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THE IMPORTANCE OF FORM FIELD VALIDATION: LESSONS LEARNT FROM A FEASIBILITY STUDY OF AN MHEALTH APPLICATION IN MALAWI, AFRICA.

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THE IMPORTANCE OF FORM FIELD VALIDATION: LESSONS LEARNT FROM A FEASIBILITY STUDY OF AN MHEALTH APPLICATION IN MALAWI, AFRICA.

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Abstract

Measuring adherence to clinical guidelines using mobile health (mHealth) technologies when form field validation is enforced or turned on could potentially be viewed as skewing the dataset, leading to 100% adherence to the clinical rule base. In theory, healthcare providers should fully abide by clinical guidelines, whether in paper or digital format, to ensure that the patient receives appropriate care. However, what happens when mHealth form field validation is turned off? As part of a feasibility study in Malawi, Africa, we explored this phenomenon. Switching off validation on the mHealth artefact served its purpose within the context of a feasibility study where a parallel paper-based clinical assessment process remained in place. The design of this technical artefact with the turnkey validation feature afforded us the opportunity to turn validation on and off seamlessly. Ultimately, from an ethical, clinical and technical perspective the optimum approach is to ensure that form field validation is switched on. With form field validation on adherence to the clinical guidelines is enforced which minimises incomplete assessment and the potential for suboptimal clinical decisions that could adversely affect patient care.

Keywords: mHealth, Validation, Adherence, Clinical Decision Support Systems (CDSS), Developing Countries.

1 INTRODUCTION

Health systems in sub-Saharan Africa and other developing settings face significant challenges in care delivery, mainly due to geographical, financial barriers and available resources (Lewis et al. 2012). In response, governments are seeking innovative ways to deliver affordable and accessible care. The unprecedented number of mobile phone users in developing countries and the growth in wireless network and mobile phone broadband coverage has resulted in heightened interest in mobile health (mHealth). Particular focus has been given to the delivery of care in rural settings where access to health facilities is limited. Over the past decade, a multitude of mHealth interventions have been developed, piloted and a limited number implemented throughout the developing world. For example, mobile phones are currently used in Sub-Saharan Africa to support communication between patients (Rotheram-Borus et al. 2012) as well as health workers and patients (Lund et al. 2012), treatment adherence (Owiti et al. 2012), vaccination adherence (Wakadha et al. 2013) patient education and screening (Chib et al. 2012), data reporting and management (Blaschke et al. 2009), among others.

Recently, there has been a shift to the utilisation of more sophisticated smartphone applications ('apps') within mHealth (Hall et al., 2014). Feasibility studies in Uganda have demonstrated the potential benefits of mobile imaging and the internet (commonly referred to as telehealth) in the diagnosis of haematological and dermatological conditions in patients (Fruhauf et al. 2013; Tuijn et al. 2011). Similar results were obtained in another telehealth study in Botswana where women suspected to have cervical cancer had cervical images obtained by their local health workers on a mobile phone sent to trained gynaecologists for reporting (Quinley et al. 2013). mHealth apps have emerged which are underpinned by clinical guidelines (commonly referred to as clinical decision support systems). Clinical guidelines are defined as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Field and Lohr, 1990, p.8). In the developed world, clinical guidelines may be embedded within clinical decision support systems (CDSS) in order to optimise clinician behaviour and improve quality of healthcare (Jaspers et al., 2011). With the profound opportunities offered by CDSS, some developers are now implementing mHealth apps embedded with CDSS for use in sub-Saharan Africa (c.f. Noormohammad et al., 2010; Anokwa et al., 2012).

Adherence to work processes (i.e. clinical guidelines) is a vital concept in many Information Systems (IS)-initiatives, often labelled as process management. Within the healthcare domain one of the key concepts is to design processes within mHealth apps to assure fulfilment of business needs (i.e. adherence to clinical guidelines). Although 'process management' is well established, it has recently regained prominence in the IS domain due to the new possibilities of managing processes with IS (Hall and Johnson, 2009). The benefits of process management are well documented. The Toyota case is one seminal report of how process management can improve the quality of a product (Parkes, 2015). In a healthcare context, when clinical guidelines are adhered to there are tangible process measures that can be evaluated for best practice and compliance (Woolf et al., 1999). Therefore, in certain circumstances it is imperative to have a 'mandatory' process in place for ensuring adherence. For this study, a mandatory process refers to enforcing validation which requires that all data entry (i.e. form) fields on the mHealth app be completed, using a specific range of values, by the healthcare provider. However, a dearth of research exists which examines voluntary and/or mandatory processes underpinned by mHealth apps. The objective of this paper is to report findings of clinical guideline adherence levels of healthcare workers from an mHealth study where form field validation was turned off (i.e. allowing healthcare workers to undertake a voluntary process). It is envisioned that the results of this study will help dictate whether process management of mHealth apps should be 'voluntary' or 'mandatory'.

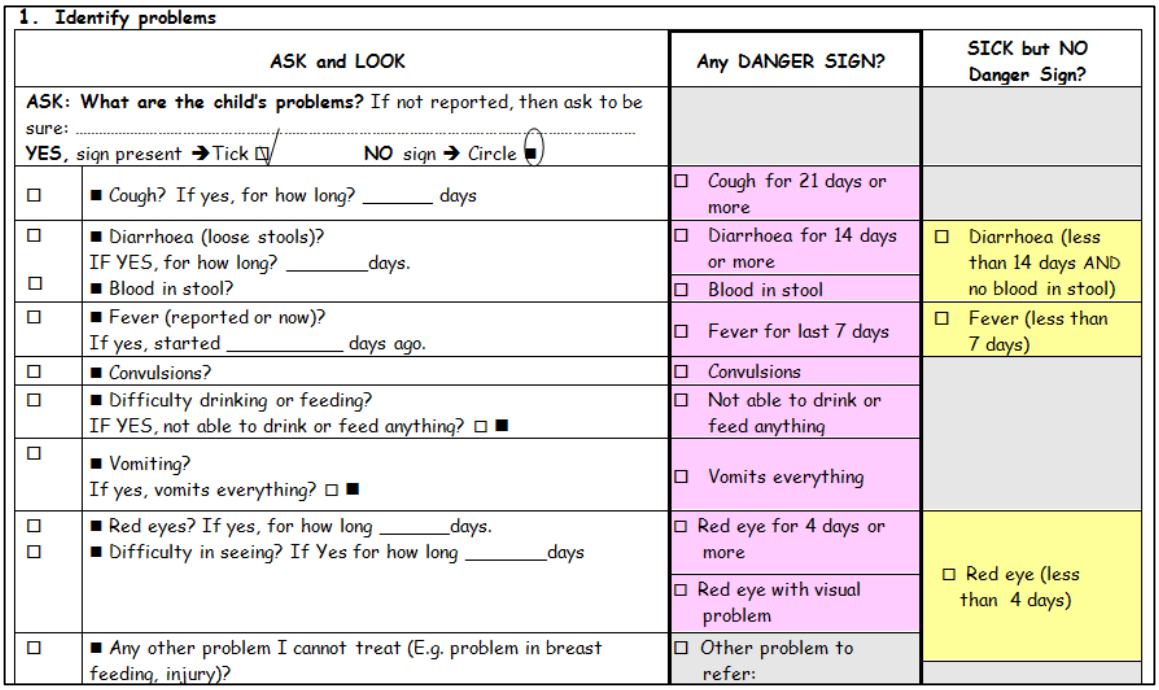
The remainder of this paper is structured as follows: The methodology employed as part of this study is documented in Section 2. The data collection and analysis as part of a feasibility study exploring the operationalisation of an mHealth App in Malawi, Africa is detailed in the next section. The findings from the dataset captured and stored in the mHealth App are subsequently reported and discussed, Sections 3 and 4 respectively. Concluding this paper (Section 5) is an overview of the paper, highlighting the limitations of the study and the key contributions to academia and practice.

2 METHODOLOGY

This section commences (Section 2.1) by briefly describing clinical guidelines known as Community Case Management (CCM) and an mHealth App based on CCM as part of this study. Section 2.2 details the feasibility study which was undertaken in Malawi, Africa. Malawi is considered as one of the ten poorest countries globally with malaria accounting for a high percentage of child mortalities and morbidities (UN, 2013).

2.1 Community Case Management and the Technological Artefact

Community Case Management guidelines were developed by the World Health Organisation (WHO) and UNICEF to assist community health workers (known locally in Malawi as Health Surveillance Assistants) when assessing, classifying and treating sick children under the age of five in rural parts of developing countries. As a subset of Integrated Management of Childhood Illness (IMCI) guidelines, CCM paper-based algorithm focuses on the detection and treatment of severe illnesses (e.g. malaria and pneumonia) which affect sick children in resource-poor settings. A snippet of the paper-based CCM guidelines are presented in Figure 1.



1. Identify problems

ASK and LOOK		Any DANGER SIGN?	SICK but NO Danger Sign?
ASK: What are the child's problems? If not reported, then ask to be sure: ..... **YES,** sign present ➔ Tick ☑ NO sign ➔ Circle ■			
☐	■ Cough? If yes, for how long? _____ days	☐ Cough for 21 days or more	
☐	■ Diarrhoea (loose stools)? IF YES, for how long? _____days.	☐ Diarrhoea for 14 days or more	☐ Diarrhoea (less than 14 days AND no blood in stool)
☐	■ Blood in stool?	☐ Blood in stool	
☐	■ Fever (reported or now)? If yes, started _____ days ago.	☐ Fever for last 7 days	☐ Fever (less than 7 days)
☐	■ Convulsions?	☐ Convulsions	
☐	■ Difficulty drinking or feeding? IF YES, not able to drink or feed anything? ☐ ■	☐ Not able to drink or feed anything	
☐	■ Vomiting? If yes, vomits everything? ☐ ■	☐ Vomits everything	
☐	■ Red eyes? If yes, for how long _____days.	☐ Red eye for 4 days or more	☐ Red eye (less than 4 days)
☐	■ Difficulty in seeing? If Yes for how long _____days	☐ Red eye with visual problem	
☐	■ Any other problem I cannot treat (E.g. problem in breast feeding, injury)?	☐ Other problem to refer:	

Figure 1. Snippet of CCM Guidelines (source: CCM Central)

An mHealth application was developed by the Supporting LIFE (**L**ow cost **I**ntervention **F**or dis**E**ase control) consortium which replicates the paper-based algorithm targeted at the sick child aged 2 months up to 5 years (referred as SL eCCM App). The SL eCCM App is underpinned by a clinical decision support system (CDSS) which classifies a child's illness and recommends treatment to the

Health Surveillance Assistants (HSA) based on the data entered by the user at the point-of-care. When mobile internet connection is available, the HSA can sync completed records to the supporting backend cloud services (for a full description on the SL eCCM App architecture c.f. O'Connor et al., 2015). The SL eCCM App has a turnkey form field validation feature (Figure 2) which allows all data input fields in the app to be controlled (i.e. all validation rules can be turned on or off), as required.

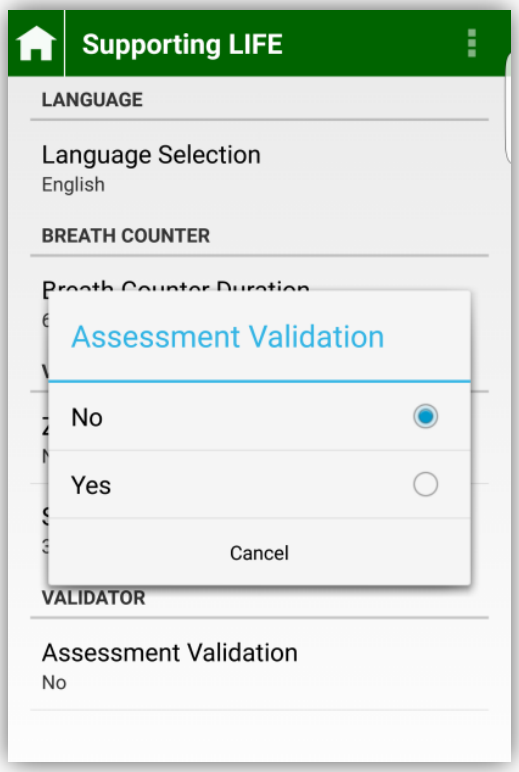


Figure 2. SL eCCM APP - Turnkey form field validation feature

2.2 Feasibility Study

A feasibility study was conducted in 2015 with a convenience sample of 12 HSAs identified from Malawi's DHSI 2 (government supported health information system) data capture system, provided to the Supporting LIFE consortium by the District Environmental Health Officer for Mzimba North. HSAs were selected from village clinics spread within a 100 km radius from the town of Mzuzu where the research team was based. Clinics had access to either a wireless mobile or data (a prepaid 3G data card was installed) network for easy synchronisation of data to the cloud. The feasibility study was undertaken in Mzimba North (which is predominantly rural) one of two regions within Mzimba district. People around Mzimba North are subsistence farmers and they earn their living through small scale farming of maize and tobacco. Mzimba North District Health Office (DH) has 23 health centres, each of which is responsible for several smaller village clinics, two Christian Health Association of Malawi (CHAM) hospitals (St Johns and Ekwendeni) and one central hospital (Mzuzu Central Hospital).

Ethics approval for this study was granted by the University of Washington Human Subject's Division (49117), USA and the College of Medicine Research Ethics Committee (COMREC) (P.03/15/1701), Malawi. The aim of the feasibility study was to explore the operationalisation of the SL eCCM App on the ground in Malawi. As part of this approach, double data assessment and entry procedures were

employed where HSAs were first required to assess, classify and treat sick children using the paper-based CCM approach (i.e. entering the data into the Village Clinic Register). Subsequently, HSAs were requested to repeat the same assessment using the SL eCCM App (i.e. entering data into the App). While HSAs utilised the SL eCCM App at the point-of-care, the clinical decisions based on following the paper-based algorithm were used for patient care. Throughout field-testing, subjects were asked to employ judgment on the children they assessed using the SL eCCM App. For children with life-threatening illness (for example, children that were unconscious, unresponsive or convulsing at presentation) at any time before or during assessment, HSAs were advised not to re-assess using the SL eCCM App (or its use should be aborted), and the child should be managed promptly using standard practice care pathways.

To be eligible for inclusion in the feasibility study HSAs were required (at a minimum) to be fluent in Tumbuka (local language in Mzuzu), attend a 1-day training workshop and provide voluntary written consent. Training workshops were conducted by the research team and held in central Mzuzu. During the workshops subjects learned how to access, use and resolve simple technical difficulties (e.g. turning on/off the phone, using the keypad) with the SL eCCM App, and were familiarised with data collection procedures to be undertaken whilst field-testing. A training manual was issued to supplement the information being presented verbally, and role-play exercises were used to leverage learning to simulate clinical use and engage with unexpected difficulties implementing study equipment and processes during field-testing. No more than four subjects (identified by the study team as a manageable number to teach) attended each session.

Data collection took place between July and September 2015. Subjects were given the mobile smartphone to deploy the SL eCCM App for 10 successive days (owing to multiple responsibilities of HSAs, village clinics are typically not open 5-days a week). The artefact was tested between 3-5 days per HSA. Whilst a mixed methods approach was employed during the feasibility study, this paper only reports on the dataset entered into the SL eCCM App as part of the double assessment procedure. This review was conducted by the research team post-feasibility study where the results were compared (i.e. content analysis was conducted) with the recommended outcomes documented in the paper-based process. The next section reports the findings from this analysis.

3 FINDINGS

The following presents a high level overview of the records synced during the feasibility study. Table 1 provides the number of records synced by each HSA during the feasibility study. In total 202 records were synced during the feasibility study. Of note, these include both clinical and 42 non-clinical (‘dummy data’) records, the latter entered when HSAs were exploring the SL eCCM App outside sick child visits. All data items (including dummy data) are fully incorporated within this study to illustrate the implications of having a voluntary process (i.e. validation switched off), in place when using an mHealth App (in this case, SL eCCM App).

Dates:	22-Jul-15	23-Jul-15	24-Jul-15	25-Jul-15	26-Jul-15	27-Jul-15	28-Jul-15	29-Jul-15	30-Jul-15	31-Jul-15	Total
HSA user number											
101	0	1	1	0	0	0	7	0	2	0	**11**
102	7	0	0	0	0	2	0	0	3	0	**12**
103	0	0	7	0	0	2	0	11	0	0	**20**
104	0	1	0	0	0	1	1	0	1	0	**4**
105	2	2	3	0	0	3	0	0	1	1	**12**
106	0	2	3	2	1	0	0	2	0	0	**10**
107	0	1	1	3	0	2	1	4	1	0	**13**
108	0	0	1	0	0	4	2	0	0	2	**9**
109	9	8	6	4	2	11	7	4	15	4	**70**
110	0	0	3	0	0	3	1	0	0	1	**8**
111	2	0	0	0	0	0	0	10	0	0	**12**
112	0	0	2	1	0	7	4	2	2	3	**21**
Number of Records:	*20*	*15*	*27*	*10*	*3*	*35*	*23*	*33*	*25*	*11*	***202***

Table 1. Overview of Records Synced by HSAs.

The team categorised the records as either adhering fully or not at all to the CCM clinical guidelines. For the purposes of this paper, *full* adherence refers to HSAs completing all the clinical items for assessing, classifying and treating sick children. *Incomplete*/*No* adherence refers to records which do not comply with the full adherence definition. That is, data required for the clinical assessment, classification and treatment of sick children is incomplete and/or incorrectly entered. Table 2 provides an overview of the adherence to the clinical guidelines, using SL eCCM App with the form field validation switched off.

	Adherence	
HSA user number	**Full**	**Incomplete/No**
101	1	10
102	0	12
103	13	7
104	4	0
105	8	4
106	2	8
107	2	11
108	5	4
109	0	70
110	6	2
111	5	7
112	7	14
Number of Records Synced:	53	149

Table 2. Overview of Adherence to Guidelines

Reviewing the records categorised as incomplete (n=149) a number of clinical assessments were incomplete or inaccurate. Table 3 provides an overview of the records categorised as incomplete/no adherence. Noteworthy, 63 incidences are reported in Table 3. Thirty four incomplete records were as a result of omitting socio-demographic details such as gender, date of birth, caregiver details. 'Other

problems' (a requirement of the CCM guidelines) was another section of the SL eCCM App which did not have an entry for patient data. This may signify that patients simply did not have additional symptoms. However, if a child has other symptoms outside of those assessed via the guidelines (e.g. swollen throat, broken leg) then they should get referred. Omission of this information may have resulted in a patient not getting referred to a first level healthcare facility (at the district level) to receive a more rigorous assessment. This accounted for 52 records.

Action Performed	**Record IDS**	**Total Number of Incidences**
No BPM captured but cough was not present	#227 #327 #168 #364 #195 #200 #246 #301 #302 #235 #315 #317 #290 #291 #189 #204 #205 #221 #222 #239 #240 #241 #254 #257 #271 #273 #337 #347 #350 #355 #370 #372 #267 #298 #305 #308 #215 #243 #259 #260 #261 #262 #265 #281 #319 #320 #356 #357	48
Vomit, fever entered. Fever not assessed.	#331	1
Diarrhoea entered but not assessed.	#363 #208 #209	3
No presence of cough but BPM taken.	#194 #238 #214	3
No Fever duration assessed although fever was present.	#311	1
BPM captured but cough was not present.	#206 #278	2
The sick child presented with a cough of 3 days. S/he also had chest indrawing but 512 breaths per minute was recorded.	#203	1
Cough present but no BPM taken	#213 #181	2
Fever, red eye entered. Red eye not assessed	#306	1
Cough and Fever entered. Fever (symptom and duration) not assessed.	#307	1
**BPM = Breaths per minute*		

Table 3. Incomplete or inaccurate Clinical Assessments

Table 4 compares the potential implications of the incomplete or inaccurate assessment items recorded by the HSAs using the SL eCCM App, based on the recommended treatment or management recommended by the paper-based CCM. In some cases incomplete assessment and/or lack of adherence to the guidelines may have resulted in failure to provide recommended treatments with potential for adverse clinical outcomes. In the vast majority of these cases the sick child should have been treated (often using antibiotics) at home. Incorrect classification and treatment of illness is a serious threat if the guidelines are not fully adhered to.

Action Performed	**Recommended Outcome from Paper-Based Algorithm/SL eCCM App**
No BPM captured but cough was not present/ BPM captured but cough was not present/ Cough present but no BPM taken.	Fast breathing exceeding 40/50 bpm (age dependent) requires the sick child to be treated at home and the caregiver is advised on the treatment. However, before going home the HSA is required to give first dose of oral antibiotic (cotrimoxazole adult tablet – 80/400): Age 2 months up to 12 months ½ tablet is required. Age 12 months up to 5 years 1 tablet is required. If the BPM was lower than 50/40 (age dependent) the HSA was required to give oral antibiotic (cotrimoxazole adult tablet—80/400). The caregiver is then responsible for providing the sick child with the antibiotic twice daily: Age 2 months up to 12 months— ½ tablet (total 5 tabs); Age 12 months up to 5 years—1 tablet (total 10 tabs). HSA are required to help caregiver give first dose now. If cough is present for 21 days or more then the sick child should be referred to a health facility.

Vomit, fever entered. Fever not assessed.	If fever is present for last 7 days then this is considered a danger sign and the sick child should be referred to a health facility. At this stage, a first dose of LA (i.e. antibiotic) should be provided to children 5 months up to 3 years - 1 tablet, children 3 years up to five years should receive 2 tablets of LA while children aged up to 5 months are not recommended to receive any medication. If fever is present for less than 7 days then the child is treated at home and the caregiver is advised on the treatment. Before leaving, the HSA is required to give the first dose of LA (i.e. antibiotic). Age up to 5 months—Not recommended; Age 5 months up to 3 years—1 tablet (total 6 tabs); Age 3 years up to 5 years—2 tablets (total 12 tabs). Caregivers are to be advised on use of a ITN. Paracetamol should also be provided 4 times a day for 3 days; Age 2months up to 3 years - ¼ tablet (total 3 tabs); Age 3 years up to 5 years – ½ tablet (total 6 tabs).
Diarrhoea entered but not assessed.	If diarrhoea is present for 14 days or more and/or if there is blood in the stool then the sick child should be referred to a health facility. Moreover, the child is required to retrieve ORS solution immediately before attending the health facility. If diarrhoea is present for less than 14 days and there is no blood in stool then the child is treated at home and the caregiver is advised on the treatment. The HSA gives ORS to the sick child demonstrating to the caregiver how it is done. It is recommended to give the caregiver 2 ORS packets to take home. HSAs are required to advise the caregiver to give as much as child wants, but at least ½ cup ORS solution after each loose stool. Also, the HSA is required to give zinc supplement. Give 1 dose daily for 10 days: Age 2 months up to 6 months – ½ tablet (total 5 tabs); Age 6 months up to 5 years—1 tablet (total 10 tabs). HSA are required to help caregiver give first dose now.
No presence of cough but BPM taken.	If cough is present for 21 days or more then the sick child should be referred to a health facility.
No fever duration assessed although fever was present.	If fever is present for last 7 days then this is considered a danger sign and the sick child should be referred to a health facility. At this stage, a first dose of LA (i.e. antibiotic) should be provided to children 5 months up to 3 years - 1 tablet, children 3 years up to five years should receive 2 tablets of LA while children aged up to 5 months are not recommended to receive any medication. If fever is present for less than 7 days then the child is treated at home and the caregiver is advised on the treatment. Before leaving, the HSA is required to give the first dose of LA (i.e. antibiotic). Age up to 5 months—Not recommended; Age 5 months up to 3 years—1 tablet (total 6 tabs); Age 3 years up to 5 years—2 tablets (total 12 tabs). Caregivers are to be advised on use of a ITN. Paracetamol should also be provided 4 times a day for 3 days; Age 2months up to 3 years - ¼ tablet (total 3 tabs); Age 3 years up to 5 years – ½ tablet (total 6 tabs).
The sick child presented with a cough of 3 days. S/he also had chest indrawing but 512 breaths per minute was captured.	Fast breathing exceeding 40/50 bpm (age dependent) requires the sick child to be referred to a health facility. However, the HSA is required to give first dose of oral antibiotic (cotrimoxazole adult tablet – 80/400): Age 2 months up to 12 months ½ tablet is required. Age 12 months up to 5 years 1 tablet is required. If fast breathing is a symptom but not considered a danger sign the HSA gives the first dose of oral antibiotic (cotrimoxazole adult tablet—80/400). Caregivers are then responsible for giving the antibiotic to the sick child twice daily for 5 days: Age 2 months up to 12 months— ½ tablet (total 5 tabs); Age 12 months up to 5 years—1 tablet (total 10 tabs); HSA is required to help caregiver give first dose now.
Fever, red eye entered. Red eye not assessed	A child suffering from red eye for 4 days or more and/or red eye with visual problem requires referral to a health facility. The HSA is required to apply antibiotic eye ointment before the child and caregiver attends the health facility. If red eye is present for less than 7 days then the HSA applies antibiotic eye ointment and then the child is subsequently treated at home and the caregiver is advised on the treatment - Squeeze the size of a grain of rice on each of the inner lower eyelids, three times a day for 3 days.

Cough and Fever entered. Fever (symptom and duration) not assessed.	If fever is present for last 7 days then this is considered a danger sign and the sick child should be referred to a health facility. At this stage, a first dose of LA (i.e. antibiotic) should be provided to children 5 months up to 3 years - 1 tablet, children 3 years up to five years should receive 2 tablets of LA while children aged up to 5 months are not recommended to receive any medication. If fever is present for less than 7 days then the child is treated at home and the caregiver is advised on the treatment. Before leaving, the HSA is required to give the first dose of LA (i.e. antibiotic). Age up to 5 months—Not recommended; Age 5 months up to 3 years—1 tablet (total 6 tabs); Age 3 years up to 5 years—2 tablets (total 12 tabs). Caregivers are to be advised on use of a ITN. Paracetamol should also be provided 4 times a day for 3 days; Age 2months up to 3 years - ¼ tablet (total 3 tabs); Age 3 years up to 5 years – ½ tablet (total 6 tabs).

Table 4. Comparing Data Entries with paper-based CCM Recommendations

In summary, the findings reveal that a mandatory process of form field validation is imperative in this scenario as without crucial information such as patient socio-demographic data and details of the absence, presence and duration of symptoms were omitted.

4 DISCUSSION

In the last decade, many papers have been published on the use of various mHealth Apps (incorporating CDSS and/or clinical guidelines) in different domains of medicine (e.g. orthopaedics, paediatrics, cardiology, geriatrics and nephrology). However, little research has been conducted on whether processes underpinned by mHealth Apps should be 'voluntary' or 'mandatory'. This paper seeks to address this gap in literature by exploring a process (i.e. adherence to clinical guidelines among healthcare workers) using mHealth technology when software data validation is turned off (i.e. voluntary process). This is clinically pertinent as the outcomes recommended to the end user based on the data provided to the application may be incorrect during this clinical/technical feasibility period. The findings documented from the feasibility study indicate the need for a process to be implemented enforcing mandatory and complete form field adherence. For HSAs, this means that each CCM field must be complete and accurate (i.e. correct data type) before they can move onto the next question.

Hall and Johnson (2009) argue however that process management and strict adherence to workflow is ill-suited to an unpredictable environment (such as healthcare). Studies of work coordination and work flow in a medical context are unpredictable and hard to foresee when designing computerised support (Kobayashi et al., 2005). It is argued if a mandatory process is implemented and some information is missing, the workflow may come to a complete stop (Andersson and Carlsson, 2009). Based on the findings in this specific case, the findings indicate that a voluntary workflow approach may be less favourable in the case of medical applications. The comparison with artistic processes or service technicians reveals that adherence transcends speed and convenience (Hall and Johnson, 2009). One of the main reasons to apply voluntary flow is the lack of detailed domain knowledge from the developer's perspective. However, in scenarios whereby the mHealth App developer knows and understands how and why the users do what they do (i.e. HSA workflows in this study) then a mandatory process should be implemented. In the case of the Supporting LIFE application, HSAs should theoretically follow a well-established set of clinical guidelines whereby the decision support algorithm recommends appropriate diagnosis and treatment but also the opportunity to actually force the user to adhere to a certain workflow. While having a mandatory process, such as form field validation, turned on could be viewed as an arduous task it is imperative that the mHealth app is designed in a safe and secure way which does not have a negative impact on the patient (The Institute of Medicine Quality, 2001).

Clinical decision support systems live at the core of health information systems, both mobile and otherwise. In many instances underlying CDSS acts as the rule base for the software solution. When

data validation rules are strictly applied to CDSS, the user is forced to fulfil or adhere to the validation rules in place, in terms of completing fields, adhering to a range of values and data types. The purpose of the study, however, was to test the feasibility of using the SL eCCM App, rather than to measure its clinical effectiveness. Lengthy double data entry procedures and the fact that the SL eCCM App was not used to guide treatment, may have altered HSAs' approach to using the IT artefact. Therefore, this could have impacted on how the HSA used SL eCCM App. Due to lack of observer recording as to what was being completed (and noting factors related to each sick child visit/environment which may have prevented subjects from using it properly) by the HSA via the App it is difficult to fully ascertain why HSAs failed to follow all the clinical guidelines.

5 CONCLUSION

In this paper, we explored the under-researched topic of community healthcare workers' adherence to clinical guidelines when form field validation is turned off. Our findings confirm that form field validation is essential for clinical guideline adherence. Adherence to clinical guidelines when form field validation is turned off was found to be incomplete in many cases. While the aim of the study was not to explore HSAs' adherence to the paper-based guidelines and cumbersome double assessment and data entry procedures were imposed on participants, the results also raise questions about whether healthcare workers do abide by clinical guidelines when using Community Case Management (CCM) paper forms to assess their patients. In theory, healthcare workers should fully adhere to clinical guidelines whether in paper or digital format to ensure that their patients receive the appropriate level of health care. Due to the current reporting systems in Malawi HSAs a dearth of information is available which accurately assesses if HSAs are adhering well or poorly to the paper forms. Digitising this approach and ensuring form field validation is switched on, mHealth have the ability to improve the quality of care which reducing costs (e.g. paying individuals to oversee procedures and check inaccurate paper records). However, it is evident from this study that some healthcare workers do not fully adhere to the guidelines. Our findings reinforce the need for use of mobile health apps to ensure adherence to clinical guidelines and therefore safe and effective care provision.

While interviews were conducted with HSAs (after the feasibility study) there was limited follow-up on how and why the HSA used the app in a particular way (i.e. not following clinical guidelines). The interviews, however, did reveal that the CCM guidelines had recently been updated prior to the feasibility study and included components not incorporated in the SL eCCM App (e.g. integration of Malaria Rapid Diagnostic Test), which will have to be embedded in future iterations to ensure adherence. In addition, the workshop and training manual were in English. Despite our best efforts to deliver clear guidance notes and simulation exercises, and although a study researcher fluent in Tumbuka was present during the training workshops to translate, it is still possible that language and cultural barriers, in terms of terminology used or delivery of communication, may have been a barrier to learning. Furthermore, one training workshop may have been insufficient for subjects to be comfortable with both the SL eCCM App and the prescribed study procedures.

Substantial evidence exists which clearly demonstrates that adhering to clinical guidelines does yield an overall improvement in clinical outcomes (van Dijk, 2013). However, it has been equally argued that clinical guidelines lack detailed patient specific consideration and thus tend to be overly rigid and generalisable (Woolf et al., 1999). A limitation of this paper stems from the fact that the level of adherence to the CCM guidelines was not correlated with any clinical outcomes. However, given that the guidelines within the SL eCCM App were not completely up to date, one could argue that having the adherence turnkey deactivated, provided the HSAs with the freedom to use their own judgement (skip/ignore recommended steps) and provide better care to the patient. This scenario equally highlights the critical requirement for robust and continuous software maintenance post deployment to ensure the mHealth solution is complying with the latest sanctioned guidelines. Had the adherence

turnkey been activated, HSAs would have been forced to abandon the App completely, or more critically, followed through with inappropriate patient care.

The next phase planned within this larger project is a stepped wedge design cluster randomised controlled trial with the participation of approximately 100 HSA clinics and over 5,000 children and their caregivers. Within this trial, the SL eCCM App will be updated with the latest CCM guidelines and the adherence turnkey will be activated. The trial will assess the effectiveness of the SL eCCM App compared with paper CCM in terms of referrals, repeat consultations to HSA clinics or other health facilities, hospitalisations, and costs. The trial will also capture HSAs' compliance with the App as well as their adherence to treatment recommendations following CCM assessment. The findings from this larger analysis will provide clear insights regarding the consequences of making the complete adherence to the CCM guidelines within the SL eCCM App mandatory.

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