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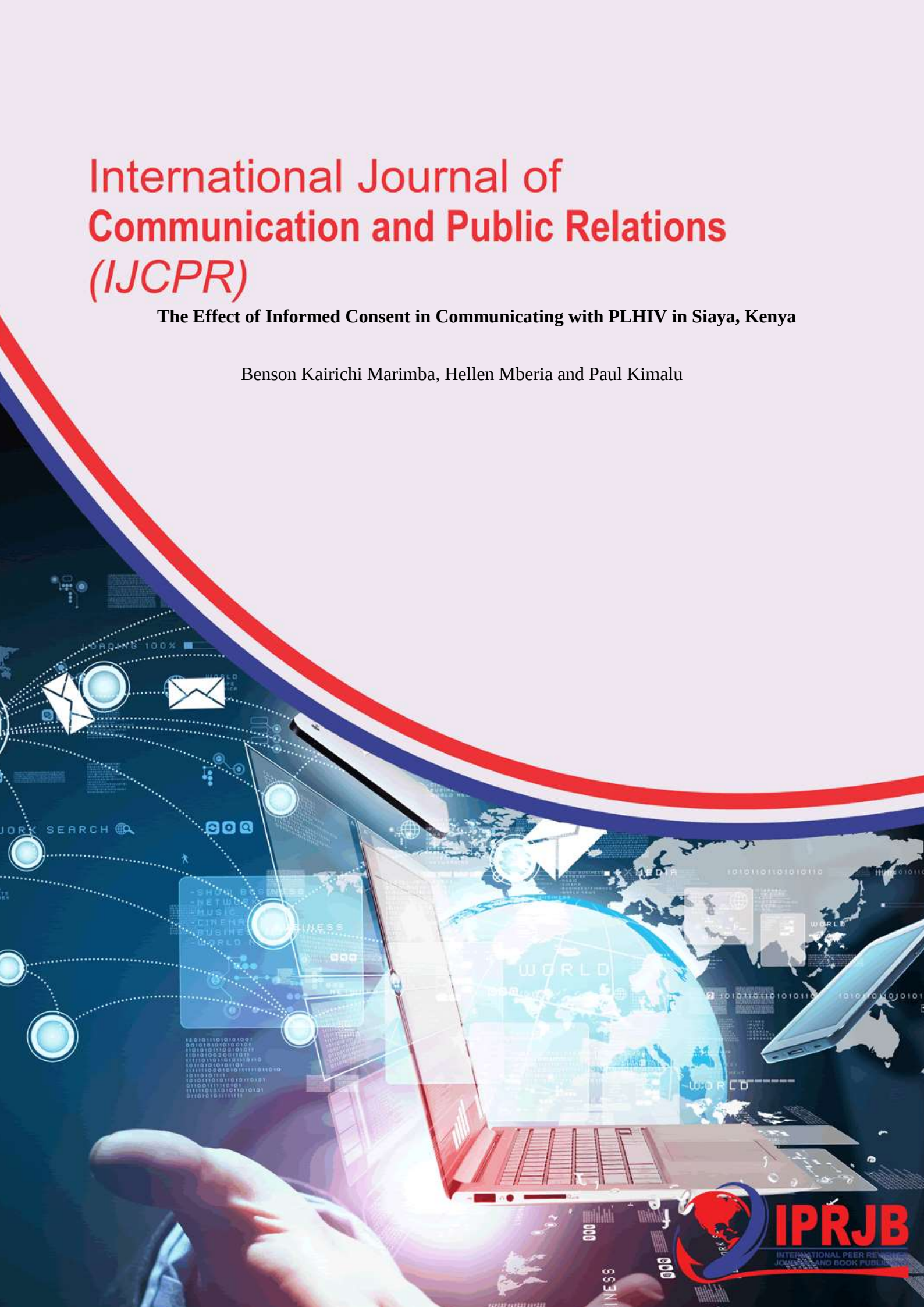

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The Effect of Informed Consent in Communicating with PLHIV in Siaya, Kenya

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Abstract

Purpose: The purpose was to establish the effect of informed consent in communicating with Person's Living with HIV (PLHIV) in Siaya, Kenya.

Methodology: This was both a descriptive research and inferential design**.** Data was collected using a field survey involving two sets of questionnaires for key informant and PLHIV interviews. Spearman's rho correlations and simple linear regression models were used to estimate the relationship between the independent variable (informed consent) and the dependent variable (communication), and ANOVA test was done to test the hypothesis.

Findings: The calculated proportionate sample size was 374. However, the respondents rose to 396 which represented 96.18% of those who agreed to be interviewed, with 17 rejections which were removed from analysis leaving a sample of 376. Normality Test was conducted to determine the study sample was drawn from normal population. Under null hypothesis, there was no difference between the sample and the population from which the sample was drawn and therefore there was significant evidence to reject the null hypothesis and accept the alternative hypothesis (p-value=0.000 CI=95%). Further, findings show that 82.30% enrolled onto the Text for Adherence (T4A) mobile app voluntarily and 70.71% signed the consent form and 6.07% stated that consent was implied.

Unique Contribution to Theory, Practice and Policy: The Technology Readiness (TR), Technology Acceptance Model (TAM) and Diffusion of Innovations (DOI were used to anchor future studies. This study has concluded that it was important for individuals enrolling into mhealth communication interventions to consent and this responsibility is for system supporters in mhealth space. The findings further established that enrolment onto mhealth apps improves health status of patients suffering from chronic illnesses. This has implications for policy changes or improvements in mhealth generally in Kenya and globally. A positive intervention such as Text for Adherence (T4A) should prompt the government to scale up enrolment by supporting system supporters or taking over the enrolment entirely as a matter of public health promotion.

Keywords: *Informed Consent, Persons Living With HIV (PLHIV), Text for Adherence (T4A).*

INTRODUCTION

HIV/Aids is a global public health challenge. According to Mwangi, C, Mberia, H, Kimalu, P, Ngugi, C, Simiyu, R, Okomo, G and Mudogo, C (2021) the population living with HIV globally has reached 38 million and efforts to track and suppress its progress by 2030 is being spearheaded by the UNAIDs. Further, they suggest that the World Health Organization (WHO) estimates show that different regions were at various levels of achieving the UNAIDS 90-90-90 program targets by 2020, while Kenya had reached 89-77-63 (United Nations Program on HIV/AIDS, 2019) targets.

Mwangi, C *et al* add that Kenya has the fifth-largest number of persons living with HIV in the world, of about1.5 Million people which translates to a prevalence rate of 4.9 per cent. This view is further supported by Medlock, J, Pandey, A, Parpia, **A**, Tang, A, Skrip, L and Galvani**, A** (2017) who observe that HIV menace continue to "impose enormous morbidity, mortality and economic burden across the globe…and that innovations in antiretroviral therapy, diagnostic approaches, and vaccine development are providing novel tools for treatment-as-prevention and prophylaxis". However, in spite of these efforts and advances in management and treatment of HIV, the pandemic has not been reversed.

Medlock, J, et al further estimate that "49 million new HIV cases [will occur] globally from 2015 to 2035". This calls for innovative ways to contain HIV spread and support those already infected with appropriate treatment regimen. This is where leveraging on mobile phones to improve health outcomes comes in handy.

Kharsany, . B., & Karim, A. (2016) suggest that HIV infection globally show an overall increase in prevalence but HIV related deaths have been reducing due to antiretroviral treatment. They also observe that global HIV burden is skewed towards Sub-Sahara Africa accounting for more than 70% of infections. Further, "success in HIV prevention in sub-Saharan Africa has the potential to impact on the global burden of HIV. Notwithstanding substantial progress in scaling up antiretroviral therapy (ART), sub-Saharan Africa accounted for 74% of the 1.5 million AIDS related deaths in 2013".

Making a case for mhealth interventions, Cooper, V., Clatworthy, J., Whetham, J., & Consortium, E. (2017) also posit that "eHealth (strategies, tools and services using information and communication technologies) have increased the accessibility of self-management interventions…and improved self-management interventions". They suggest that ehealth is the quickest growing intervention bolstered by advances in mobile technologies and penetration around the world noting that "by 2018 the majority of all mobile phone users will have smartphones [and] mHealth has the potential to provide consistency in the delivery of interventions across a wide population at low cost". This is further supported by Devi, B, Syed-Abdul, S, Kumar, A, Iqbal, U, Nguyen, P, Li, C, & Jian, W (2015), who also suggest that use of cellular phone technology is an "effective tool for HIV/AIDS and TB long-term care and that it can substantially reduce disease burden on health care systems".

According to Mehl, G & Labrique, A (2014), innovative ways are needed to realize universal health coverage and especially for "millions who need care". They suggest that innovations are needed that would bring about free access and full use of quality and affordable health services. Indeed, with unprecedented growth on mobile phones, public health managers should leverage on this to reach out to thousands of patients who suffer HIV and other chronic conditions.

Informed consent is a *sine qua non* for research participants. O'Sullivan, L., Savinelli, S., O'Hare, S. *et al.* (2022) suggests that "Informed consent depends on the communication of relevant information, capacity to consent, and voluntariness". Further, they posit that accurate, useful and understandable information should be provided in order to preserve the autonomy of the respondents and protect their rights. Additionally, in clinical trials, research participants should clearly be informed the purpose of the trail, nature of the trail treatments and any risks or inconveniences that may occur. Theoretically, these conditions if met fully, the integrity of the consent to participate in the trail or research activity can be assumed to be legitimate. Nevertheless, O'Sullivan, L., Savinelli, S., O'Hare, S. *et al.* (2022 further suggest recent systematic reviews have shown "that research study participants often have a poor understanding of vital concepts which are important in ensuring valid informed consent".

Consenting process, Sylvia N, Joseph O, David K-M, et al. (2022), also argue that it provides respondents with information to enable them make informed consent and also prepare them to receive and understand the research findings. Further, they add, "an effective informed consent process is fundamental for avoiding the exploitation of research participants". This is more so when clinical trials involve illiterate participants as observed by Mystakidou, K., Panagiotou, I., Katsaragakis, S., Tsilika, E., & Parpa, E. (2009)

Informed consent is also influenced by what Marshall, P. A. (2006) calls power inequities that are occasioned by study sponsors or researchers 'perceived' class issues by the participants. Indeed, in preparing consent forms, Marshall argues that translations in the respondent's language are necessary so that as they sign the consent forms, they are sure what they are consenting to.

Study Objective

To establish the effect of informed consent in communicating with PLHIV in Siaya, Kenya

Study Hypothesis

H_0: There is no significant relationship between informed consent and communicating with PLHIV in Siaya, Kenya

H_1: There is significant relationship between informed consent and communicating with PLHIV in Siaya, Kenya

Theoretical Framework

This study is in mass communication field and focuses on use of mobile phones to communicate to PLHIV. Therefore, it used Technology Readiness (TR) and Technology Acceptance Model (TAM) to appreciate how uptake of technology generally and the conditions which make consumers willing to buy technological products or services offered online including enrolling on mhealth systems. TR and TAM suggest that a person's personality influence uptake of technology (Porter & Donthu, 2006). TR was proposed by Parasuranam (2000). Parasuranam introduced the technology acceptance index (TRI), which sets out 4 personality constructs that explain how consumers respond to adoption of technology. These distinctive constructs are optimism, innovativeness, discomfort, and insecurity. Panasuraman's suggestions are supported by Lai, P, 2017, Başgöze, 2015, & Colby, 2001). Indeed, Başgöze, (2015) [while] citing Parasuraman, (2000) defines TR, as the adopters' willingness to accept and use technology to achieve stated goals in their lives and in business." Constructs of optimism and innovativeness if present will increase readiness of uptake of technology, while

presence of discomfort and insecurity will discourage adoption of technology (Parasuraman, 2000).

There are other constructs that influence adoption of a technological product or service. The constructs of perceived usefullness and ease of use proposed by Başgöze, (2015) who extended technology Readiness into Technology Readiness Acceptance Model. Therefore, Technology Acceptance Model has six constructs of optimism, innovativeness, discomfort, insecurity, perceived usefullness and ease of use. These last two are moderating constructs.

The moderating constructs help to explain why patients who suffer chronic illnesses would enroll onto an mhealth platform. That even if they are persuaded to sign up, they can only do so because they perceive the service as useful and easy to interact with. Figure 1 show the integrated model, which depict the Technology Readiness Index as the dependent variables against actual use being independent variable and are moderated by perceived usefulness and perceived ease of use.

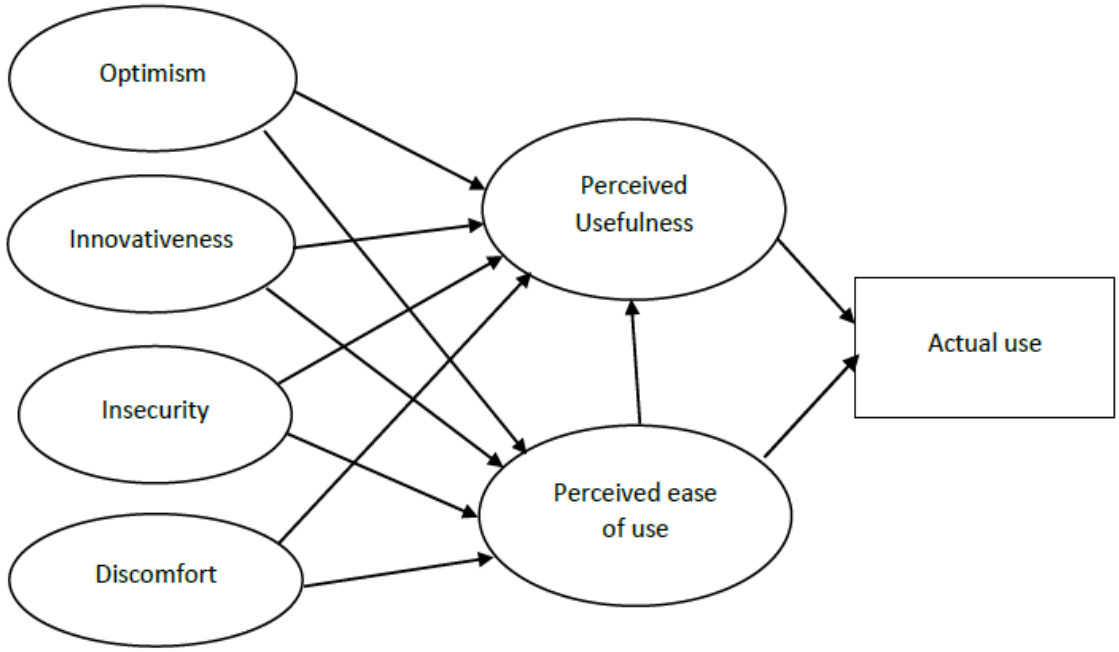

Figure 1: TRAM.

Source: Lin et.al. (2007)

The second theory used in this study is the Diffusion of Innovations (DOI) proposed by Rogers in 1962. This theory belongs to a group of theories used in behaviour change communication. Ymcaust (2019) citing Rogers define diffusion as "the process in which an innovation is communicated thorough certain channels over time among the members of a social system". This definition clearly isolates the components of diffusion, which are: innovation, communication channels, time, and a social system through which the innovation is diffused.

Historically, DOI can be traced to Gabriel Tarde, a French sociologist and legal scholar who proposed and developed initial constructs such as opinion leadership and the S curve of adoption. Tarde's work was extended by Clark Wissler, Bruce Ryan and Neil (1942) and finally Everett Rogers in 1962.

It is observed that not all people in a social system will adopt the recommended product, idea or service, at the same time and this the reason why adopter categories were proposed to explain this adoption process (Ymcaust, 2019) as shown in the Figure 2.

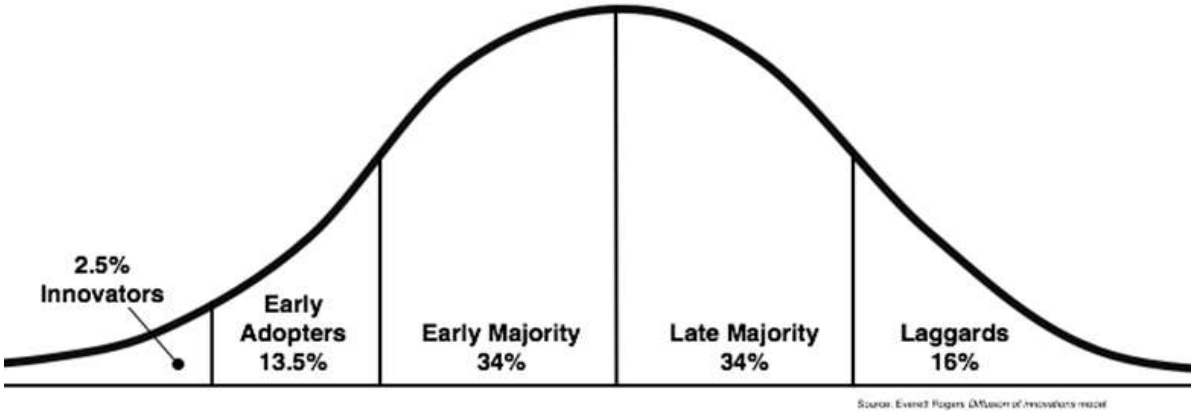

Figure 2: Adoption of the Recommended Product

Source: http://blog.leanmonitor.com/early-adopters-allies-launching-product

Those who adopt late and laggards constitute 50% of the population. Further, Ymcaust (2019) citing Rogers suggests that there are four stages in diffusion of innovation namely: the spread of a new idea; the innovation itself; communication channels; time, and a social system or community of interest. Before the process of adoption or enrolment into an mhealth platform or buying a service, individuals would assess its value relative to competing services or products "to establish if it meets their needs recognizing that products, services or ideas have substitutes in the market, individuals would assess the relative advantage of the proposed innovation to establish if it meets their needs, values and experiences before they adapt and also accorded an opportunity to experiment" (Boston University, 2019)

The relevance of DOI to this study and in Communication studies in particular, has been summarised by Littlejohn & Foss (2009), who suggests that "while DOI has been studied across disciplines, diffusion is of importance to communication because introducing an innovation in a social system is in itself a communication process involving persuasion to buy a product, service or adopt a behaviour change. Without communication tactics and strategies an innovation would not be diffused." Enrolment into mhealth platforms and communicating to PLHIV justifies the communication angle in this study

Furthermore, because of the focus of this study, DOI Theory was found to be the most suitable theory to use because of its focus on adoption of new innovations, to which mHealth interventions apply. Mobile health apps are new innovations offering many solutions and have considerably improved health status of patients around the world.

The third theory used was Utilitarian or Happiness Theory. This ethical theory can be traced to Jeremy Bentham, (1780). It's a theory used to decide right from wrong by focusing on the end product of a given action. According to University of Texas (2019), it's also regarded as a form of consequentialism. Utility is the core idea of this theory as the basis of morals and argues that life ought to promote the Greatest Happiness for all. It postulates that actions will be right

if their intention is to bring about happiness and if they do not bring about happiness then they are wrong. The main thrust of utilitarian theory is twofold: man should seek pleasure and avoid pain (John Stuart Mill, 1863).

Utilitarian ethical theories are based on a person's ability to predict the outcome of their actions and that acceptable outcomes are those that bring about "greatest good for the greatest number of people". Choko, proposes two types, namely act utilitarianism and rule utilitarianism, where the latter is premised on the greatest benefit to most people regardless of individual feelings or what the society forbids, while the former has its basis on the rule of law and fairness. This means even as man seeks to promote greater good for the majority, we ought to "do so in the fairest and most just means obtainable" (Chonko, 2019).

Utilitarian theory was found appropriate for this study in that mhealth interventions being offered to PLHIV would greatly bring about happiness to a majority of people who are already infected with HIV and would benefit by increasing adherence as a result of text messages. When their health status improves as result of enrolment to T4A, a greater good is thus achieved for most people and this is the basis of this ethical theory.

METHODOLOGY

The target population for this study was Persons Living with HIV in Kenya. Siaya was chosen as the study site because it had the highest HIV prevalence in the country according to the Kenya AIDs Response Progress Report (2018). This report indicates that the five counties with the highest HIV incidence were Busia, Migori, Kisumu, Homa Bay and Siaya as shown in Table 1.

Table 1: HIV Prevalence in 5 Leading Counties (2018 Statistics)

No.	Name of County	Prevalence Rate
1	Siaya	21.0%
2	Homa Bay	20.7%
3	Kisumu	16.3%
4	Migori	13.3%
5	Busia	7.7%
	Total	**79.0%**

The second focus on choice of the county was also based on mhealth enrolments. Siaya also qualified on this criterion with a high adoption rate of mhealth enrolment. Consequently, the overall population for the study was drawn from 9 mhealth system supporters in Kenya.

The total health facilities in Siaya are 101, while the accessible population in this study were 9 mhealth system supporters and 21 health facilities, which were active on T4A mhealth system with an enrolment of PLHIV 12,886 at the time of data collection. These patients were all PLHIV as the defining characteristic.

Out of the 9 mhealth system supporters shown in Table 2 MRS, Kenya Electronic Medical Records (EMR) and IQCARE were excluded because they are not mobile based/SMS solutions. The reason is because any SMS communication happening from IQCARE and Kenya EMR is through T4A as part of the Interoperability Layer (IL). Since T4A was already part of the systems in the study, these two were also excluded. Even though WelTel is a mobile based solution, it operates in Isiolo County, which has a very low HIV/AIDs prevalence and therefore it was also eliminated. mLab was also expunged from the study because lab results

were not being sent to patients directly. Through this process of elimination, T4A system or ushauri remained relevant and therefore this is what the study examined. Mhealth System providers are shown in Table 2.

Table 2: mhealth System Providers/Supporters

No.	System Name	Supporter	Type of solution	Location
1	mLab	Mhealth Kenya	sms	Homabay
			sms	Siaya
2	T4A	Mhealth Kenya	sms	Homabay
3			sms	Siaya
4	weltel	weltel	sms	Isiolo
5	mUzima	Faces	sms	Kisumu
6		FACES	sms	Kisumu
7	(IQCARE)	Palladium	Electronic Medical records	Eldoret & Siaya
8	Open MRS system	Ampath	Electronic Medical records	Uasin Gishu
9	Kenya EMR	Palladium	Electronic Medical records	National presence

Sample and Sampling Technique

The sampling technique was probabilistic and employed a random method in selecting the health facilities. The facilities that were active on Ushauri mHealth platform during the data collection period were 21 and were drawn from the 6 sub-counties of Siaya County with a total client base of 12,886. Out of these 21 active health facilities, 11 were randomly sampled based on the expansive nature of Siaya County which extends to 2,496 square kilometres and has 6 sub-counties. The other reason was budgetary constraints. These two reasons justified sampling 11 health facilities and were also limitations of the study

The Sampling Process

Stage 1: The health facilities were sorted by the MFLNo. Starting from the least to the largest. The 21 facilities were then divided by 11 (Required number of facilities) to obtain an interval of 2). Starting point was determined by randomly picking one among the 1st and 2nd MFLNo. MFLNO 13,471 was picked and therefore became the starting point. From 13471, one MFLNo. was counted and selected until the end.

Stage 2: The total population of registered clients in the 21 active facilities were 12,886 comprising of consented and non -consented clients. The population for the 11 randomly selected health facilities was 8,921.

Stage 3: Random selection of PLHIV

Sample Size Formula

$$n = \frac{t^2 \times p(1-p)}{m^2}$$

= 368

To determine the sample size for each health facility, a proportionate random sampling method was applied. Thus, the product of the population sample size for each health facility and the total sample size (368) was divided by the total PLHIV for the 11 sampled facilities, which is 8,921 patients. Therefore, the consented sample was 344, while the proportionate sample for non- consented was 24 (increased to 30). This totals to 368 but since the non -consented sample was raised from 24 to 30, the sample size reached 374. According to Johnnie, D, (2012), in correlation research, the minimum allowed sample is 30 participants. This study was designed to examine if there was a correlation between enrolment into T4A for PLHIV and those not enrolled in terms of improved health outcomes.

Sampling patients for the interviews also involved random sampling by selecting every 3rd patient attending the clinic with a random start. The 21 facilities are shown in Table 3.

Table 3: Number of 21 Health Facilities

MFLNO	Facility	No. Clients on Ushauri/ Consented	Non-Consented	Total Clients	Appt4a	Sampled patients by facility	Consented Clients	Non-Consented Clients
13471	Akala Health Centre	1171	76	1247	T4A	51	48	3
13476	Ambira Sub-District Hospital	497	267	764	T4A			
13507	Bondo District Hospital	2152	33	2185	T4A	90	89	1
13588	Got Agulu Sub-District Hospital	418	13	431	T4A			
13590	Got Matar Dispensary	226	5	231	T4A	10	9	0
13600	Hawinga Health Centre	288	11	299	T4A			
13644	Kagwa Health Centre	103	165	268	T4A	11	4	7
13747	Madiany S.C Hospital	93	9	102	T4A			
13750	Mageta Dispensary	279	8	287	T4A	12	12	0
13780	Masala Dispensary	396	10	406	T4A	17	406	17
13837	Naya Health Centre	520	8	528	T4A	22	21	1
13845	Ndori Health Centre	337	2	339	T4A			
13944	Nyathengo Dispensary	404	33	437	T4A	18	17	1
13961	Ogam Dispensary	265	8	273	T4A			
13987	Ong'ielo Health Centre	876	1	877	T4A	36	36	0
14080	Siaya District Hospital	830	20	850	T4A			
14085	Sigomere Health Centre	206	218	424	T4A	17	8	9
14148	Ting'wangi Health Centre	120	3	123	T4A			
14156	Ukwala S.C Hospital	707	28	735	T4A	30	29	1
14159	Urenga Dispensary	366	12	378	T4A			
14164	Usigu Dispensary	1,698	4	1,702	T4A	70	70	0
		11,952	934	12,886		368	344	24

Data Collection Tools

This was a field survey. Two sets of questionnaires were used to collect data. One was administered to a key informant and the other 376 respondents who were Persons Living with HIV. Triangulation by different methods was considered unsuitable because the respondents were all HIV positive. Even though they were attending HIV clinics, they remained anonymous and their files only bore numbers. Focus group discussion for example would have exposed their HIV status.

Research Design

The study adopted a descriptive research and inferential design and used largely a quantitative approach though a few questions were open ended to capture qualitative perspectives. The study utilized a field survey targeting a sample of respondents enrolled on T4A and one mhealth system developer and supporter. Two sets of questionnaires were used to collect data. Data was analysed through SPSS and STATA.

Data Collection Methods

Data collection was two- fold. One, involved interviewing a key informant drawn from the mhealth system supporter and secondly research respondents randomly sampled from the 11 active health centres. The study largely used quantitative and qualitative data.

Data Analysis

Quantitative data were analyzed using descriptive and inferential methods. Once data was collected it was loaded into SPSS version 25 and STATA to enable analysis. Further, the Kolmogorov-Smirnov test was performed. This test, otherwise known as normality test "is used to test the null hypothesis that a set of data comes from a normal distribution". The study also used logistic regression and ordinary linear regression model to determine the ethical considerations (variables) of informed consent, voluntary participation, confidentiality and data security against communication interventions/solutions. Qualitative data was presented in a narrative format.

RESULTS

Response Rate and Profile of the Respondents

The response rate was 96.18% with a total of 376 records for analysis. Determining the response rate, according to Baruch and Holton (2008) is important in order to assess the value of research findings. The distribution of respondents by gender was 225 (59.84%) females and 151 (40.16%) males. The response rate is in keeping with the Kenya population -based HIV prevalence assessment, (2018), which found a marked difference in HIV prevalence between women and men (women at 6.6% (95% CI: 6.0%-7.1%) compared to men at 3.1% (95% CI: 2.7%-3.5%). The current study is also consistent with other studies drawn from fishing communities which show prevalence of HIV is higher in females (Okello, P. et al. (2013). Generally, as Kwena, Z (2010, Glynn, R & Buve, A 2001, Amornkul P & De Cock, K, et al. 2009).

The respondent's age was distributed in 6 age clusters ranging from 18- 58+ years as shown in Table 4. The findings show that ages 26-33 were leading with 25.80%., while 26 to 49 account for 72.30% out of the 376 respondents. Older persons 58 plus were 9.57%, while ages 18-25 posted 8.24%. On marital status, data indicate that the majority of respondents 66.22% were

married, followed by windowed at 17.82% and singles at 13.03%. The HIV prevalence among the married is supported by previous studies and disproportionately affects the females more owing to the fish for sex factor (Fagbamigbe et al., 2016, Kwena, et al. 2019).

On education level, findings indicate primary school level were the majority at 51.60% followed by secondary school at 31.91% and only 1.33% of the respondents had university education. On the other hand, 6.91% had no formal school education. The respondent's employment type indicates that a majority (68.62%) were unemployed, while 23.67% (were in informal employment) and only 7.71% were in formal employment. Lastly, on respondent's income, a majority (58.51%) had an income of Kshs 10,000 or less, while 13.03% reported Kshs 20,000 or less followed by 4.52% who had an income of Kshs 30,000. Those who had an income of over Kshs 40,000 were a minority at 1.06%. Education, higher income and low levels of HIV prevalence have been supported by previous studies (Vandemoortele, J & Delamonica, E, 2000, De Walque , D & Whitworth, J, 2005, Ogunmola, O, Oladosu, Y & Olamoyegun, M , 2014). Details are shown in Table 4.

Table 4: Demographic Characteristics

Attribute	Category	Number of respondents	%
Gender	Female	225	59.8%
	Male	151	40.2%
Age bracket	18-25	31	8.2%
	26-33	97	25.8%
	34-41	91	24.2%
	42-49	84	22.3%
	50-57	37	9.8%
	58 +	36	9.6%
Marital status	Cohabiting/Live-in partners	1	0.3%
	Divorced/separated	10	2.7%
	Married	249	66.2%
	Single	49	13.0%
	Windowed	67	17.8%
Level of education	College level	31	8.2%
	None	26	6.9%
	Primary school level	194	51.6%
	Secondary school level	120	31.9%
	University & above	5	1.3%
Employment type	Formal employment	29	7.7%
	Informal employment	89	23.7%
	Unemployed	258	68.6%
Where do you get money to support your needs?	*Boda boda* operator	3	1.2%
	Business	94	36.4%
	Farming	94	36.4%
	Family members	42	16.3%
	Fishing	12	4.7%
	Jua kali	10	3.9%
	None	3	1.2%
Income level	</=10,000 pm	220	58.5%
	</=20,000 pm	49	13.0%
	<=/30,000 pm	17	4.5%
	None	86	22.9%
	Over 40,000 pm	4	1.1%

N=376

Method of Enrolment into T4A App

The study sought to establish if the respondents registered voluntarily as an indicator of informed consent. Data indicate that 82.30% enrolled voluntarily, while 16.21% were persuaded by a health worker. This finding is consistent with Guo, X., Vittinghoff, E., Olgin, J. *et al*. (2017) who suggest emerging technologies allow for recruitment of participants purely online. Details are highlighted in Table 5.

Table 5: How Did You Enroll?

	Freq.	%	cum
I enrolled voluntarily	284	82.30	82.30
I was persuaded by a health worker	56	16.21	98.51
I enrolled under peer pressure	5	1.49	100
Total	**345**	**100.00**	

On signing of consent form before enrolment, 70.71% stated that they had signed, while 17.73% stated that they had not been given any form to sign. The system supporter indicated that patients were given consent forms to sign before they were enrolled and indeed there was evidence of signed consent forms in the health facilities during the data collection exercise. However, as Guo, X., Vittinghoff, E., Olgin, J *et al*. 2017, Motes, K, Edwards, A, Waalen, j, Edmonds, S, Mehta, Ariniello, R, et al. 2019) suggest, it is not necessary to require physical signing of consent form as technology allows you to consent before enrolment process can be completed. Further, Moore S, Tassé A, Thorogood A, Winship I, Zawati M, Doerr M (2017) found "app-based consent processes was present by informing participants about how data will be curated from the phone". Table 6 show the details.

Table 6: Did You Sign a Form of Consent before You Were Enrolled?

Did you sign a form of consent before you were enrolled?	Freq.	%	Cum.
I signed a consent form	244	70.71	70.71
I was not given any form to sign	64	17.73	89.22
Consent was implied by my agreeing to enrol	21	6.07	95.26
I do not remember	32	4.71	100.00
Total	**345**	**100.0**	

Hypothesis Testing

Hypothesis testing on the objective was performed to establish the effect of informed consent on communication withPLHIV in Siaya, Kenya. ANOVA of informed consent and communication was performed as shown in Table 7. The hypothesis that was tested was:

H_0: There is no significant relationship between informed consent and communication withPLHIV in Siaya, Kenya

H_1: $Y= \beta_0 + \beta_1 X_1 + \varepsilon$

Where Y= communication

β_0 = The intercept

β_1= Regression coefficients shows the change in the value of Y from a unit change in X

X_1= informed consent

ε = Random error

Findings indicate that informed consent as an independent variable without the moderating variable had significant influence on communication at p value = 0.035, CI=95%. The findings provide strong evidence to reject the null hypothesis thus accept the alternative hypothesis (There is a significant relationship between informed consent and communication with PLHIV in Siaya, Kenya).

It is evident that there is significant relationship between informed consent and communication using text messaging to people living with HIV in Siaya county. When people provide consent, they are likely to have better outcomes in terms of keeping appointments. Providing consent means the individuals have understood the intervention and therefore stand high chances of benefitting from it. Details are shown in Table 7

Table 7: ANOVA of Informed Consent and Communication

ANOVA[a]						
Model	**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**	
1	Regression	4.385	1	4.385	4.464	.035[b]
	Residual	336.899	343	0.982		
	Total	**341.283**	**344**			
a. Dependent Variable: Zscore: In the last one year, how many appointments did you honour at the clinic?						
b. Predictors: (Constant), Zscore: Did the system supporter disclose fully how the system operates before signing up?						

When moderated by perceived usefulness, still the informed consent had a significant influence on the communication outcome. The hypothesis that was tested was:

H_0: There is no significant moderating influence of perceived usefulness on the relationship between informed consent and communication with PLHIV in Siaya, Kenya

Hypothesis 1: $Y= \beta_0 + \beta_1 X_{1m} + \varepsilon$

Where Y= communication

β_0 = The intercept

β_1= Regression coefficients shows the change in the value of Y from a unit change in X

X_1= informed consent

$_m$=usefulness (moderating variable)

ε = Random error

With a p-value = 0.034; CI 95%, the study finding rejected the null hypothesis. This indicates that perceived usefulness did have significant moderating influence on the relationship between informed consent and communication.

Under null hypothesis, we assert that there is no relationship between dependent and independent variable/s. Hence when null hypothesis is rejected then it means there is a relationship.

Table 8: ANOVA of Informed Consent and Communication Moderated by Perceived Usefulness

ANOVA[a]						
Model	**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**	
1	Regression	6.658	2	3.329	3.403	.034[b]
	Residual	334.625	342	0.978		
	Total	**341.283**	**344**			
a. Dependent Variable: Zscore: In the last one year, how many appointments did you honour at the clinic?						
b. Predictors: (Constant), Zscore: Usefulness, Zscore: Did the system supporter disclose fully how the system operates before signing up?						

The Pearson correlation shows that there was weak negative relationship (-.113) between informed consent and communication (p value = 0.035, CI=95%)

Table 9: Pearson Correlation between Informed Consent and Communication

ANOVA[a]						
Model		**Sum of Squares**	**df**	**Mean Square**	**F**	**Sig.**
1	Regression	4.385	1	4.385	4.464	.035[b]
	Residual	336.899	343	0.982		
	Total	341.283	344			
a. Dependent Variable: Zscore: In the last one year, how many appointments did you honour at the clinic?						
b. Predictors: (Constant), Zscore: Did the system supporter disclose fully how the system operates before signing up?						

When moderated by perceived usefulness, still the informed consent had a significant influence on the communication outcome

Correlation between informed consent and communication was significant at 0.05 with a weak negative relationship of -0.113.

Table 10: Correlation between Informed Consent and Communication

	1	2
1.Zscore: Did the system supporter disclose fully how the system operates before signing up?	1	
2.Zscore: In the last one year, how many appointments did you honour at the clinic?	**-.113***	1
*. Correlation is significant at the 0.05 level (2-tailed).		

The adjusted R square linear regression model showed that informed consent without the moderating variable could predict only 1.3% of the changes in the communication and with moderating variable 2%.

Table 11: Linear Regression Summary of Informed Consent and Communication

Model summary without the moderating variable				
Model	**R**	**R Square**	**Adjusted R Square**	**Std. Error of the Estimate**
1	.113[a]	0.013	0.010	0.99106602
a. Predictors: (Constant), Zscore: Did the system supporter disclose fully how the system operates before signing up?				
Model summary with the moderating variable				
Model	**R**	**R Square**	**Adjusted R Square**	**Std. Error of the Estimate**
1	.140[a]	0.020	0.014	0.98915914
a. Predictors: (Constant), Zscore: Usefulness, Zscore: Did the system supporter disclose fully how the system operates before signing up?				

Main findings indicate that combined demographic characteristics have significant relationship with communication P-value=0.003 CI=95%. This implies that an individual's socio-demographic characteristics are influencers of communication in terms of keeping appointments. Further, informed consent was the only significant ethical consideration related to communication. The study has established that mobile health communication to PLHIV improves their health status. Therefore, this study points to the need to make enrolment to mhealth interventions mandatory. It also concluded that it was important for individuals enrolling into mhealth communication interventions to consent. The findings and recommendations may be used by the apps solution developers, the government and may as well have implications for policy changes or improvements in mhealth generally in Kenya and globally.

Discussion

Research objective was meant to establish the effect of informed consent in communicating with PLHIV in Siaya, Kenya. Data indicate that 82.32% stated that they enrolled voluntarily and 67.59% of the respondents' said that they had signed a consent form.

Further, there was significant relationship between informed consent and communication (p-value=0.05). When consent was correlated with the moderating variable of perceived usefulness, it returned a p-value = 0.034; CI 95%, there by rejecting the null hypothesis and accepting the alternative hypothesis that there is a significant relationship between informed consent and communication. This indicates that perceived usefulness did have significant moderating influence on the relationship between informed consent and communication. These findings suggest that when individuals consent to receive messages then the intended purpose of mhealth communication is likely to be achieved. It is important for targeted participants to provide consent because during the process of enrolment they are introduced to the mhealth intervention. This creates understanding on the role of the intervention hence individuals may read messages and benefit from them. Enrolment into mhealth apps has been established to improve adherence to medications and in keeping medical appointments.

The benefits of enrolment into mhealth apps is in keeping with previous studies. For instance, Dillingham, R, Ingersoll, K, Flickinger,T, Waldman, A, Grabowski, M, Laurence,C et al. (2018) suggests "that a mobile health intervention can have a positive impact on retention in care and clinical outcomes for vulnerable PLWH …and that , interventions to improve engagement have shown promise……and ….enhanced contact by phone between clinic visits and involvement of peer mentors or coaches can reduce rates of missed appointments.''

The issue of obtaining informed consent has been challenged by Rodriguez-Patarroyo, M, Angelica Torres-Quintero, Vecino-Ortiz, A, Kristina Hallez, K, Franco-Rodriguez, A & Rueda Barrera, E et tal. (2020) who suggest that consent may be waived if the intervention will contribute to the formulation of public policies or in the case of the current study contribute to promotion of public health. Each country however has specific laws and guidelines which would be cited to support the waiver of consent in public interventions. Further, they add, "respondents who favoured consent emphasized that consent communications ought to promote understanding and voluntariness, and implicitly suggested that information disclosure conform to a reasonable person standard". In theory, "reasonable person standard" could fail nations in times of medical emergencies and therefore strong rules, regulations and laws are required to ensure consent is obtained *ab initio* before the intervention. Emerging from the covid-19 global health challenge and the discourse on voluntary vaccine up take, it is clear it would be imprudent to argue for the reasonable person standard. It therefore beholds the global community to prevent spread of HIV and to ensure those already infected have access to antiretroviral medicines in order to reduce viral load and morbidity.

The importance of enrolling into a mhealth app cannot be gainsaid. It improves adherence to medications and in keeping a doctor's appointment to review viral loads and antiretroviral treatment. This has also been supported by Anthony, N., Molokwu, J., Alozie, O., & Magallanes, D. (2019) who "found a statistically significant reduction in our no-show rates (individuals failing to keep scheduled appointments) of 24.8% versus 17.7%, *P* value .05." This finding is further reinforced by Sánchez, S. A., Ramay, B. M., Zook, J., de Leon, O., Peralta, R., Juarez, J., & Cocohoba, J. (2021), who also found a "small but significant mean improvement in adherence over the six-month period (4%, *P* 01)…and that text message interventions effectively support antiretroviral adherence in paediatric patients living with human immunodeficiency virus".

Dillingham, R, Ingersoll, K, Flickinger, Waldman, A, Grabowski, M, Laurence, C et al. (2018) suggests "that a mobile health intervention can have a positive impact on retention in care and clinical outcomes for vulnerable PLWHIV …and that, interventions to improve engagement have shown promise. For example, enhanced contact by phone between clinic visits and involvement of peer mentors or coaches can reduce rates of missed appointments…..and generally, can improve patient self-management and adherence in chronic disease''. However, they add that further research work is needed in these mobile interventions to "evaluate long-term outcomes while maximizing potential benefits of mobile health and mitigating its risks."

Conclusion

This study has established that T4A met the requirement for informed consent with over 80% with a further 17% stating that consent was implied. A mobile health intervention/solution such as T4A and supported by other studies has demonstrated that there are improved health outcomes for HIV patients and others who suffer from chronic illnesses. The study also suggests that whereas it is important to secure informed consent of patients before enrolment, the app itself need to be improved to allow for consent before enrolment can proceed. HIV like other contagious diseases is a global public health challenge and requirement for consent need to be reviewed against the anticipated health benefits as a matter of public health policy.

Recommendations

Mobile health interventions in management of HIV and other chronic diseases have proven beneficial in supporting patients to adhere to medication regimen and honouring doctor's appointments whenever they are due through text messaging. There is therefore a need for scaling up enrolment in counties and countries with high HIV prevalence. This scalability should not be left to private app system developers. Governments should take it up as a matter of public health and make funds available. In addition, since mhealth and telemedicine is set to grow even bigger, future mobile Apps interventions across the spectrum should have an option to accept all the terms including consenting before proceeding with the enrolment. If a patient declines to accept the online consent, the system will automatically prevent progression to the next stage.

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