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Using clinical guidelines and card sheets for guiding the design of data-driven clinical pathways

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Abstract

Clinical pathways(CP) aim to link evidence to practice for standardizing and managing the quality of healthcare services. However, putting evidence into practice is challenging in health systems with limited resources where limited digitalization represents one of the main hurdles. This study aims at investigating the need for designing automated and data driven clinical pathways for low resource settings and more specifically for the case of female reproductive health care. We conducted a case study on the Ethiopian primary health system in general and Jimma Health Center in particular. After securing ethical clearance, (i) the existing paper-based clinical guidelines(CGs), annual reports, point of care charts and card sheets were examined, (ii) a digitized CP dataset was derived from a previously created electronic template, and (iii) a python based interactive CP tool was developed for automating pre-processing, interactive visualization and analysis of the data. We found that the health center patient card sheet only contains very limited information. CGs have demonstrated a potential advantage in identifying and making referral decisions on cases that relate to several concurrent health problems. The existing paper-based point of care instruments have the disadvantage of not being interactive and proved difficult to use for extracting relevant clinical information, summarizing the patient history, constructing a patient flow diagram, diagnosing all potential underlying diseases and in the end for delivering optimal clinical pathways. The study demonstrates that health care services, as they are implemented now, have severe shortcomings and prevailing paper-based methods are inefficient for delivering useful evidence to the frontline health workers. Utilizing existing care information for delivering adaptive evidence-based health services in low resource settings will require a suitable algorithm that works with limited input (i.e. clinical signs and symptoms) and updates the generated clinical pathway incrementally each time additional information becomes available.

Keywords: Clinical decision support system; Clinical Pathway; Limited resource setting; Clinical data visualization; Health information needs.

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1. Introduction

A clinical pathway (CP) is one of the main tools used to link evidence to practice for managing the quality in healthcare and standardizing the patient care processes [1, 2, 4]. The introduction of automated and data-driven CPs has been effective in improving clinical outcomes. Even though it is well-known that automated CPs are more advantageous in examining variations and cluster similar patients to suggest an effective pathway, in reducing the cost of care and service delay through constructing an evidence-based plan of care [2, 3, 4]. The enabling process to put evidence into practice is challenging in health systems with limited resources [8]. The paper describes the first steps of such an enabling process.

The primary health care system in low resource settings (LRS) aims to deliver clinical care mainly for uncomplicated health problems requiring minimal investigations and to refer cases that require more advanced diagnosis and treatment to clinical settings of a higher level [5, 6]. To achieve these goals [7], health care professionals need to be updated at the point of care with the latest good practice guidelines, be able to design personalized treatment efficiently, deliver evidence-based treatment and act according to the patients' changing conditions.

There are several hurdles to take in the process of implementing evidence into practice in LRS [8]. The health system in these settings mostly relies on hard-copy clinical guidelines (CGs), patient card sheets, point of care charts and training manuals. Despite considerable efforts to deliver the best standard of care through CGs, there remains an important need for improved.

Figure 1: Card Warehouse

evidence-based clinical care which can only be achieved through standardization, variation re-

duction and decision-support tools that are easily accessible at the point of care [6]. In this regard, current health systems still face numerous unresolved challenges including inadequate digital access, quality of data, competencies, skills, data collection and referral instruments, follow-up of patient records, report timeliness, report completeness and digitization [5, 6, 9].

The primary health care systems in LRS require more resources, support, and specific skills to deliver and translate evidence into context-specific and user-friendly formats. There is a need to implement a learning health system that promotes evidence-based practice and health care service delivery. The hypothesis we want to verify in this paper is that the current paper-based approach, as used in the Jimma Health Center Maternity and Antenatal Care, fails due to conceptual flaws in its implementation and will continue to fail to avoid inconsistencies in (i) delivering evidence to the frontline health workers at the point of care and (ii) translating such evidence into context-specific and user-friendly guidance. Therefore, to examine the need for designing low cost auto-mated clinical pathways; this paper explores existing paper-based clinical guidelines, annual reports, point of care charts, and patient card sheets for (i) assessing the reported incidence of diseases related to frequently reported health complaints (signs or symptoms) in women at reproductive age, (ii) investigating the referral or treatment decisions that were made, and (iii) examining the incidence of findings for each of the underlying diseases and multiple diseases.

2. Methods

This study was conducted in the Ethiopian primary healthcare system and more specifically at Jimma Health Center. We focused on women of reproductive age in LRS because (i) it is a national priority and a global sustainable development goal to be achieved by 2030 – SDG 3 [5, 6], (ii) the service at the health center is challenged to deliver optimal care in terms of cost, time and outcomes, and (iii). the translation of evidence into context specific and user-friendly formats i.e., automated guidelines, algorithms or point of care instruments remains a challenge in LRS [8].

The paper based CGs, annual reports, point of care charts, and card sheets were used to create a set of clinical data elements that can potentially be useful for enabling data driven decision support at the point of care. Ethical approval was obtained before data collection. Two data collectors were recruited from the Jimma Health Center to collect the data from the patient card-sheet and register in the electronic datasheet. The electronic data-sheet template is depicted in Figure 3. The data collection was conducted from April to October 2019 using a pre-prepared electronic datasheet template.

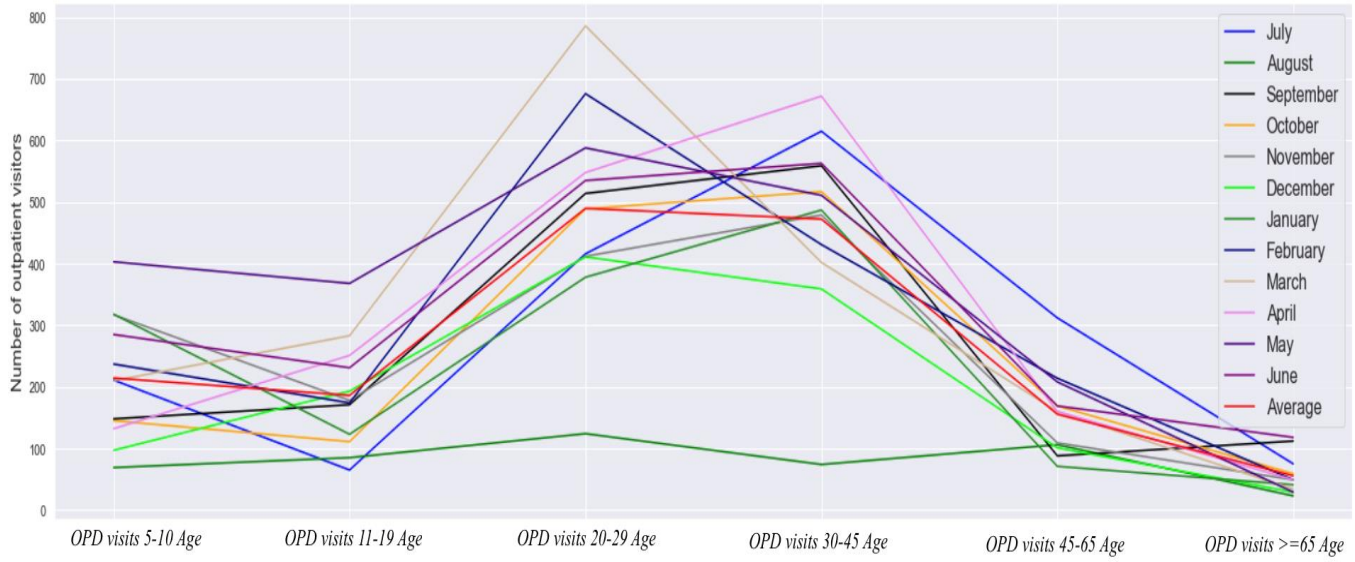

Figure 2: Summary of outpatient department (OPD) service delivery (Female) report and analysis

To assure the quality of data, the data collectors were recruited based on their familiarity and experience with the existing workflow process, patient card-sheet management, professional expertise, and exposure to handle clinical and health information. The data collectors were already working as full-timers, and they agreed to cooperate on the data collection process during the weekend and after working hours.

Table 1

This SPT research focus on adult women whose age greater than 15											
No.	Disease Code/ Classification	Disease Name	Age	Category	Collected Sign and Symptoms	Write all the finding of the disease	Is there any related disease ?		Conclusion (treated in the clinic or referred to hospital)	Visting Date	Referred or Treated Date
							Yes (List all the findings)	NO			
1											
2											

Figure 3: An electronic data-sheet template for digitizing patient card-sheets.

To identify the most frequently reported health problems, we analyzed the health center reports, patient card-sheet as well as the clinical guidelines. A CP data collection sheet was then developed based on the data elements derived from clinical guidelines and analysis of templates from previously published relevant literature [11, 12, 13]. Figure 3 depicts additional information on the electronic data collection sheet template.

The data were obtained from the health center card-sheets, CGs, annual reports, and point of care charts. We collected n=2443 cases from the patient card-sheets to investigate our research questions.

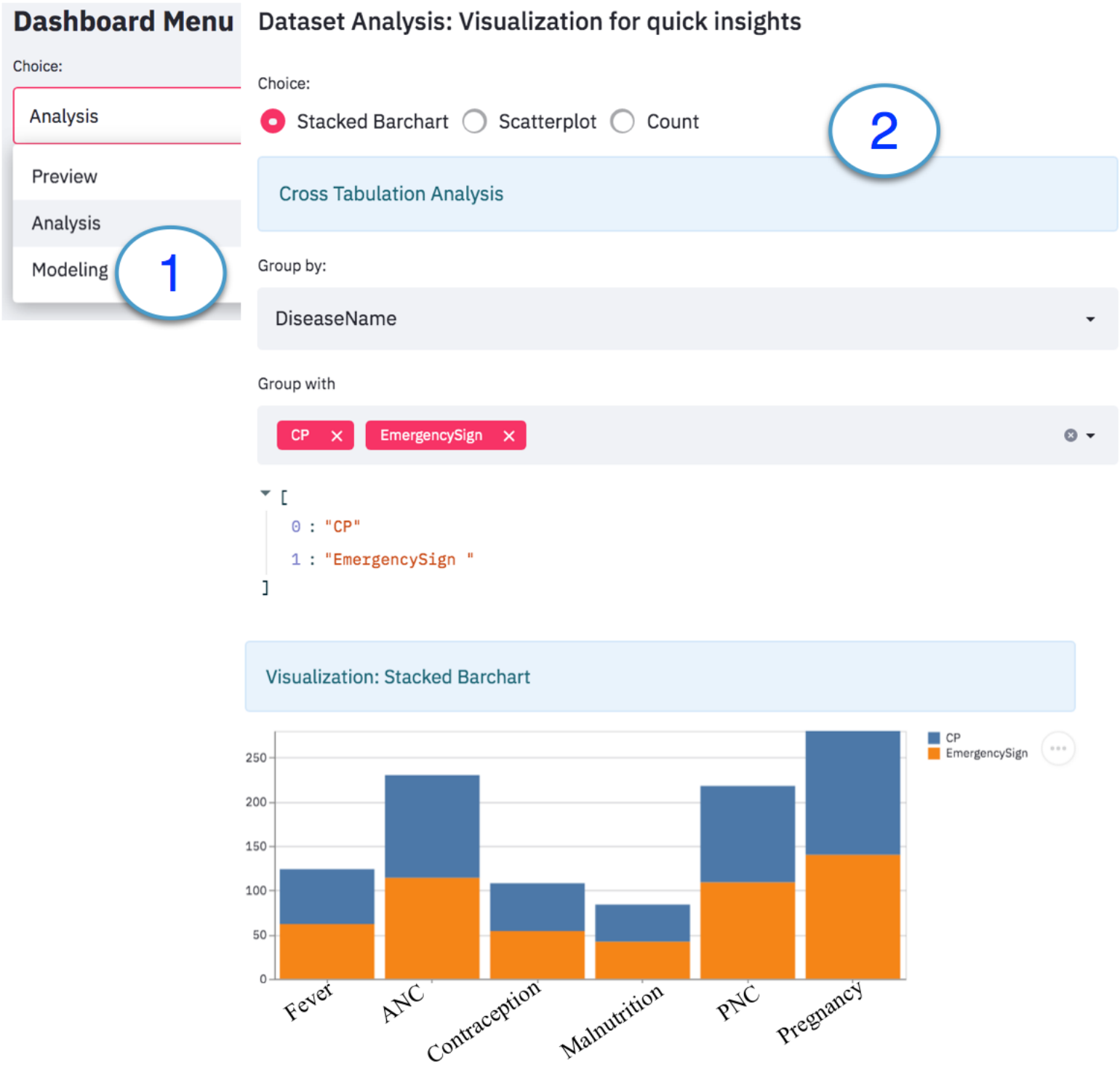

Figure 4: An interactive dashboard for CP data preprocessing, analysis, and visualization.

The estimated number of women in the reproductive age who received services in the health center during one year September 2010 to August 2011 E.C (Ethiopian Calendar) (i.e., between September 2018 G.C. (Gregorian Calendar) to August 2019 G.C.) is N=15646. We calculated the minimum sample size n(minimum)= 375. The following formulae were applied:

$$n(minimum) = N*X / (X + N - 1) \quad \text{equation 1}$$

$$X = Z\alpha/22 *p*(1-p) / MOE2 \quad \text{equation 2}$$

In which $Z\alpha/2$ is the critical value of the Normal Distribution at $\alpha/2$ (confidence level is set to 95% and hence the critical value is 1.96, α is 0.05), the margin of error (MOE) is 0.05, p is the sample proportion and N is the population size. The theory behind these calculations is explained in [25, 26]. We follow the recommendations of WHO stepwise approach to surveillance for the remaining values [27]. These value settings allow us to simplify the calculations as formulated in equations 1 and 2: p = 0,5 maximizes the nominator in equation 2 and produces a worst case (i.e. maximal) value for n(minimum) and p = 0,5 is recommended in cases where no a priori results can be used from previous studies; since we only consider women of reproductive age (age 15-48), the number of "age-gender" categories is equal to 1; the response rate is ~100 % since we are per-forming a retrospective analysis based on card sheets; the design effect is set equal to 1 which is recommended for random samples, following the WHO guidelines no finite population correction is applied. The representativeness of the data in our sample is guaranteed, since we digitalized records of n = 2443 consultations.

In general, medical record number, disease name, age, status, signs and symptoms, related dis-eases, the acuteness of the treatment (i.e., whether it requires urgent attention or not), treatment recommendation, clinical conclusion, visiting date and treatment (or referral) date was obtained from the patient card-sheets and digitized on the data collection sheets. As shown in Figure 1, the existing dataset was available in a paper-based format and obtaining the required information was time-consuming and was tougher than we expected. We also recorded and aligned the in-formation according to International Classification of Primary Care (ICPC2) and International Classification of Diseases 11th Revision (ICD11) standards [14, 15].

Then, we developed a python-based tool for automatic pre-processing, visualization and analysis. Figure 4 presents a Python-based user interface (UI) for preprocessing, analysis, and visualization of health-center data. The labels 1 and 2 in Figure 4 represent the dashboard menu, and analysis and visualization, respectively. The tool is used for preparing the CP's raw data for further processing including data cleaning, detecting missing referred with consideration and noisy values, and interactive data visualization. The subject for CP analysis was classified into treatable, referred, treated with consideration

or. Treated (or referred) with consideration indicates a patient presenting symptoms of multiple diseases such as being pregnant with hypertension, headache and chest pain. In this case, we started by identifying the patient's dominant symptom, then considering the other symptoms based on their severity, leading to either the treatment or to referral pathways. We found only minimal documented information in the clinical card sheet, and it appeared to be challenging to extract decisions and findings that point towards more than one dis-ease (tunnel vision). To overcome this problem, we set up strategies to generate data from the CGs and compare with the card-sheet record to understand how the health professionals diagnose their patients at the primary healthcare level in comparison with the applicable guidelines.

3. Results

We found that the health center patient card sheet only contains very limited information. Pregnancy, childbearing and family planning are the second most frequently reported cases after general and unspecified health problems (e.g.. fever of other or unknown origin). CGs have demonstrated a potential advantage in identifying and making referral decisions on cases that relate to several concurrent health problems. Extracting relevant clinical information, summarizing the patient history, constructing a patient flow diagram, diagnosing all potential underlying diseases, and suggesting optimal clinical pathways were difficult tasks when using the existing paper-based point of care instruments.

3.1.Health Center Patient Flow and Service

A typical health center patient flow starts from the card section and passes the necessary steps which includes cashier, triage, antenatal care, vaccination, emergency, family planning, outpatient, pediatrics, laboratory and pharmacy depending on the signs and symptoms until a diagnostic hypothesis is obtained. The health center annual report and patient card-sheet were examined to explore frequently reported cases and get insight into the health center service delivery and the continuing care of patients. Among the female outpatient department (OPD) visitors at the health center, the number of visitors between the age of 20 – 45 years is higher in comparison with the other age groups as shown in Figure 2. We also visualized a summary of the health center annual service delivery, which is presented in Figure 5. The stacked bar chart, based on the health center annual report, depicts the number and analysis of services given at the health care facility. For example, as indicated in row number 9 in Figure 5, for women who received tetanus toxoid (TT) vaccination service, the colored bar denotes the number of women who received TT vaccination TT1, TT2, TT3, TT4, and TT5 respectively.

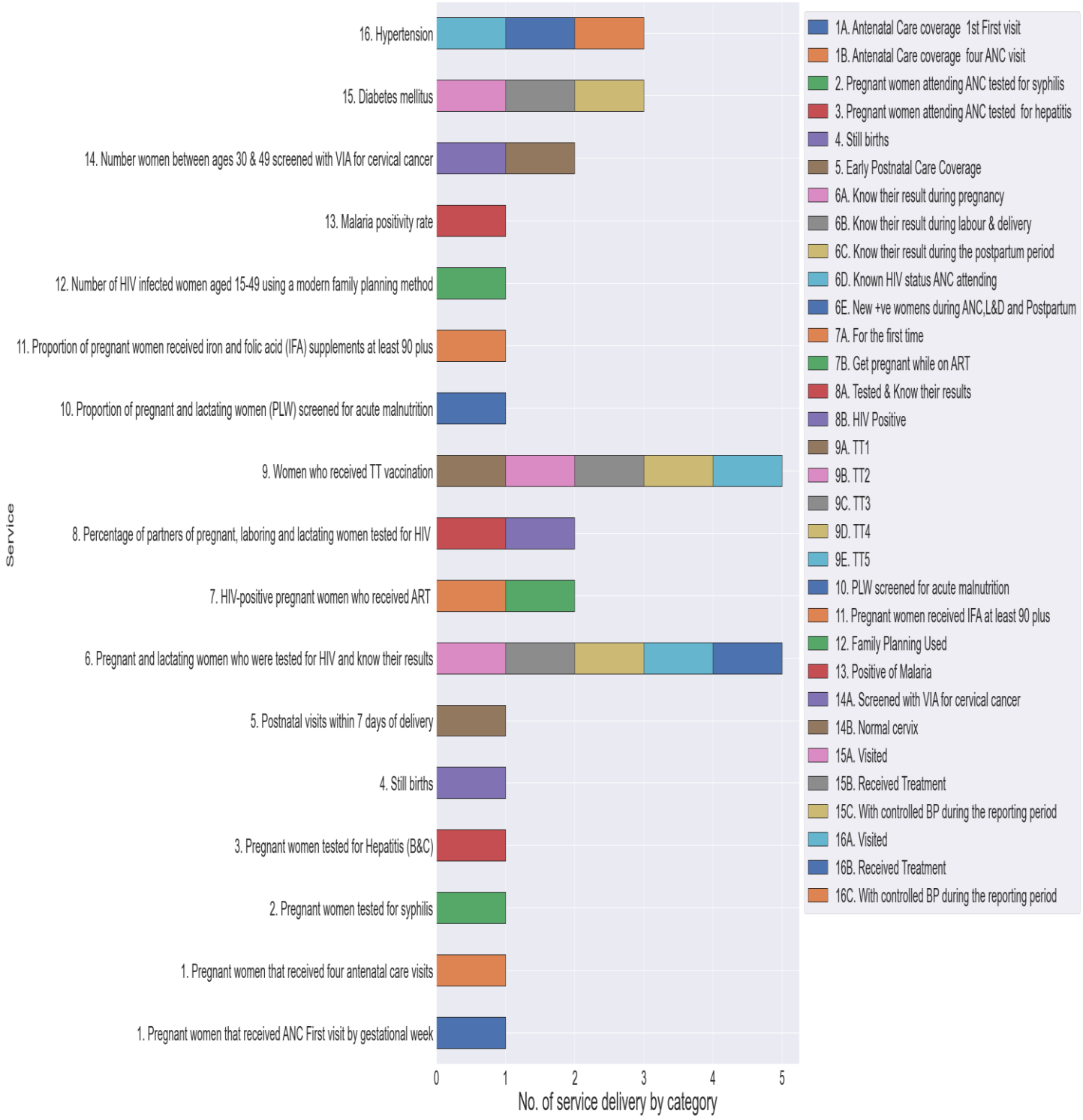

Figure 5: Analysis and visualization of service delivery based on the health center annual report

3.2. Evidence-Based Decision Instruments and Practice

Analyzing the existing paper-based instruments and handwritten patient records is time-consuming, and it is very difficult to extract the right information from them. Figures 1 and 6 visualize

the existing paper-based patient card warehouse and the effects of manually searching the records. We also found that the clinical guidelines and the paper-based care-charts at the point of care are not interactive, portable or easily usable and it may take a fair amount of time to pick the right CP. More information on the layout and format of the paper-based care-chart is presented in Ethiopian primary health care clinical guidelines [11]. There is a huge difference in the number of inputs considered in the CGs and those that are actually used in the card-sheets. For instance, as shown in Table 1, fever (with a value of either no, yes or persistent), headache (with a value of either no, yes or persistent), and chillness (with a value of yes or no) only leads to a decision "referred" or "treated" on the examined card sheets. The CG s present a much larger list of signs and symptoms that can lead to any of the four recommended pathways (i.e., treated, treated with consideration, refer and refer with consideration).

Figure 6: Effect of paper-based searching retrieved from: https://www.facebook.com/pg/HakimEthio/posts

3.2.1. Clinical Card-sheet

"Pregnancy, childbearing and family planning" is the most frequently reported category next to the "general and unspecified diseases" as shown in Figure 7. Prolonged labor, maternal care related to prolonged pregnancy, maternal care related to premature rupture of membranes, maternal care for known or suspected disproportion, and postpartum hemorrhage all lead to an automatic referral to the next level of care according to the card sheets. However, the card-sheet has not been effectively used when it comes to documenting signs and symptoms that can be explained by more than one disease. Only a very limited number of inputs (signs and symptoms) have been documented in the patient card-sheets in order to decide whether a case must be treated in the clinic or referred to the next level.

Out of 1216 "pregnancy, childbearing and family planning" and "general and unspecified diseases", 84.6% and 15.4% were classified as "treatable" and "referral" respectively (see Table 2). We

selected these two disease categories because they were the most frequent ones in our study dataset as demonstrated in Figure 8. Only "treatable" decisions were found for "Fever" (also named as general and unspecified under ICPC2 classification) while only the "treatable" and "referral" decisions were obtained for "pregnancy, childbearing and family planning". Figure 8 illustrates the visualization of CPs using the health center card-sheet for the above-mentioned disease categories.

Table (1) CGs Vs Card-sheet Dataset Summary

	Clinical Guideline Based CP			Card-Sheet Based CP		
	Signs & Symptoms		Target Class	Signs & Symptoms		Target Class
Disease Name/Case	Input	Input_Value	CP (4 Class)	Input	Input_value	CP(2 Class)
Fever	Fever	Yes, Persistent, No	Treated, Refer, Treated + Consideration, Refer + Consideration	Headache	Yes, No, Persistent	Treated, Refer,
	Satus	1 days, 3 days, 7 days or more		Fever	Yes, Persistent, No	
	Convulsion	Yes/No		chillness	Yes/No	
	Drowsiness, confusion or agitation	Yes/No				
	Neck Stiffness or meningism	Yes/No				
	Respiratory rate	>30				
	difficulty breathing	Yes/No				
	BP	<90/60, >90, >=140/90, >=160/110				
	Abdominal pain	Yes, No, Severe				
	Jaundice	Yes/No				
	Easy Bleeding or bruising	Yes/No				
	Unable to sit up or walk unaided	Yes/No				
	purple rash	Yes/No				
	Temperature	>=38°C, <38°C				
	headache	Yes, No, Persistent				
	weak fast pulse					
	capillary refill >3 seconds					

Table (2) Summary CP from Card-sheet

CP	Percentage from Card-sheet: Out of 1216 (%)
Treated	84.6
Refer	15.4

3.2.2. Clinical Guidelines

We generated 2037 disease paths from the CGs and found that clinical decisions based on the CGs were more explicit than the card-sheets in capturing paths which are related to more than one disease (crossroads). The sample extracted pathways from CGs are depicted in Table 3.

Table (3) Sample extracted pregnant pathways from CGs [11]

Path	Finding	CPs
1	If BP>=140/90, persistent headache, blurred vision and abdominal pain	Referred Path, Treat as severe anemia
2	If BP>=160/110	Referred Path, Treat as severe anemia
3	If painful contraction <37 weeks	Referred Path, Treat severe hypertension
4	If sudden gush of clear or pale fluid from vagina with no contractions	Referred Path, PROM (Premature rupture of membranes) likely
5	If breathing difficulty	Referred Path, Give face mask oxygen and refer urgently
6	If BP<90/60	Treatable Path, Give normal saline 1L IV rapidly and repeat until systolic BP>90 and continue 1L 6 hourly. Stop if breathing worsens

We found that the CGs show a potential advantage in making referral decisions and identifying multi-disease cases. For instance, in a patient presenting one or more symptoms (e.g., fever, bleeding, chest pain, vomiting), the information provided in the CGs helps to pick the dominant symptoms and to drill down to either the referred or treatment paths depending on the secondary signs and symptoms and the level of acuteness. The CGs are able to generate and construct all potential paths (treatable, referral, treated with consideration and referred with consideration) as shown in Figure 9. Figure 10 shows the CPs distribution, among others for both “general and unspecified” and “pregnancy, childbearing and family planning disease categories”.

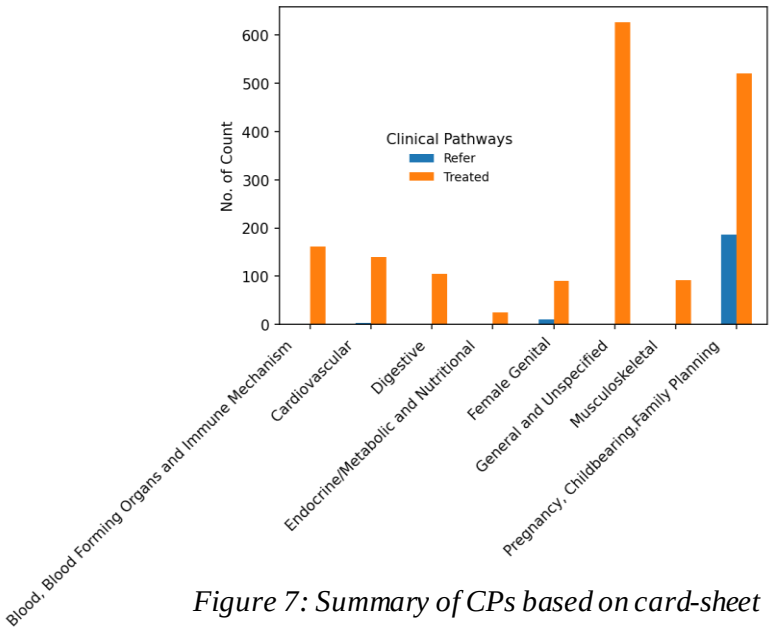

Figure 7: Summary of CPs based on card-sheet

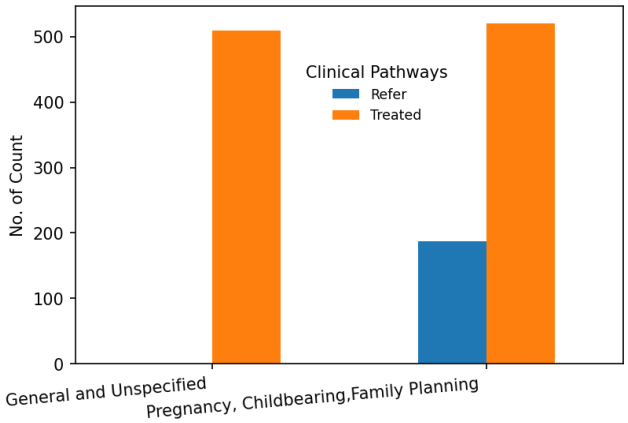

Figure 8: Extracted frequent CPs based on card-sheet

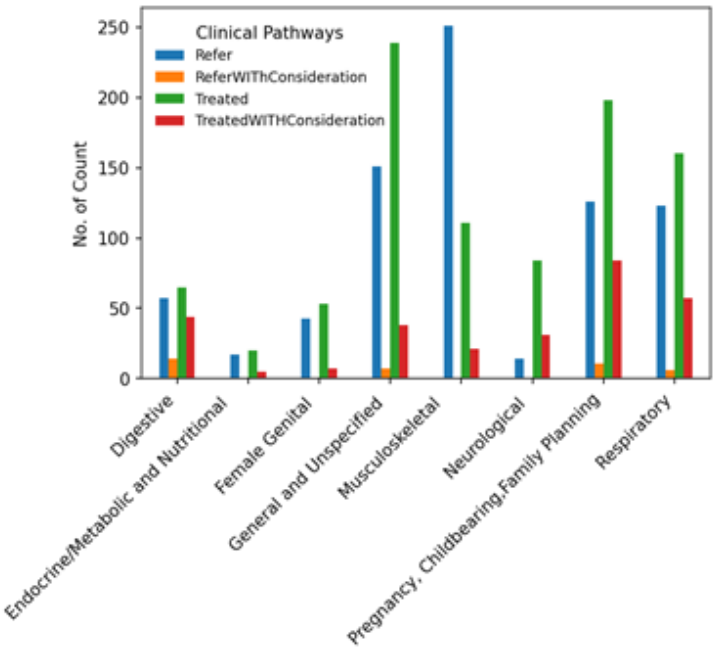

Figure 9: Summary of CPs based on CGs

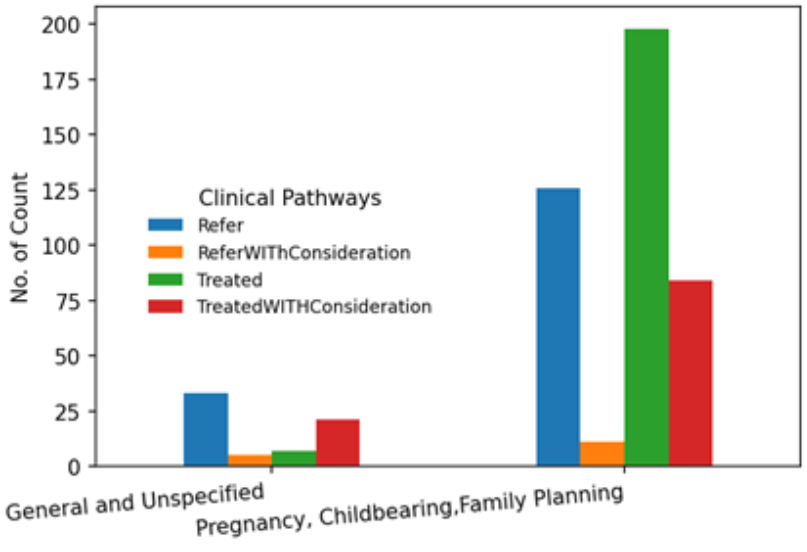

Figure 10: Extracted CPs from the CGs

4. Discussion

This study was set up to investigate the need for designing low cost and data-driven clinical pathways in low resource settings. The current study indicates that: (i) most OPD patients are in the age category of 20 – 45 years, (ii) the existing point of care instruments (point of care charts and CGs) are not automated, not interactive or dynamic as depicted in Figures 1 and 6, (iii) only limited information is documented in the patient card-sheets, and (iv) health professionals find it difficult to investigate multiple disease CPs using the existing paper based instruments.

In low resource settings, following the Clinical Guidelines is the traditionally recommended practice. The hardcopy CGs are used as a quick and action-oriented reference for the health officers and nurses in the health center [16]. The point of care charts are also used as a quick reference for assisting the care planning process.

Evaluation of the existing patient card-sheets, which can be expected to be compatible with the adopted point of care charts, showed that it takes much time to capture the required information and process it in a consistent manner. For instance, to get information from a specific patient record, the corresponding card-sheet must first be retrieved from the card warehouse using manual searching as shown in Figure 6, Once the card-sheet is found, it remains challenging and time consuming to summarize the required clinical data and construct a patient flow sheet to monitor and record the progress of care.

We analyzed the completeness of documentation and available evidence in the existing patient card-sheets. Table 1 summarizes the very limited clinical card-sheet information granularity versus the more complete set of potential clinical data elements that can be derived from the clinical guidelines. The study reveals that clinical investigation is stopped in an early stage, as soon as a first possible differential diagnosis is being thought of, thereby making referral or local treatment decisions based on too few documented signs or symptoms. Because of this, multi-disease CPs (referral or treatable with consideration) are most often missing in the clinical card-sheets as shown in figures 7 and 8.

Aligning automated and data-driven CPs with the existing care process may improve the quality of clinical reasoning and the care standardization process [2]. In particular, it will "support the care process through evidence and offer several investigations flows for different decisions to be made"[18]. Introducing digital health information technology can be used to introduce interactive workflows, generate pre-defined treatments automatically, store medical conditions and encourage timely documentation, reduce inefficiencies, reduce errors, and promote information transfer [19, 20].

We also observed that the CGs have shown a potential advantage in making referral decisions and identifying multi-diseases CPs. However, the effectiveness and utilization of CGs in primary care remains

disputed and needs further exploration [17]. Digital tools incorporating the CGs should be complemented by tools to enhance the point-of-care charts, in order to be able to document and assess the quality of care and compare the digital CG-approach with the local probabilistic evidence-based approach. The benefits from the digitalization process are supported by literature: Akhu Zaheya et al. 2018 have researched automated records and demonstrated that better processes were obtained in comparison with the paper-based records [21]. Introducing automated clinical pathways furthermore leads to structured medical treatment and more complete documentation [3]. Therefore, it seems reasonable to expect that also in LRS the quality of the care process through designing an interactive, automated and adaptive point of care clinical decision instrument can be improved.

In general, the quality of documentation and scientific evidence is crucial for the quality of decision making as described in [9, 21, 22]. With the current paper-based patient management system, it is difficult to deliver evidence for the frontline workers by uncovering historical patterns, extracting best practices, and generating optimal clinical pathways (in terms of cost, time and outcome). Promoting evidence-based practice has significant impact on the quality of the decision-making processes [2, 4, and 22] but it is also important to consider the quality of evidence, the individual's decision-making attributes and the influence of the external context [24]. Previous studies have also shown that improved documentation was associated with the use of CPs, and that CPs are a documentation-based tool for translating evidence into practice, enforcing im-proved documentation, getting better outcomes, reducing costs and length of hospital stay [2, 4, and 8].

5. Conclusion

The study examined the need for designing automated and data-driven clinical pathways in low resource settings. The analysis of the existing paper-based CGs and card-sheets is a mandatory first step in the design of automated and interactive CPs integrated with the routine health information system, which are expected to enhance the documentation of the care process, improve the quality of care, and promote evidence-based health service provisioning. We observe that currently the hard-copy CGs, patient card-sheets and point of care-charts are the readily accessible resources for assisting the frontline workers and their decision. However, the existing point of care instrument is not automated, interactive and dynamic. It's not easy to capture and summarize the required clinical data, process it in a consistent manner, construct a patient flow sheet to monitor and record the progress of care. Hence, it is almost impossible to assess the quality of the care services that are delivered. We also observe that only limited information is documented in the card-sheets, and additional differential diagnostic options are rarely investigated. Therefore, the care service is compromised and doesn't deliver the expected evidence for

the frontline workers at the point of care. In order to promote evidence-based care in LRS, there is a clear case for designing automated, interactive, and data-driven CPs that work with small sets of clinical signs and symptoms and incrementally updating the CP process when new information is added. Designing an appropriate point of care instrument should support the documentation of the care process (e.g., electronic medical registration), improve the standardization of the care process and reduce delay. More complete documentation and automated care processes may deliver better evidence for decision making and lead to better quality of care. This will bring benefits for the health center, healthcare professionals, researchers, and management by enabling: (i) a clinical decision support instrument in cases where the medical and administrative expertise is not locally available, (ii) easier access to medical records and reports, (iii) automatic triage classification, (iv) automatic CPs (treatable or referred paths) processing, (v) active learning and active feature-value acquisition models that can be deployed successfully in a setting with limited infrastructure, and (vi) new methods for low resource settings to promote evidence-based decision making and practice.

6. Declarations

6.1 Conflict of Interest Statement

The authors have no conflict of interests to declare.

6.2 Funding Disclosure

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

6.3 Acknowledgements

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