

Formulation of a Written Counseling Resource for COVID-19 Patients Undergoing Subcutaneous Anticoagulant Treatment

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ABSTRACT

There is no written advice tool for the use of subcutaneous anticoagulants in patients with COVID-19, so this study aimed to develop and validate one. A prospective cohort study was conducted with patients and expert panels, and hospital chemists used the content validity index (I-CVI), scale-level-CVI (S-CVI), and universal acceptance (UA) to validate the tool. The item acceptance index (IAI) and universal acceptance (UA) were used to assess the patients' face validity. The mean age of hospital chemists ($n = 26$) was 35.82.9 years, and the majority were Chinese ($n = 20$, 76.9%) and female ($n = 18$, 69.2%). Hospital chemists evaluated every item pertinently ($n = 18$, 100%), with I-CVIs ranging from 0.96 to 1.00. I-CVI average, or the average proportion of items (sum of I-CVI/number of items: 17.88/18) was 0.99. High content validity was demonstrated with the reported S-CVI/UA (sum of UA/no. of items: 15/18) being 0.83 and S-CVI/Average (sum of I-CVI/no. of items: 17.88/18) being 0.99. The mean age of the 28 patients who participated in the face validation of the construct was 38.0 ± 9.8 years, with the majority being female ($n = 19$, 67.9%), Malay ($n = 46.4\%$), and tertiary educated ($n = 20$, 71.4%). All items were marked as relevant ($n = 18$, 100%), with the IAI ranging from 0.93 to 1.00, indicating that patients accepted each construct item; the average proportion of items was reported as 0.99 (sum of IAI/no. of items: 17.82/18), indicating excellent acceptance and content comprehension among patients. The counselling tool that was developed is suitable for anticoagulant education among COVID-19 patients.

Keywords: Counseling tool, Validation, Medication education, Anticoagulants, COVID-19 patients

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Introduction

The SARS-CoV-2 virus, which causes COVID-19, spread quickly around the world and sparked a pandemic in 2019 [1]. During this period, 27.3 million COVID-19 cases were documented globally, with 900,000 deaths [2]. Fever, headache, sore throat, cough, dyspnoea, generalised weakness, and impaired mental status were among the symptoms observed in COVID-19 patients [3]. Furthermore, thrombus development has been documented to cause serious problems in COVID-19 patients [3].

Deep vein thrombosis (DVT) and pulmonary embolism (PE) are typically involved in thromboembolism [4]. Globally, the incidence of PE is typically 23 to 107 per 100,000 people, but the incidence of DVT is reported to be 60 to 100 per 100,000 people [4]. Endothelial dysfunction, coagulation pathway activation, and increased D-dimers increase the risk of DVT and PE in individuals with COVID-19 [5]. According to reports, people with COVID-19 are more likely to experience thromboembolism due to increased inflammation, platelet activation, and endothelial dysfunction that causes stasis during infection [5]. 24% of the 137 patients in a research with a confirmed diagnosis of COVID-19 had PE, and half of those patients ended up in the intensive care unit (ICU) due to clinical deterioration that manifested at the time of hospitalisation [6]. DVT was observed in 4% of infected

COVID-19 patients in the medical ward and 13% of patients in the intensive care unit [7]. Both DVT and PE had pooled incidence rates of 14.8% and 16.5%, respectively, according to a meta-analysis of 27 studies comprising 3342 infected COVID-19 patients [8]. Sadly, in COVID-19 patients, thromboembolism is strongly linked to substantial morbidity and mortality [3, 9].

Clinical evidence has demonstrated the critical impact anticoagulation treatment plays in thromboembolism during infection, making it essential for COVID-19 patients. It shows beneficial effects on survival and lowers the mortality rate and danger of thrombus development [3, 10]. Given the increased risk of bleeding, anticoagulant therapy may not be advised for high-risk patients with uncontrolled high blood pressure, kidney or liver disease, heavy alcohol consumption, or concurrent use of specific medications like non-steroidal anti-inflammatory drugs (NSAIDs) [3]. Therefore, in addition to reducing the possibility of medication confusion, appropriate education regarding anticoagulants is necessary to enhance comprehension and treatment results in infected hospitalised COVID-19 patients [11, 12]. However, infected hospitalised COVID-19 patients in Malaysia do not have access to adequate counselling resources about the administration of anticoagulants.

Counselling tools have been created to encourage medication education to maximise therapy and reduce undesirable side effects with anticoagulants [13–15]. However, COVID-19 patients' concerns that are confused with the requirement for anticoagulants for other conditions cannot be adequately addressed by the current counselling guidelines on anticoagulant use [14, 16]. Therefore, to address problems among COVID-19 patients who are prescribed anticoagulants, the right tools are needed. Although a more specialised tool for COVID-19 patients is required, chemists are now required to counsel patients using generic anticoagulant instruments.

There is no written advice tool for the use of subcutaneous anticoagulants in patients with COVID-19, so this study aimed to develop and validate one.

Materials and Methods

Study Type and Design

To develop COVID-19 subcutaneous anticoagulants with written counselling aids, a group of professionals from clinical, anticoagulant, and infectious disease chemists participated in this prospective cohort study. The created counselling tool's content was then verified by patients and hospital chemists, respectively. Registered, active hospital pharmacists were among the pharmacists who participated in the content validation. Incomplete questionnaires were not included. Adult patients who were at least eighteen years old were included in the content validation. Additionally, patients' incomplete surveys were not included. The validated written counselling tool was then used to create the infographic counselling tool.

Sample Size

A total of 20-30 pharmacists and patients, respectively, were included in the study. This is sufficient for a validation study [15, 17].

Development of the Counseling Tool

Six professionals with backgrounds in clinical, anticoagulant, and infectious disease pharmacy made up the expert committee. Based on earlier anticoagulant counselling tools, the committee helped determine the items in the COVID-19 subcutaneous anticoagulant counselling tool were relevant [14–16, 18]. As a result, according to national and international guidelines, the written counselling tool on the use of subcutaneous anticoagulants during COVID-19 covered information on COVID-19 and its thromboembolic complications, medication indication, dosage, frequency, drug-drug/-food interactions, and side effects [14–16]. The tool was validated after everyone had given their approval.

Validation of the Counseling Tool

The content validity index (CVI), a metric for the relevance and representativeness of the intended goal, was used to evaluate every component of the counselling tools that were developed [19]. In addition to recognising vague and deceptive phrases, the construct's features cover every facet of the tool that may influence how well patients and chemists comprehend drug education, such as sentence clarity and phrasing simplification [15, 17].

Twenty hospital chemists with diverse backgrounds evaluated each item of the developed instrument to ensure its content was legitimate [15, 20]. To evaluate the content's clarity, agreement, and relevance, as well as to allow

hospital chemists and patients to voice their opinions due to its comprehensiveness and reliability, content validation was carried out using a 5-point Likert scale for each item, ranging from strongly disagree-1 to strongly agree-5 [21]. A neutral middle point (3), or a disagreement with the item (strongly disagree = 1, disagree = 2), would be removed. If an item received an agreement rating (agree=4, strongly agree=5), it was deemed acceptable. The written instrument's items were evaluated for content relevancy and intelligibility [15, 20]. The draft's contents were then revised in light of the comments obtained [15].

To confirm that each item in the created tool was accepted, a total of 20 patients who could read on their own were enlisted, with an emphasis on the content's relevancy and intelligibility [15, 20]. Following the distribution of the built tool, patients were asked to complete a questionnaire designed to gauge their level of acceptance of each construct tool item. Each item on the questionnaire has two possible answers: "Yes" or "No." "Yes = 1" and "No = 0" would be on a dichotomous scale. If the percentage of patients who answered "Yes" was equal to 80% (0.8) or more, the item would be considered accepted [19]. In the meantime, if more than 20% (0.2) of patients felt that an item lacked clarity, it would be eliminated.

Data Analysis

To confirm the degree of agreement among assessors about the sufficiency of the evaluated items, the content validity index (CVI), the item-CVI (I-CVI), and the scale-level-CVI (S-CVI) were computed as the sum of the relative frequencies [17, 20]. The fewer adjustments needed for improvement, the higher the CVI score [17, 20]. Regarding the item's appropriateness in terms of content clarity and relevance, an I-CVI of 0.8 or above was deemed indicative [17, 20]. The number of experts who rate each item's relevancy as agree = 4 or strongly agree = 5 is divided by the total number of experts to get the I-CVI [22].

The two primary scales that make up S-CVI are S-CVI/Ave and S-CVI/UA. The calculation of S-CVI/Ave involves dividing the total number of items by the sum of the I-CVIs, which is determined by summing all items having an I-CVI of 1 [22]. Excellent content validity is indicated by an S-CVI/Ave > 0.9 and an S-CVI/UA ≥ 0.8 [22].

A total dichotomous score of "Yes = 1" or "No = 0" derived from patient replies was used to gauge patients' acceptance based on clarity and relevance. To assess the degree of acceptance of the material, these were then assessed using the item acceptance index and universal acceptance, which were calculated as the sum of the relative frequencies [23]. The total number of patients is then divided by the sum of the correct responses, "Yes = 1," for each item to calculate the item acceptance index [23]. Because the information was clear and pertinent to the tool created, an item was considered accepted by patients if its item acceptance index was 0.8 or higher [24]. The item acceptance index average is calculated by dividing the total number of items by the sum of the item acceptance index scores. Good content understanding and patient acceptability for use are indicated by an average item acceptability index score of ≥ 0.9. When the item acceptance index is equal to 0.8 or higher, an item is considered universally accepted if it receives a score of 1 [24].

Results and Discussion

The demographic details of hospital chemists and patients involved in the validation of the written COVID-19 anticoagulant counselling tool are shown in Table 1. The study comprised 28 patients and 26 hospital chemists in total. The hospital chemists were mostly Chinese (n = 20, 76.9%) and female (n = 18, 69.2%), with an average age of 35.82.9 years. Every hospital chemist (n = 26, 100%) had a degree and three to thirteen years of experience in their line of work. Clinical pharmacy (n = 13, 50.0%) was the most common field in which hospital chemists worked, followed by anticoagulation (n = 8, 30.8%) and infectious disease (n = 5, 19.2%). Hospital chemists have been in practice for an average of 5.82.5 years. With an average age of 38.0 ± 9.8 years and a range of 22 to 70 years, the patients who participated in the face and content validation of the written counselling tool were primarily Malay (46.4%) and female (n = 19, 67.9%). In terms of education, university education is held by the majority of patients (n = 20, 71.4%).

Table 1. Demographic characteristics of hospital pharmacists (n = 26) and patients (n = 28)

Characteristics	Pharmacists (n = 26)	Patients (n = 28)
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Gender (n (%))		
Female	18 (69.2)	19 (67.9)
Male	8 (30.8)	9 (32.1)
Age (mean (SD))		
	35.8 (2.9)	38.0 (9.8)
Ethnicity (n (%))		
Malay	4 (15.4)	13 (46.4)
Chinese	20 (76.9)	11 (39.3)
Indian	2 (7.7)	3 (10.7)
Others (Sarawakian)	0 (0)	1 (3.6)
Education background (n (%))		
Primary	0 (0)	1 (3.6)
Secondary	0 (0)	7 (25)
Tertiary (diploma/ degree)	26 (100)	20 (71.4)
Practice field (n (%))		
Clinical	13 (50.0)	-
Anticoagulant	8 (30.8)	-
Infectious disease	5 (19.2)	-
Years in current practice (mean (SD))		
	5.8 (2.5)	-

Table 2 displays the I-CVI estimations for each item's relevance as determined by hospital chemists. According to hospital chemists, all products were deemed relevant ($n = 18$, 100%), with I-CVIs ranging from 0.96 to 1.00. The I-CVI average (sum of I-CVI/no. of items: $17.88/18$) was then used to determine the average percentage of items deemed relevant by 26 hospital chemists, which came out to be 0.99.

Next, the S-CVI, or total questionnaire relevancy, was computed. For hospital chemists, the S-CVI/UA (Sum of UA/no. of items: $15/18$) was 0.83. According to reports, the S-CVI/Average (sum of I-CVI/number of items: $17.88/18$) was 0.99. The UA approach exhibits good content validity overall. All of the items were deemed acceptable by the S-CVI and I-CVI averages.

Additionally, all items were rated as relevant by patients ($n = 18$, 100%) (**Table 2**), with 28 patients' acceptance of the tool's content indicating the total dichotomous scores of each item with a "Yes" response, ranging from 26 to 28. Every item in the created tool was deemed acceptable and suitable for patients, according to the total item acceptance index, which ranged from 0.93 to 1.00. The average item acceptance index value (sum of item acceptance index/no. of items: $17.82/18$) was also used to determine the average percentage of things regarded as accepted among 28 patients. The result was 0.99, showing high acceptance and content understanding among patients. As a result, every patient concurred that everything on the instrument was simple, pertinent to the goals, and simple to comprehend. In line with this, the universal acceptance approach shows that every item in the counselling tool is accepted.

Table 2. Expert agreement and patient acceptance scores of the COVID-19 subcutaneous anticoagulant written counseling tool among hospital pharmacists ($n = 26$) and patients ($n = 28$)

No	Information	Expert agreement			Patients acceptance		
		Agreement I-CVI UA			Score IAI UA “Yes”		
What is blood clotting in COVID-19?							
1	COVID-19 can cause blood to clot.	26	1	1	28	1	1
2	Blood clots can occur in COVID-19 when blood thickens and clumps together.	26	1	1	28	1	1
3	Blood clots usually form in the deep veins in the body (Examples: lower leg and thigh).	26	1	1	26	0.93	1
4	The blood clots can break off to form loose clots.	26	1	1	28	1	1
5	The loose clots will then travel through the bloodstream and cause the blockage of other veins in the body.	26	1	1	28	1	1
6	This will disrupt the blood flow in your body.	26	1	1	28	1	1
7	Medication can be given to prevent the formation of blood clots in the veins.	26	1	1	28	1	1
What is this medication used for in COVID-19?							

8	To prevent or treat blood clots due to COVID-19.	26	1	1	27	0.96	1
What is the dose of the medication?							
9	This medication is given as an injection dose daily for the duration of time set by the clinician.	25	0.96	0	28	1	1
10	The medication must be used at the same time every day. In the hospital, the nurse will help give the drug to you.	26	1	1	28	1	1
11	You may be discharged with oral anticoagulants if the clinician decides you need them.	26	1	1	26	0.93	1
More information will be given if this occurs.							
What are the side effects of the medication?							
12	To prevent adverse effects from interactions, please let us know if you are taking any vitamins, herbal remedies, or other prescriptions before we start the medication.	25	0.96	0	28	1	1
13	Using this drug may have adverse consequences, including bleeding.	25	0.96	0	28	1	1
14	Black stools, gum bleeding, excessive menstrual bleeding, bruising, and blood in or dark urine are all signs of bleeding.	26	1	1	28	1	1
15	Headache, lightheadedness, joint discomfort, stiffness, numbness, or tingling are other symptoms.	26	1	1	28	1	1
16	Some people may experience blood-filled oedema at the injection site.	26	1	1	28	1	1
17	If you have any bleeding or clotting signs, please let the doctor or chemist know.	26	1	1	28	1	1
What if I have any questions?							
18	Please inform us if you have any questions.	26	1	1	28	1	1

I-CVI = item-content validity index; UA = universal agreement; IAI = item acceptance index

Thromboembolism is one of the health issues that COVID-19 has produced, which emphasises the necessity of recommending subcutaneous anticoagulants to COVID-19 patients [11, 25–28]. To guarantee that patients comprehend their medications and take them as prescribed, counselling methods are frequently employed [29]. COVID-19 patients who receive education about prescribed subcutaneous anticoagulants are more likely to use them safely and experience fewer problems, which lessens the impact on an already overburdened healthcare system [30]. A counselling tool for COVID-19 patients using subcutaneous anticoagulants was validated in this trial. The written counselling tool that was created includes a special tool to help medical professionals inform COVID-19 patients about the usage of subcutaneous anticoagulants in COVID-19 illness. The pathophysiology of thromboembolism in COVID-19 disease, the indication for subcutaneous anticoagulants, dosage, frequency, drug-drug or drug-food interactions, side effects, self-monitoring of bleeding signs, and the management of side effects are all included in the current work, which complies with international recommendations and Malaysian guidelines [14, 16, 18]. The parameters used to create the current subcutaneous anticoagulant counselling tool are nearly the same as these established anticoagulant guidelines, except INR monitoring. Because hospitalised COVID-19 patients require frequent counselling on the administration of anticoagulants during and after the pandemic, the developed subcutaneous anticoagulant counselling tool is only appropriate for these patients. Experts in the domains of clinical, anticoagulant, and infectious diseases gave each component of the created counselling tool a high CVI. It has been suggested that a high CVI is necessary to guarantee a tool's validity [17]. Content validity assesses, quantitatively, how well the items relate to or depict a certain topic, in this case, the use of anticoagulants during COVID-19 [17]. The creation of counselling tools has undergone numerous iterations to guarantee that the currently established counselling tool was well-structured, properly stated, and included issues essential to COVID-19 patients who are prescribed subcutaneous anticoagulants.

The main therapeutic goal for patients receiving anticoagulant treatment continues to be educating and counselling them about their drugs [14, 16, 18]. Positive comments were given to the written counselling tool that is now being created to inform patients on the use of subcutaneous anticoagulants in the COVID-19 disease. Most patients agreed that every element of the created counselling tool was straightforward, relevant to the goals, and simple to understand. The results suggest that the counselling tool currently under development for the use of subcutaneous anticoagulants in COVID-19 disease may benefit patient care and clinical outcomes. The capacity to effectively provide written counselling materials for the use of subcutaneous anticoagulants in COVID-19 disease mostly

rests on the patients' understanding and acceptance, in addition to improved healthcare services [31]. Patients need an efficient way to make sure they are taking their medications as prescribed [25]. The results show that for patients to profit from the tool, it should be easy to understand [25]. Research has indicated that textual and visual counselling aids improved communication and satisfaction for both patients and clinicians among hospitalised adults and children [25]. Furthermore, visual aids or discharge tools promote understanding, boost the capacity for self-care, and enhance outcomes for patients after discharge [32].

Even though the study's goal was accomplished, it should be highlighted that it had certain limitations. The counselling tools were created for COVID-19 hospitalised patients, and it is crucial to stress that, even if specialists give a prepared counselling tool a favourable assessment, it still needs to be reviewed and enhanced regularly to make sure it remains applicable in the future [33]. Additionally, a convenient sample of experts was conducted, and a randomised approach can be used to improve validation in the future.

Conclusion

In addition to reducing medication errors and patient confusion, counselling tools, which chemists frequently utilise to educate patients about medications, are essential to attaining potentially substantial pharmacological advantages. Pharmacists were frequently asked to advise patients on the use of anticoagulants during COVID-19, but there was no particular instrument for this purpose. As a result, this counselling tool can be helpfully used in the clinical context to guarantee that patients receive sufficient medication education regarding the anticoagulants.

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Conflict of Interest: None

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Ethics Statement: The study protocol was approved by the Medical Research Ethics Committee, Malaysia (NMRR-21-1790-61304 (IIR)) and the Universiti Kebangsaan Malaysia Research Ethics Committee (JEP-2022-501). This study was conducted in compliance with the Declaration of Helsinki and the Malaysian Good Clinical Practice Guideline.

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