

# Development of Written Counseling Tool for Subcutaneous Anticoagulant Use in COVID-19 Patients

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## Abstract

There is a lack of subcutaneous anticoagulant counseling tools for COVID-19 patients. This study aims to develop and validate a written counseling tool for subcutaneous anticoagulant use in COVID-19 patients. A prospective cohort study was performed with expert panels and patients. The tool was validated by hospital pharmacists using Content Validity Index (I-CVI), Scale-level-CVI (S-CVI), and Universal Acceptance (UA). Face validation by patients was determined using Item Acceptance Index (IAI), and Universal Acceptance (UA). Hospital pharmacists (n=26) were mostly female (n=18, 69.2%) and Chinese (n=20, 76.9%), with a mean age of 35.8±2.9 years. All items were assessed relevantly (n=18, 100%), I-CVIs ranging from 0.96-1.00 by hospital pharmacists. The average proportion of items, I-CVI average, (Sum of I-CVI/no. of items: 17.88/18) was reported as 0.99. S-CVI/UA (Sum of UA/no. of items: 15/18) was reported as 0.83, and S-CVI/Average (Sum of I-CVI/no. of items: 17.88/18) was reported as 0.99 indicating high content validity. Patients (n=28) involved in face validation of the construct were mostly female (n=19, 67.9%), Malay (n=46.4%), and tertiary educated (n=20, 71.4%) with a mean age of 38.0±9.8 years. All items were marked as relevant (n=18, 100%), with IAI ranging from 0.93-1.00, suggesting patients accepted each item of the construct. 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 developed counseling tool is acceptable for anticoagulant education among COVID-19 patients.

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

## INTRODUCTION

COVID-19 is caused by the SARS-CoV-2 virus that rapidly spread around the world causing a pandemic in 2019 [1]. During this time, a total of 900,000 deaths out of 27.3 million COVID-19 cases worldwide were reported [2]. Patients that were affected by COVID-19 were noted to show various symptoms including fever, generalized weakness, headache, sore throat, cough, dyspnea, and altered mental status [3]. In addition to this, thrombus formation has also been reported among COVID-19 patients causing severe complications [3].

Thromboembolism generally involves deep vein thrombosis (DVT) and pulmonary embolism (PE) [4]. The incidence of DVT is reported to be 60 to 100 per 100,000 people worldwide while the incidence of PE is generally 23 to 107 per 100,000 people worldwide [4]. In patients with COVID-19, the risks of DVT and PE are higher due to endothelial dysfunction, activation of the coagulation pathway, and elevated D-dimers [5]. It has been reported that COVID-19 patients are predisposed to thromboembolism given excessive inflammation, activation of platelets, and dysfunction of endothelial leading to stasis during infection [5]. A study involving 137 patients with a confirmed diagnosis of COVID-19 reported PE in 24% of the patients and 50% of the PE patients ended up in the intensive care unit (ICU) given presenting clinical deterioration during hospital

admission [6]. DVT was reported in 13% of infected COVID-19 patients in the ICU and 4% in the medical ward [7]. A meta-analysis of 27 studies involving 3342 infected COVID-19 patients found both DVT and PE in pooled incidence rates of 14.8% and 16.5% respectively [8]. Unfortunately, thromboembolism is highly associated with significant morbidity and mortality in COVID-19 patients [3, 9].

Anticoagulation therapy is vital in COVID-19 patients and is clinically proven to play a key role in thromboembolism during infection. It reduces the risk of thrombus formation and mortality rate, as well as indicates positive impacts on survival [3, 10]. However, high-risk patients with

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uncontrolled high blood pressure, kidney or liver disease, consuming a large amount of alcohol, or concurrent use of certain medications such as non-steroidal anti-inflammatory drugs (NSAIDs) may not be recommended for anticoagulant therapy given the increased risk of bleeding [3]. Hence, proper education on anticoagulants is required to improve understanding and therapeutic outcomes in infected hospitalized COVID-19 patients apart from minimizing potential medication confusion [11, 12]. However, there is a lack of counseling tools on the administration of anticoagulants available for infected hospitalized COVID-19 patients in Malaysia.

To optimize therapy and minimize unwanted side effects with anticoagulants, counseling tools have been developed to promote medication education [13-15]. The existing counseling guidelines on anticoagulant use, however, are not sufficient to address COVID-19 patients' concerns that are confused with the need for anticoagulants for other diseases [14, 16]. Thus, appropriate tools are required to address concerns among COVID-19 patients prescribed anticoagulants. At present, pharmacists are required to counsel patients using general anticoagulant tools although a more specific tool for COVID-19 patients is necessary.

## MATERIALS AND METHODS

### *Study Type and Design*

This was a prospective cohort study involving an expert committee consisting of experts from clinical, anticoagulant, and infectious disease pharmacists in the development of COVID-19 subcutaneous anticoagulants with written counseling tools. The content of the constructed counseling tool was then validated by hospital pharmacists, as well as by patients respectively. Pharmacists included in the content validation were those that were registered, practicing hospital pharmacists. Incomplete questionnaires were excluded. Patients included in the content validation were adults 18 years and above. Incomplete questionnaires from patients were also excluded. The infographic counseling tool was then generated from the validated written counseling 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*

The expert committee consisted of six experts with credentials in clinical, anticoagulant, and infectious disease pharmacy. The committee was involved in determining the relevance of items in the COVID-19 subcutaneous anticoagulant counseling tool based on previous anticoagulant counseling tools [14-16, 18]. Therefore, the written counseling tool on subcutaneous anticoagulant use during COVID-19 included the knowledge of COVID-19 disease and its thromboembolic complication, medication

indication, dose, frequency, drug-drug/-food interactions, and side effects based on local and international guidelines [14-16]. Once the items were collectively approved the tool was validated.

### *Validation of the Counseling Tool*

All aspects of the constructed counseling tools were assessed using Content Validity Index (CVI) as a measurement for the relevance and representative of the targeted purpose [19]. The elements of construct involve all aspects of the instrument which can affect the understanding of medication education among pharmacists and patients such as clarity of the sentences and wording simplification, apart from identifying ambiguous and misleading terms [15, 17].

Each item of the developed instrument was assessed for content validation by 20 hospital pharmacists from various backgrounds [15, 20]. Content validation was performed based on a 5-point Likert scale ranging from strongly disagree-1 to strongly agree-5 for each item to assess clarity, agreement, and relevance of the content, as well as to enable hospital pharmacists and patients to express their views given its comprehensiveness and reliability [21]. A disagreement with the item (Strongly Disagree-1, Disagree-2) or an item with a neutral middle point-3 would be eliminated. An item was considered acceptable if there was an agreement rating (Agree-4, Strongly Agree-5). Each item in the developed written instrument was also assessed for clarity & relevance of content [15, 20]. Items in the draft were then reworded based on the feedback received [15].

A total of 20 patients with the ability to read independently were recruited to validate acceptance of each item in the developed tool, focusing on the clarity and relevance of the content [15, 20]. Patients were provided with the developed tool and were subsequently required to answer the questionnaire that was intended to measure the ability of patients to accept each item of the construct tool. The questionnaire consists of two choices for each item, either "Yes" or "No". A dichotomous scale would be applied for "Yes=1" and "No=0". Acceptance of an item would be applicable if the number of patients that replied with a "Yes" answer was equivalent to 80% (0.8) and above [19]. Meanwhile, an item would be abolished if more than 20% (0.2) of patients did not feel that the item had clarity.

### *Data Analysis*

Content Validity Index (CVI), the Item-CVI (I-CVI), and the Scale-level-CVI (S-CVI) were calculated as the sum of the relative frequencies to verify the level of agreement among assessors regarding the adequacy of the evaluated items [17, 20]. The higher the CVI value, the smaller the number of changes required for improvement [17, 20]. An I-CVI greater than or equal to 0.8 was considered indicative of the suitability of the item with respect to the clarity and relevance of content [17, 20]. An I-CVI is computed as the number of experts giving a rating of Agree-4 or Strongly Agree-5 to the

relevancy of each item, divided by the total number of experts [22].

S-CVI comprises two main scales; S-CVI/Ave and S-CVI/UA. S-CVI/Ave is calculated by taking the sum of the I-CVIs divided by the total number of items, calculated by adding all items with I-CVI equal to 1 divided by the total number of items [22]. An S-CVI/Ave  $\geq 0.9$  and S-CVI/UA  $\geq 0.8$  have excellent content validity [22].

Acceptance of patients was measured through clarity and relevance using a total dichotomous score of “Yes=1” or “No=0” from patient responses. These were then calculated using the Item Acceptance Index and Universal Acceptance, which were computed as the sum of the relative frequencies to evaluate the level of acceptance of the content [23]. The Item Acceptance Index is then determined by dividing the sum of appropriate answers, “Yes=1” for each item by the total number of patients [23]. An Item Acceptance Index of 0.8 or above was regarded as indicating that the item was accepted by patients as the content had clarity and was relevant to the tool developed [24].

The average of the Item Acceptance Index refers to the sum of the Item Acceptance Index divided by the total number of items. An average Item Acceptance Index value  $\geq 0.9$  indicates good content comprehension and acceptance for usage among patients. Universal Acceptance is defined as a method for acceptance of an item (scored as 1) if the Item Acceptance Index is equivalent to 0.8 or above [24].

## RESULTS AND DISCUSSION

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

Characteristics	Pharmacists N=26	Patients N=28
<b>Gender, n (%)</b>		
Female	18 (69.2)	19 (67.9)
Male	8 (30.8)	9 (32.1)
<b>Age, mean (SD)</b>	35.8 (2.9)	38.0 (9.8)
<b>Ethnicity, n (%)</b>		
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)
<b>Education background, n (%)</b>		
Primary	0 (0)	1 (3.6)
Secondary	0 (0)	7 (25)
Tertiary (Diploma/ Degree)	26 (100)	20 (71.4)
<b>Practice field, n (%)</b>		
Clinical	13 (50.0)	-
Anticoagulant	8 (30.8)	-
Infectious Disease	5 (19.2)	-
<b>Years in current practice, mean (SD)</b>	5.8 (2.5)	-

**Table 1** demonstrates the demographic characteristics of hospital pharmacists and patients in the validation of the written COVID-19 anticoagulant counseling tool. A total of 26 hospital pharmacists and 28 patients were included in the study. The mean age of the hospital pharmacists was 35.8±2.9 years, with the majority being female (n=18, 69.2%) and Chinese (n=20, 76.9%). All hospital pharmacists had a degree (n=26, 100%) with 3 to 13 years of working experience in their field. Hospital pharmacists were most frequently employed in clinical pharmacy (n=13, 50.0%), followed by anticoagulant (n=8, 30.8%) and infectious disease (n=5, 19.2%) areas. The mean of years in current practice among hospital pharmacists was 5.8±2.5 years.

The patients involved in face and content validation of the written counseling tool were mostly female (n=19, 67.9%) and Malay (n=46.4%), with an average age of 38.0±9.8 years ranging from 22 to 70 years old. In terms of education, the majority of patients (n=20, 71.4%) hold a tertiary education. The I-CVI calculations for the relevancy of each item as assessed by hospital pharmacists are shown in **Table 2**. All items were marked as relevant (n=18, 100%) with the I-CVIs ranging from 0.96-1.00 as assessed by hospital pharmacists. The average proportion of items judged as relevant across 26 hospital pharmacists was then calculated through the I-CVI average (Sum of I-CVI/no. of items: 17.88/18), reported as 0.99.

S-CVI or relevancy of the overall questionnaire was then calculated. The S-CVI/UA (Sum of UA/no. of items: 15/18) was reported as 0.83 for hospital pharmacists. The S-CVI/Average (Sum of I-CVI/no. of items: 17.88/18) was reported as 0.99. Overall, the UA method demonstrates high content validity. Based on the I-CVI average and S-CVI reports, all items were acceptable.

Similarly, all items were marked as relevant by patients (n=18, 100%) (**Table 2**), with total dichotomous scores of each item with a “Yes” response, ranging from 26-28, as assessed by 28 patients’ acceptance towards the content of the tool. The overall Item Acceptance Index ranged from 0.93-1.00 suggesting that each item of the developed tool was accepted and appropriate for patients.

The average proportion of items judged as accepted across 28 patients was also calculated through the average Item Acceptance Index value (Sum of Item Acceptance Index/no. of items: 17.82/18), reported as 0.99 indicating excellent acceptance and content comprehension among patients. Consequently, all of the patients agreed that each item of the tool was straightforward, relevant to the objectives, and easy to understand. Correspondingly, the Universal Acceptance method exhibits acceptance of all items in the counseling tool.

**Table 2.** Expert agreement and patient acceptance scores of 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 vein 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 vein.	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. More information will be given if this occurs.	26	1	1	26	0.93	1
	What are the side effects of the medication?						
12	Before we start the medication, please inform us if you are taking any other medications, vitamins, or herbal medication to avoid interaction side effects.	25	0.96	0	28	1	1
13	Side effects may occur with the use of this medication such as bleeding and others.	25	0.96	0	28	1	1
14	Symptoms of bleeding are bruises, blood in urine/dark-colored urine, black stools, gum bleeding, or heavy menstrual bleeding.	26	1	1	28	1	1
15	Other symptoms include headache, dizziness, joint pain, stiffness, numbness, or tingling.	26	1	1	28	1	1
16	At the injection site, some patients may develop swelling that is filled with blood.	26	1	1	28	1	1
17	Please inform the doctor or pharmacist if you experience any symptoms of bleeding or clotting.	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

COVID-19 has caused several health complications, including thromboembolism, highlighting the need to counsel COVID-19 patients to prescribe subcutaneous anticoagulants [11, 25-28]. Counseling tools are often used to ensure good understanding and medication adherence among patients [29]. Education on prescribed subcutaneous anticoagulants among COVID-19 patients ensures safe use and reduces complications, preventing further burden on a strained health system [30]. This study validated a counseling tool for subcutaneous anticoagulant use among COVID-19 patients. The developed written counseling instrument features a unique resource to assist healthcare providers to educate COVID-19 patients regarding the use of subcutaneous anticoagulants in COVID-19 disease.

In the current work, all features are incorporated including the pathophysiology of thromboembolism in COVID-19 disease, subcutaneous anticoagulant indication, dose, frequency, drug-drug or drug-food interactions, side effects, self-monitoring of bleeding signs, and the management of side effects which is in-line with the Malaysian Guidelines and international recommendations [14, 16, 18]. Except for INR monitoring, the criteria for constructing the current counseling tool for subcutaneous anticoagulants are approximately identical to these established guidelines for anticoagulants. The generated subcutaneous anticoagulant counseling tool is only applicable for hospitalized COVID-19 patients due to the need for frequent counseling of

hospitalized COVID-19 patients on the use of anticoagulants during and post-pandemic. Each item of the developed counseling tool was well represented by a high CVI by experts in clinical, anticoagulant, and infectious disease fields. The need for a high CVI has been recommended to ensure the validity of a tool [17]. Through a quantitative approach, content validity evaluates how effectively the items are related to or represent a particular topic, in this case, anticoagulant use during COVID-19 [17]. To ensure the currently developed counseling tool was well structured, clearly phrased, and encompassed aspects crucial to COVID-19 patients who are prescribed subcutaneous anticoagulants, the construction of counseling tools had undergone extensive iterations.

Educating and counseling patients regarding their medications remains the primary therapeutic concern of patients given anticoagulant treatment [14, 16, 18]. The currently developed written counseling tool for educating patients on subcutaneous anticoagulant use in COVID-19 disease received positive feedback. The majority of patients concurred that each component of the developed counseling tool was simple, pertinent to the objectives, and easy to comprehend. The findings imply that the currently developed counseling tool for subcutaneous anticoagulant use in COVID-19 disease may be advantageous for clinical outcomes and patient care. Along with better healthcare services, the ability to successfully generate written counseling tools for subcutaneous anticoagulant use in COVID-19 disease mainly depends on the comprehension and acceptance of the patients [31]. An effective tool is required for patients to ensure the appropriate utilization of medication [25]. According to the findings, appropriate tools should be simple to comprehend to ensure patients can benefit from the tool [25]. Studies have shown that for adult and pediatric hospitalized patients, written and visual counseling tools enhanced satisfaction and communication in both patients and providers [25]. Additionally, visual aid or discharge tools enhance comprehension, increase self-care ability, and improve post-discharge impacts among patients [32].

Although the study's aim was achieved, a few limitations of the study should be noted. The counseling tools were developed for COVID-19 hospitalized patients and it is important to emphasize that even if a developed counseling tool receives a positive review from experts, it must be evaluated and improved regularly to ensure it is still relevant in the future [33]. Furthermore, a convenient sampling of experts was performed in which future validation can be improved using a randomized approach.

## CONCLUSION

Counseling tools are materials often used by pharmacists to educate patients regarding medications and are crucial to achieving potentially significant pharmacotherapy benefits apart from minimizing medication errors and patient

confusion. During COVID-19, pharmacists were often required to counsel patients on the use of anticoagulants, in which a specific tool was lacking, therefore this counseling tool can be usefully applied in the clinical setting to ensure that patients receive adequate medication education of the anticoagulants.

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