothing else, this is what I think [DM/HPT patient 6, Janie Speaks FGD]

'What I know is that the computer has a password which is available to only the person who operates it so that no one from somewhere can come and pick information from it. These passwords are mostly specific to the practitioners, and no one knows another person's password. The password lock is not that okay to me but that is what we have so we just have to accept it the way it is' [DM/HPT patient 4, FGD-4].

Patient Rights

The majority of the participants implied that digital interventions still respect and uphold patients' rights and do not undermine their rights in any facet, hence their rights as patients are not at risk when using digital health technologies. The few however believe that they do not have the right as patients not only with the use of digital interventions rather at the healthcare facility in general.

'It does not hamper on the right of the patient because I willingly gave out my information if I were not interested, I would have said no' [DM/HPT patient 1, St. Patrick's FGD].

'It does not violate our right, it only helps to know your condition and then treat it so, it's good' [DM/HPT patient 7, Holy Family FGD].

'As we speak right now, the patient does not have any right. Once you come here what they want is what they do for you' [DM/HPT patient 1, St. Michaels FGD].

Ethics of patient-healthcare professional interactions

Majority of the participants implied that their consent was sought, and the process was clear, transparent and they willingly consented for their health information to be taken using digital health tools. A few participants on the other hand claimed that a patient has a little choice to reject anything that comes from healthcare practitioners.

'Our consent was sort, when I came; I was informed that this is the new trend so I should come for a card and I will be added. They clearly explained everything to my understanding and inquired whether I agree or not and I said "yes" I do agree' [DM/HPT patient 3, Janie Speaks FGD].

'It was willingly but once we are sick, we have little choice' [DM/HPT patient 6, St. Patrick's, FGD].

Patients' engagement on regulation of digital health technologies

The study revealed that the majority of patients suggested that they can effectively be engaged through meetings at the various health care facilities to have discussions on the regulations of digital health technologies. They recommended that these meeting days should be planned to coincide with their clinic and check-up days. A few participants, on the other hand, suggested that there should be someone or a group of people acting as an intermediary between the participants and regulators through whom participants could channel all suggestions and recommendations through to the regulators and vice versa.

'What I think is that as you have come and engaged us, if they want to engage us, it should be done the same way. So that they can explain to us how it will be done before we can side with them' [DM/HPT patient 1, Janie Speaks FGD].

'If it will be possible to have someone whom we can channel all our suggestions and recommendations through then it would have been good. So, the person can submit on behalf of the patients so that our views can also be recognised and also bring us feedback' [DM/HPT patient 6, St. Michael's FGD].

Recommendations on regulation of digital health technologies

The participants suggested as citizens of a country they have the right to healthcare hence it will be necessary to make laws, rules and regulations that will protect the rights of the patient and prevent healthcare practitioners from impeding on patients' right while using digital health interventions. Others also recommended that laws that force practitioners to treat all information with strict confidentiality and anonymity need to be established while using digital health technology to ensure effective healthcare practices. It was also recommended that digital health solutions such as Akoma Pa should consider the idea of providing DM/HPT drugs free for the aged population.

'We have the right and freedom to good healthcare, so I think if there are laws and regulations to protect the patients as citizens of the country while using digital health technology then it will be of great benefit' [DM/HPT patient 1, Dabaa Hope FGD].

'Please I want the government to make laws that as you have taken our information onto these devices, you should be able to prevent others from having access to it' [DM/HPT patient 6, St. Patrick's FGD].

'As we are all aware at a certain age like 70 and above, their strength reduces so as Akoma pa has been offering this help, we wanted to plead so that the aged people are able to make DM/HPT drugs free for us' [DM/HPT patient 2, Holy Family FGD].

Discussion

The study investigated the digital health technologies' regulatory information sources, user preferences and regulatory concerns. The study revealed that their major source of digital health regulatory information is from the health professionals/facility (97.1%) followed by television and radio (32.3%), and social media (3.8%). In relation to the study, research conducted in Pakistan revealed that even though mass media like television and radio, among others, can be productive resources pertaining to digital health information sources, the majority did not consider mass media as information sources. The study revealed that patients do not rely on mass media for acquiring health information but considered healthcare professionals as an unswerving information resource [21]. Patients believe that health providers care for them and that any information they provide is credible and could help in the treatment and management of their condition. This corresponds with a study conducted in the USA among Korean women in America. The study revealed that very few of the women had social media and the internet as source of digital health information with majority having more than two times higher likelihood of using print media as the main source of digital health information [22]. In the same study, the authors reported that the women had higher likelihood of using television and radio as the main source of digital health information [22].

The study revealed that nearly half (48.4%) were aware that their health information is anonymised/protected before it is shared/transmitted. Majority implied that they are not at risk when using digital health technologies because they believe their information is anonymised or protected before it is shared. The few however believe that they do not have the right as patients not only with the use of digital interventions rather at the healthcare facility. Additionally, nearly two-thirds (60.1%) were

unsure whether their health information could be deleted from the Akoma pa Spice App upon discontinuation from accessing care at the facility. There is a swift increase in pressure to share individual patient health information for secondary purposes including policy and research. Following that, it is extremely essential and challenging to only rely on informed consent as primary sharing mechanism [23]. This posits that data or health information sharing transcends beyond informed consent to data anonymisation. One key method for protecting the privacy of patients in accordance with privacy laws and regulations is to anonymise the data before it is shared [24] as revealed in the study as nearly knew their data is anonymised before sharing. The careful removal of direct patient identifier, careful evaluation and modification of indirect identifiers would help to drastically decline the risk of patient's identification [23].

The study revealed that more than one-third (39.2%) were moderately sure that assurance of confidentiality would influence their decision to use digital health technology and more than half (54.7%) indicated they had to seek permission before they could access their personal data or information on the Akoma pa Spice App. Confidentiality is key in research, intervention and digital health. Before an individual would consent for his/her health information to be taken/kept using digital health technology, assurance of confidentiality is key. As a result, research have revealed that clinicians are not obliged to disclose confidential information given by a patient to another party without the patient's authorisation [25]. In the same vein, following the rapid growth in the availability and incorporation of digital technologies in almost every aspect of our lives including digital health, coupled with its extraordinary opportunities and unique challenges [26], patients should be assured of confidentiality before enrolment onto digital health technologies and associated interventions.

The study revealed that more than three-fourths (77.8%) consented before they were enrolled on the Akoma pa intervention/Spice App. Majority of the participants implied that their consent was sort and the process was clear, transparent and they willingly consented for their health information to be taken using digital health tools. Ethics is an inherent and inseparable part of clinical medicine as the physician has an ethical obligation to benefit the patient [25]. There is growing interest in understanding the patient perspective on digital health consent in the context of providing clinical care. Even though digital health is a developing field, consent for patients to be enrolled in these technologies cannot be overemphasised. Evidence indicates that many patients are willing to consent for various purposes, including enrolling in digital health technologies [27]. Health data are also increasingly exchanged across services, including digital health technologies, applications and some point-of-care devices that are mostly not regulated and have weak data protection regulations. Research revealed that in most primary care settings in India, general practitioners seldom maintain any records, and consent is not sought from patients enrolling them in a study or care [28]. Meanwhile, for the patient to make an informed decision whether to enrol in the intervention or not, the patient must be given enough information to make an informed choice. Therefore, health providers must target clients and seek their consent for enrolment or participation, which is an ethically appropriate way to obtain consent for many standard-of-care [29].

The study revealed that nearly three-fourths (73.1%) are unaware if their health information is shared with third parties without their consent, and nearly half (45.3%) agreed that their health information is kept confidential from unauthorised persons. However, participants were unsatisfied with restricted access to their personal health information only to health providers. They believe there could be a possibility of breach of confidentiality of health information when using digital health technology. Majority of respondents (83.0%) indicated they would speak to a health professional/facility in the event there is a breach of confidentiality of health information/data. Corroborating the research's findings, a study conducted in Europe found that there are issues of data access, as patients do not have full control over their own data. It is therefore appropriate for patients to have control of the data [28]. Patients should be allowed to control who accesses their data at all times, receive notification from third-party access (whether authorised or not), or be able to revoke access at will, when permitted by law [28].

The study revealed that more than one-third (39.2%) indicated pricing moderately influences their trust in using digital health technologies, nearly half (46.6%) indicated they had no concern with their enrolment on the Akoma pa Spice App, and more than one-third (38.8%) indicated their major concern are confidentiality/privacy of health information. The primary justification for protecting personal privacy is to protect the interests of individuals. In contrast, the primary justification for collecting personally identifiable health information for health research is to benefit society [30]. The common issues that need to be addressed in the electronic medical record system are privacy and security [2]. Transferring or sharing sensitive health data when not authority can lead to data breach. Privacy can as well be breached in many situations through unpreventable systemic identification that occurs in the entire electronic health infrastructure and by central technologies and parties that look at the actions of healthcare workers and patients [30].

The study revealed that nearly two-thirds (61.7%) do not know any regulatory for digital health in Ghana. The qualitative study also revealed that all participants had no knowledge of policies, regulations or guidelines that oversee digital health technologies usage in Ghana. This finding corresponds with a cross-national study conducted in 12 African countries including Ghana on the major regulatory landscape of Artificial intelligence and digital health. The study revealed that even though there are recent developments of AI adoption, including in digital health, data protection, and consumer protection in Africa, however, there is no specific regulators or regulations for digital health technologies [31]. Similarly, a cross-sectional study conducted in Cape Coast, Ghana revealed that there are no formal regulatory policy in existence to deepen primary healthcare at the lowest level [32]. Although, the mission of the Ghana Health Service is to empower health professionals, patients, and *technological* enthusiasts with cutting-edge information and insights into digital health, however, there are no specific regulations and regulator of digital health in Ghana. The main obstacle of adopting and regulating AI technologies in Ghana's healthcare is the regulatory gap and technical understanding of how these modern technologies differ from traditional medical tools/equipment being regulated in Ghana [33]. Ghanaian oversight bodies/regulators like the Food and Drugs Authority, Ministry of Health Standards Board, and Health Facility Regulatory Agencies (HeFRA) may manage approval and inspection technologies like MRI

scanners with defined engineering specifications [33], however, there are no regulations for digital health technologies.

Strengths and limitations of the study

The study had some strengths and limitations, indicating that findings must be cautiously interpreted. The strength of the study resides in its novelty as the first study to investigate digital health information sources, user preferences and regulatory concerns among patients in Ghana. Additionally, the adoption of the triangulation techniques (both qualitative and quantitative) to triangulate the findings is also a strength of the study. This notwithstanding, the study had some weaknesses that cannot be overemphasised. A major limitation, however, is the inability to make causal inferences in this study due to the cross-sectional design employed. There was also the possibility of recall and selection bias due to the study design, which could affect the accuracy of responses given by the women. However, the rigorous procedures adopted in our study were able to suppress the effects of the weaknesses thus making the findings viable for decision making.

Conclusion

As the use of digital health technology is inalienable and ubiquitous in healthcare with now and improved and better health outcomes, it is extremely essential to investigate the information sources of digital health and regulatory concerns in order to bridge health inequality gap. The major sources of digital health information are health professionals/facility, television and radio, and social media. There are regulatory issues and challenges associated with digital health in Ghana; concerns of data privacy, confidentiality, data protection and sharing, and violation of patients' rights. Additionally, there is no regulator and/or regulations/laws governing digital health interventions in Ghana. Therefore, the authors recommended urgent need to heighten patient's education on digital health intervention with special focus on regulatory issues and concerns including data protection, privacy, sharing, consent, ethics, and confidentiality of health information. Additionally, regulations and laws governing digital health and operations should be available to govern digital health usage in Ghana. This would avert impeding on patients' right and enforce practitioners to treat all information with strict confidentiality and anonymity whilst providing comprehensive care to patients.

Declarations

Ethics approval and consent to participate

This study was conducted in accordance with declaration of Helsinki and guidelines by the Council for International Organizations of Medical Sciences (CIOMS). Ethics approval was sought from the Committee for Human Research, Publication and Ethics of the Kwame Nkrumah University of Science and Technology with reference number (CHRPE/AP/257/24) and from the Institutional Review Board of Christian Heath Association of Ghana (CHAG) with reference number (CHAG-IRB04072023) before

conducting the study. Moreover, permission was requested from the Heads of Departments at the various diabetic/hypertensive clinics and was granted. Informed consent was obtained from participants before data collection. All ethical principles/procedures were duly followed throughout the study.

Consent for publication

Not applicable

Availability of data and materials

The datasets generated and/or analysed in this study are freely available upon making a reasonable request to the corresponding author; daniel.opoku@tu-berlin.de

Competing interests

The authors declare no competing interest exists in the preparation and publication of this paper.

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Author's contributions

GA, DO, DB, AM, WQ and KAM developed the concept. GA, STB and PN collected data and conducted the formal analysis and interpreted the results. GA, STB, PN and CH and drafted the manuscript. DO, DB, AM, WQ and KAM reviewed the manuscript. All authors proofread the manuscript for important intellectual content before submission for publication.

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Figures

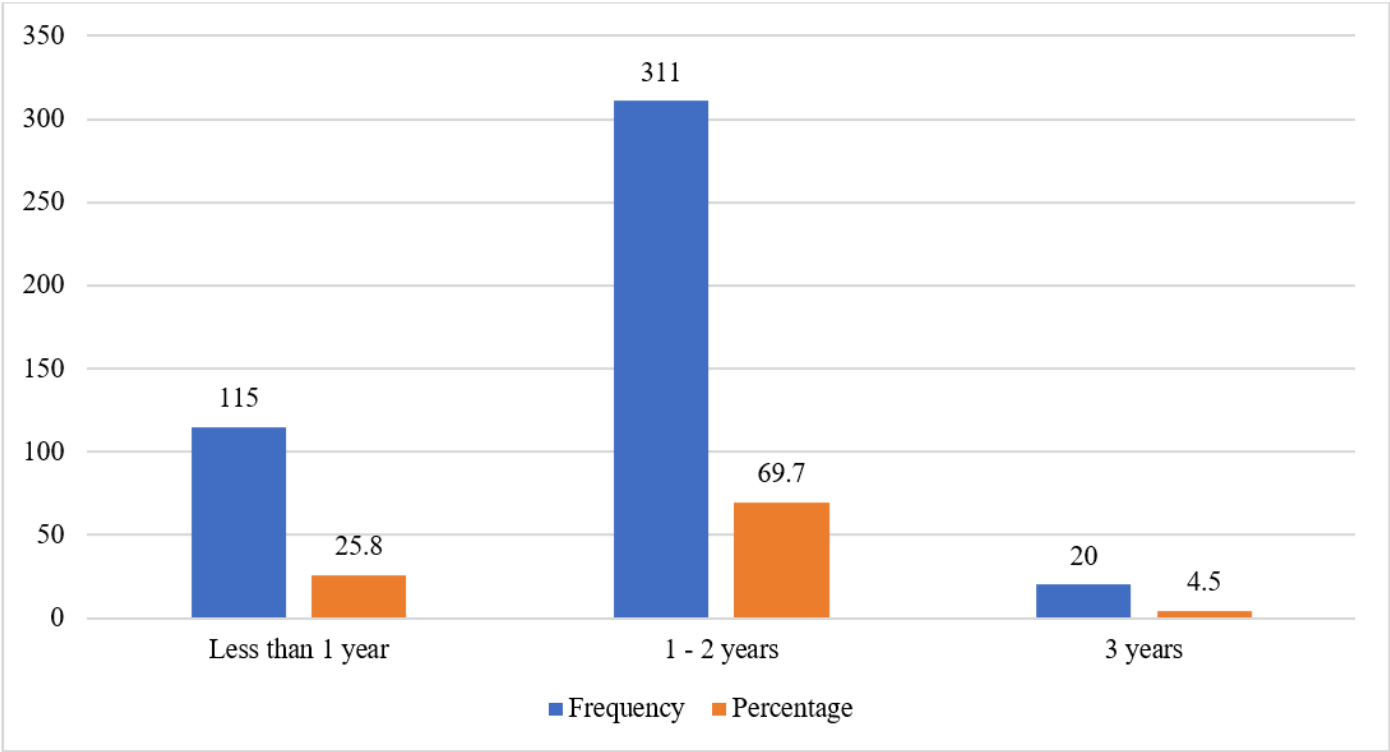


Figure 1

Duration of patients on Akoma pa intervention/Spice App

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- [RegulationofDigitalHealthTechnologiesinGhanaPatientsSurveyQuestionnaire.docx](#)
- [RegulationofDigitalHealthTechnologiesinGhanaPatientsFGDGuide.docx](#)