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Original article

Comparison of medical documentation between pharmacist-led anticoagulation clinics and physician-led anticoagulation clinics: A retrospective study

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ABSTRACT

Background and objectives: High-quality documentation is critical in medical settings for providing safe patient care. This study was done with the objective of assessing the standard of medical records in anticoagulation clinics and investigating the distinctions between notes written by pharmacists and physicians.

Methods: A retrospective cross-sectional analysis of data from electronic health records (EHRs) was performed on patients who received anticoagulation and were observed at anticoagulation clinics from October to December 2020. Patients were monitored in two anticoagulation clinics, one administered by pharmacists and the other by physicians. The quality of the documentation was assessed using a score, and the note was assigned one of five categories according to its score: very good, good, average, poor, and very poor. The data was analyzed using Stata/SE 13.1. P value<0.05 was considered significant in all analytical tests.

Results: A total of 331 patients were included. While 160 patients (48.3%) were followed by the physician-led clinic, 171 (51.6%) were by the pharmacist-led clinic. The average age of the patients was 54 ± 15. 60.73% of them were female, and 90.3% of them were Saudi nationals. Warfarin was the most widely used anticoagulant (70%), followed by rivaroxaban (15.7%). Compared to physicians, pharmacists demonstrated very strong documentation (54% vs. 18%). The examination of the variables considered in the study revealed that physicians had significantly less drug-drug interaction documentation (17 vs. 71 times) or drug-food interaction documentation (23 vs. 71 times) than pharmacists. In terms of follow-up frequency, pharmacists were found to adhere to the clinic protocol (150 times) more frequently than physicians (104 times). However, there was no significant difference in therapeutic plan documentation between the two groups. (p = 0.416).

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Conclusion: Pharmacists were more comprehensive in their documentation than physicians in anticoagulation clinics. Unified clinic documentation can ensure consistent documentation within EHRs across all disciplines.

1. Introduction

The health of a nation can be greatly enhanced, and its citizens better served by the services provided by healthcare facilities. Data should be collected, organized, and made available to hospital administrators and decision-makers at appropriate times after being monitored, classified, and inferred (Sharifi et al., 2021). The medical record serves as a repository where patients' information about their clinical status, diagnosis, and physician's visit details is documented. It facilitates healthcare providers' communication to ensure optimal patient care. Moreover, this information is utilized for research, audits, legal, and quality improvement projects (Wood, 2001). High-quality documentation in the medical field is essential to providing safe patient care, as it is one of the five rights (Wood, 2001). In the event of a medicolegal dispute, the doctor can also rely heavily on their medical records as evidence (Ridyard and Street, 2015). Many studies reported that outpatient documentation in medical records underestimates the actual indicators of the quality of care, such as medication history, allergy information, and smoking status (Dresselhaus et al., 2000; Luck et al., 2000; Peabody et al., 2000; Soto et al., 2002). Over the past years, many quality initiatives have been introduced to improve clinical documentation; however, performing good clinical documentation is still an issue in the health profession (Cowan et al., 2000).

Within the medication use system, Grainger-Rousseau and colleagues have proposed eight fundamental elements that must be included to provide safe and effective medication therapy. The list includes timely recognition of drug interaction and therapy problems, accessibility to safe and effective products, prescribing for definite objectives, providing tailored patient counselling upon dispensing medications, active patient/carer cooperation, drug therapy problem detection and resolution, documentation and decision communication, and performance evaluation. Documentation and communication were the seventh elements that should be fulfilled to reduce the risk of experiencing a medication-related problem (Grainger-Rousseau et al., 1997).

Mortality reduction is one of the indicators used to assess the excellence of medical services. Medical errors were the third leading cause of death in the United States after cardiovascular disease and cancer, highlighting this problem's burden (Makary and Daniel, 2016). It has been defined as an act of omission or commission in planning or execution that contributes to or could contribute to an unintended result that can cause patient harm (Grober and Bohnen, 2005). This might be related to many factors, such as healthcare products, procedures, systems, or personal practise. Also, it may happen at any stage during prescribing; order communication, product labelling, packaging, compounding; dispensing; distribution, administration, education, or monitoring (Rita and Deborah, 2015).

Studies have revealed that incomplete patient information and illegible handwriting are among the reasons for medical errors. Technology provides solutions to many of these issues; however, clinicians' efforts in documentation are still needed (Edwards and Moczygemba, 2004). A *meta*-analysis conducted to assess the impact of electronic health records on healthcare quality found that implementing electronic health records can decrease medication errors and notably enhance patient care quality (Campanella et al., 2016).

As a result, many hospitals established electronic health records to improve their care and achieve the best patient safety outcomes. However, many clinicians found it challenging to balance documentation and patient care, making them feel rushed when interacting with patients as they were overwhelmed by their documentation tasks (Momenipur and Pennathur, 2019; Christino et al., 2013).

The collaborative efforts of the healthcare team are required to manage the ever-increasing burden of chronic diseases. The role of pharmacists in the clinical setting has evolved in recent times, and they are now included in managing several clinics in the hospital to improve patients' adherence to medications (Francis and Abraham, 2014). Pharmacists' collaborative practice agreements with physicians have enhanced therapeutic outcomes and patient care (McDonough, 2001). Worldwide, there are many promising experiences with collaborative practice agreements like medication therapy management or specialty clinics such as solid organ transplant, heart failure, diabetes mellitus, anticoagulation, asthma or chronic obstructive pulmonary disease, psychiatry, human immunodeficiency virus, and hepatitis C virus clinics (Jun 2017). The pharmacists' role in collaborative practice agreements usually includes therapy initiation, modification, and discontinuation based on an agreement with the provider (Centers for Disease Control and Prevention, 2017).

Anticoagulation clinics are one of the successful methods described in the literature. The majority of published research reported that anticoagulation services handled by pharmacists had better International Normalised Ration (INR) management and fewer anticoagulation-related problems than standard care (Lalonde et al., 2008; Bungard et al., 2009; Young et al., 2011). A study conducted in Saudi Arabia to evaluate differences in anticoagulation control of warfarin using time in the therapeutic range showed that pharmacist-led clinics had significantly greater time in the therapeutic range levels than those followed in the physician-led clinic (Alghadeeer et al., 2020).

To our knowledge, no study was conducted to assess the quality of documentation in anticoagulation clinics in Saudi Arabia. For that, this study aimed to evaluate the quality of medical documentation in anticoagulation clinics and investigate the differences between pharmacist-led and physician-led clinic notes.

2. Materials and methods

2.1. Study design and population

This was a retrospective cross-sectional study in which the data was extracted from electronic health records of a governmental tertiary care teaching super specialty facility, King Khalid University Hospital, Riyadh, Saudi Arabia. More than 1.2 million outpatients and about 46,000 inpatients are treated in the hospital each year. The anticoagulant clinics run three times a week, and about 90 patients visit the clinic each week. The clinics are part of the ambulatory care services provided in the hospital. All the patients who received anticoagulation and were followed from October to December 2020 were included. Patients were followed in two anticoagulation clinics, one run by clinical pharmacists and the other by physicians, and data from both clinics was included. Only the first visits of the patients were included. The patients

were randomly assigned to each clinic, regardless of their underlying disease or the anticoagulant they were using. Those who did not have documentation or did not show up were excluded.

2.2. Data source and data extraction

The current study used data retrieved from a tertiary teaching hospital's electronic health records database. Patient-related data were collected confidentially and in compliance with the Declaration of Helsinki. The institutional review board of King Saud University granted approval to conduct this study (Ref. No. 20/0058/IRB, dated 17/09/2020). The informed consent was waived off due to the retrospective nature of the study. The health records were assessed and reviewed by two interns under the supervision of academic faculty. The two interns reviewed the health records together to minimize the discrepancy between the evaluations. This process took about three months. Demographic data, including patient gender, age, nationality of the patients, anticoagulation medications, reasons for visits (indications), and the health care provider's gender, were collected. The comparison between documentation was based on writing a comprehensive note including the following elements: diagnosis, name of the anticoagulation medication used by the patient, therapeutic plan, relevant lab results, next follow-up appointment, drug or diet interactions with anticoagulation medications, and assessing the adverse effects. A score from 0 to 10 was used to evaluate the documentation.

The variables used for assessing the quality of the note were as follows:

- Documenting the clinic visit reason (1 point)
- Document the name of the anticoagulant used with dose and frequency, i.e., Warfarin, Rivaroxaban, Apixaban, Enoxaparin, and Dabigatran (1 point).
- Documenting the therapeutic plan (dose adjustment, discontinuation, switching, or continuing the same plan) (1 point)
- Documenting the patient's related lab results (e.g., INR in the case of warfarin) (1 point)
- Documenting the next follow-up appointment due (1 point)
- Documenting the appropriateness of the follow-up frequency following the clinic protocol (1 point)
- Documenting the assessment of possible interactions with diet and medications (2 points)
- Documenting the assessment of any adverse events, i.e., bleeding and thrombosis (2 points).

The documentation evaluation is presented as a percentage. Those with 80%-100% were rated as very good, 60%-79% as good, 40%-59% as average, 20%-39% as poor, and 0%-19% as very poor. The scale was developed by academic faculty based on clinical protocols and reviewed by volunteer experts consisting of physicians and ambulatory care clinical pharmacists.

2.3. Statistical analysis

Descriptive analyses were conducted, and the results were presented as frequencies and percentages. Student's *t*-test, chi-square, and Fisher exact were used as appropriate. The significance level was set at $P < 0.05$. All the statistical analyses were performed using Stata/SE 13.1.

3. Results

After reviewing 469 patients' records from October to December 2020, a total of 331 patients were included. The data for 138 of the 469 patients were eliminated because they lacked crucial information such as the medical record number, patient gender, name of the specific anticoagulant used, and indication for anticoagulant usage. The pharmacist-led clinic followed 171 (51.6%) of the patients, while 160 (48.3%) were followed by the physician-led clinic. The mean patients' age was 54 ± 15 years. Around two-thirds of the patients (60.73%) were female, and (90.3%) of them were Saudi nationals. Of the 171 patients who were seen by a pharmacist, a total of 29 patients were seen by a male pharmacist, and 142 patients were seen by a female pharmacist. Of the 160 patients who were seen by physicians, a total of 95 patients were seen by male physicians, and 65 patients were seen by female physicians. Regarding the agents used, the most used anticoagulant was warfarin (70%), followed by rivaroxaban (15.7%), and the most reported indication was valve replacement (37.5%), followed by venous thromboembolism (25.07%) and atrial fibrillation (17.52%). Demographic data are presented in Table 1.

The result revealed a significant difference in documentation between pharmacists and physicians ($p < 0.001$) (Table 2). Pharmacists did (54%) of very good documentation compared to (18%) done by physicians. Only (2%) of documentation done by pharmacists was found to be very poor compared to (8%) of documentation in physician-led clinics.

Table 1
Demographic characteristics of the participants.

Variables	Pharmacist-Led Clinic* n = 171	Physician-Led Clinic* n = 160
Patients gender, n (%)		
Male	64 (37%)	66 (41%)
Female	107 (63%)	94 (59%)
Patients age in years, mean ± S.D.	53.4 ± 14	54.2 ± 15
Patients Nationality, n (%)		
Saudi	159 (93%)	140 (88%)
None- Saudi	12 (7%)	20 (13%)
Anticoagulation used, n (%)		
Warfarin	129 (75%)	103 (64%)
Rivaroxaban	31 (18%)	21 (13%)
Enoxaparin	4 (2%)	1 (0.6%)
Dabigatran	1 (0.6%)	0
Apixaban	1 (0.6%)	8 (5%)
Bridging therapy	2 (1%)	1 (0.6%)
(Warfarin + Enoxaparin)	3 (1.8%)	26 (16%)
Not documented		
Indication, n (%)		
Atrial fibrillation (A.F.)	33 (19%)	25 (16%)
Venous thromboembolism (VTE)	47 (27%)	36 (23%)
Antiphospholipid syndrome (APS)	7 (4%)	5 (3%)
Valve replacement	71 (42%)	53 (33%)
Multiple indications	2 (1%)	2 (1%)
for anticoagulation therapy	11 (6%)	39 (24%)
Not documented		
Provider gender, n (%)		
Male	29 (17%)	95 (59%)
Female	142 (83%)	65 (41%)

*Data is expressed as frequency (percentage).

Table 2
Assessment rating on documentation.

Assessment rating	Pharmacist-Led clinic n = 171*	Physician-Led clinic n = 160*
Very good	93 (54%)	28 (18%)
Good	48 (28%)	46 (29%)
Average	22 (13%)	46 (29%)
Poor	5 (3%)	27 (17%)
Very poor	3 (2%)	13 (8%)

*Data is expressed as frequency (percentage).

Table 3
Documentation Sub-analysis of cohorts.

Variables	Pharmacists n = 171	Physicians n = 160	P-value
Medication documentation			< 0.001
Yes	167 (98%)	134 (84%)	
No	4 (2%)	26 (16%)	
Purpose of visit documentation			< 0.001
Yes	161 (94%)	123 (77%)	
No	10 (6%)	37 (23%)	
Therapeutic plan documentation			0.416
Yes	161 (94%)	147 (92%)	
No	10 (6%)	13 (8%)	
Follow-up documentation.			< 0.001
Yes	156 (91%)	123 (77%)	
No	15 (9%)	37 (23%)	
Follow-up frequency (following the clinic protocol)			< 0.001
Yes	150 (88%)	104 (65%)	
No	21 (12%)	56 (35%)	
Bleeding risk assessment documentation			< 0.0001
Yes	119 (70%)	42 (26%)	
No	52 (30%)	118 (74%)	
Thrombosis risk assessment documentation			< 0.0001
Yes	114 (67%)	39 (24%)	
No	57 (33%)	121 (76%)	
Drug-drug Interaction assessment documentation			< 0.0001
Yes	71 (42%)	17 (11%)	
No	100 (58%)	143 (89%)	
Drug-Food Interaction assessment documentation			< 0.0001
Yes	71 (42%)	23 (14%)	
No	100 (58%)	137 (86%)	

Sub-analysis results showed that physicians were found to have lower drug-drug interactions documentation (17 times) or drug-food interactions documentation (23 times) compared to pharmacists (Table 3). Regarding follow-up frequency, pharmacists were found to follow the clinic protocol (150 times) more than physicians (104 times). There was a statistically significant difference in most of the variables ($p < 0.001$) except in therapeutic plan documentation, where there was no significant ($p = 0.416$) difference between physician and pharmacist groups.

4. Discussion

A concept that has been widely held belief among healthcare providers and hospital administrators over the years is that "if you have not written it, you have not done it" (Morrissey-Ross, 1988). Therefore, more time has been spent on documentation, leaving clinicians burdened to balance documentation tasks and patient care (Momenipur and Penn, 2019).

In the current study, more than half of the physicians' documentation quality ranges from average to very poor. It is known that the anticoagulation clinic holds one of the highest loads in the hospital, which may impose a time constraint on them to perform high-quality documentation. Moreover, those who handle the documentation tasks are usually junior residents, which may make it overwhelming to cope with the clinic load. Previous studies reported that healthcare workers' time allocated for documentation tasks equals half of their working hours, which is considered high and may interfere with their clinical duties (Christino et al., 2013; Oxentenko et al., 2010).

The quality of pharmacists' documentation is a product of their training and shows their understanding of their roles and duties in the healthcare team. Documenting interventions and patient interaction is a professional obligation included in the standard of pharmacy practice to ensure safe and effective patient care (Hammond et al., 2003; Adam et al., 2019). In our study, pharmacists' documentation in the anticoagulation clinics was more inclusive than physicians, which can have several explanations. Since undergraduate years and even postgraduate programs such as residency, documentation represents a big part of the candidates' training curriculum using different documenting systems. Also, documentation is an integral element of all candidates' evaluations during their rotations, and their preceptors frequently review their documentation and provide feedback (MacKinnon et al., 2007). Another factor is that in many hospitals, clinical pharmacists are in the establishing phase of their ambulatory care services. Documentation of their interventions and patient interaction will show their contribution and value as an essential and integral part of the healthcare team (Divall et al., 2010). Furthermore, the present study was conducted in a teaching hospital where several studies showed that pharmacy students and residents' contributions, including documentation, positively impacted patient care (King et al., 2007; Taylor et al., 2000; Andrus et al., 2016).

Pharmacists were found to document drug-drug interactions and drug-food interactions more frequently than physicians. Our findings are in accordance with an earlier report, which found that the combination of the self-evaluation instrument and training, note quality, and readability have been steadily rising among pharmacy professionals (Zimmer et al., 2019). Such information is fundamental in managing anticoagulation therapy since most of the patients seen in these clinics are warfarin users. The scope of specialty might play a role in this as most pharmacists' responsibilities are medication-related, which mandates checking interactions more frequently. That was supported by a study conducted to assess pharmacists' competency in documentation, a total of 115 pharmacist notes. The study found that pharmacist notes were concise and clear and had a diplomatic tone and the most frequent note types were drug-related problems (43%), pharmacokinetics (22%), and patient education (17%) (Baranski et al., 2017). Furthermore, a study conducted in community anticoagulation clinics reported that pharmacists have excellent communication and interpersonal skills, allowing them to gather more information and lead to comprehensive documentation (Ingram et al., 2018).

Regarding therapeutic plan documentation, there was no difference between physicians and pharmacists. That was expected as clinicians considered the assessment and plan sections to be the most important and the first thing they would read among all progress note sections (Koopman et al., 2015). That was supported by a study that used eye-tracking data to determine what information clinicians focused on while reviewing electronic progress notes. They found that clinicians spent most of their time reading the Assessment and Plan section (Brown et al., 2014). Moreover, another study was conducted among thirteen outpatient clinics to evaluate clinician satisfaction after adopting Assessment, Plan, Subjective, and Objective (APSO) notes instead of the standard order Subjective, Objective, Assessment, and Plan (SOAP). The study found that clinicians largely favored the APSO notes (Lin et al., 2013). Collectively, these findings justify the clinicians' commitment to documenting these parts.

Pharmacists were found to follow the anticoagulation clinic protocol in terms of follow-up visit frequency more than physicians. That may be due to the collaborative practice agreements that control the pharmacists' practice in ambulatory care settings. That was consistent with previous studies that found clinical pharmacists' practices in the anticoagulation clinic are according to an established protocol, while physicians are generally influenced by their experience and clinical judgment (Young et al., 2011; Dib et al., 2014).

Developing a clinic-specific note template that includes all the elements needed to be assessed at each visit may help standardize the practice to achieve better patient outcomes and prevent possible medical errors. However, previous studies that evaluated the utilization of unified note templates reported mixed impacts on some parts of the notes without affecting the overall quality (Neri et al., 2014; Edwards et al., 2014). A randomized clinical trial was conducted to test the effect of outpatient note templates on note quality compared to standard notes. They reported that both note types were equivalent in overall quality, which might be due to the exclusion of nearly all auto-imported information on the new template mandating residents to enter the data manually, which may affect the overall quality of the notes (Epstein et al., 2021). Establishing a project plan to develop and test templates and conduct frequent audits may result in an efficient template that may increase documentation quality. Moreover, the quality of documentation should be assigned and addressed by the quality assurance department in the hospital to explore the reasons behind poor documentation and design improvement programs, including workshops on high-quality documentation. Another suggestion to improve documentation is to mandate the clinician to have specific training in patient safety as part of continuing education for the health care providers.

There are some limitations to the current study. It presents a snapshot of the documentation quality for a three-month period which may affect the assessment as we may not be able to capture the whole population due to scheduling. Moreover, it is a single-center study in a tertiary academic hospital which may affect the generalizability. Lastly, due to the nature of this study (retrospective design), it was not possible to know the years of experience of the clinicians who ran the clinics. However, the clinics are not allowed to run the clinics unless they finish at least 2 years of residency. To our knowledge, this is the first study to evaluate the documentation quality in ambulatory-care settings in Saudi Arabia. Conducting such studies in different clinics would help to capture the differences between clinicians and develop a unified inclusive documentation template tailored to each clinic.

5. Conclusions

Documentation is a vital component in the healthcare field. Pharmacists were more comprehensive in their documentation compared to physicians in anticoagulation clinics. Unified documentation may improve the quality of reporting and patient care.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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