

# A toolkit for the collection of thrombosis-related data elements in COVID-19 clinical studies

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## Key Points

- This toolkit contains standardized customizable thrombosis-related data elements for incorporation into COVID-19 studies.
- Standardization can enhance the quality of data collection, create efficiency, and facilitate comparison of results and pooling of data sets.

Thrombosis has emerged as an important complication of coronavirus disease 2019 (COVID-19), particularly among individuals with severe illness. However, the precise incidence of thrombotic events remains uncertain due to differences in study design, patient populations, outcome ascertainment, event definitions, and reporting. In an effort to overcome some of these challenges and promote standardized data collection and reporting in clinical studies, the American Society of Hematology Research Collaborative COVID-19 Non-Malignant Hematology Task Force, in collaboration with the International Society on Thrombosis and Haemostasis COVID-19 Task Force, developed sets of data elements in the following domains: venous thromboembolism, myocardial infarction, stroke/transient ischemic attack, peripheral arterial thrombosis, bleeding, laboratory investigations, and antithrombotic therapy. Data elements in each of these domains were developed with 3 levels of detail to facilitate their incorporation into studies evaluating a range of interventions and outcomes. Previously published data elements were included where possible. The use of standardized variables in a range of clinical studies can enhance the quality of data collection, create efficiency, enhance comparison of results across studies, and facilitate future pooling of data sets.

## Introduction

The global fight against coronavirus disease 2019 (COVID-19) has galvanized the global research community into action, with >3600 registered clinical studies and almost 60 000 publications to date listed on PubMed (accessed October 18, 2020).

Coagulopathy and an apparent increased risk of both venous and arterial thrombosis have emerged as prominent features of severe COVID-19.<sup>1</sup> COVID-19 coagulopathy seems distinct from the hyperfibrinolytic consumptive disseminated intravascular coagulation typical of non-COVID 19 sepsis. It is characterized by markedly elevated D-dimer levels, normal or increased fibrinogen levels, and normal prothrombin time, partial thromboplastin time, and platelet counts. A high incidence of venous thromboembolism (VTE) has been reported in some cohort studies, particularly among hospitalized patients (3%) and those admitted to intensive care units (11%-69%).<sup>2-9</sup> The wide range of event rates, which precludes precise estimates of incidence, likely reflects differences in study design, patient populations, outcome ascertainment, and event definitions. Furthermore, results are difficult to compare

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Requests for data sharing may be submitted to the corresponding author (Grégoire Le Gal; e-mail: glegal@ohri.ca).

The full-text version of this article contains a data supplement.  
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**Table 1. VTE data elements**

Variable	Level 1 (basic)	Level 2 (intermediate)	Level 3 (comprehensive)
Date of acute VTE	Date VTE diagnosed: MM/DD/YYYY	Date VTE diagnosed: MM/DD/YYYY	Date VTE diagnosed: MM/DD/YYYY
Anticoagulant therapy at time of event	Antithrombotic therapy form	Antithrombotic therapy form	Antithrombotic therapy form
Type and location of VTE	Type and location of VTE (select one) <input type="checkbox"/> <b>DVT</b> <input type="checkbox"/> Lower extremity DVT <input type="checkbox"/> Upper extremity/neck DVT <input type="checkbox"/> Non-limb DVT <input type="checkbox"/> <b>Superficial vein thrombosis</b> <input type="checkbox"/> <b>PE</b> Fatal PE <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown	Type and location of VTE (select all that apply): <input type="checkbox"/> <b>DVT</b> <input type="checkbox"/> Lower extremity DVT Select location(s): <input type="checkbox"/> Right <input type="checkbox"/> Left Select the most proximal involved veins: <input type="checkbox"/> Proximal veins (IVC, iliac, femoral, popliteal veins) <input type="checkbox"/> Calf veins (anterior tibial, posterior tibial, peroneal, soleal, gastrocnemius) <input type="checkbox"/> Upper extremity/neck DVT Select location(s): <input type="checkbox"/> Right <input type="checkbox"/> Left <input type="checkbox"/> Non-limb venous thrombosis <input type="checkbox"/> Splanchnic vein (portal, splenic, or mesenteric) <input type="checkbox"/> Cerebral venous sinus <input type="checkbox"/> Renal vein <input type="checkbox"/> Gonadal veins <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> <b>Superficial vein thrombosis</b> Fatal PE <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Select location(s): <input type="checkbox"/> Unknown location (ie, presumed PE due to inability to obtain imaging and based on clinical presentation and ancillary tests (eg, echocardiogram)) <input type="checkbox"/> Subsegmental pulmonary arteries only <input type="checkbox"/> Segmental or larger pulmonary artery	Type and location of VTE (select all that apply): <input type="checkbox"/> <b>DVT</b> <input type="checkbox"/> Lower extremity DVT Select location(s): <input type="checkbox"/> Right <input type="checkbox"/> Left Select the most proximal involved vein: <input type="checkbox"/> IVC <input type="checkbox"/> Iliac vein <input type="checkbox"/> Femoral vein <input type="checkbox"/> Popliteal vein <input type="checkbox"/> Calf veins (anterior tibial, posterior tibial, peroneal, soleal, gastrocnemius) Associated with central venous catheter? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Upper extremity/neck DVT Select location(s): <input type="checkbox"/> Right <input type="checkbox"/> Left Select most proximal involved vein: <input type="checkbox"/> Distal to axillary vein (radial, ulnar) <input type="checkbox"/> Axillary <input type="checkbox"/> Subclavian <input type="checkbox"/> Internal jugular <input type="checkbox"/> Brachiocephalic <input type="checkbox"/> Innominate <input type="checkbox"/> SVC Associated with central venous catheter? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> Non-limb venous thrombosis <input type="checkbox"/> Splanchnic vein (portal, splenic, or mesenteric) <input type="checkbox"/> Cerebral venous sinus <input type="checkbox"/> Renal vein <input type="checkbox"/> Gonadal veins <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> <b>Superficial vein thrombosis</b> Select location(s): <input type="checkbox"/> Lower extremity <input type="checkbox"/> Upper extremity Associated with peripheral or central venous catheter? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown <input type="checkbox"/> PE (choose one): Fatal PE <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Unknown Select location(s): <input type="checkbox"/> Unknown location (ie, presumed PE due to inability to obtain imaging and based on clinical presentation and ancillary tests (eg, echocardiogram)) <input type="checkbox"/> Subsegmental pulmonary arteries only <input type="checkbox"/> Segmental or larger pulmonary artery
Symptoms of VTE	<input type="checkbox"/> Asymptomatic, detected on systematic VTE screening test <input type="checkbox"/> Incidental finding on a test performed for another indication <input type="checkbox"/> Symptoms triggered testing <input type="checkbox"/> Unknown	<input type="checkbox"/> Asymptomatic, detected on systematic VTE screening test <input type="checkbox"/> Incidental finding on a test performed for another indication <input type="checkbox"/> Symptoms triggered testing <input type="checkbox"/> Unknown	<input type="checkbox"/> Asymptomatic, detected on systematic VTE screening test <input type="checkbox"/> Incidental finding on a test performed for another indication <input type="checkbox"/> Symptoms triggered testing <input type="checkbox"/> Unknown
Diagnosis of VTE	<input type="checkbox"/> <b>Objectively confirmed using diagnostic imaging</b> (eg, CTPA, V/Q scan, ultrasound, MRI) <input type="checkbox"/> <b>Clinical/empirical diagnosis only</b> → indicate reason(s) objective confirmation not done: <input type="checkbox"/> Unable to obtain imaging due to clinical status of patient (eg, hemodynamically unstable) <input type="checkbox"/> Unable to obtain imaging due to resource limitations (eg, timely imaging not available)	<input type="checkbox"/> <b>Objectively confirmed using diagnostic imaging</b> (eg, CTPA, V/Q scan, ultrasound, MRI) <input type="checkbox"/> <b>Clinical/empirical diagnosis only</b> → indicate reason(s) objective confirmation not done: <input type="checkbox"/> Unable to obtain imaging due to clinical status of patient (eg, hemodynamically unstable) <input type="checkbox"/> Unable to obtain imaging due to resource limitations (eg, timely imaging not available)	<input type="checkbox"/> <b>Objectively confirmed using diagnostic imaging</b> (select all that apply) PE diagnostic findings → <input type="checkbox"/> High-probability V/Q or positive SPECT V/Q <input type="checkbox"/> Intraluminal filling defect on CTPA <input type="checkbox"/> Other (specify): _____ DVT diagnostic findings → <input type="checkbox"/> Lack of compressibility of a deep vein on compression

CT, computed tomography; CTPA, computed tomography pulmonary angiogram; DVT, deep vein thrombosis; IVC, inferior vena cava; MRI, magnetic resonance imaging; MRV, magnetic resonance venography; PE, pulmonary embolism; SPECT, single-photon emission computed tomography; SVC, superior vena cava; V/Q, ventilation/perfusion.

**Table 1. (continued)**

Variable	Level 1 (basic)	Level 2 (intermediate)	Level 3 (comprehensive)
Antithrombotic treatment of VTE	<input type="checkbox"/> Unable to obtain imaging due to need for patient isolation or risk of infectious exposure <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown	<input type="checkbox"/> Unable to obtain imaging due to need for patient isolation or risk of infectious exposure <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown	ultrasound <input type="checkbox"/> Intraluminal filling defect on CT venography <input type="checkbox"/> Intraluminal filling defect on MRI/MRV <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> <b>Critical/empirical diagnosis only</b> → indicate reason(s) objective confirmation not done: <input type="checkbox"/> Unable to obtain imaging due to clinical status of patient (eg, hemodynamically unstable) <input type="checkbox"/> Unable to obtain imaging due to resource limitations (eg, timely imaging not available) <input type="checkbox"/> Unable to obtain imaging due to need for patient isolation <input type="checkbox"/> Unknown
Additional interventions			Antithrombotic therapy form  Additional interventions for VTE (select all that apply) <input type="checkbox"/> Thrombolysis—systemic <input type="checkbox"/> Thrombolysis—catheter directed <input type="checkbox"/> Mechanical thrombectomy <input type="checkbox"/> IVC filter insertion <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown

CT, computed tomography; CTPA, computed tomography pulmonary angiogram; DVT, deep vein thrombosis; IVC, inferior vena cava; MRI, magnetic resonance imaging; MRV, magnetic resonance venography; PE, pulmonary embolism; SPECT, single-photon emission computed tomography; SVC, superior vena cava; V/Q, ventilation/perfusion.

across studies due to inconsistent reporting about the nature and location of VTE, the clinical context in which it was diagnosed, and the use of antithrombotic therapy.

For example, some studies did not report the location of the VTE (ie, distal vs proximal deep vein thrombosis, subsegmental vs more proximal pulmonary embolism), which has prognostic implications.<sup>10,11</sup> Furthermore, diagnostic strategies for VTE were variable, and there was inconsistent reporting of whether VTE was diagnosed based on the presence of clinical signs or symptoms, incidental imaging findings, or systematic screening of asymptomatic patients. Finally, standardized collection of information on antithrombotic therapy use (eg, anticoagulants, antiplatelet therapies) and dosing preceding thrombotic events is crucial for understanding the magnitude of the thrombotic risk, which is affected by these agents administered for the prevention and treatment of thrombotic disease in at-risk patients (eg, VTE, atrial fibrillation, mechanical heart valve, coronary artery disease, stroke, peripheral arterial disease). In addition to evidence suggesting a high risk of VTE, the rate of ischemic stroke seems to be higher among patients with COVID-19 who are hospitalized or have emergency department visits compared with similar patients with influenza A/B.<sup>12</sup>

Methodologic limitations inherent to observational study designs (eg, selection and ascertainment bias) preclude firm conclusions about the degree of risk and incidence of thrombosis in patients with COVID-19. As a result, substantial uncertainty remains regarding the incidence, risk factors, and natural history of different types of thrombotic complications in patients with COVID-19, which has limited the clinical utility of these findings and impaired the ability to provide clear guidance to physicians.<sup>13,14</sup>

Although clinical trials assessing antithrombotic strategies in patients with COVID-19 are underway, studies evaluating other treatments (eg, antiviral therapies, immunomodulatory drugs, convalescent plasma) offer additional opportunities to further characterize the risk of thrombosis, predictors, and prognosis of thrombotic complications in patients with COVID-19. Harmonizing data elements with standardized collection and reporting of the type and location of events, the method of diagnosis (including the presence of symptoms), the use of antithrombotic therapies (including anticoagulant and antiplatelet treatments) at the time of thrombotic events, and the presence of preceding risk factors will help achieve this goal.

We aim to support and enhance the collection and reporting of data elements involved in key thrombosis (and related) end point events in COVID-19 studies by providing investigators with a set of clinical and biological variables with a range of details ranging from limited (eg, for capturing events as secondary outcomes) to comprehensive (eg, for more in-depth analyses) along with associated variable definitions. Our intent was not to be overly prescriptive but to allow for the flexibility needed by global investigators conducting clinical research. These data elements are a first step in developing a common language for capturing thrombosis and related events in clinical research in COVID-19.

## Methods

### Writing committee composition

The American Society of Hematology Research Collaborative (ASHRC) convened a COVID-19 Non-Malignant Hematology Task Force to develop and implement projects related to hematologic

**Table 2. Myocardial infarction (MI) data elements**

Variable	Level 1 (basic)	Level 2 (intermediate)	Level 3 (comprehensive)
Date of acute MI	Date acute MI diagnosed: DD/MM/YYYY	Date acute MI diagnosed: DD/MM/YYYY	Date acute MI diagnosed: DD/MM/YYYY
Antithrombotic therapy at time of MI	Antithrombotic therapy form	Antithrombotic therapy form	Antithrombotic therapy form
Type of acute MI	Select one: <input type="checkbox"/> Type 1: spontaneous <input type="checkbox"/> Type 2: ischemic imbalance <input type="checkbox"/> Type 3: death, no biomarkers <input type="checkbox"/> Type 4a: percutaneous coronary intervention related <input type="checkbox"/> Type 4b: stent thrombosis <input type="checkbox"/> Type 5: coronary artery bypass grafting related <input type="checkbox"/> Unknown	Select one: <input type="checkbox"/> Type 1: spontaneous <input type="checkbox"/> Type 2: ischemic imbalance <input type="checkbox"/> Type 3: death, no biomarkers <input type="checkbox"/> Type 4a: percutaneous coronary intervention related <input type="checkbox"/> Type 4b: stent thrombosis <input type="checkbox"/> Type 5: coronary artery bypass grafting related <input type="checkbox"/> Unknown	Select one: <input type="checkbox"/> Type 1: spontaneous <input type="checkbox"/> Type 2: ischemic imbalance <input type="checkbox"/> Type 3: death, no biomarkers <input type="checkbox"/> Type 4a: percutaneous coronary intervention related <input type="checkbox"/> Type 4b: stent thrombosis <input type="checkbox"/> Type 5: coronary artery bypass grafting related <input type="checkbox"/> Unknown
Cardiovascular risk factors	Select all that apply: <input type="checkbox"/> Known cardiovascular disease (coronary artery disease, peripheral arterial disease, cerebrovascular disease) <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Current smoker <input type="checkbox"/> Former smoker <input type="checkbox"/> Hypercholesterolemia <input type="checkbox"/> Obesity	Select all that apply: <input type="checkbox"/> Known cardiovascular disease (coronary artery disease, peripheral arterial disease, cerebrovascular disease) <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Current smoker <input type="checkbox"/> Former smoker <input type="checkbox"/> Hypercholesterolemia <input type="checkbox"/> Obesity	Select all that apply: <input type="checkbox"/> Known cardiovascular disease (coronary artery disease, peripheral arterial disease, cerebrovascular disease) <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Current smoker <input type="checkbox"/> Former smoker <input type="checkbox"/> Hypercholesterolemia <input type="checkbox"/> Obesity
Symptoms of acute MI	Presence of symptoms of myocardial ischemia: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Presence of symptoms of myocardial ischemia: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Presence of symptoms of myocardial ischemia: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown
Acute ischemic ECG changes	Presence of new or presumed new ischemic ECG changes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Presence of new or presumed new ischemic ECG changes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Ischemic changes on ECG <input type="checkbox"/> Left bundle branch block <input type="checkbox"/> Unknown	Presence of new or presumed new ischemic ECG changes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Ischemic changes on ECG <input type="checkbox"/> Left bundle branch block <input type="checkbox"/> Unknown
New Q waves on ECG	Presence of new Q waves: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Presence of new Q waves: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Presence of new Q waves: <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown
Change in noninvasive imaging	Change in noninvasive imaging <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Change in noninvasive imaging <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> New loss of viable myocardium <input type="checkbox"/> New regional wall motion abnormality <input type="checkbox"/> Unknown	Change in noninvasive imaging <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> New loss of viable myocardium <input type="checkbox"/> New regional wall motion abnormality <input type="checkbox"/> Unknown
Cardiac biomarker	Cardiac biomarker >99% upper reference limit <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Cardiac biomarker >99% upper reference limit <input type="checkbox"/> No <input type="checkbox"/> Yes, specify biomarker: _____ <input type="checkbox"/> Unknown	Cardiac biomarker >99% upper reference limit <input type="checkbox"/> No <input type="checkbox"/> Yes, specify biomarker: _____ <input type="checkbox"/> Unknown
Reperfusion treatment	Did the patient undergo reperfusion treatment of this MI: <input type="checkbox"/> No (medical management) <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Did the patient undergo reperfusion treatment of this MI: <input type="checkbox"/> No (medical management) <input type="checkbox"/> Yes (select all that apply): <input type="checkbox"/> Percutaneous coronary intervention <input type="checkbox"/> Coronary artery bypass grafting <input type="checkbox"/> Systemic thrombolytic therapy <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown	Did the patient undergo reperfusion treatment of this MI: <input type="checkbox"/> No (medical management) <input type="checkbox"/> Yes (select all that apply): <input type="checkbox"/> Percutaneous coronary intervention <input type="checkbox"/> Coronary artery bypass grafting <input type="checkbox"/> Systemic thrombolytic therapy <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown
Antithrombotic treatment of MI	Antithrombotic therapy form	Antithrombotic therapy form	Antithrombotic therapy form
ECG, electrocardiogram.			

**Table 3. Stroke/Transient ischemic attack (TIA) data elements**

Variable	Level 1 (basic)	Level 2 (intermediate)	Level 3 (comprehensive)
Date of acute stroke/TIA	Date acute stroke/TIA diagnosed: DD/MM/YYYY	Date acute stroke/TIA diagnosed: DD/MM/YYYY	Date acute stroke/TIA diagnosed: DD/MM/YYYY
Antithrombotic therapy at time of event	Antithrombotic therapy form	Antithrombotic therapy form	Antithrombotic therapy form
Stroke/TIA subtype	Select one: <input type="checkbox"/> TIA <input type="checkbox"/> Stroke (select one type below) <input type="checkbox"/> Ischemic stroke <input type="checkbox"/> Hemorrhagic stroke <input type="checkbox"/> Unknown	Select one: <input type="checkbox"/> TIA <input type="checkbox"/> Stroke (select one type below) <input type="checkbox"/> Ischemic stroke Etiology of ischemic stroke (select one): <input type="checkbox"/> Cardioembolic <input type="checkbox"/> Small vessel disease <input type="checkbox"/> Large vessel disease <input type="checkbox"/> Other identified cause <input type="checkbox"/> Undetermined etiology Was ischemic stroke complicated by hemorrhagic transformation? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> Hemorrhagic stroke <input type="checkbox"/> Unknown	Select one: <input type="checkbox"/> TIA <input type="checkbox"/> Stroke (select one type below) <input type="checkbox"/> Ischemic stroke Etiology of ischemic stroke (select one): <input type="checkbox"/> Cardioembolic (select all that apply) <input type="checkbox"/> Atrial fibrillation/flutter <input type="checkbox"/> Acute MI (<2 wk) <input type="checkbox"/> Intracardiac thrombus <input type="checkbox"/> Rheumatic mitral stenosis <input type="checkbox"/> Sick sinus syndrome <input type="checkbox"/> Dilated cardiomyopathy <input type="checkbox"/> Prosthetic heart valve <input type="checkbox"/> Akinetic of ventricular wall <input type="checkbox"/> Ischemic cardiomyopathy (EF <28%) <input type="checkbox"/> Paradoxical embolism <input type="checkbox"/> Other <input type="checkbox"/> Small vessel disease <input type="checkbox"/> Large vessel disease <input type="checkbox"/> Other identified cause <input type="checkbox"/> Undetermined etiology Was ischemic stroke complicated by hemorrhagic transformation? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown <input type="checkbox"/> Hemorrhagic stroke (select all that apply) <input type="checkbox"/> Lobar <input type="checkbox"/> Basal ganglia <input type="checkbox"/> Brainstem <input type="checkbox"/> Intraventricular involvement <input type="checkbox"/> Cerebellum <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown <input type="checkbox"/> Unknown
Cardiovascular risk factors			Select all that apply: <input type="checkbox"/> Known cardiovascular disease (coronary artery disease, peripheral arterial disease, cerebrovascular disease) <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Current smoker <input type="checkbox"/> Former smoker <input type="checkbox"/> Hypercholesterolemia <input type="checkbox"/> Obesity

EF, ejection fraction; TIA, transient ischemic attack.

Table 3. (continued)

Variable	Level 1 (basic)	Level 2 (intermediate)	Level 3 (comprehensive)
Presenting symptoms	Select one: <input type="checkbox"/> No <input type="checkbox"/> Yes (select one) <input type="checkbox"/> Focal symptom <input type="checkbox"/> Non-focal symptom <input type="checkbox"/> Other neurologic symptom <input type="checkbox"/> Unknown	Select one: <input type="checkbox"/> No <input type="checkbox"/> Yes (select one) <input type="checkbox"/> Focal symptom <input type="checkbox"/> Non-focal symptom <input type="checkbox"/> Other neurologic symptom <input type="checkbox"/> Unknown	Select one: <input type="checkbox"/> No <input type="checkbox"/> Yes (select one) <input type="checkbox"/> Focal symptom <input type="checkbox"/> Non-focal symptom <input type="checkbox"/> Other neurologic symptom <input type="checkbox"/> Unknown
Duration of symptoms	Was neuroimaging done for this event? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Was neuroimaging done for this event? <input type="checkbox"/> No <input type="checkbox"/> Yes (indicate type of image, select all that apply) <input type="checkbox"/> Single brain CT scan <input type="checkbox"/> Multiple brain CT scans separated in time <input type="checkbox"/> MRI <input type="checkbox"/> Diffusion-weighted MRI <input type="checkbox"/> Unknown	Was neuroimaging done for this event? <input type="checkbox"/> No <input type="checkbox"/> Yes (indicate type of image, select all that apply) <input type="checkbox"/> Single brain CT scan (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Result not available <input type="checkbox"/> Multiple brain CT scans separated in time (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Result not available <input type="checkbox"/> MRI (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Result not available <input type="checkbox"/> Diffusion-weighted MRI (select one) <input type="checkbox"/> Positive <input type="checkbox"/> Negative <input type="checkbox"/> Result not available <input type="checkbox"/> Unknown
Reperfusion treatment	Did the patient undergo reperfusion treatment of this stroke? <input type="checkbox"/> No (medical management) <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	Did the patient undergo reperfusion treatment of this stroke? <input type="checkbox"/> No (medical management) <input type="checkbox"/> Yes (select all that apply): <input type="checkbox"/> Mechanical thrombectomy <input type="checkbox"/> Systemic thrombolytic therapy <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown	Did the patient undergo reperfusion treatment of this stroke? <input type="checkbox"/> No (medical management) <input type="checkbox"/> Yes (select all that apply): <input type="checkbox"/> Mechanical thrombectomy <input type="checkbox"/> Systemic thrombolytic therapy <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown
Antithrombotic treatment of stroke/TIA			Antithrombotic therapy form EF, ejection fraction; TIA, transient ischemic attack.

**Table 4. Peripheral arterial and other arterial thrombosis data elements**

Variable	Level 1 (basic)		Level 2 (intermediate)		Level 3 (comprehensive)	
	Date of acute arterial ischemic event YYYY	Date of acute arterial ischemic event diagnosed: MM/DD/YYYY	Date of acute arterial ischemic event YYYY	Date of acute arterial ischemic event diagnosed: MM/DD/YYYY	Date of acute arterial ischemic event MM/DD/YYYY	Date of acute arterial ischemic event diagnosed: MM/DD/YYYY
Antithrombotic therapy at time of event	Antithrombotic therapy form		Antithrombotic therapy form		Antithrombotic therapy form	
Type of event	Indicate type of arterial thrombotic event (select one): <input type="checkbox"/> Peripheral arterial thromboembolism <input type="checkbox"/> Abdominal arterial thromboembolism <input type="checkbox"/> Microvascular thrombosis <input type="checkbox"/> Other (specify): _____		Indicate type of arterial thrombotic event (select one): <input type="checkbox"/> Peripheral arterial thromboembolism <input type="checkbox"/> Abdominal arterial thromboembolism <input type="checkbox"/> Microvascular thrombosis <input type="checkbox"/> Other (specify): _____		Indicate type of arterial thrombotic event (select one): <input type="checkbox"/> Peripheral arterial thromboembolism (select one) <input type="checkbox"/> Atherosclerotic plaque <input type="checkbox"/> Arterial embolism <input type="checkbox"/> Other known cause (specify): _____ <input type="checkbox"/> Unknown <input type="checkbox"/> Abdominal arterial thromboembolism (select one) <input type="checkbox"/> Atherosclerotic plaque <input type="checkbox"/> Arterial embolism <input type="checkbox"/> Other known cause (specify): _____ <input type="checkbox"/> Unknown <input type="checkbox"/> Microvascular thrombosis (select one) <input type="checkbox"/> Diagnosed on biopsy <input type="checkbox"/> Biopsy not done <input type="checkbox"/> Unknown <input type="checkbox"/> Other (specify): _____	
Cardiovascular risk factors	Select all that apply: <input type="checkbox"/> Known cardiovascular disease (coronary artery disease, peripheral arterial disease, cerebrovascular disease) <input type="checkbox"/> Hypertension <input type="checkbox"/> Diabetes mellitus <input type="checkbox"/> Current smoker <input type="checkbox"/> Former smoker <input type="checkbox"/> Hypercholesterolemia <input type="checkbox"/> Obesity					
Reperfusion treatment (vascular intervention)	Did the patient undergo reperfusion treatment of this arterial thrombotic event: <input type="checkbox"/> No <input type="checkbox"/> Yes (select all that apply): <input type="checkbox"/> Angioplasty <input type="checkbox"/> Stent <input type="checkbox"/> Bypass <input type="checkbox"/> Systemic thrombolytic therapy <input type="checkbox"/> Catheter-directed thrombolytic therapy <input type="checkbox"/> Embolectomy <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown		Did the patient undergo reperfusion treatment of this arterial thrombotic event: <input type="checkbox"/> No <input type="checkbox"/> Yes (select all that apply): <input type="checkbox"/> Angioplasty <input type="checkbox"/> Stent <input type="checkbox"/> Bypass <input type="checkbox"/> Systemic thrombolytic therapy <input type="checkbox"/> Catheter-directed thrombolytic therapy <input type="checkbox"/> Embolectomy <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown		Did the patient undergo reperfusion treatment of this arterial thrombotic event: <input type="checkbox"/> No <input type="checkbox"/> Yes (select all that apply): <input type="checkbox"/> Angioplasty <input type="checkbox"/> Stent <input type="checkbox"/> Bypass <input type="checkbox"/> Systemic thrombolytic therapy <input type="checkbox"/> Catheter-directed thrombolytic therapy <input type="checkbox"/> Embolectomy <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown	
Limb amputation	Did the patient undergo limb amputation? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown		Did the patient undergo limb amputation? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown		Did the patient undergo limb amputation? <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> Unknown	
Antithrombotic treatment of thrombotic event	Antithrombotic therapy form					



**Table 5. Bleeding data elements**

Variable	Level 1 (basic)	Level 2 (intermediate)	Level 3 (comprehensive)
Date of bleeding event	Date acute bleeding event diagnosed: MM/DD/YYYY	Date acute bleeding event diagnosed: MM/DD/YYYY	Date acute bleeding event diagnosed: MM/DD/YYYY
Antithrombotic therapy at time of bleeding event	Antithrombotic therapy form	Antithrombotic therapy form	Antithrombotic therapy form
Type of bleeding event—ISTH definitions	<p>Indicate type of bleeding event (select one):</p> <input type="checkbox"/> Major bleeding <input type="checkbox"/> Clinically relevant non-major bleeding <input type="checkbox"/> Other bleeding (specify): _____ <input type="checkbox"/> Unknown	<p>Indicate type of bleeding event (select one):</p> <input type="checkbox"/> Major bleeding (choose all that apply) <input type="checkbox"/> Fatal bleeding <input type="checkbox"/> Symptomatic bleeding in a critical area or organ <input type="checkbox"/> Overt bleeding causing a fall in hemoglobin level of 20 g/L (2 g/dL, 1.24 mmol/L) or more, or leading to transfusion of 2 or more units of whole blood or red blood cells <input type="checkbox"/> Clinically relevant non-major bleeding (choose all that apply) <input type="checkbox"/> Requiring medical intervention by a health care professional <input type="checkbox"/> Leading to hospitalization or increased level of care <input type="checkbox"/> Prompting an evaluation <input type="checkbox"/> Other bleeding (specify): _____ <input type="checkbox"/> Unknown	<p>Indicate type of bleeding event (select one):</p> <input type="checkbox"/> Major bleeding (choose all that apply) <input type="checkbox"/> Fatal bleeding <input type="checkbox"/> Symptomatic bleeding in a critical area or organ <input type="checkbox"/> Overt bleeding causing a fall in hemoglobin level of 20 g/L (2 g/dL, 1.24 mmol/L) or more, or leading to transfusion of 2 or more units of whole blood or red blood cells <input type="checkbox"/> Clinically relevant non-major bleeding (choose all that apply) <input type="checkbox"/> Requiring medical intervention by a health care professional <input type="checkbox"/> Leading to hospitalization or increased level of care <input type="checkbox"/> Prompting an evaluation <input type="checkbox"/> Other bleeding (specify): _____ <input type="checkbox"/> Unknown
Blood products given for bleeding		<p>Select all that apply:</p> <input type="checkbox"/> Red blood cell transfusion <input type="checkbox"/> Whole blood transfusion <input type="checkbox"/> Plasma transfusion <input type="checkbox"/> Platelet transfusion <input type="checkbox"/> Cryoprecipitate <input type="checkbox"/> Fibrinogen concentrate <input type="checkbox"/> Prothrombin complex concentrate (4-factor) <input type="checkbox"/> Prothrombin complex concentrate (3-factor) <input type="checkbox"/> Activated prothrombin complex concentrate <input type="checkbox"/> Recombinant factor VIIa <input type="checkbox"/> Other (specify): _____	<p>Select all that apply:</p> <input type="checkbox"/> Red blood cell transfusion <input type="checkbox"/> Whole blood transfusion <input type="checkbox"/> Plasma transfusion <input type="checkbox"/> Platelet transfusion <input type="checkbox"/> Cryoprecipitate <input type="checkbox"/> Fibrinogen concentrate <input type="checkbox"/> Prothrombin complex concentrate (4-factor) <input type="checkbox"/> Prothrombin complex concentrate (3-factor) <input type="checkbox"/> Activated prothrombin complex concentrate <input type="checkbox"/> Recombinant factor VIIa <input type="checkbox"/> Other (specify): _____
Hemostatic treatments given for bleeding event		<p>Indicate hemostatic treatments given (select all that apply):</p> <input type="checkbox"/> Tranexamic acid <input type="checkbox"/> Aminocaproic acid <input type="checkbox"/> Desmopressin (DDAVP)	<p>Indicate hemostatic treatments given (select all that apply):</p> <input type="checkbox"/> Tranexamic acid <input type="checkbox"/> Aminocaproic acid <input type="checkbox"/> Desmopressin (DDAVP)
Specific anticoagulant reversal agents		<p>Select all that apply:</p> <input type="checkbox"/> Idarucizumab <input type="checkbox"/> Andexanet alfa	<p>Select all that apply:</p> <input type="checkbox"/> Idarucizumab <input type="checkbox"/> Andexanet alfa
Surgeries or invasive procedures to treat acute bleeding		<p>Did the patient undergo surgery or invasive procedure to treat bleeding?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes (select all that apply): <input type="checkbox"/> Surgery <input type="checkbox"/> Endoscopic procedure <input type="checkbox"/> Angioembolization <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown	<p>Did the patient undergo surgery or invasive procedure to treat bleeding?</p> <input type="checkbox"/> No <input type="checkbox"/> Yes (select all that apply): <input type="checkbox"/> Surgery <input type="checkbox"/> Endoscopic procedure <input type="checkbox"/> Angioembolization <input type="checkbox"/> Other (specify): _____ <input type="checkbox"/> Unknown
DDAVP, 1-deamino-8-D-arginine vasopressin.			



**Table 6. Laboratory testing data elements**

Variable	Level 1 (basic)	Level 2 (intermediate)	Level 3 (comprehensive)
<b>At study enrollment</b>			
Hemoglobin	Hemoglobin Hemoglobin units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL <input type="checkbox"/> mmol/L	Hemoglobin Hemoglobin units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL <input type="checkbox"/> mmol/L	Hemoglobin Hemoglobin units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL <input type="checkbox"/> mmol/L
Platelet count	Platelet count Platelet count units <input type="checkbox"/> per $\mu\text{L}$ <input type="checkbox"/> $\times 10^9/\text{L}$	Platelet count Platelet count units <input type="checkbox"/> per $\mu\text{L}$ <input type="checkbox"/> $\times 10^9/\text{L}$	Platelet count Platelet count units <input type="checkbox"/> per $\mu\text{L}$ <input type="checkbox"/> $\times 10^9/\text{L}$
PT	PT PT reference range _____ s to _____ s	PT PT reference range _____ s to _____ s	PT PT reference range _____ s to _____ s
aPTT	aPTT aPTT reference range _____ s to _____ s	aPTT aPTT reference range _____ s to _____ s	aPTT aPTT reference range _____ s to _____ s
Fibrinogen activity	Fibrinogen activity Fibrinogen activity units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL	Fibrinogen activity Fibrinogen activity units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL	Fibrinogen activity Fibrinogen activity units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL
D-dimer	D-dimer level (indicate absolute level, or level above upper limit of assay) D-dimer upper limit of assay _____ D-dimer units (choose one) <input type="checkbox"/> mg/L <input type="checkbox"/> $\mu\text{g}/\text{mL}$ <input type="checkbox"/> ng/mL Other (specify): _____	D-dimer level (indicate absolute level, or level above upper limit of assay) D-dimer upper limit of assay _____ D-dimer units (choose one) <input type="checkbox"/> mg/L <input type="checkbox"/> $\mu\text{g}/\text{mL}$ <input type="checkbox"/> ng/mL Other (specify): _____	D-dimer level (indicate absolute level, or level above upper limit of assay) D-dimer upper limit of assay _____ D-dimer units (choose one) <input type="checkbox"/> mg/L <input type="checkbox"/> $\mu\text{g}/\text{mL}$ <input type="checkbox"/> ng/mL Other (specify): _____
<b>At the time of thrombotic event</b>			
Hemoglobin	Hemoglobin Hemoglobin units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL <input type="checkbox"/> mmol/L	Hemoglobin Hemoglobin units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL <input type="checkbox"/> mmol/L	Hemoglobin Hemoglobin units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL <input type="checkbox"/> mmol/L
Platelet count	Platelet count Platelet count units <input type="checkbox"/> per $\mu\text{L}$ <input type="checkbox"/> $\times 10^9/\text{L}$	Platelet count Platelet count units <input type="checkbox"/> per $\mu\text{L}$ <input type="checkbox"/> $\times 10^9/\text{L}$	Platelet count Platelet count units <input type="checkbox"/> per $\mu\text{L}$ <input type="checkbox"/> $\times 10^9/\text{L}$

aPTT, activated partial thromboplastin time; INR, international normalized ratio; LMWH, low-molecular-weight heparin; PT, prothrombin time.

**Table 6. (continued)**

Variable	Level 1 (basic)	Level 2 (intermediate)	Level 3 (comprehensive)
PT	PT PT reference range _____ s to _____ s	PT PT reference range _____ s to _____ s	PT PT reference range _____ s to _____ s
aPTT	aPTT aPTT reference range _____ s to _____ s	aPTT aPTT reference range _____ s to _____ s	aPTT aPTT reference range _____ s to _____ s
Fibrinogen	Fibrinogen activity level Fibrinogen activity units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL	Fibrinogen activity level Fibrinogen activity units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL	Fibrinogen activity level Fibrinogen activity units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL
Anti-Xa activity (for patients receiving heparin, LMWH)		<input type="checkbox"/> Heparin <input type="checkbox"/> LMWH	<input type="checkbox"/> Heparin <input type="checkbox"/> LMWH
Antithrombin		Antithrombin Antithrombin reference range _____ % to _____ IU/dL	Antithrombin Antithrombin reference range _____ % to _____ IU/dL
D-dimer	D-dimer (indicate absolute level, or level above upper limit of assay) D-dimer upper limit of assay _____ D-dimer units (choose one) <input type="checkbox"/> mg/L <input type="checkbox"/> µg/mL <input type="checkbox"/> ng/mL Other (specify): _____ D-dimer commercial assay (choose one) <input type="checkbox"/> IL HemosIL D-dimer <input type="checkbox"/> IL HemosIL D-dimer HS <input type="checkbox"/> IL HemosIL D-dimer HS500 <input type="checkbox"/> Radiometer AQT90 Flex <input type="checkbox"/> Siemens Innovance <input type="checkbox"/> Siemens Acute Care <input type="checkbox"/> Stago/Roche Liatest D-dimer <input type="checkbox"/> Stago Liatest D-dimer Plus <input type="checkbox"/> Roche Cardiac Reader DD test <input type="checkbox"/> Roche Tina-quant 2nd gen <input type="checkbox"/> bioMérieux Vidas <input type="checkbox"/> Diagon Dia-D-Dimer <input type="checkbox"/> Beckman Coulter D-Dimer <input type="checkbox"/> Diagnostica STA Liatest Other (specify): _____	D-dimer (indicate absolute level, or level above upper limit of assay) D-dimer upper limit of assay _____ D-dimer units (choose one) <input type="checkbox"/> mg/L <input type="checkbox"/> µg/mL <input type="checkbox"/> ng/mL Other (specify): _____ D-dimer commercial assay (choose one) <input type="checkbox"/> IL HemosIL D-dimer <input type="checkbox"/> IL HemosIL D-dimer HS <input type="checkbox"/> IL HemosIL D-dimer HS500 <input type="checkbox"/> Radiometer AQT90 Flex <input type="checkbox"/> Siemens Innovance <input type="checkbox"/> Siemens Acute Care <input type="checkbox"/> Stago/Roche Liatest D-dimer <input type="checkbox"/> Stago Liatest D-dimer Plus <input type="checkbox"/> Roche Cardiac Reader DD test <input type="checkbox"/> Roche Tina-quant 2nd gen <input type="checkbox"/> bioMérieux Vidas <input type="checkbox"/> Diagon Dia-D-Dimer <input type="checkbox"/> Beckman Coulter D-Dimer <input type="checkbox"/> Diagnostica STA Liatest Other (specify): _____	D-dimer (indicate absolute level, or level above upper limit of assay) D-dimer upper limit of assay _____ D-dimer units (choose one) <input type="checkbox"/> mg/L <input type="checkbox"/> µg/mL <input type="checkbox"/> ng/mL Other (specify): _____ D-dimer commercial assay (choose one) <input type="checkbox"/> IL HemosIL D-dimer <input type="checkbox"/> IL HemosIL D-dimer HS <input type="checkbox"/> IL HemosIL D-dimer HS500 <input type="checkbox"/> Radiometer AQT90 Flex <input type="checkbox"/> Siemens Innovance <input type="checkbox"/> Siemens Acute Care <input type="checkbox"/> Stago/Roche Liatest D-dimer <input type="checkbox"/> Stago Liatest D-dimer Plus <input type="checkbox"/> Roche Cardiac Reader DD test <input type="checkbox"/> Roche Tina-quant 2nd gen <input type="checkbox"/> bioMérieux Vidas <input type="checkbox"/> Diagon Dia-D-Dimer <input type="checkbox"/> Beckman Coulter D-Dimer <input type="checkbox"/> Diagnostica STA Liatest Other (specify): _____
Serum creatinine		Serum creatinine Creatinine units <input type="checkbox"/> µmol/L <input type="checkbox"/> mg/dL	Serum creatinine Creatinine units <input type="checkbox"/> µmol/L <input type="checkbox"/> mg/dL
<b>At the time of bleeding event</b>			
Hemoglobin	Hemoglobin Hemoglobin units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL	Hemoglobin Hemoglobin units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL	Hemoglobin Hemoglobin units <input type="checkbox"/> g/L <input type="checkbox"/> mg/dL <input type="checkbox"/> mmol/L
Platelet count	Platelet count Platelet count units <input type="checkbox"/> per µL <input type="checkbox"/> × 10 <sup>9</sup> /L	Platelet count Platelet count units <input type="checkbox"/> per µL <input type="checkbox"/> × 10 <sup>9</sup> /L	Platelet count Platelet count units <input type="checkbox"/> per µL <input type="checkbox"/> × 10 <sup>9</sup> /L

aPTT, activated partial thromboplastin time; INR, international normalized ratio; LMWH, low-molecular-weight heparin; PT, prothrombin time.

Table 6. (continued)

Variable	Level 1 (basic)	Level 2 (intermediate)	Level 3 (comprehensive)
PT		PT PT reference range _____ to _____ s	PT level _____ s PT reference range _____ to _____ s
aPTT		aPTT aPTT reference range _____ to _____ s	aPTT _____ s aPTT reference range _____ to _____ s
INR		INR	INR _____
Fibrinogen activity		Fibrinogen activity Fibrinogen activity units _____	Fibrinogen activity _____ <input type="checkbox"/> g/L _____ <input type="checkbox"/> mg/dL

aPTT, activated partial thromboplastin time; INR, international normalized ratio; LMWH, low-molecular-weight heparin; PT, prothrombin time.

complications of COVID-19. In collaboration with the International Society on Thrombosis and Haemostasis (ISTH) COVID-19 Task Force, the objective of the initiative described herein was to provide uniform definitions of thrombosis, bleeding, and laboratory data elements for incorporation into COVID-19 clinical studies addressing a diverse range of interventions. The writing committee with international representation consisted of 8 individuals with expertise in VTE, cardiovascular medicine, hematology, clinical research, epidemiology, outcomes assessment, medical informatics, health information management, and health care services research. The manuscript was drafted by the writing committee and reviewed by members of the ASHRC COVID-19 Non-Malignant Hematology Task Force and ISTH COVID-19 Task Force.

## Data elements and definitions

The writing panel focused on variables that were inconsistently reported in initial studies about thrombosis in patients with COVID-19.

We identified data elements and definitions in the following domains: (1) VTE; (2) myocardial infarction; (3) stroke; (4) peripheral arterial thromboembolism; (5) bleeding; (6) antithrombotic therapy; and (7) basic laboratory investigations. The writing committee recognized that individual study objectives, interventions, and available resources will influence the desired level of detail about thrombosis-related outcomes. Therefore, to facilitate incorporation of data element collection and reporting by investigators, we identified the following 3 levels of detail: (1) limited; (2) intermediate; and (3) comprehensive. For example, the limited data set contains basic data elements required for analysis and interpretation (eg, as secondary outcomes), whereas the comprehensive data set contains data elements that could be used for more advanced preplanned analyses or substudies.

For VTE, bleeding, antithrombotic therapy, and laboratory data points, the writing panel selected and/or adapted data elements from the recently released ISTH Common Data Elements for VTE project, a large initiative aimed at harmonizing data elements collected and reported in VTE-related clinical trials.<sup>15</sup> A draft document including the sets of variables was reviewed by the members of the ASHRC COVID-19 Non-Malignant Hematology Task Force and the ISTH COVID-19 Task Force. All comments were considered by the group, and final decisions on data elements to be retained were made by consensus.

## Results

The thrombosis-related data elements are presented according to level of detail in Tables 1 through 7. Detailed definitions of data elements and corresponding references are provided in the supplemental Tables 1 through 7 and the supplemental Data Elements Definitions and References Spreadsheets.

## Discussion

The goal of this initiative was to maximize high-quality collection of COVID-19–related thrombosis outcomes by providing a customizable data collection tool for use in clinical studies on COVID-19 that may focus on areas other than thrombosis. Depending on the individual study objectives, design, and available resources, investigators can select from 3 levels of detail in the following domains: VTE, myocardial infarction, stroke, peripheral arterial and other arterial thromboembolism, antithrombotic therapy, bleeding, and laboratory tests. This approach is designed to

**Table 7. Antithrombotic therapy form (refer to Antithrombotic Therapy Dictionary)**

Date antithrombotic therapy form completed (MM/DD/YYYY): \_\_\_\_\_

Indicate patient's most recent documented or reported weight at the time of thrombotic event: \_\_\_\_\_ kg, OR \_\_\_\_\_ lb, OR  unknown

Height \_\_\_\_\_ cm, OR \_\_\_\_\_ inches, OR  unknown

**Section 1: Anticoagulant treatment:**

**No**  **Yes (indicate the type, dose, and frequency below)**

<input type="checkbox"/> <b>Low-molecular-weight heparin</b>	<b>Drug</b>	<b>Dose</b>	<b>Frequency</b>
<input type="checkbox"/>	Enoxaparin	_____ mg _____ mg/kg _____ units _____ units/kg	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	Dalteparin	_____ units _____ units/kg	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	Tinzaparin	_____ units _____ units/kg	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	Nadroparin	_____ units _____ units/kg	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	Centoparin	_____ units _____ units/kg	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	Bemiparin	_____ units _____ units/kg	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	Other (specify): _____	_____ mg _____ mg/kg _____ units _____ units/kg	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Other (specify): _____

**Unfractionated heparin (indicate method of administration and dose, frequency):**

<b>Route of administration</b>	<b>Dose</b>	<b>Frequency</b>
<input type="checkbox"/> Intravenous infusion	_____ Units/kg/h	Continuous infusion
<input type="checkbox"/> Subcutaneous	_____ units _____ units/kg	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Other (specify): _____

**Fondaparinux (indicate dose and frequency):**

<b>Dose</b>	<b>Frequency</b>
_____ mg	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Other (specify): _____

ER, extended release; INR, international normalized ratio.

**Table 7. (continued)**

Direct oral anticoagulants (indicate drug, dose, frequency):	Drug	Dose and frequency
<input type="checkbox"/>	<input type="checkbox"/> Apixaban	<input type="checkbox"/> 2.5 mg twice daily <input type="checkbox"/> 5 mg twice daily <input type="checkbox"/> 10 mg twice daily <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	<input type="checkbox"/> Rivaroxaban	<input type="checkbox"/> 2.5 mg twice daily <input type="checkbox"/> 10 mg once daily <input type="checkbox"/> 15 mg once daily <input type="checkbox"/> 15 mg twice daily <input type="checkbox"/> 20 mg once daily <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	<input type="checkbox"/> Edoxaban	<input type="checkbox"/> 30 mg once daily <input type="checkbox"/> 60 mg once daily <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	<input type="checkbox"/> Dabigatran	<input type="checkbox"/> 75 mg twice daily <input type="checkbox"/> 110 mg twice daily <input type="checkbox"/> 150 mg twice daily <input type="checkbox"/> 220 mg once daily <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	<b>Vitamin K antagonist (indicate drug and target INR):</b>	<b>Target INR</b>
<input type="checkbox"/>	<input type="checkbox"/> Warfarin	<input type="checkbox"/> INR 1.5 to 2.5
<input type="checkbox"/>	<input type="checkbox"/> Phenprocoumon	<input type="checkbox"/> INR 2 to 3
<input type="checkbox"/>	<input type="checkbox"/> Acenocoumarol	<input type="checkbox"/> INR 2.5 to 3.5
<input type="checkbox"/>	<input type="checkbox"/> Flindione	<input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	<input type="checkbox"/> Other (specify): _____	<input type="checkbox"/> Unknown
<input type="checkbox"/>	<input type="checkbox"/> Unknown	
<input type="checkbox"/>	<b>Unknown anticoagulant</b>	
<input type="checkbox"/>	<b>Other anticoagulant not listed above (specify below):</b>	
<input type="checkbox"/>	Argatroban	<b>Dose</b> _____ <b>Route</b> Intravenous <b>Frequency</b> <input type="checkbox"/> Continuous infusion <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	Bivalirudin	<b>Dose</b> _____ <b>Route</b> Intravenous <b>Frequency</b> <input type="checkbox"/> Continuous infusion <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	Other (specify): _____	<b>Dose</b> _____ <b>Route</b> <input type="checkbox"/> Oral <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Intravenous <b>Frequency</b> <input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Continuous infusion <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	<b>Section 2: Antiplatelet therapy:</b>	<b>No <input type="checkbox"/> Yes (indicate the type, dose, and frequency below)</b>
<input type="checkbox"/>	<input type="checkbox"/> Aspirin (acetylsalicylic acid)	<input type="checkbox"/> Low dose ( $\leq 100$ mg daily) <input type="checkbox"/> 325 mg once daily <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/>	<input type="checkbox"/> Clopidogrel	<input type="checkbox"/> 75 mg once daily <input type="checkbox"/> 150 mg once daily
<input type="checkbox"/>	<input type="checkbox"/> Ticagrelor	<input type="checkbox"/> 60 mg twice daily <input type="checkbox"/> 90 mg twice daily
<input type="checkbox"/>	<input type="checkbox"/> Prasugrel	<input type="checkbox"/> 5 mg once daily <input type="checkbox"/> 10 mg once daily

ER, extended release; INR, international normalized ratio.

**Table 7. (continued)**

<input type="checkbox"/> Acetylsalicylic acid and dipyridamole ER <input type="checkbox"/> Cangrelor <input type="checkbox"/> Other antiplatelet therapy, including nonsteroidal anti-inflammatory drugs (specify below): _____	<input type="checkbox"/> Aspirin 25 mg/dipyridamole ER 200 mg twice daily <input type="checkbox"/> Aspirin 25 mg/dipyridamole ER 200 mg once daily <input type="checkbox"/> 30 µg/kg bolus then 4 µg/kg/min (for percutaneous intervention) <input type="checkbox"/> 0.75 µg/kg/min (for bridging therapy before cardiac surgery)	<input type="checkbox"/> Oral <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Intravenous	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Continuous infusion <input type="checkbox"/> Other (specify): _____
<input type="checkbox"/> Other antiplatelet therapy, including nonsteroidal anti-inflammatory drugs (specify below): _____	<input type="checkbox"/> mg <input type="checkbox"/> units <input type="checkbox"/> Other (specify): _____	<input type="checkbox"/> Oral <input type="checkbox"/> Subcutaneous <input type="checkbox"/> Intravenous	<input type="checkbox"/> Every 24 h <input type="checkbox"/> Every 12 h <input type="checkbox"/> Every 8 h <input type="checkbox"/> Continuous infusion <input type="checkbox"/> Other (specify): _____

**Section 3: Mechanical thromboprophylaxis:**  No  Yes (indicate the type below)

Intermittent pneumatic compression  
 Graduated compression stockings  
 Antiembolism stockings  
 Other (specify): \_\_\_\_\_

ER, extended release; INR, international normalized ratio.

create efficiency in study design and implementation by providing a pre-established, standardized set of variables vetted by experts in thrombosis and hemostasis and clinical trial development. Where available, we incorporated definitions that are widely accepted in the thrombosis and hemostasis community.<sup>16-18</sup> We also used common data elements from the ISTH Common Data Elements for VTE Research project and adapted other previously published common data elements.<sup>15,19,20</sup>

A specific challenge with the COVID-19 pandemic has been the unprecedented need for rapid development and implementation of clinical studies worldwide, which has resulted in multiple small studies addressing similar research questions without the benefit of large-scale communication and collaboration. Logistical challenges and declining infection rates in some areas may impair the ability to execute and complete clinical trials. The use of standardized variables can leverage data collection efforts across studies for potential future pooled analyses, including individual participant data meta-analyses. Working together, ASH and ISTH have developed a multimodal promotional strategy including direct e-mails to members, announcements on social media, resources posted on their Web sites, and direct outreach to other professional societies and funding agencies.

Our initiative has some limitations. Given the need to provide urgent guidance to investigators, we did not conduct a systematic review or use conventional consensus methods (eg, Delphi). However, the panel comprised physicians and researchers with experience in clinical trials and observational studies on venous and arterial thrombosis and data harmonization efforts. Although the variables were reviewed and selected by the ASHRC COVID-19 Non-Malignant Hematology Task Force and ISTH COVID-19 Task Force with a view to providing flexible options for a range of non-thrombosis clinical trials, the data collection sets may not be suitable for every study depending on the specific objectives or patient population. We also acknowledge that with the rapid evolution of the COVID-19 pandemic, the current set of proposed variables may require modification to incorporate new developments or emerging knowledge of the disease. This initiative can therefore also serve as an adaptable platform to support future research efforts through an iterative review process.

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## Authorship

Contribution: D.M.S., G.D.B., N.J.L., A.L., S.M., L.S., W.A.W., and G.L.G. developed the variables; D.M.S. and G.L.G. wrote the manuscript; and L.S., A.L., G.D.B., N.J.L., W.A.W., and S.M. revised the manuscript.

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