Appropriate management of thrombotic risk in patients with primary immune thrombocytopenia in the UK: a modified Delphi consensus

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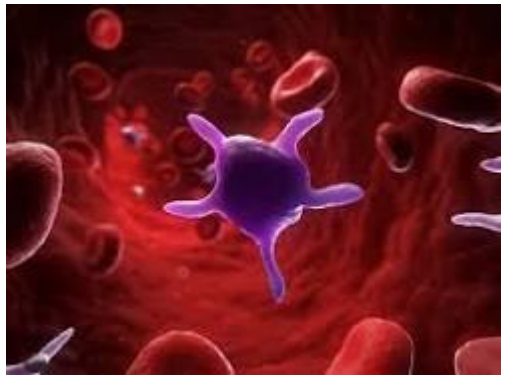

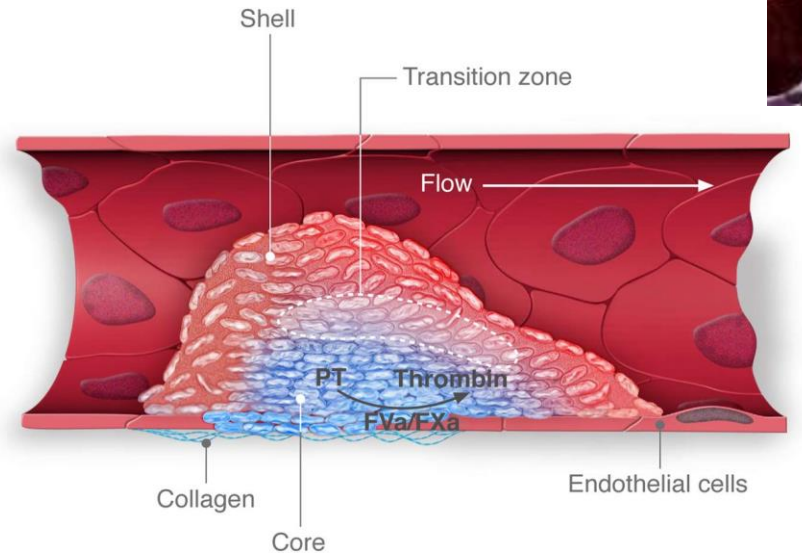

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Disclosures:

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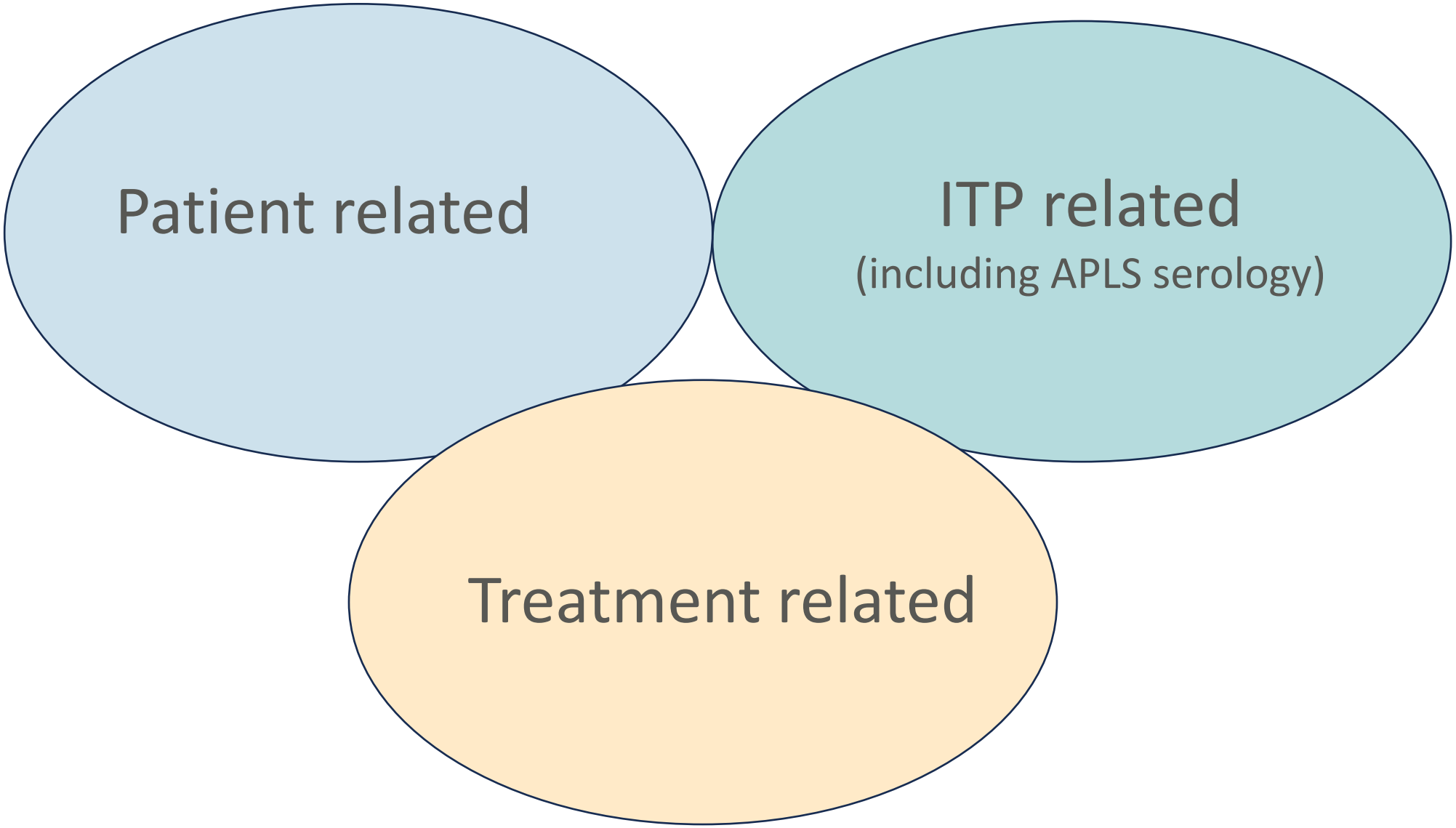
Background: ITP is associated with increased thrombotic risk

- Patients with ITP are at risk of bleeding, but thrombocytopenia does NOT protect against thrombosis
- Increased rates of both venous and arterial thromboembolic complications are reported[1-6]
- Management of thrombotic risk and thrombotic events can be challenging in thrombocytopenic patients and those with fluctuating platelet counts
- Lack of robust evidence and guidance on prevention and management of thrombosis in patients with ITP

Abbreviations: ITP, immune thrombocytopenia; References: 1. Doobaree et al. *Eur J Haematol*. 2016; 2. Rodegheiro et al. *Am J Haematol*. 2016; 3. Ruggeri et al. *J Thromb Haemst*. 2014; 4. Severinsen et al. *Br J Haematol*. 2011; 5. Norgaard et al. *Br J Haematol*. 2016; 6. Sarpatwari et al. *Haematologica*. 2010

Risk factors



APLS: antiphospholipid syndrome

Development of an expert consensus

Modified Delphi consensus study

Led by a UK-wide steering group of 3 haematologists experiences in the management of ITP from across the NHS.

Informed by a further 46 HCPs with interest and expertise in the management of ITP

Funded by SOBI and independently facilitated by Triducive, a specialist healthcare consensus consultancy.

Study objective and core output

Develop an expert consensus to optimise thrombotic risk management and treatment in patients with primary ITP in the UK.

HCP: healthcare professional, **ITP:** Immune thrombocytopenia.

Regional multidisciplinary expert steering group

Healthcare Professionals followed the Delphi approach

Steering group

Dr Charlotte Bradbury, Consultant Haematologist, University Hospitals Bristol NHS Foundation Trust, Bristol, UK

Dr Will Lester, Consultant Haematologist, Institute of Cardiovascular Sciences, University Hospitals Birmingham NHS Foundation Trust, Birmingham, UK

Dr Jecko Thachil, Consultant Haematologist, Manchester Royal Infirmary and MAHSC Professor in the University of Manchester

Modified Delphi approach (supported by independent facilitator)

Stage	Who	Output
Scoping & statement development	Steering group (N=3 – see opposite)	Defined 42 statements describing potential best practices. Threshold level for consensus set at 75% agreement[1]
Statement testing	Wider expert peer group (N=46 – anonymous)	Tested strength of agreement with wider peer group using a four-point *Likert-scale** survey
Expert recommendations	Steering group (N=3)	Discussed results and the experts made recommendations to support improvements

*Responses included 'strongly agree', 'agree', 'disagree', 'strongly disagree', 'outside my scope of practice'.

1. Diamond IR *et al. J Clin Epidemiol* 2014;67(4):401–409.

Consensus domains

Developed by the steering group, leading to N=42 accompanying consensus statements

Domain	Title	# statements
A	Management of patients already on antithrombotic treatment who present with ITP	8
B	Risk assessing newly diagnosed patients with ITP (newly diagnosed – thrombotic risk assessment)	11
C	Managing new acute thrombotic events in patients with ITP	9
D	Optimising a multi-disciplinary team (MDT) approach to care	6
E	Scenario testing of platelet thresholds in treatment decisions (Matrix of factors and platelet thresholds to establish consensus regarding when to treat)	8
	Total	**n=42**

ITP: Immune thrombocytopenia, **MDT:** multidisciplinary team..

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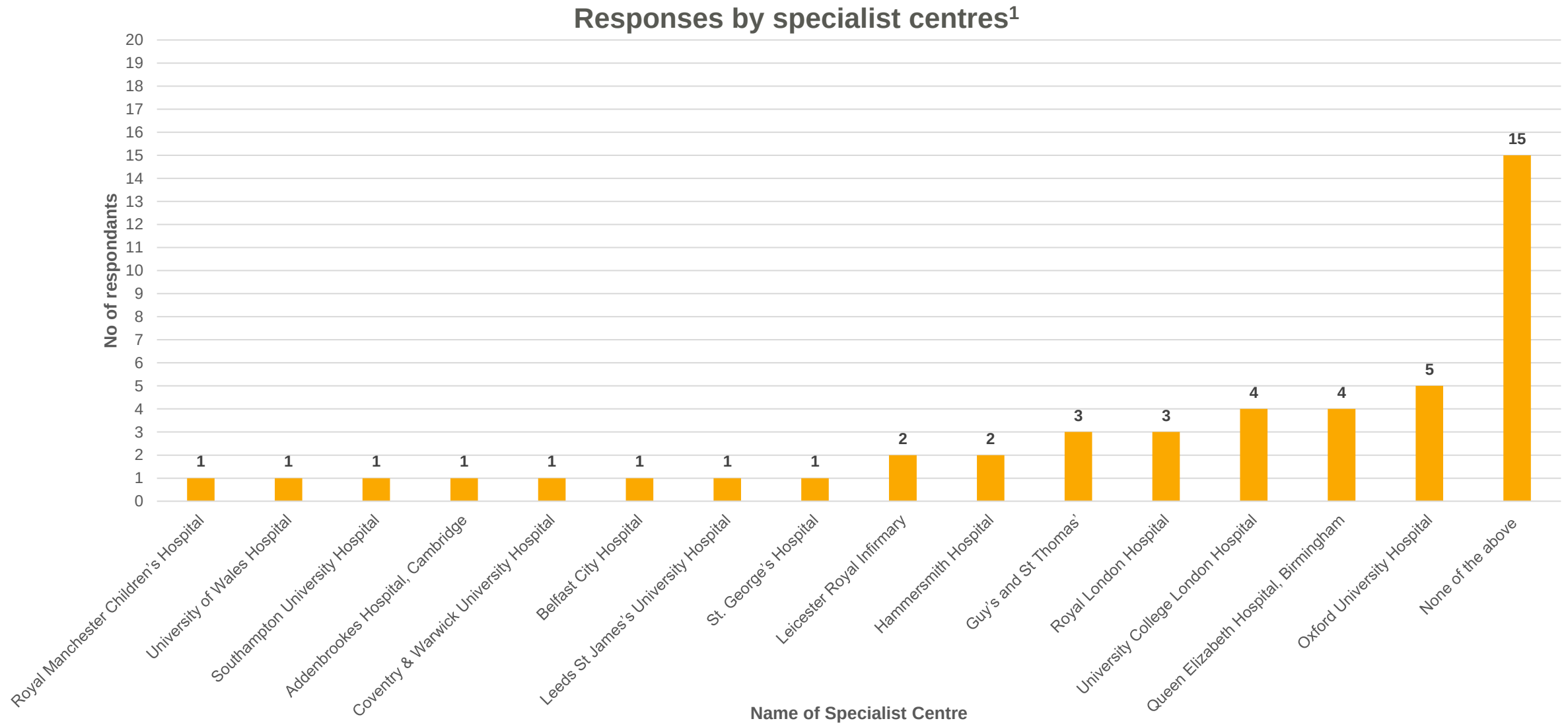
Representation from N=46 responses

Represents members from different centres



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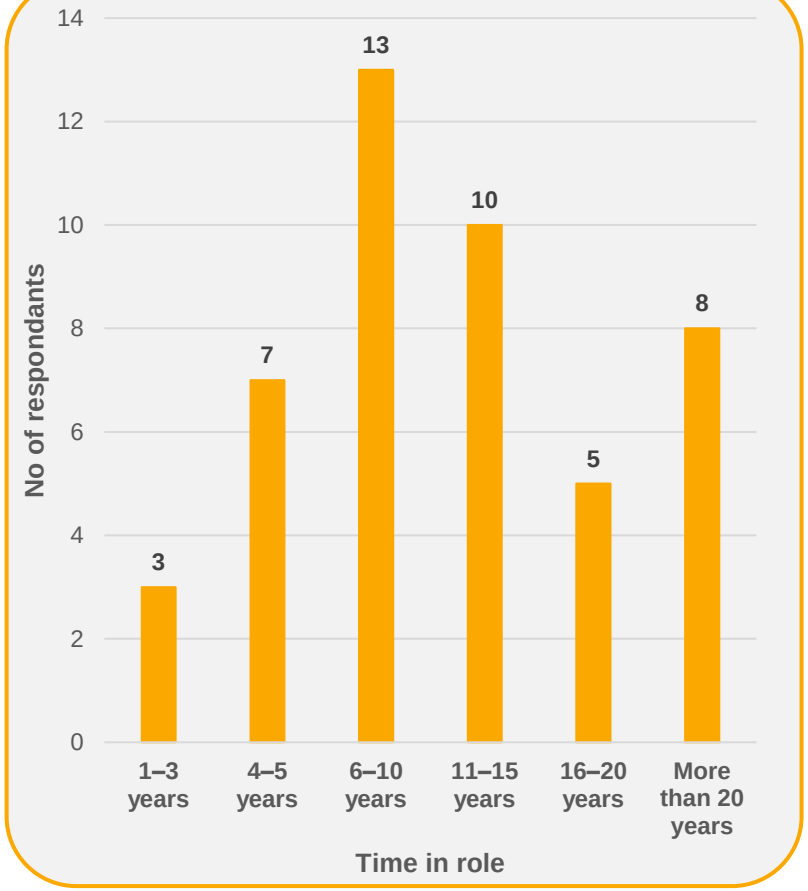
Delphi consensus headline results

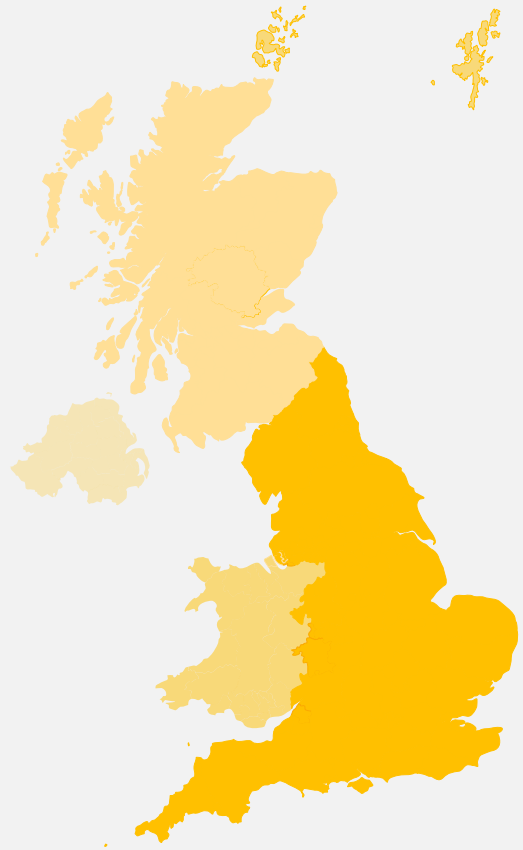
33/34 statements passed *a priori* threshold for consensus of ≥75%

Responses by time in role



Good level of experience

Responses by location*



Wide representation

Responses by strength of agreement

(≥75% agreement)

33/34
statements reached consensus

21/34
statements reaching very high agreement

(≥90% agreement)

Peer consensus

*Darker colours represent locations with a higher number of respondents.

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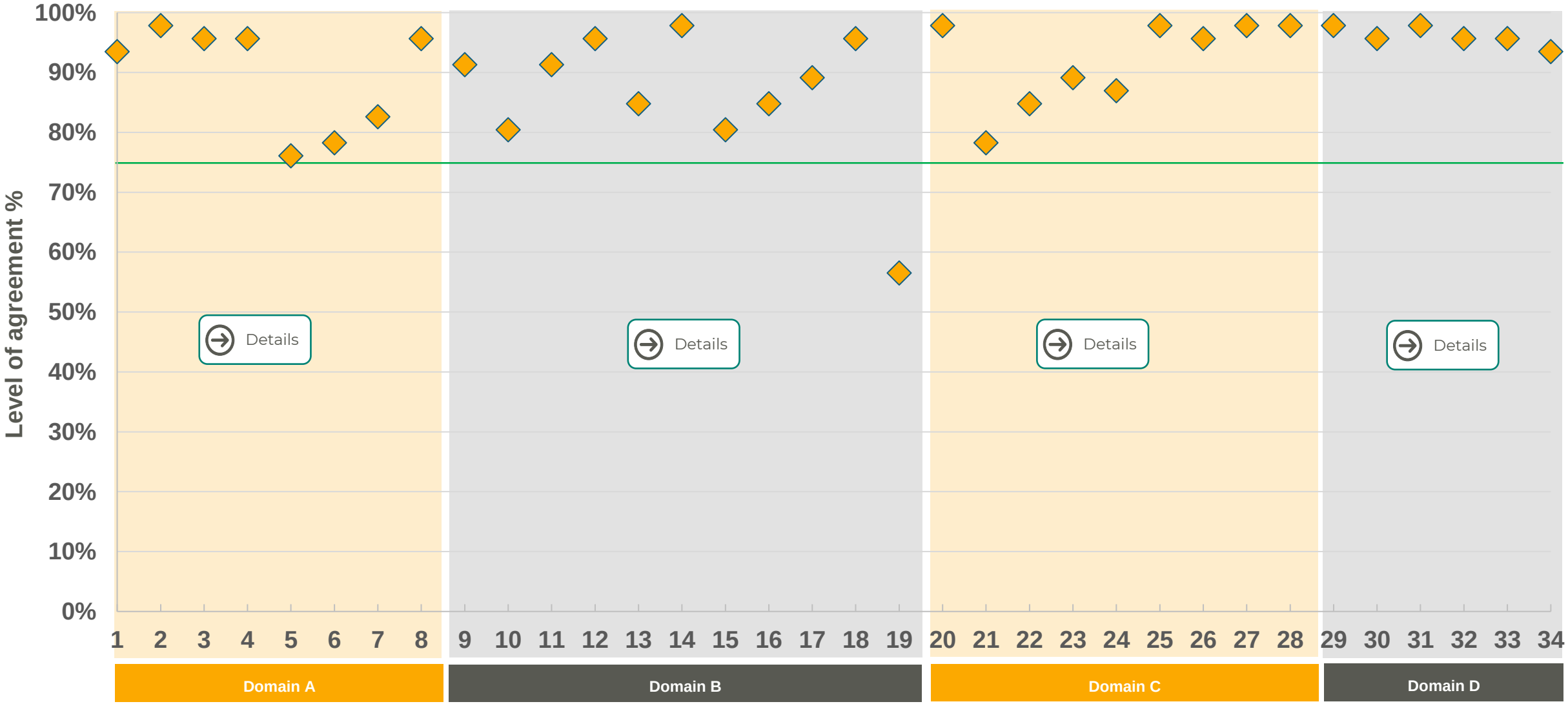
Consensus results by domain and statement

Click on each topic area to review specific statements*[1]



The 75% threshold for consensus is represented as a green line.

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Expert recommendations

Consensus statements developed by the steering group after analysing responses from **46** Healthcare Professionals

Domain A. Management of patients already on antithrombotic treatment who present with ITP. Examples:

- Assessment of thrombotic risk should be done in conjunction with the relevant specialist to determine the risks of reducing/pausing antithrombotic treatment
- Assessing bleeding risk is vital to determine the risk of continuing anticoagulation (includes platelet count, clinical phenotype, type/dose of antithrombotic, and bleeding)
- When platelets <50 $x10^9$/l, a decision needs to be made whether to pause, reduce, or modify antithrombotic treatment
- A plan for restarting antithrombotic treatment once the platelet count has improved should be in place for all patients

Domain B. Risk assessing newly diagnosed patients with ITP. Examples:

- Arterial and venous thrombotic risk factors should be assessed in ITP patients
- Modifiable risk factors should be reviewed, and the benefits of changing them should be weighed against the risk and downsides of this
- Thrombotic risk is one factor to consider when choosing an ITP directed treatment, but in general, thrombotic risk factors should not contraindicate the use of a TPO-RA
- Alternative treatments for ITP (e.g. rituximab) may be preferred in patients with strongly positive antiphospholipid (APS) serology

Domain C. Managing new acute thrombotic events in patients with ITP. Examples:

- Withdrawing/pausing effective ITP therapy (e.g. TPO-RA) should be avoided as managing an acute thrombotic event relies on a haemostatic platelet count
- In general, patients can be treated as per standard care/indication if platelets ≥50 $x10^9$/L and not bleeding

Questions?

Appendix

Consensus statements

Domain A: Management of patients already on antithrombotic treatment who present with ITP

Back to consensus results

No	Statement	Agreement
1	Assessment of thrombotic risk should be done in conjunction with the relevant specialist to determine the risks of reducing/pausing antithrombotic treatment	93%
2	Assessing bleeding risk is vital to determine the risk of continuing anticoagulation	98%
3	Assessment of bleeding risk should include platelet count, clinical phenotype, type and dose of antithrombotic, and the presence of active bleeding	96%
4	When platelet count is low (<50 x10^9/L), a decision needs to be made whether to pause, reduce, or modify antithrombotic treatment	96%
5	Uncertainty exists about which patients to pause antithrombotic medication in patients with ITP	76%
6	Uncertainty exists about when to restart antithrombotic medication in patients with ITP	78%
7	Uncertainty exists about when to modify antithrombotic medication in patients with ITP	83%
8	A plan for restarting antithrombotic treatment once the platelet count has improved should be in place for all patients	96%

≥90% agreement **<90% and ≥75% agreement** **<75% agreement**

ITP: Immune thrombocytopenia

Consensus statements

Domain B: Risk assessing newly diagnosed patients with ITP (newly diagnosed – thrombotic risk assessment)

Back to consensus results

No	Statement	Agreement
9	Assessment of thrombotic risk in ITP should be done in conjunction with a relevant haematology ITP specialist	91%
10	Arterial and venous thrombotic risk factors should be assessed in newly diagnosed ITP patients	80%
11	Thrombotic risk is one factor to consider when choosing an ITP directed treatment, but in general, thrombotic risk factors should not contraindicate the use of a TPO-RA	91%
12	Arterial and venous thrombotic risk factors should be regularly reassessed (e.g., at times of increased risk such as surgery) as thromboprophylaxis may be indicated even in the presence of thrombocytopaenia	96%
13	Alternative immunomodulatory treatments for ITP (e.g. rituximab) may be preferred in patients with strongly positive antiphospholipid (APS) serology	85%
14	Modifiable risk factors should be reviewed, and the benefits of changing them should be weighed against the risk of doing this	98%

≥90% agreement **<90% and ≥75% agreement** **<75% agreement**

ITP: Immune thrombocytopenia, **TPO-RA:** Thrombopoietin receptor agonist

Consensus statements

Domain B: Risk assessing newly diagnosed patients with ITP (newly diagnosed – thrombotic risk assessment)

Back to consensus results

No	Statement	Agreement
15	The risk and downsides of stopping HRT or oral contraception may outweigh the thrombotic risk of continuing	80%
16	Antiphospholipid syndrome screening, including anticardiolipin antibodies (aCL); lupus anticoagulant (LA); anti-beta2-glycoprotein-1 (anti-B2GP1), should be carried out in selected newly diagnosed patients as it may influence choice of subsequent therapy for ITP	85%
17	ITP treatments carry some level of thrombotic risk, but this is only one factor to consider when deciding the individual treatment approach	89%
18	Thrombocytopenia does not protect patients from thrombosis	96%
19	There is no evidence that high platelet counts on TPO-RA treatment correlate with thrombotic risk	57%

≥90% agreement **<90% and ≥75% agreement** **<75% agreement**

ITP: Immune thrombocytopenia, **HRT:** Hormone replacement therapy, **TPO-RA:** Thrombopoietin receptor agonist

Consensus statements

Domain C: Managing new acute thrombotic events in patients with ITP

Back to consensus results

No	Statement	Agreement
20	Assessment of bleeding risk versus the severity of thrombotic event is vital	98%
21	Withdrawing/pausing effective ITP therapy (e.g. TPO-RA) should be avoided due to the risk of rebound thrombocytopenia	78%
22	Withdrawing/pausing effective ITP therapy (e.g. TPO-RA) should be avoided as managing an acute thrombotic event relies on a haemostatic platelet count	85%
23	In general, patients can be treated as per standard care/indication if the platelet count is ≥50 $x10^9$/L and the patient is not bleeding	89%
24	A platelet count <50 $x10^9$/L is not necessarily a contraindication for antithrombotic treatment	87%

≥90% agreement **<90% and ≥75% agreement** **<75% agreement**

ITP: Immune thrombocytopenia, **TPO-RA:** Thrombopoietin receptor agonist

Consensus statements

Domain C: Managing new acute thrombotic events in patients with ITP

Back to consensus results

No	Statement	Agreement
25	Assessing bleeding risk is important to decide the risk of antithrombotic treatment. Platelet count is one factor to consider but other bleeding risks should also be assessed including previous bleeding, current bleeding, renal failure, type and dose of antithrombotic treatment indicated	98%
26	While the platelet count is <50 x10^9/L, a decision needs to be made about whether to initiate full antithrombotic treatment, withhold, or modify the dose of antithrombotic treatment	96%
27	A decision needs to be made as to whether ITP-directed therapy is needed to increase the platelet count	98%
28	A plan for restarting antithrombotic treatment once the platelet count has improved should be in place for all patients	98%

≥90% agreement **<90% and ≥75% agreement** **<75% agreement**

ITP: Immune thrombocytopenia,

Consensus statements

Domain D: Optimising a multi-disciplinary (MDT) approach to care

Back to consensus results

No	Statement	Agreement
29	Education on thrombotic management in ITP should be available for the care team	98%
30	Support for clinicians regarding decision making in challenging cases needs to be accessible via expert centres	96%
31	Support for patients, including via nursing and through access to psychology is desirable	98%
32	Nurses play an important/critical role in the MDT	96%
33	The role of the MDT is important when making treatment decisions	96%
34	Involving patients in the treatment decision is important	93%

ITP: Immune thrombocytopenia, **MDT:** Multi-disciplinary team

Consensus statements

Domain E: Scenario testing of platelet thresholds in treatment decisions (Matrix of factors and platelet thresholds to establish consensus regarding when to treat)

Back to consensus results

No	Statement	Full dose anticoagulant	Half dose anticoagulant	Prophylactic anticoagulant	No anticoagulant	Other
35	Patient with ITP and platelet count of **15 x10^9/L** develops new DVT. Not actively bleeding	0%	26%	22%	39%	13%
36	Patient with ITP and platelet count of **25 x10^9/L** develops new DVT. Not actively bleeding	4%	43%	35%	13%	4%
37	Patient with ITP and platelet count of **35 x10^9/L** develops new DVT. Not actively bleeding	24%	54%	17%	2%	2%
38	Patient with ITP and platelet count of **45 x10^9/L** develops new DVT. Not actively bleeding	50%	41%	4%	2%	2%

DVT: Deep vein thrombosis, **ITP:** Immune thrombocytopenia

Consensus statements

Domain E: Scenario testing of platelet thresholds in treatment decisions (Matrix of factors and platelet thresholds to establish consensus regarding when to treat)

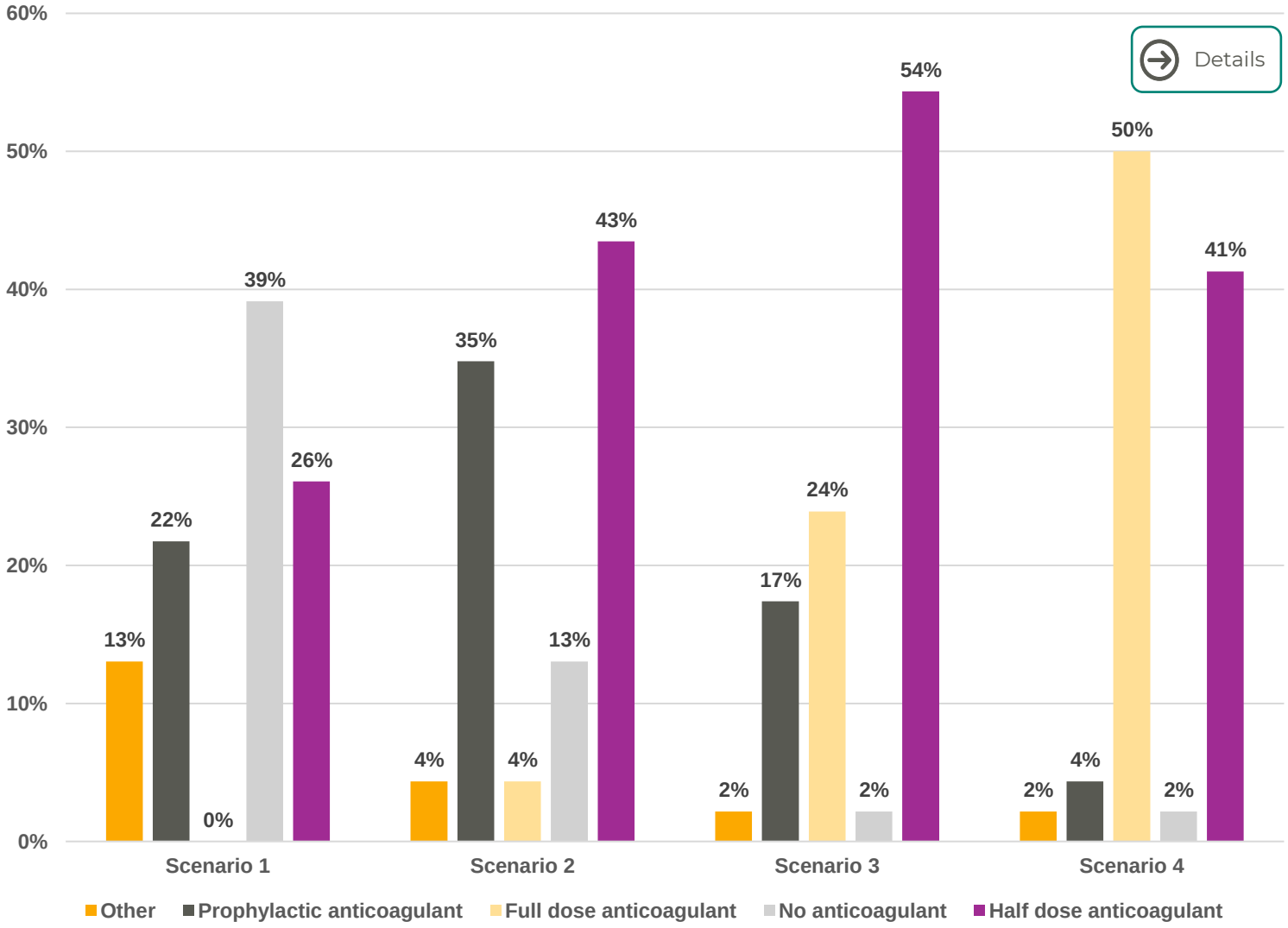
Back to consensus results

No	Statement	Continue DAPT	Continue aspirin monotherapy	Continue clopidogrel monotherapy	Stop DAPT until platelets improve
39	55-year-old patient with ITP receives IVIg for a viral triggered exacerbation. They have an MI while platelet count is normal. They have LAD PCI and are started on clopidogrel and aspirin. Three months later, they had a further exacerbation of ITP, and platelet count is **15 x10^9/L**. There is no bleeding. You give treatment to boost the platelet count. Antiplatelet treatment options (assuming close monitoring)	4%	35%	7%	54%
40	55-year-old patient with ITP receives IVIg for a viral triggered exacerbation. They have an MI while platelet count is normal. They have LAD PCI and are started on clopidogrel and aspirin. Three months later, they had a further exacerbation of ITP, and platelet count is **25 x10^9/L**. There is no bleeding. You give treatment to boost the platelet count. Antiplatelet treatment options (assuming close monitoring)	9%	57%	11%	24%
41	55-year-old patient with ITP receives IVIg for a viral triggered exacerbation. They have an MI while platelet count is normal. They have LAD PCI and are started on clopidogrel and aspirin. Three months later, they had a further exacerbation of ITP, and platelet count is **35 x10^9/L**. There is no bleeding. You give treatment to boost the platelet count. Antiplatelet treatment options (assuming close monitoring)	35%	43%	15%	7%
42	55-year-old patient with ITP receives IVIg for a viral triggered exacerbation. They have an MI while platelet count is normal. They have LAD PCI and are started on clopidogrel and aspirin. Three months later, they had a further exacerbation of ITP, and platelet count is **45 x10^9/L**. There is no bleeding. You give treatment to boost the platelet count. Antiplatelet treatment options (assuming close monitoring)	57%	24%	17%	2%

ITP: Immune thrombocytopenia, **IVIg:** Intravenous immunoglobulin, **LAD**: Left anterior descending **MI:** Myocardial infarction, **PCI:** Percutaneous coronary intervention

Responses by Scenario

Patient with ITP develops new DVT



Patient with ITP develops new DVT. Not actively bleeding. Platelet count of:	
Scenario 1 (S35)	15 x10^9/L
Scenario 2 (S36)	25 x10^9/L
Scenario 3 (S37)	35 x10^9/L
Scenario 4 (S38)	45 x10^9/L

DVT: Deep vein thrombosis

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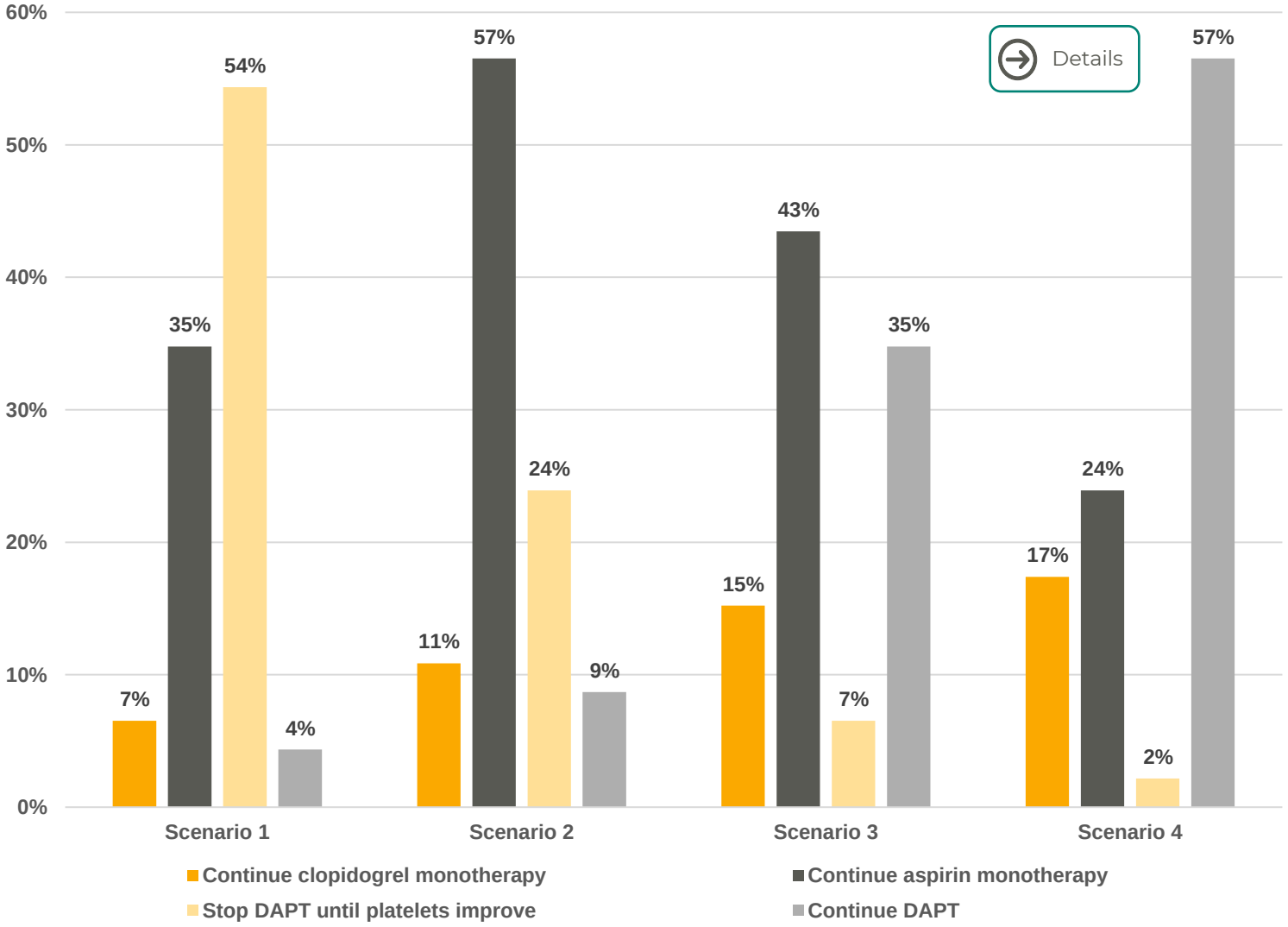
Responses by Scenario

55-year-old patient with ITP receives IVIg for a viral triggered exacerbation



55-year-old patient with ITP receives IVIg for a viral triggered exacerbation. They have an MI while platelet count is normal. They have LAD PCI and are started on clopidogrel and aspirin. Three months later, they had a further exacerbation of ITP, and platelet count is [SCENARIO]. There is no bleeding. You give treatment to boost the platelet count. Antiplatelet treatment options (assuming close monitoring)

Scenario 1 (S39)	15 $x10^9$/L
Scenario 2 (S40)	25 $x10^9$/L
Scenario 3 (S41)	35 $x10^9$/L
Scenario 4 (S42)	45 $x10^9$/L

DAPT: dual antiplatelet therapy; LAD PCI: left anterior descending artery percutaneous coronary intervention

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Expert recommendations

Developed by the steering group after analysing responses from **46** Healthcare Professionals

1. The assessment of thrombotic and bleeding risks in patients with ITP should be conducted by a multidisciplinary team, including haematologists and nurses, to develop patient-centred treatment plans.
2. Bleeding risk evaluation, including the assessment of platelet count, clinical phenotype, type and dosage of antithrombotic medications, and the presence of active bleeding, is required for the treatment decision-making.
3. Arterial and venous thrombotic risk factors should be reassessed regularly, especially during high-risk events (e.g., surgery), with considerations of thromboprophylaxis even in patients with thrombocytopenia.
4. Newly diagnosed patients with ITP should be screened for APS as it may influence treatment choices.
5. In the event of a thrombotic event, effective ITP therapy should not be automatically stopped to avoid rebound thrombocytopenia and ensure the maintenance of a haemostatic platelet count to facilitate any necessary anticoagulation/antiplatelet therapy

APS: Antiphospholipid syndrome, **ITP:** Immune thrombocytopenia

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Expert recommendations

Developed by the steering group after analysing responses from **46** Healthcare Professionals

6 It is important to involve patients in treatment decisions, taking their preferences into account.

7 Ongoing education for healthcare professionals and patients is crucial, particularly regarding thrombotic and bleeding risk management in patients with ITP.

ITP: Immune thrombocytopenia

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